

Acknowledging the Centrality of the Precautionary Principle in Judicial Review of EU Risk Regulation: Why It Matters

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The precautionary principle lies at the heart of the institutional architecture of EU risk regulation; EU institutions are fully entitled to take the precautionary principle and its overarching tenets into due consideration when enacting risk management measures. This article analyses judicial review of EU risk regulation, focusing on cases where EU acts have been challenged for being too restrictive. It enquires to what extent the Court's application of different standards may safeguard precautionary measures and do justice to the key role of the precautionary principle. It identifies two problematic aspects in the Court's case law: these are associated with the increasing focus on (mere) administrative discretion and application of the "all relevant factors" test in direct actions for annulment, and the analysis of the precautionary principle under the umbrella of proportionality review in preliminary rulings. Against the background of this analysis, the article puts forward two arguments and advocates a clearer and fuller acknowledgment of the role of the precautionary principle in the Court's case law.

This article analyses judicial review of EU risk regulation, enquiring to what extent the Court's application of different standards may safeguard precautionary measures and do justice to the key role and function of the precautionary principle. It focuses on cases where EU acts have been challenged for being *too restrictive*, encompassing direct actions for annulment and challenges through the preliminary reference procedure. Scientific uncertainty and recourse to the precautionary principle are at stake in all the cases under analysis; the thread in all cases is the risk manager's focus on persisting uncertainties, reliance on the results of a prudential risk assessment and precautionary risk management.

The precautionary principle lies at the heart of the institutional architecture of EU risk regulation. At a minimum, it enshrines the risk manager's broad discretionary *power* to enact precautionary measures whenever uncertain risks may not meet the intended EU level of protection. Under a maximalist interpretation, the precautionary principle can be framed as an "inner limit" to the risk manager's administrative discretion. Under this reconstruction, the risk manager is under a *duty* to take the overarching tenets of the precautionary principle into due consideration, in order to pursue a high level of public health and environmental protection.¹

In either case, when the risk manager has resorted to the precautionary principle and precautionary measures are challenged for being too restrictive, the Court cannot conduct substantive or quasi-substantive review. In other words, it can neither scrutinise whether

¹ In this perspective, see the analysis of cases involving challenges to EU acts deemed insufficiently protective in Leonelli, "Judicial review of compliance with the precautionary principle from *Paraquat* to *Blaise*: quantitative thresholds, risk assessment and the gap between regulation and regulatory implementation", forthcoming 21 German Law Journal (2020). Whether taking into consideration the precautionary principle and its tenets should be framed as a discretionary power of the risk manager or as a duty (and, in the latter case, what the specific boundaries of this duty are) is irrelevant for the purposes of the present enquiry. Indeed, all cases analysed in the following sections involve EU precautionary measures challenged for being too restrictive.

hazards and risks² have been conclusively proven, nor review the “quality” and “soundness” of the scientific evidence relied upon by the risk manager. Precautionary risk management must be safeguarded.

The article identifies and highlights two problematic aspects in the Court’s procedural review of EU risk regulation. The first problem relates to direct actions for annulment. The Court’s starting point has consistently been the acknowledgment of the risk manager’s broad administrative discretion in cases involving complex technical-scientific evaluations, and the finding that only a manifest error of assessment may invalidate EU acts. However, in cases involving acts which are deemed too restrictive, more than administrative discretion is at stake; EU institutions are exercising their power to pursue enhanced levels of protection by resorting to the precautionary principle.

The analysis illustrates how the Court has increasingly put the accent on (mere) *administrative discretion*, rather than on *precautionary risk management*. The role of the precautionary principle in the Court’s interpretation of the notion of *legally relevant* manifest errors of assessment³ has then been considerably reduced. This has gone hand in hand with an increasing application of the “all relevant factors” test. Under this strand of case law, the boundaries of the notion of a manifest error are no longer interpreted *in light of the precautionary principle*; rather, the Court has come to associate a manifest error of assessment with the risk manager’s failure to *procedurally take all relevant factors* at stake into account. The article deconstructs this evolution, emphasising that the Court’s review of whether “all relevant factors” have been taken into consideration is problematic in many respects. Most importantly, the acknowledgment of the risk manager’s broad administrative discretion in cases where the “all relevant factors” test is applied is insufficient to safeguard precautionary risk management. An expansion of this test results in quasi-substantive review of the evidence relied upon by the risk manager. This threatens precautionary risk management and undermines the risk manager’s power to have recourse to the precautionary principle.

The second problematic aspect relates to preliminary rulings. The analysis shows that preliminary rulings on the validity of EU acts which are challenged for being too restrictive frame the question of a *breach or misapplication of the precautionary principle* in terms of an infringement of *proportionality*. While this is of course legally tenable, the two principles should arguably be analysed separately. A set of reasons militate in favour of an autonomous examination of the precautionary principle. Most importantly, an analysis of the precautionary principle under the umbrella of proportionality review can obscure the rationale of precautionary risk management, the risk manager’s reliance on a prudential risk assessment and his focus on persisting uncertainty, as emerging from the risk assessment stage. This cannot do justice to the scientific dimension of the precautionary principle and its key role under EU risk regulation.

The first and second sections of the article set the ground for the enquiry. They provide an overview of the relevant notions, highlight the crucial importance of scientific uncertainty and the precautionary principle within EU risk regulation, analyse the relevant implications for judicial review and explore the complex relationship between the precautionary principle and

² See *infra* section 1.

³ For a reference to the notion of a “legally relevant” manifest error of assessment, see the Opinion of A.G. Kokott in Case C-343/09, *Afton Chemical Limited v. Secretary of State for Transport*, EU:C:2010:258, para 30.

proportionality. The third section focuses on *Pfizer*⁴ and *Alpharma*,⁵ which lay the foundations for the Court's procedural standard of review and for an interpretation of manifest errors of assessment in light of the precautionary principle. The fourth section examines *Afton Chemical*,⁶ with a particular focus on the Opinion of the Advocate General. For the purposes of the enquiry, this case has twofold relevance. Not only does it shed light on the implications of analysing the precautionary principle under the umbrella of proportionality. It also exemplifies the rise of the "all relevant factors" test, paving the way for an examination of the problems associated with this standard of review.

The fifth section analyses different coexisting strands. Against this overall backdrop, the sixth section draws all relevant conclusions. First, it suggests that in preliminary rulings involving challenges to acts which are deemed too restrictive the question of a breach or misapplication of the precautionary principle should be examined separately, rather than under the umbrella of proportionality review. This would do justice to the precautionary principle and its function under EU risk governance. Where questions surrounding a breach or misapplication of the precautionary principle *and* manifest errors of assessment are referred, the two should be addressed together; in any case, the question whether EU institutions have manifestly erred in their assessment should always be examined against the background of the precautionary principle.

Secondly, the conclusive section argues that the *Pfizer* and *Alpharma* strand of procedural review is more faithful to the institutional architecture of EU risk regulation. The Court should always draw an explicit connection between *administrative discretion* and *precautionary risk management*; further, and crucially, it should always interpret the notion of a manifest error of assessment *in light of* the precautionary principle, as occurs under the *Pfizer* and *Alpharma* line of cases. This would effectively safeguard precautionary risk management and acknowledge the key function of the precautionary principle within the system of EU risk regulation.

1. Scientific Uncertainty, Precautionary Risk Management and The Implications for Judicial Review of EU Risk Regulation

The boundaries of risk regulation, as a field, are marked by the notion of scientific uncertainty. Uncertainties may emerge at different stages of *risk assessment*; this precedes risk management and consists in a technical-scientific evaluation of relevant risks.⁷ Uncertainty is ubiquitous in the field of risk regulation. Different forms of scientific uncertainty can be categorised as "hazard-related", "risk-related" or "methodological" uncertainties.⁸

⁴ Case T-13/99, *Pfizer Animal Health SA v. Council*, EU:T:2002:209.

⁵ Case T-70/99, *Alpharma v. Council*, EU:T:2002:210.

⁶ Judgment in Case C-343/09, *Afton Chemical*, EU:C:2010:419, and Opinion of A.G. Kokott in Case C-343/09, *Afton Chemical*, cited *supra* note 3.

⁷ See Art. 3(11) and 6(2) of Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 Jan. 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, O.J. 2002, L 31/1, the General Food Law (hereafter, "GFL").

⁸ For this categorisation and an in depth overview on the notion of scientific uncertainty, see Leonelli, *Transnational narratives and regulation of GMO risks* (Hart Publishing, forthcoming 2021).

In the first case, uncertainties relate to the existence or the specific nature of a “hazard”; this is defined as a biological, chemical or physical agent with the potential to cause adverse effects.⁹ Ultimately, uncertainty persists as to the existence of a direct *causal link* between the (potentially hazardous) *properties* and *characteristics* of a product or process, on the one hand, and public health or environmental *adverse effects*, on the other.¹⁰ To put it differently, scientific evidence can neither conclusively prove nor exclude the existence of a hazard and of specific adverse effects. The factual background of *Pfizer* and *Alpharma*, analysed in the third section, provides an example. In these two cases, the available evidence could not provide conclusive scientific proof of a causal relationship between the use of antibiotics in animal feed, on the one hand, and the development of antibiotic resistance in humans, on the other.

By contrast, in the case of “risk-related” uncertainties, the existence of a hazard and of potential adverse effects is uncontroversial. Uncertainties stem from the process of evaluation and (qualitative or quantitative) characterisation of the relevant risks; under risk regulation, the notion of “risk” refers to the *probability of exposure* to a *hazard*, or *probability of adverse effects*, and the *severity* of any relevant consequences.¹¹ Risk-related uncertainties may refer to “exposures” or to “probabilities”.¹² In the first respect, for instance, uncertainty as to exposure in real life conditions or multiple exposures may be at stake. In the second respect, available evidence may be regarded as insufficient for the purposes of a reliable qualitative or quantitative evaluation of probabilities. Diverging data may also cast doubts on the possibility to adequately evaluate probabilities. Case law in the field of pesticidal products, under analysis in the fifth section, shows how these forms of uncertainty may come into play. Where data gaps are identified, or the available data on exposures or probabilities is deemed insufficient or inadequate, regulators may refrain from authorising a pesticidal product or restrict its use through stringent risk management measures.

Finally, the application of different scientific models and methods may yield (very) different results. This is where “methodological” uncertainties emerge; the decision to have recourse to specific methods might then be the object of controversy.¹³ Case law in the field of chemicals, analysed in the fifth section, sheds some light on methodological uncertainties and their relevance.

The notion of scientific uncertainty plays a key role under EU risk regulation; adherence to “sound” science, by contrast, does not belong to the system of EU risk governance. For the purposes of the present analysis, the 2001 Communication from the Commission on the Precautionary Principle provides the most detailed overview of the notions of uncertainty, prudential risk assessment and precautionary risk management, emphasising their crucial relevance within the EU risk regulation system. As the Communication clarifies, a *prudential* approach to risk assessment postulates that uncertainties emerging from all stages of the risk

⁹ See for instance COM(2000)1 Final, Communication from the Commission on the Precautionary Principle, Annex III, p. 28.

¹⁰ Leonelli, op. cit. *supra* note 8. It is worth adding that uncertainties may also relate to hazard characterisation, i.e. the qualitative or quantitative determination of the nature and severity of the relevant adverse effects. On this stage, see Communication on the Precautionary Principle, Annex III, p. 28.

¹¹ See for instance Communication on the Precautionary Principle, Annex III, p. 28. For a detailed overview, see Leonelli, op. cit. *supra* note 8.

¹² Leonelli, op. cit. *supra* note 8.

¹³ *Ibid.*

assessment process should be taken into due consideration and be expressly addressed in the final findings.¹⁴

“Hazard-related” and “risk-related” uncertainties should thus be clearly conveyed by risk assessors, with a view to adequately informing the technical-scientific knowledge of the risk manager and enabling him to take precautionary action, if warranted. Further, where the characterisation of hazards and risks is at stake and (“methodological”) uncertainties emerge, risk assessors should apply “prudential” methods and models and the risk manager should rely on these results; these methods are the ones which are more likely to over-estimate (rather than under-estimate) the relevant hazards and risks. As the Communication expressly mentions, “when the available data are inadequate or non-conclusive, a prudent and cautious approach [...] could be to opt for the worst case hypothesis”.¹⁵

The application of the precautionary principle, on the other hand, is part of *risk management*. This stage consists in the political determination of the threshold of acceptable risk and subsequent enactment of risk management measures, weighing and balancing all relevant interests and taking alternative risk governance measures into account.¹⁶ The precautionary principle and the principle that a high level of public health and environmental protection shall be pursued in the Union are enshrined in the Treaties and all legislative frameworks in the field of EU risk regulation.¹⁷ However, yet again, this section will take a closer look at the more detailed definition laid out in the Commission Communication.

As noted in the Communication, the precautionary principle encompasses two limbs. The former consists in the decision to act or not to act; the latter involves a decision as to how to act, i.e. the enactment of specific risk management measures.¹⁸ Starting from the decision on “whether to act”, the Communication stipulates that the precautionary principle may (or should) apply where “scientific information is insufficient, inconclusive, or uncertain and where there are indications that the possible effects on the environment or human, animal or plant health may be potentially dangerous and inconsistent with the chosen level of

¹⁴ On this point, see the reference in Communication on the Precautionary Principle, p. 13, sub-section 5.1.2.

¹⁵ Communication on the Precautionary Principle, p. 28, Annex III.

¹⁶ See Art. 3(12) and 6(3) of the GFL cited *supra* note 7.

¹⁷ In the Treaties, see Art. 191(2) TFEU. In legislative acts, see inter alia recital (21), art. 6(3) and art. 7(1) of the GFL cited *supra* note 7; recital (8), art. 1(1) and art. 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”); the cross-reference to the GFL in art. 7(1) of Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 Sept. 2003 on Genetically Modified Foods O.J. 2003, L 268/1 (“GM Food and Feed Regulation”); recital (8), and arts. 1(4) and 13(2) of 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; and recital (9) and (69) and art. 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”). References to the principle that a high level of public health and environmental protection shall be ensured are ubiquitous in legislation and in the Treaties (starting from Art. 114(3) and 191(2) TFEU).

¹⁸ Communication on the Precautionary Principle, p. 12, section 5.

protection”.¹⁹ The precautionary principle thus applies when, in the face of *persisting uncertainty*, a risk may be *too high* to comply with the EU *intended level of protection*.

An analysis of the definition enshrined in the Communication triggers two considerations. First, it is worth emphasising that this definition has a broad scope of application and may encompass all (“hazard-related”, “risk-related” and “methodological”) forms of uncertainty, as illustrated above in this section. Uncertainty may surround the existence as well as the extent or magnitude of a risk; indeed, the Communication clarifies that “the precautionary principle is relevant [...] in the event of a potential risk, even if this risk cannot be *fully demonstrated* or *quantified* or *its effects determined* [...]” (emphasis added).²⁰

Secondly, this definition shows that recourse to the precautionary principle entails the exercise of discretion in several respects: in the evaluation of the kind and extent of *uncertainty* triggering application of the principle, in the determination of the *intended level of protection* in a specific field and in the final decision that, having regard to the intended level of protection, a *specific risk* is too high to meet the *threshold of acceptable risk* and *precautionary action* is warranted.²¹ In this respect, the Communication expressly acknowledges that the decision on whether to act is the result “of an *eminently political* decision, a function of the risk level that is *acceptable to the society* on which the risk is imposed” (emphasis added).²² This lies at the heart of the institutional framework of EU risk governance, wherein functional expertise shall be complemented by political-democratic legitimacy.²³

What are the relevant implications for judicial review of EU risk regulation? As the following sections show, scientific uncertainty and scientific pluralism trigger multiple disagreements as to the scientific substantiation of the final risk management measures. The decision to employ prudential methods and models, yielding specific results, might also be the object of controversy. These disagreements will feed into complaints on manifest errors of assessment and alleged breaches or misapplication of the precautionary principle.

In cases involving acts which are deemed too restrictive, the Court should *not* deploy a substantive or quasi-substantive standard of review. It should neither review whether the relevant hazards and risks have been conclusively proven, nor scrutinise the “quality” and “soundness” of the scientific evidence relied upon by the risk manager; in other words, the Court should not be in a position to directly or indirectly replace the risk manager’s evaluation of uncertain risks and identification of the threshold of acceptable risk.²⁴ *Different forms of*

¹⁹ Ibid., p. 7, section 1, and p. 12, section 5.

²⁰ Ibid., p. 13, sub-section 5.1.

²¹ On this point, see also Leonelli, *op. cit. supra* note 1; even where the precautionary principle is framed as an “inner limit” to the risk manager’s broad discretion, a distinction must be drawn between compliance with the duty to take into due consideration the precautionary principle and its tenets, on the one hand, and the risk manager’s exercise of discretion in complying with this duty, on the other.

²² Communication on the Precautionary Principle, p. 15, sub-section 5.2.1.

²³ See COM(1997)176 Final, Commission Communication on the General Principles of Food Legislation in the European Union; COM(1997)183 Final, Commission Communication on Consumer Health and Food Safety; and COM(1999)719 final, White Paper on Food Safety. See also Case T-13/99, *Pfizer*, para. 149, as further explained *infra* in section 3. Under EU risk regulation, risk assessors only inform the technical-scientific knowledge of risk managers; the latter may at any time decide to disregard the positive results of a risk assessment, drawing different inferences and conclusions from the available data or referring to alternative scientific evidence.

²⁴ For an argument in favour of substantive review by the Court of the risk manager’s adherence to sound science, see Alemanno, annotation of Case C-77/09, *Gowan Comércio Internacional e Servicos Lda v. Ministero della Salute*, EU:C:2010:803, 48 CML Rev. (2011), 1329; Janssen and Van Asselt, “The precautionary principle in

uncertainty, high levels of *scientific complexity* and the risk manager's *power to resort to the precautionary principle* when uncertain risks may not meet the intended EU level of protection call for limited judicial review of the factual evaluations underpinning risk management measures and of the exercise of administrative discretion in precautionary risk management. Ultimately, the Court should *not* directly or indirectly review the risk manager's decision to focus on "hazard-related", "risk-related" or "methodological" uncertainties, or indirectly scrutinise the level of protection which has been set in a specific field. Precautionary risk management must be safeguarded.

The Court has consistently stated that, in cases involving complex technical-scientific evaluations, EU institutions enjoy a broad administrative discretion. Consequently, as the third section explains in further detail, only a finding that they have manifestly erred in their assessment will result in the annulment of an EU act which is deemed too restrictive. Yet, the notion of administrative discretion is differently framed in judicial review of EU risk regulation. As anticipated in the introductory section, some strands of case law put the accent on (mere) administrative discretion; a different line of cases, on the other hand, draws a clear connection between administrative discretion and the exercise of precautionary risk management. This results in a different interpretation of legally relevant manifest errors of assessment. As the analysis of the third, fourth and fifth sections illustrates, this has a set of substantive implications in judicial review of precautionary risk management measures.

The final aspect to take into consideration in this section pertains to the "how to act" limb of the precautionary principle. This relates to the selection and enactment of specific risk management measures. The Communication states that precautionary risk management measures shall comply with general principles. These encompass proportionality, non-discrimination, consistency, examination of the benefits and costs of action or inaction and examination of scientific developments.²⁵ For the purposes of the present analysis, proportionality and the examination of costs and benefits are the most relevant principles.

In respect of proportionality, the Communication provides that risk management measures must make it possible to achieve the appropriate level of protection; however, they should not be disproportionate to the desired level of protection. The Communication acknowledges that uncertainty may "considerably limit the number of options available to the risk managers";²⁶ potential long-term, indirect or cumulative adverse effects must also be taken into account.²⁷ A ban could thus be perfectly proportionate to the desired level of protection. As the next section explains, this suggests that the Court should take a highly deferential approach to proportionality review in the field of risk regulation.

The requirement that an examination of the costs and benefits of risk management measures should be conducted overlaps with strict proportionality. The Communication mandates that an examination of the advantages and disadvantages associated with risk regulation should include an economic cost-benefit analysis where this is *appropriate* and *possible*.²⁸ However,

Court. An analysis of post-*Pfizer* case law", in Van Asselt, Versluis and Vos (Eds.), *Balancing between Trade and Risk. Integrating Legal and Social Science Perspectives* (Routledge, 2013), 197; Janssen and Rosenstock, "Handling uncertain risks: An inconsistent application of standards?" 7 EJRR (2016) 144.

²⁵ Communication on the Precautionary Principle, p. 7, section 6.3.

²⁶ *Ibid.*, p. 17, sub-section 6.3.1.

²⁷ *Ibid.*

²⁸ *Ibid.*, p. 19, sub-section 6.3.4.

as the Communication emphasises, the examination of the relevant advantages and disadvantages *cannot* be reduced to economic cost-benefit analysis; it is much wider in scope and shall include different considerations.²⁹ Against this background, the economic cost-benefit effectiveness of risk regulation, i.e. the enactment of regulatory measures which are expected to maximise aggregate wealth, is only one (and by no means the most relevant) factor to be taken into consideration at the risk management stage.³⁰ Indeed, the precautionary principle encapsulates the risk manager's discretionary power to find that, in the face of uncertainty and in light of the intended level of protection, *collective* public health and environmental benefits outweigh the *individual* economic costs to market actors. As the Communication concludes, "a society may be willing to pay a higher cost to protect an interest, such as the environment or health, to which it attaches priority".³¹

As anticipated in the introductory section, preliminary rulings involving acts which are deemed too restrictive frame the question of a breach or misapplication of the precautionary principle in terms of an infringement of proportionality. For this reason, the next section takes a closer look at the relationship and interconnection between the two principles.

2. The Precautionary Principle and Proportionality

The relationship between the precautionary principle and proportionality is highly complex. Early case law did neither take into consideration a breach or misapplication of the precautionary principle, nor use it to determine the boundaries of the notion of a manifest error of assessment. This is unsurprising, given that the precautionary principle was only enshrined in the Treaties in 1992, at the time of the Treaty of Maastricht. Further, the Communication dates back to 2001, and the precautionary principle was only introduced in legislative frameworks in EU risk regulation in the 2000s. Early case law thus implicitly or obliquely took the precautionary principle into account when assessing the proportionality of risk management measures.³² In the following years, and still nowadays, preliminary rulings on the validity of EU legislative or regulatory acts which are deemed too restrictive have framed the question of a breach or misapplication of the precautionary principle in terms of an infringement of proportionality.³³ Is there a perfect correspondence and symmetry between the two principles, though?

²⁹ Ibid., p. 18, sub-section 6.3.4. The article does not take into consideration Other Legitimate Factors ("OLFs"), which also feed into the determination of the intended level of protection. For references to OLFs in EU legislation, see recital (19), art. 3(12) and art. 6(3) of the GFL cited *supra* note 7. See also recitals (9), (57), (58) and art. 31(7)(d) of the Deliberate Release Directive cited *supra* note 17, and recital (32) and art. 7(1) of the GM Food and Feed Regulation cited *supra* note 17.

³⁰ For a detailed overview, see Leonelli, *op. cit. supra* note 8.

³¹ Communication from the Commission on the Precautionary Principle, p. 19, sub-section 6.3.4.

³² See Case C-331/88, *The Queen v. Minister of Agriculture, Fisheries and Food and Secretary of State for Health, ex parte: Fedesa and others* (hereafter, "*Fedesa*"), EU:C:1990:391; Case C-157/96, *Ex parte National Farmers' Union and Others*, EU:C:1998:191 ("*BSE I*"), particularly at paras 63 and 64; Case C-180/96, *United Kingdom v. Council*, EU:C:1998:192 ("*BSE II*"), particularly at para 99; Case T-199/96, *Laboratoires Pharmaceutiques Bergaderm and Goupil v. Commission*, EU:T:1998:176.

³³ See *infra* section 4.

Undoubtedly, an overlap exists between the two. Proportionality review encompasses a threefold examination.³⁴ First, the Court will focus on whether a measure is suitable or appropriate to achieve its aim. Secondly, it will enquire whether the measure is necessary or whether less restrictive means (less burdensome measures) could have been used to achieve the same aim. Thirdly, it will analyse whether the measure is excessive. The last prong, strict proportionality, entails an evaluation of whether the means go beyond the aim. In judicial review of EU risk regulation, strict proportionality has on some occasions been analysed from two different angles: whether the disadvantages are disproportionate to the aim pursued, and whether they are disproportionate to the specific advantages associated with the regulatory measure (*stricto sensu* economic cost-benefit analysis).³⁵

As explained in the previous section, the precautionary principle encompasses a “whether to act” and a “how to act” limb. The analysis of both limbs can be absorbed within proportionality review. An examination of relevant case law shows that the applicants or referring courts have raised the point of suitability-appropriateness by pointing to lack of scientific proof of the existence or extent of specific risks; on these grounds, they have raised doubts as to whether the measures were appropriate to achieve public health or environmental protection.³⁶ This pertains to the “whether to act” limb of the precautionary principle. On the other hand, complaints or questions surrounding the necessity of the measures or their excessive nature regard risk management measures and the “how to act” limb.

Clearly, safeguarding precautionary risk management calls for a highly deferential review of proportionality. If a measure is deemed not appropriate to achieve its aim, the Court would ultimately be encroaching on the risk manager’s discretionary evaluation of whether uncertain risks meet the intended level of protection. If the Court finds that a risk management measure goes beyond what is necessary, or is excessive, the Court would still be encroaching on the determination of the intended level of protection and threshold of acceptable risk, for at least two reasons.

The first reason is that other (less trade restrictive) measures may not be *available* or *effective* to meet the intended level of protection, so that the risks which are run in practice would turn out to be higher than the ones that the risk manager deemed acceptable. Indeed, the availability and efficacy of alternative risk management options are among the factors that the risk manager shall take into account when enacting precautionary measures.³⁷ On these grounds, any finding that a measure goes beyond what is necessary is liable to affect precautionary risk management.³⁸

³⁴ Proportionality is only analysed in this article in so far as it overlaps with the precautionary principle. For a detailed overview of proportionality, see for all Tridimas, *The general principles of EU law* (OUP, 2006), and Turk, *Judicial review in EU law* (Edward Elgar, 2009).

³⁵ For this distinction in strict proportionality, see for instance Case T-13/99, *Pfizer*, para 407.

³⁶ See inter alia Case C-331/88, *Fedesa*; Case T-13/99, *Pfizer*, particularly at paras. 414 et seq., Opinion of A.G. Kokott in Case C-343/09, *Afton Chemical*, paras. 77 to 80, and Case C-78/16, *Pesce and Others*, EU:C:2016:428, paras. 57 et seq. (hereafter, “*Xylella*”).

³⁷ Under risk regulation, the availability and efficacy of risk management measures qualifies as an OLF that the risk manager may take into consideration. See for instance the reference in Communication from the Commission on the Precautionary Principle, p. 19, sub-section 6.3.4.

³⁸ For a clear example and acknowledgment of this point, see inter alia Opinion of A.G. Mischo in Case C-331/88, *Fedesa*, EU:C:1987:440, paras. 34, 35 and 39.

The second reason is that strict proportionality ultimately weighs and balances public health and environmental benefits vis-à-vis the economic costs which risk regulation imposes on market actors.³⁹ This, however, is the form of economic cost-benefit analysis that, under the Commission Communication, need *not* inform precautionary risk management. In fact, a precautionary approach to risk management can hardly be cost-benefit effective. As an analysis of different models of risk regulation shows, the application of cost-benefit analysis heuristics goes hand in hand with adherence to “sound” science.⁴⁰ Referring to what has been scientifically proven and established relieves market actors from the regulatory burdens and costs associated to precautionary regulation; this responds to the regulators’ pursuit of a *cost-benefit effective* level of protection, wherein the expected benefits of risk governance outweigh the relevant economic costs. Conversely, focusing on persisting uncertainties and pursuing *enhanced* levels of protection creates additional economic costs. In this light, finding that a measure is excessive suggests that the high level of public health and environmental protection pursued is unjustified in the lack of conclusive scientific evidence, on the one hand, and the measure’s impact on economic rights, on the other.⁴¹ Ultimately, an intrusive review of the proportionality of risk management measures can have the same effects as substantive review of the “soundness” of the scientific evidence relied upon by the risk manager.⁴²

Against this backdrop, and with a view to safeguarding precautionary risk management, the Court should take – and indeed has taken – a highly deferential approach to proportionality review. Are there any reasons then, in cases involving acts which are deemed to be too restrictive, to distinguish between the analysis of a breach or misapplication of the precautionary principle, on the one hand, and review of proportionality, on the other? Arguably, a set of reasons militate in favour of this distinction.

When the applicants or referring courts raise the issue of compliance with the *precautionary principle*,⁴³ they are pointing to the *scientific basis and scientific substantiation of the relevant measures* and to the “*whether to act*” limb of the precautionary principle. In fact, even when a breach or misapplication of the precautionary principle is not called into question but a *manifest error of assessment* is alleged, the applicants or the referring court are still pointing to the scientific basis of the relevant measures. On these grounds, scientific uncertainty and scientific matters are always at stake when a violation of the precautionary principle or a manifest error are alleged.

On the other hand, when the issue of *proportionality* is raised, the applicants or the referring courts are pointing to the specific *risk management measures* enacted and the *level of*

³⁹ Admittedly, strict proportionality and cost-benefit analysis are in relationship to risk management measures adopted on the basis of the precautionary principle *as well as* OLFs. For this reason, the finding that a risk management measure is excessive may *not only* have to do with the application of the precautionary principle, *but also* OLFs. In risk regulatory terms, *quantitative* cost-benefit analysis (the rule of aggregate wealth maximisation) is directly opposed to *qualitative* OLFs; for more information see Leonelli, *op. cit. supra* note 8. The analysis does not take this aspect into consideration in order to simplify the overview, and given that the focus of the article is on the precautionary principle.

⁴⁰ On this point, see Leonelli, *op. cit. supra* note 8.

⁴¹ For a similar acknowledgment, see *inter alia* Opinion in Case C-331/88, *Fedesa*, para 42.

⁴² In this respect, see the analysis of 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, *Artogodan and Others v. Commission*, EU:T:2002:283 in sub-section 5.4.

⁴³ For the sake of clarity, again, reference is being made to actions where a breach of the precautionary principle is alleged in so far as an act is deemed to be *too restrictive*.

protection pursued by the regulator; thus, they are referring to the “*how to act*” limb of the precautionary principle. In other words, they are disputing the *necessity* of the specific *risk management measures* and challenging the enhanced *level of protection* that the measures pursue, on the grounds that it is *not cost-benefit effective*. The scientific basis of the measures does not directly come into play.

From this perspective, at a *conceptual* level, it is both possible and beneficial to draw a distinction between the two forms of review. In terms of *legal analysis*, an examination of alleged breaches or misapplication of the precautionary principle under the umbrella of proportionality review has an important implication; it can easily obscure the relevance of the precautionary principle and its key role in the face of scientific uncertainty. In other words, as the fourth section shows, proportionality review can hardly do justice to the scientific dimension in which the precautionary principle is embedded. Lastly, and as the fourth section also shows, a contextual analysis of the precautionary principle and proportionality has one further effect. If the precautionary principle and proportionality are assessed together, the precautionary principle can no longer mark the boundaries of the Court’s review of manifest errors of assessment in scientific matters.⁴⁴

On these grounds, and despite their overlaps, the two principles should arguably be kept separate. A breach or misapplication of the precautionary principle should always be analysed autonomously, by reference to scientific matters and to the notion of scientific uncertainty; symmetrically, the precautionary principle should always be used to interpret the scope and boundaries of the risk manager’s alleged manifest errors of assessment in scientific matters.⁴⁵ Both sets of complaints, as explained above, relate to the “whether to act” part. Proportionality review, on the other hand, should always focus on risk management measures and on the “how to act” part.

This draws a clearer distinction between complaints on the scientific substantiation of the measures, on the one hand, and complaints on the measures, on the other. In line with the interconnections and overlaps between the two principles, only *manifest* errors of assessment and *manifestly* disproportionate risk management measures should be sanctioned by the Court.⁴⁶ This concludes the preliminary overview of scientific uncertainty, the precautionary principle and its relationship to proportionality. Against this overall backdrop, the next part of the article analyses the evolution of the Court’s procedural standard of review of EU risk regulation. The third section starts by examining the “twin” *Pfizer* and *Alpharma* cases, which set the foundations for the Court’s procedural standard of review.

3. The Foundations of Procedural Review and the Role of the Precautionary Principle

⁴⁴ See *infra* section 4.

⁴⁵ See *infra* sections 3 and 5.

⁴⁶ For the acknowledgment that a deferential review of precautionary measures goes hand in hand deferential review of proportionality, see also Turk, *op. cit. supra* note 34, at 136 and 145, and Anderson, “Contrasting models of EU administration in judicial review of risk regulation” 51 CML Rev. (2014) 424, at 434.

The famous *Pfizer* and *Alpharma* decisions⁴⁷ were delivered on the same day, in 2002; thus, both Judgments follow the enactment of the Commission Communication on the Precautionary Principle. Both cases involved direct actions for the annulment of EU withdrawals of the authorisation of antibiotics used as growth promoters in animal feed. Both decisions reflect a shift from early proportionality review of EU risk regulatory measures to a new focus on the scientific evidence underlying risk management. “Scientification” of judicial review, as a trend, is by no means unique to EU law.⁴⁸ Under EU case law, a *procedural* standard applies to the review of the scientific substantiation of risk management measures. *Pfizer* and *Alpharma* lay the foundations for the application of this standard.

The first relevant consideration is that the Court’s procedural review builds on the acknowledgment of the risk manager’s broad discretionary powers in cases involving complex evaluations, including technical-scientific assessments. The acknowledgment of broad administrative discretion was already apparent in the earlier strand of cases;⁴⁹ however, it was elaborated further in *Pfizer* and *Alpharma*. When determining the level of risk deemed acceptable for society, EU institutions enjoy a broad discretion.⁵⁰ Moreover, where EU institutions are required to make complex assessments, their discretion “also applies, to some extent, to the establishment of the factual basis of [their] action”.⁵¹ Therefore, risk regulation measures will only be invalid where the underlying scientific evaluations are vitiated by a manifest error of assessment, where the risk manager has misused its powers or where he has manifestly exceeded the limits of its discretion.⁵²

Broad administrative discretion as to the examination of the relevant facts and determination of whether uncertain risks meet the intended level of protection entails that the Court *cannot* substitute its evaluations for the ones of the risk manager.⁵³ As explained in the first section, and as acknowledged in *Pfizer* and *Alpharma*, the Court *cannot* scrutinise the “quality” or “soundness” of the scientific evidence relied upon and substantiating the risk management measures, as would occur under a substantive standard of review.⁵⁴ A manifest error in the examination of scientific evidence is all that could invalidate the measures. What is truly remarkable about *Pfizer* and *Alpharma*, however, is rather the role played by the precautionary principle. This brings us to the second relevant consideration. The acknowledgment of the risk manager’s broad *administrative discretion*, as such, is complemented in *Pfizer* and *Alpharma*

⁴⁷ Case T-13/99, *Pfizer*, cited *supra* note 4, and Case T-70/99, *Alpharma*, cited *supra* note 5. Neither case was appealed.

⁴⁸ For an analysis of the science-based obligations laid out in the WTO Agreement on Sanitary and Phytosanitary Measures (“SPS Agreement”) and DSB’s standard of review, see Scott, *The WTO Agreement on Sanitary And Phytosanitary Measures. A Commentary* (OUP, 2009).

⁴⁹ See for instance the Opinion in Case C-331/88, *Fedesa*, para 12, citing para 25 of Case C-138/79, *Roquette v. Council*, EU:C:1980:249, and the Judgment in Case C-331/88, *Fedesa*, para 8. In the assessment of proportionality, the Opinion (para 13) refers to Case C-138/78, *Stölting v. Hauptzollamt Hamburg-Jonas*, EU:C:1979:46, para 25, and Case C-265/87, *Schräder v. Hauptzollamt Gronau*, EU:C:1989:803, para 22. The Judgment in Case C-157/96, *BSE I*, paras. 39 to 41, cites Case C-98/78 *Racke v. Hauptzollamt Mainz*, EU:C:1979:14.

⁵⁰ Case T-13/99, *Pfizer*, para 167, and Case T-70/99, *Alpharma*, para 178.

⁵¹ Case T-13/99, *Pfizer*, para 168, Case T-70/99, *Alpharma*, para 179, as well as the case law cited therein.

⁵² Case T-13/99, *Pfizer*, para 166, and Case T-70/99, *Alpharma*, para 177.

⁵³ Case T-13/99, *Pfizer*, para 169, and Case T-70/99, *Alpharma*, para 180, “the judicature is not entitled to substitute its assessment of the facts for that of [EU] institutions”.

⁵⁴ See e.g. Case T-13/99, *Pfizer*, para 393, “it is not for the Court to assess the merits of either of the scientific points of view argued before it and to substitute its assessment for that of [EU] institutions [...]”.

by a strong assertion of the *precautionary principle*. Symmetrically, the notion of a *manifest error of assessment* is interpreted against the backdrop of *precautionary risk management*.

The applicants in these cases alleged several manifest errors of assessment as well as a breach or misapplication of the precautionary principle.⁵⁵ Crucially, the GC⁵⁶ considered it appropriate to examine these pleas in law together, rather than analysing the precautionary principle under the umbrella of proportionality. On these grounds, the GC used the precautionary principle to draw the boundaries of a “manifest” error of assessment and establish its nature.

The vast majority of the applicants’ complaints on manifest errors related to lack of scientific proof of specific adverse effects (development of antibiotic resistance in humans) associated with the use of antibiotics in animal feed, in so far as a causal relationship could not be scientifically established and relevant exposures and probabilities could not be quantified.⁵⁷ EU institutions, on the other hand, clearly drew on scientific controversies and disagreement as to the uncertain risks that the use of these substances in animal feed could pose, referencing studies on persisting uncertainty and the need to conduct further assessments. The GC examined whether EU institutions had manifestly erred in their findings, *in light of* the precautionary principle.⁵⁸

In *Pfizer*, the GC found that EU institutions had not disregarded or distorted the positive results of the Opinion delivered by the Scientific Committee; rather, they had drawn different inferences and conclusions from all the available scientific data, taking the margins of scientific uncertainty into account. On these grounds, and without incurring any manifest error, “they concluded that [...] they had a proper scientific basis for taking action under the precautionary principle”.⁵⁹ Similarly, when examining Pfizer’s allegations on the absence of proof of a causal link between use of the products and development of antibiotic resistance, the GC noted that Pfizer could not reasonably criticise the institutions for basing themselves on “scientific studies which [do] not admit of scientific certainty”.⁶⁰ This is inherent to the logics of the precautionary principle, so that persisting uncertainties and the impossibility to carry out a quantitative risk assessment do not prevent the competent authority “from taking preventive protective measures [...], regard being had to the level of risk [...] which the authority has decided is the critical threshold [...]”.⁶¹ Indeed, in the opposite case, the precautionary principle would be rendered devoid of purpose.⁶²

Similar considerations apply to *Alpharma*. The GC was adamant in remarking that the precautionary principle allows for consideration of scientific uncertainty, and more specifically the impossibility to determine the *existence* or the *extent* of a risk in the lack of conclusive

⁵⁵ Case T-13/99, *Pfizer*, para 107 (as two separate pleas in law), and Case T-70/99, *Alpharma*, paras. 99 and 100 (as a single plea in law).

⁵⁶ For the sake of clarity, in cases decided by the Court of First Instance reference is made to the General Court (“GC” in the text).

⁵⁷ Case T-13/99, *Pfizer*, paras. 312 et seq. and 347 et seq., and Case T-70/99, *Alpharma*, paras. 99 and 100.

⁵⁸ Throughout these two Judgments, it is very common to find references to the manifest errors alleged by the applicants *followed by* references to the precautionary principle. See for instance Case T-13/99, *Pfizer*, para 170, and Case T-70/99, *Alpharma*, para 181.

⁵⁹ Case T-13/99, *Pfizer*, paras. 231 and 246.

⁶⁰ Case T-13/99, *Pfizer*, para 383.

⁶¹ *Ibid.*, para 382.

⁶² Case T-13/99, *Pfizer*, para 386, and Case T-70/99, *Alpharma*, paras. 173 and 282.

scientific evidence.⁶³ Thus, in a situation in which the precautionary principle is applied and “which by definition coincides with a situation [of uncertainty], a risk assessment cannot be required to provide [EU] institutions with conclusive scientific evidence of the reality of the risk and the seriousness of the potential adverse effects [...]”.⁶⁴ On these grounds, the GC found in both cases that the institutions had sufficient scientific grounds to conclude that uncertain risks existed and that they exceeded the threshold of acceptable risk; thus, they had *not* committed any manifest errors.

What are, then, the *procedural* limits to the risk manager’s exercise of his discretionary powers in the enactment of precautionary measures? The identification of these limits, which are also the object of the GC’s procedural review, is the third contribution of *Pfizer* and *Alpharma*. In these two cases, compliance with the procedural preconditions for the exercise of administrative discretion is framed in terms of a general obligation to conduct a comprehensive risk assessment.⁶⁵ The competent authority must ensure that risk management measures are based on “as thorough a scientific risk assessment as possible [...]”;⁶⁶ it must have “sufficiently reliable and cogent information to allow it to understand the ramifications of the scientific question raised”⁶⁷ and “sufficient scientific indications to conclude on [...] a scientific basis” that uncertain risks are not acceptable.⁶⁸ In this sense, as famously acknowledged, “a scientific risk assessment carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence is an important *procedural guarantee* whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any *arbitrary* measures” (emphasis added).⁶⁹ The question of arbitrariness is also connected to the distinction between scientific uncertainty, on the one hand, and hypothetical risk, on the other. The uncertain risks that the risk manager identifies and considers above the threshold of “acceptable risk” cannot be mere hypothetical risks. Thus, as the GC held in both cases, a precautionary measure cannot “be based on a purely hypothetical approach [...], founded on mere conjecture which has not been scientifically verified. Rather, [...] [a precautionary measure] may be taken only if the risk, although the reality and extent thereof have not been fully demonstrated by conclusive scientific evidence, appears nevertheless to be

⁶³ Case T-70/99, *Alpharma*, para 164. See also para 174 therein.

⁶⁴ Case T-13/99, *Pfizer*, para 142, and Case T-70/99, *Alpharma*, paras. 153 to 155, as well as the case law cited therein.

⁶⁵ See Case T-70/99, *Alpharma*, para 183. *Pfizer* takes a more “restrictive” perspective on the scientific standard of proof and scientific substantiation of the relevant measures; however, it is necessary to stress that these have remained isolated statements, on which the Court has *not* drawn in following years. See for instance *Pfizer*, para 198, “the competent [EU] institution must, first, prepare for [the experts] the factual questions which need to be answered before it can adopt a decision and, second, assess the probative value of the opinion delivered [...]”. In that regard, the [EU] institution must ensure that the reasoning in the opinion is full, consistent and relevant”, and para 199, “to the extent to which the institution opts to disregard the opinion, it must provide specific reasons for its findings by comparison with those made in the opinion and its statement of reasons must explain why it is disregarding the latter. The statement of reasons must be of a scientific level at least commensurate with that of the opinion in question. In such a case, the institution may take as its basis either a supplementary opinion from the [experts] or other evidence, whose probative value is at least commensurate with that of the opinion concerned”. For a similar perspective, see also 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*, paras. 199 and 200.

⁶⁶ Case T-13/99, *Pfizer*, paras 162 and 165, and Case T-70/99, *Alpharma*, para 175.

⁶⁷ Case T-13/99, *Pfizer*, para 162, and Case T-70/99, *Alpharma*, para 175.

⁶⁸ Case T-13/99, *Pfizer*, para 165.

⁶⁹ Case T-13/99, *Pfizer*, para 172 and also 159, and Case T-70/99, *Alpharma*, para 183 and also 172.

adequately backed up by the scientific data available [...]”.⁷⁰ On these grounds, procedural review strikes a balance between the risk manager’s broad discretionary power to set the intended level of protection and take precautionary action, and the need to check compliance with the procedural conditions for the exercise of this power.

The final consideration relates to proportionality.⁷¹ In the wake of the Commission Communication, *Pfizer* and *Alpharma* have drawn a clearer distinction between review of the scientific substantiation of risk management measures and review of risk management measures, manifest errors of assessment and proportionality. These cases testify that the more the Court’s review of scientific substantiation expands, the more proportionality review shrinks. Unsurprisingly, the GC’s deferential procedural review of science in *Pfizer* and *Alpharma* has gone hand in hand with a deferential approach to proportionality review.⁷²

Against this overall backdrop, and to draw some conclusions, *Pfizer* and *Alpharma* have played a key role in the elaboration of the Court’s procedural standard for the review of scientific evidence. By tying *administrative discretion*, the *precautionary principle* and the notion of a *manifest error of assessment* together, these cases have emphasised the interconnections between these three elements. In this sense, the acknowledgment of the crucial role of the precautionary principle under EU risk regulation reinforces the broad administrative discretion of the risk manager and qualifies its scope, assisting the Court in the interpretation of the notion of a “manifest” error. Further, it sheds light on the institutional dynamics underlying EU risk regulation and the delicate balance between democratic legitimacy and technical expertise.⁷³ As the fifth section shows, a strand of more recent cases follows the *Pfizer* and *Alpharma* standard of review and interpretation of the notion of a manifest error of assessment. The next section, on the other hand, turns to an analysis of *Afton Chemical*. This paves the way for the following examination of coexisting strands.

4. Proportionality Review in Preliminary Rulings and the Rise of the “All Relevant Factors” Test

The following stage in the case law has marked a development in the Court’s procedural standard of review. The Court’s examination of whether the risk manager has incurred a manifest error has come to be increasingly disassociated from the broader context of

⁷⁰ Case T-13/99, *Pfizer*, paras 143 and 144, and Case T-70/99, *Alpharma*, paras 156 and 157.

⁷¹ In *Pfizer*, see paras. 405 et seq.; in *Alpharma*, see paras. 320 et seq., particularly paras. 325, 338, 349 and 363.

⁷² Case T-13/99, *Pfizer*, para 412 et seq., and Case T-70/99, *Alpharma*, para 325 et seq.

⁷³ See *Pfizer* para 151, and *Alpharma* para 164: “[...] it is for the [EU] institutions to determine the level of protection which they deem appropriate for society. It is by reference to that level of protection that they must then [...] determine the level of risk — i.e. the critical probability threshold for adverse effects on human health and for the seriousness of those possible effects — which in their judgment is no longer acceptable for society [...]. Therefore, determining the level of risk deemed unacceptable involves the [EU] institutions in defining the political objectives to be pursued under the powers conferred on them by the Treaty”. See also *Pfizer* para 201: “that finding can also be justified on grounds of principle relating to the political responsibilities and democratic legitimacy of the Commission. Whilst the Commission's exercise of public authority is rendered legitimate [...] by the European Parliament's political control, [technical experts], although they have scientific legitimacy, have neither democratic legitimacy nor political responsibilities. Scientific legitimacy is not a sufficient basis for the exercise of public authority”.

precautionary risk management; in these cases, the Court sets its analysis against the different backdrop of the risk manager's broad *administrative discretion*.

This incremental evolution in the case law is probably most clearly exemplified by the Opinion of Advocate General Kokott and the ECJ's Judgment in *Afton Chemical*.⁷⁴ In this case the ECJ was called upon to deliver a preliminary ruling on the validity of limits for the use of a metallic additive for motor vehicles fuel; the limits had been imposed pending the development of a test methodology, which would allow for an adequate and comprehensive risk assessment. Clearly, the need (and temporary impossibility) to conduct a thorough risk assessment, uncertainty as to the extent of the public health risks posed by the use of this metallic additive and the precautionary principle were at stake in this case. The national court referred questions on the alleged invalidity of the act as being based on a manifest error of assessment, a breach of the precautionary principle and a breach of proportionality.

Afton Chemical has twofold relevance and triggers two sets of considerations. First, in the Opinion in this preliminary ruling, Advocate General Kokott did not examine the questions on a manifest error of assessment and alleged breaches of the precautionary principle together. Indeed, since the beginning of her analysis, she found that the emphasis of the questions was "on the principle of proportionality, in the framework of which the precautionary principle [...] [is] also relevant".⁷⁵ In examining the precautionary principle and proportionality together, the Advocate General drew on early case law (the *Fedesa* strand)⁷⁶ as well as preliminary rulings delivered in the previous years. In these preliminary rulings on the validity of acts challenged for being too restrictive, the ECJ took the precautionary principle into consideration in the examination of questions surrounding proportionality. As a result, the two principles were analysed together.⁷⁷ However, it is worth highlighting that these preliminary references, with two partial exceptions,⁷⁸ did not include specific questions on manifest errors or an alleged breach of the precautionary principle. The questions of the referring courts largely focused on proportionality, so that the precautionary principle was mentioned by the ECJ in the only context where it could fit. Nor were *scientific uncertainty* and the *precautionary principle*

⁷⁴ Opinion of A.G. Kokott in Case C-343/09, *Afton Chemical*, cited *supra* note 3, and Judgment in Case C-343/09, *Afton Chemical*, cited *supra* note 6. It is worth noting that the Court had in other cases before *Afton Chemical* employed the "all relevant factors" test; see for instance Case T-75/06, *Bayer CropScience and Others v. Commission*, EU:T:2008:317 (hereafter, "*Bayer CropScience I*"), and Case C-425/08, *Enviro Tech Europe*, EU:C:2009:635 (hereafter, "*Enviro Tech I*"), both analysed in sub-section 5.1. Incidental references to the duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case can also be found in *Pfizer*, at para 171, and *Alpharma*, para. 184. However, the Opinion in *Afton Chemical* exemplifies this shift in a much clearer way.

⁷⁵ Opinion, para 25.

⁷⁶ See *supra* note 32.

⁷⁷ Case C-453/03, *ABNA and Others*, EU:C:2005:741; Case C-154/04, *Alliance for Natural Health and Others*, EU:C:2005:449; Case C-504/04, *Agrarproduktion Stebelow*, EU:C:2006:30; Case C-448/06, *cp-Pharma*, EU:C:2008:418; Case C-558/07, *S.P.C.M. and Others*, EU:C:2009:430; Case C-425/08, *Enviro Tech I*, cited *supra* note 74. See also the references to the precautionary principle in the context of proportionality in the first tobacco rulings; Case C-491/01, *British American Tobacco*, EU:C:2002:741, and Case C-434/02, *Arnold André*, EU:C:2004:800.

⁷⁸ The first exception is Case C-453/03, *ABNA and Others*; however, scientific uncertainty and the precautionary principle "stricto sensu" were hardly at stake in this case. The second exception is Case C-425/08, *Enviro Tech I*. In this case, analysed in sub-section 5.1, uncertainty and precautionary risk management were at stake. However, the ECJ found that the Commission had not resorted to the precautionary principle at all; for this reason, it did not assess whether the measures were in breach of the precautionary principle.

“*stricto sensu*”, as applicable to risk regulation and as distinguished from the general pursuit of a high level of public health, consumer or environmental protection, at stake in each and every of these cases.

These considerations do not apply to *Afton Chemical*, where separate and specific questions on a manifest error of assessment, the precautionary principle and proportionality were referred. Further, scientific uncertainty and a “*stricto sensu*” application of the precautionary principle were directly at stake. The Advocate General merged review of a breach or misapplication of the precautionary principle and proportionality review; the ECJ followed the Opinion.⁷⁹ This approach has entrenched in preliminary rulings where acts are challenged for being too restrictive; in these cases, unlike in direct actions for annulment, review of a breach or misapplication of the precautionary principle is always absorbed in the Court’s review of the proportionality of the final measures.⁸⁰ This occurs regardless of whether specific questions on manifest errors or the precautionary principle have been referred and regardless of whether legislative or regulatory acts are at stake.

In her overlapping assessment of the precautionary principle and proportionality, the Advocate General drew an analogy with the regulation of trade supplements,⁸¹ the Habitats Directive⁸² and the regulation of chemicals,⁸³ remarking that EU institutions can issue bans or set limits without (or pending) a comprehensive risk assessment.⁸⁴ She found that uncertainty has an effect “on the manner in which the principle of proportionality is applied”,⁸⁵ allowing for the adoption of protective measures, and that it is an authorisation (rather than a prohibition) which must be based on a comprehensive risk assessment.⁸⁶ After an analysis of the three prongs of proportionality, she concluded that the legislative act at issue did not breach the principle; the ECJ largely followed the Opinion.

Despite the acknowledgment of the risk manager’s broad discretion and the Court’s deferential review of proportionality, this case shows that an examination of the precautionary principle under the umbrella of proportionality cannot quite do justice to the former. In cases where scientific uncertainty and a “*stricto sensu*” application of the precautionary principle are at

⁷⁹ It is worth adding that, in para 54 of the Opinion, A.G. Kokott found that “[...] Directive 2009/30 was adopted directly on the basis of Article 95 EC. A legislative measure of that sort cannot be directly assessed according to whether it observes the precautionary principle. However, the precautionary principle applies primarily in connection with the assessment of the principle of proportionality”. Yet, in some preliminary rulings where legislative acts adopted under the same legal basis (now Article 114 TFEU) are challenged for not being protective enough, the ECJ has examined alleged breaches of the precautionary principle autonomously. See Case C-528/16, *Confédération Paysanne and others v. Premier Ministre and Ministre de l’Agriculture, de l’Agroalimentaire et de la Forêt*, EU:C:2018:583, even though the ECJ did not need to address and answer the relevant question in this case; and Case C-616/17, *Blaise and others*, EU:C:2019:800.

⁸⁰ See Case C-77/09, *Gowan*, EU:C:2010:803; Case C-221/09, *AJD Tuna*, EU:C:2011:153; Case C-157/14, *Neptune Distribution*, EU:C:2015:823; Case C-78/16, *Xylella*, cited *supra* note 36. See also the new tobacco rulings, Case C-477/14, *Pillbox 38*, EU:C:2016:324; Case C-547/14, *Philip Morris Brands and Others*, EU:C:2016:325; Case C-151/17, *Swedish Match*, EU:C:2018:938. Again, not all of these preliminary rulings involved scientific uncertainty and a “*stricto sensu*” application of the precautionary principle. However, in either case, the latter principle is always mentioned or analysed in the context of proportionality review.

⁸¹ Opinion, para 68.

⁸² Opinion, para 70.

⁸³ Opinion, para 72.

⁸⁴ *Ibid.*, paras. 67 and 69.

⁸⁵ Para 62.

⁸⁶ Para 70.

stake, a contextual analysis of the two principles obscures the rationale for precautionary risk management, the aims pursued by the risk manager and the key role of precaution. The scientific dimension of the precautionary principle, the relevance of different forms of uncertainty and the pursuit of enhanced levels of protection are not explicitly or fully addressed. Ultimately, the broader context of scientific uncertainty and the scientific basis for recourse to the precautionary principle are not explicitly or fully addressed.

The analysis of alleged breaches of the precautionary principle overlaps with the (different) question of the necessity of risk management measures and with strict proportionality review; arguably, then, the analysis of the precautionary principle becomes “ancillary” to and is absorbed within proportionality review. In this sense, an examination of alleged breaches of the precautionary principle under the umbrella of proportionality does not do justice to the reasons why precautionary action is being taken. To a greater or lesser extent, this emerges from all preliminary rulings on the validity of EU risk regulation measures;⁸⁷ it is also apparent from a comparison of these rulings with the analysis of the precautionary principle in cases like *Pfizer* and *Alpharma*.

Turning to the second relevant aspect in *Afton Chemical*, the examination of the national court’s question on an alleged manifest error of assessment shows the “vacuum” left by the precautionary principle. How to set the boundaries of a “manifest” error, where this is not analysed in the context of *precautionary* risk management? The referring court’s question was developed on the grounds that the risks connected to the use of the metallic additive had not been investigated by means of a comprehensive risk assessment. The Advocate General remarked that “an error of assessment cannot, on its own, call into question the validity of [an act]. Rather, what matters is whether the error of assessment [is] *legally relevant*” (emphasis added).⁸⁸

This statement is of crucial importance. What is the *legally relevant* manifest error of assessment that the Advocate General referred to, and how should it be interpreted? Under the *Pfizer* and *Alpharma* strand, legally relevant manifest errors of assessment are the ones committed in so far as EU institutions have misapplied the precautionary principle; risk managers will incur these errors if they have not conducted as thorough a risk assessment as possible in the present circumstances and if they are referring to hypothetical risks. Had the Advocate General analysed the questions on manifest errors and the precautionary principle together, she would have arguably found that the EU legislator had neither committed legally relevant manifest errors nor misapplied the precautionary principle; in the face of insufficient data, and in so far as it was provisionally impossible to conduct a thorough risk assessment, precautionary measures were warranted.⁸⁹ Indeed, waiting for the relevant risks to materialise would make the precautionary principle nugatory.

By contrast, the Opinion in *Afton Chemical* sets the notion of *legally relevant* manifest error of assessment against a different background. The Opinion emphasises that EU institutions “[...] must be able to show before the Court that in adopting [an] act they actually exercised their discretion, which *presupposes* the taking into consideration of *all the relevant factors and*

⁸⁷ For a more thorough engagement with the precautionary principle and its overarching tenets, albeit under the umbrella of proportionality review, see Case C-78/16, *Xylella*.

⁸⁸ Opinion, para 30.

⁸⁹ See *supra* section 3 and in particular Case T-13/99, *Pfizer*, para 160.

circumstances of the situation the act was intended to regulate” (emphasis added).⁹⁰ Not only must the [...] Courts, inter alia, establish whether the evidence relied on is factually accurate, reliable and consistent but also whether that evidence contains all the information which must be taken into account [...] and whether it is capable of substantiating the conclusions drawn from it”.⁹¹

The Opinion draws on the “all relevant factors” test;⁹² the exercise of the EU institutions’ broad discretionary powers *presupposes* the taking into consideration of *all the relevant factors and circumstances* of the situation that the act was intended to regulate. EU institutions, then, will incur a *legally relevant* manifest error of assessment if they fail to take into consideration *all the relevant factors*; in that case, they will have failed to comply with the *procedural preconditions* for the exercise of their broad discretion. In her Opinion, taking a deferential approach to review of administrative discretion, the Advocate General found that no errors of assessment had been incurred.⁹³ The Court followed the Opinion.

This different standard of procedural review triggers a set of considerations. First, the “all relevant factors” test has added a further layer of complexity to judicial review of EU risk regulation. Secondly, if compared to the *Pfizer* and *Alpharma* standard, it has considerably expanded the Court’s procedural scrutiny. Thirdly, this test builds on *administrative discretion* and an analysis of the procedural preconditions for its exercise. In cases where the “all relevant factors” test is applied, the Court does *not* draw any connection between administrative discretion and the precautionary principle; nor does it acknowledge the precautionary nature of risk management. In this sense, as the next sub-sections show, it fails to take the prudential nature of the relevant risk assessments and the risk manager’s focus on uncertainties and choice to resort to a precautionary approach into due consideration.

Fourthly, this test does not establish clear boundaries for the assessment of compliance with the procedural duty to take all relevant factors into consideration; in other words, it is unclear what the “relevant factors” may be in the highly complex field of EU risk regulation and in the face of scientific uncertainty. This, as shown in sub-section 5.4, affects the consistency of application of this standard, given that the relevant procedural elements to be taken into account are open to different interpretations.

Finally, a non-deferential application of this standard of review can catch precautionary measures. If the Court does not take a deferential approach, and if it opts for a thorough scrutiny of the factors taken (or not taken) into account, this standard of review results in quasi-substantive scrutiny of the relevant evidence.⁹⁴ To make some examples, the Court might hold that the results of an assessment conducted by means of a specific scientific method, one set of data, one body of scientific evidence or the results of an impact assessment are relevant factors that the risk manager should have taken into due consideration. This *directly* encroaches on the

⁹⁰ Para 35. For the same statement, see first and foremost Case C-269/90, *Technische Universität München*, para 14.

⁹¹ Para 29, citing inter alia Case C-269/90, *Technische Universität München*, EU:C:1991:438, para 14; Case C-425/08, *Enviro Tech I*, para 62; and Case C-326/05 P, *Industrias Químicas del Vallés v. Commission*, EU:C:2007:443, para 76. See also para 34, citing Case C-138/79, *Roquette*, Case C-326/05 P, *Industrias Químicas*, and Case C-425/08, *Enviro Tech I*.

⁹² See the clarification *supra* in the text of note 74.

⁹³ Paras. 42 to 50, and 42 and 49 in particular.

⁹⁴ See *infra* sub-section 5.4.

risk manager's discretion in the evaluation of the relevant facts and decision to draw specific inferences from the available scientific evidence, in light of the intended level of protection; further, it *indirectly* undermines his ability to enact precautionary risk management measures. Indeed, as sub-section 5.4 illustrates, the line between procedural review of administrative discretion and quasi-substantive review of the evidence relied upon can be a fine one. The acknowledgment of *administrative discretion* is *insufficient* to protect *precautionary risk management*; nor can the Court's deference be taken for granted.

5. Following Developments: Coexisting Strands

The following sub-sections take a closer look at the evolution of the Court's case law, analysing relevant cases under four different groups. This overview shows how the Court has differently framed the notion of administrative discretion and differently interpreted "manifest" errors of assessment, assessing the relevant implications for precautionary risk management.

The cases in the first group are the ones more closely adhering to the "all relevant factors" standard of review. The precautionary principle is barely mentioned in these cases, if at all. The Court's finding that the risk manager did not incur a manifest error of assessment thus relies on the (mere) acknowledgment of his broad administrative discretion. The cases in the second group are located halfway along the spectrum; the notion of a high level of protection and the precautionary principle surface at some point in the analysis, and are not immaterial to the Court's examination. However, the connection between administrative discretion and the power to pursue enhanced levels of protection and follow a precautionary approach remains implicit. These cases still draw on an application of the "all relevant factors" test.

The third group of cases draws on *Pfizer* and *Alpharma*. In these cases, the Court expressly acknowledged the precautionary nature of the measures, drew a clear connection between administrative discretion and precautionary risk management, and interpreted the notion of a manifest error of assessment in light of the precautionary principle. This effectively safeguards precautionary measures. Finally, the cases in the fourth group blur the boundaries between procedural and quasi-substantive review; in all cases but one, this has occurred through an expansion of review of the risk manager's duty to take "all relevant factors" into account. As illustrated in sub-section 5.4, quasi-substantive review is liable to undermine precautionary risk management.

A further, preliminary clarification is necessary. The specific pleas in law of the applicants or the specific questions raised by the referring courts can make it more or less easy for the Court to engage with the precautionary principle; clearly, this will be easier if the applicants allege a breach or misapplication of the precautionary principle, or if national courts refer specific questions surrounding the principle. Perhaps more worryingly, EU institutions themselves are too often reluctant to acknowledge their adherence to a precautionary approach to risk management.⁹⁵ However, none of this really prevents the Court from taking the precautionary

⁹⁵ This emerges clearly from an analysis of cases in the field of chemicals, where EU institutions never refer to uncertainties or invoke the precautionary principle; however, an analysis of most cases in the field of pesticides also shows that the contested measures rarely – if ever – mention the precautionary principle as their basis. To give just one example, see Case T-584/13, *BASF Agro and Others v. Commission*, EU:T:2018:279, para. 152.

principle into account and using it to set the boundaries of (legally relevant) manifest errors of assessment.

There are at least two reasons for this. First, all the cases under analysis involve different forms of scientific uncertainty and challenges to acts which are deemed too restrictive. On these grounds, all cases involve a focus on persisting uncertainty, adherence to a prudential risk assessment and precautionary risk management. Secondly, all cases include complaints or questions on manifest errors of assessment or breaches of law. As explained in the previous sections, the notion of a manifest error of assessment can (and arguably should) be interpreted against the backdrop of the precautionary principle.

Admittedly, express references to the precautionary principle can be slightly more difficult in cases involving “methodological” uncertainties; in these cases, as already explained, scientific uncertainty stems from different results obtained through the use of different (more or less prudential) methods. Unsurprisingly then, the vast majority of cases on chemicals fall within the first group and fail to acknowledge that precautionary risk management measures are at stake; these cases relate to scientific methodological aspects. Conversely, it is easier to identify the preconditions for the application of the precautionary principle where “hazard-related” or “risk-related” uncertainties are at stake. Cases on pesticidal active substances, which involve more direct references to absence of scientific proof of a causal link or scientific insufficiency, deploy the precautionary principle to a greater extent.

However, as clearly stated in the Commission Communication, the precautionary principle may apply in *all* cases of scientific uncertainty; it is irrelevant what the specific dimension of uncertainty at stake is.⁹⁶ And indeed, as the Court itself remarked, “the application of the precautionary principle is not limited to cases in which it is uncertain that there is a risk; the principle may also be applied where a risk has been proved to exist and where the Commission must assess whether that risk is acceptable or not [...], or assess how it should be dealt with in a risk management context [...]”.⁹⁷ Against this backdrop, it is all the more important that the Court explicitly addresses the boundaries of scientific uncertainty and precautionary risk management in its case law.

5.1 “All Relevant Factors” and Administrative Discretion

This line of cases shows a clear focus on administrative discretion, combined with an application of the “all relevant factors” test. In the application of this test, the Court took a deferential approach; for this reason, these cases have not had an impact on precautionary risk management. However, the Court’s findings rely on the mere acknowledgment of the risk manager’s broad discretion. No connection is drawn between the notion of administrative discretion and the precautionary principle; nor do these cases acknowledge uncertainties or recognise the precautionary nature of the relevant risk management measures.

⁹⁶ For a reference to this point, see *supra* section 1. And indeed, it is worth stressing that even the original definition of the precautionary principle in the Court’s case law, refers to “scientific uncertainty as to the *existence* or *extent* of risks”. See Case C-157/96, *BSE I*, paras 63 and 64, and Case C-180/96, *BSE II*, para 99.

⁹⁷ Case T-429/13, *Bayer CropScience v. Commission*, EU:T:2018:280, para 340, referring to the examination carried out in paras. 122, 124 and 125 (hereafter, “*Bayer CropScience II*”).

In Case T-75/06 *Bayer CropScience I* the applicant sought the annulment of a Commission Decision on (non-)inclusion of a pesticidal active substance in the relevant Annex to Directive 91/414. Under their first plea, the applicants alleged inter alia that the assessment was incomplete and based on selective use of the data submitted by the applicant, and that the Commission had failed to examine new data provided in response to the newly adopted evaluation criteria.⁹⁸

As the GC pointed out, the issues at stake in this case boiled down to “whether the Commission could legitimately base [its refusal] on the *absence of sufficient data*” (emphasis added),⁹⁹ indeed, the applicants alleged that the Commission had based its evaluation on a zero risk threshold, that it had referred to lack of information rather than identified risks, and that it had required the applicants to produce a probatio diabolica, proving that the active substance was safe.¹⁰⁰ All these assertions could have been easily rebutted by framing the notion of a manifest error of assessment against the background of the precautionary principle. However, the GC’s review of manifest errors was explicitly connected to the examination of whether the Commission had examined “all the relevant facts of the case which support the conclusion reached”.¹⁰¹ There is no reference to the precautionary principle, the notion of scientific uncertainty or hypothetical risk.

In *Enviro Tech I*¹⁰² the ECJ delivered a preliminary ruling on the validity of the classification of n-propyl bromide (“nPB”) as a highly flammable and toxic for reproduction substance. The Commission’s classifications were clearly based on results obtained through prudential risk assessments; in the face of diverging data and multiple uncertainties, the relevant risks were over-estimated and the resulting classification drew on a precautionary approach. The referring court asked whether the classification as a highly flammable substance was valid in light of the non-application of the assessment criteria enshrined in Directive 67/458; further, it raised doubts in so far as the classification as a toxic for reproduction substance had been adopted “without clear results in appropriate animal studies where toxic effects have been observed to justify a strong presumption that human exposure [...] may result in developmental toxicity”, and on the basis of tests using a considerably higher concentration of nPB than the one to which a person would be exposed when handling the product. The referring court asked whether such classifications, which it expressly considered to be based on the precautionary principle rather than on the methods and criteria of Directive 67/458, were valid and in compliance with the principle of proportionality.¹⁰³

In respect of the classification as a highly flammable substance, despite a brief acknowledgment of scientific uncertainty,¹⁰⁴ the ECJ focused on the broad discretion of EU institutions to choose the most appropriate methods of risk assessment.¹⁰⁵ It also emphasised that the Commission based its findings on a “number of scientific factors [...] which permitted

⁹⁸ Case T-75/06, *Bayer CropScience I*, cited *supra* note 74, paras. 72 and 73. The Appeal was dismissed in Case C-517/08 P, *Makhetshim-Agan Holding and Others v. Commission*, EU:C:2010:190.

⁹⁹ Para 112.

¹⁰⁰ Para 128.

¹⁰¹ Case T-75/06, *Bayer CropScience I*, para 184.

¹⁰² Case C-425/08, *Enviro Tech I*, cited *supra* note 74.

¹⁰³ Para 28.

¹⁰⁴ Para 61.

¹⁰⁵ Paras. 50 to 55.

them to classify that substance in the category [...]”. On these grounds, it conducted a review of the risk manager’s duty to take all relevant factors into consideration¹⁰⁶ and concluded that the exercise of the Commission’s classification was not vitiated by a manifest error of assessment. Similar considerations were developed on the issue of toxicity for reproduction. Yet again expanding the “discretionary powers” element to the detriment of precautionary risk management, the ECJ found that a manifest error of assessment had not been incurred. Finally, in its joined examination of the precautionary principle and proportionality, the Court found that “contrary to the allegations [...] the Commission did not base its [classification] on the precautionary principle [...]”;¹⁰⁷ on these grounds, it did not assess the alleged breach of the precautionary principle.

In Case T-291/04 *Enviro Tech II*,¹⁰⁸ the applicants sought the annulment of the very same classifications of nPB and damages for alleged non-contractual liability of the EU institutions for unlawful conduct. In its review of the alleged manifest errors of assessment the GC drew on the ECJ’s decision in *Enviro Tech I*, again emphasising the Commission’s broad margins of administrative discretion to support the finding that it had complied with legislative requirements and taken all relevant data into due account.¹⁰⁹ This was confirmed on appeal by the ECJ.¹¹⁰

A similar approach can be seen in Cases C-14/10 *Nickel Institute*¹¹¹ and C-15/10 *Etimine*.¹¹² In *Nickel Institute*, the ECJ delivered a preliminary ruling on the validity of the classification of a number of nickel-based substances. The referring court asked whether, inter alia, the classifications were valid in so far as they were based on tests conducted using the read-across method; this choice was challenged by the applicants in front of the national court, on the grounds that Directive 67/548 did not provide for use of this method.

The Court justified the use of the read-across method by reference to the latter’s inclusion in other legislative instruments, by emphasising the non-exhaustive nature of the list of sources from which data may be extracted, and by stressing the complementarity of different scientific methods.¹¹³ In so far as the applicants claimed that, even if recourse to this method was permissible, its application in the present case was manifestly flawed, the Court drew on the risk manager’s broad discretion to conclude that these arguments did “not in themselves permit the view to be taken that the Commission [...] manifestly exceeded the limits of its discretion”.¹¹⁴ The focus is clearly on the notion of administrative discretion, without any acknowledgment of the risk manager’s discretionary power to take into account the results of prudential risk assessments.

¹⁰⁶ Paras. 62 to 64.

¹⁰⁷ Para 74. The Commission, which also focused on its broad administrative discretion, contended that the classification was “in no way based [...] solely on the precautionary principle” (emphasis added); see para 44.

¹⁰⁸ Case T-291/04, *Enviro Tech Europe and Enviro Tech International v. Commission*, EU:T:2011:760 (hereafter, “*Enviro Tech II*”).

¹⁰⁹ Para 157.

¹¹⁰ Case C-118/12, *Enviro Tech Europe v. Commission*, EU:C:2013:37.

¹¹¹ Case C-14/10, *Nickel Institute*, EU:C:2011:503.

¹¹² Case C-15/10, *Etimine*, EU:C:2011:504.

¹¹³ Paras. 62 to 75.

¹¹⁴ Para 77.

Among the most recent cases in this strand, we find T-400/17 *Deza II*.¹¹⁵ In this case the applicant pointed to the absence of conclusive evidence establishing a causal link between the ingestion of anthraquinone and the carcinogenic effects observed in laboratory tests; uncertainty persisted as to what extent carcinogenic effects were connected to exposure to this substance. In its examination of the various points raised by the applicants, the GC merely found that they had failed to prove that EU institutions had not taken all relevant factors into account, with a view to establishing that the final decision was vitiated by a manifest error of assessment.

5.2 “All Relevant Factors”, Administrative Discretion and a High Level of Protection

This strand of case law draws on procedural review of the duty to take all relevant factors and circumstances into account; the notion of a manifest error of assessment is not interpreted in light of the precautionary principle. However, a careful analysis of these cases shows that the notion of a high level of protection and the precautionary principle are not immaterial to the Court’s examination. Rather, the connection between administrative discretion and the risk manager’s power to draw on a precautionary approach remains implicit, as the relevant notions and implications are not fleshed out.

In Case T-93/10 *Bilbaina I*¹¹⁶ the applicants sought the partial annulment of the ECHA’s decision to identify CTPHT as a substance meeting the criteria laid out in Article 57 REACH. By their second plea, the applicants claimed an error of assessment or error of law in so far as the identification of CTPHT as a substance with persistent, bioaccumulative and toxic (“PBT”) and very persistent and very bioaccumulative (“vPvB”) properties resulted from the application of the summation method, which involves an assessment of the properties of the constituents of the substance rather than an assessment of the properties of the substance. The applicants complained that the ECHA’s dossier did not observe the requirements of REACH because the summation method is not laid down in the Annexes to the Regulation.¹¹⁷

The GC found that, given that “the constituents of a substance are an integral part of it, it cannot simply be held that the ECHA made a manifest error of assessment in taking the view that [CTPHT] had PBT and vPvB properties on the grounds that its constituents had such

¹¹⁵ Case T-400/17, *Deza v. Commission*, EU:T:2018:712 (“*Deza II*”), under appeal.

¹¹⁶ Case T-93/10, *Bilbaina de Alquitranes and Others v. ECHA*, EU:T:2013:106 (“*Bilbaina I*”). See also Case T-94/10, *Rütgers Germany and Others v. ECHA*, EU:T:2013:107; Case T-95/10, *Cindu Chemicals and Others v. ECHA*, EU:T:2013:108; and Case T-96/10, *Rütgers Germany and Others v. ECHA*, EU:T:2013:109. The Appeals were respectively dismissed in Case C-287/13 P, *Bilbaina de Alquitranes and Others v. ECHA*, EU:C:2014:599; Case C-288/13 P, *Rütgers Germany and Others v. ECHA*, EU:C:2014:2176; Case C-289/13 P, *Cindu Chemicals and Others v. ECHA*, EU:C:2014:2175; and Case C-290/13 P, *Rütgers Germany and Others v. ECHA*, EU:C:2014:2174..

¹¹⁷ Case T-93/10, *Bilbaina I*, para 74. The applicants also alleged that the assessment of the constituents at issue did not provide a sufficient basis to identify CTPHT as a substance having PBT and vPvB properties, on the grounds that none of the constituents besides anthracene had been individually identified as having PBT and vPvB properties and that, in the case of anthracene, the 0.1% threshold had not been met. The Court found that they had failed to prove a manifest error of assessment in this respect.

properties”.¹¹⁸ Notably, the GC remarked that the opposite conclusion would “not take sufficient account of the objective pursued by [REACH], [...] which is to ensure a *high level of protection of human health and the environment* [...]” (emphasis added).¹¹⁹ Against this backdrop, drawing on the technical-scientific reasons adduced by the ECHA and on a teleological interpretation of REACH, the GC found that whilst an application of the summation method was not expressly indicated in the Regulation, the latter did “not preclude such approach”.¹²⁰

The GC then engaged in a thorough procedural analysis of the points raised by the applicants, with a view to ascertaining whether the ECHA had taken all relevant factors into consideration in the application of the summation method. Importantly, it noted that assessing hazardous substances on the basis of their constituents allows for an analysis of how the constituents will behave as independent substances in the environment and release hydrocarbons with PBT or vPvB properties. By contrast, the study of a substance as a whole does not lead to significant results in this respect. The physical form of the substance may impede the release of the constituents in laboratory tests; however, in reality, the single constituents will release hydrocarbons with PBT or vPvB properties in the environment after a certain time.¹²¹

Clearly, the choice to resort to the summation method drew on a prudential approach to risk assessment, whose results then fed into precautionary risk management. However, despite its initial reference to the notion of a high level of protection, the GC did neither mention scientific uncertainty, nor the prudential nature of this risk assessment. In a different vein, it underlined that the substance “was not identified as having PBT and vPvB properties *solely because* a constituent of that substance has a certain number of PBT and vPvB properties, *but that the proportion in which such a constituent is present and the chemical effects of the presence of such a constituent were also taken into account* [...]”;¹²² in other words, it focused on the procedural duty to take all factors into account and found that, in this respect, the decision was not vitiated by a manifest error of assessment.

A similar focus on procedural factors, combined with references to a high level of protection and the precautionary principle, emerges from an analysis of Case T-368/11 *Polyelectrolyte*.¹²³ In this case the applicants challenged various restrictions on Acrylamide. The applicants claimed that, in its evaluation of risks, the Commission had failed to take account of all relevant factors and incurred a manifest error; more specifically, they alleged that the information relied upon did neither relate to exposure arising from uses of acrylamide that are known or reasonably foreseeable, nor to uses to which humans would be likely to be exposed.¹²⁴ Again, the GC conducted a thorough procedural review. Among its complaints, the applicants raised the point that the Commission had made a manifest error of assessment by drawing on information on exposure scenarios that were not known or reasonably foreseeable in the EU,

¹¹⁸ Para 83.

¹¹⁹ Ibid.

¹²⁰ Para. 83.

¹²¹ Paras. 90 and 91.

¹²² Para 100.

¹²³ Case T-368/11, *Polyelectrolyte Producers Group and Others v. Commission*, EU:T:2013:53. The Appeal was dismissed in Case C-199/13 P, *Polyelectrolyte Producers Group and Others v. Commission*, EU:C:2014:205.

¹²⁴ Para 25.

i.e. not representative.¹²⁵ The GC examined whether, in relying on data about worst-case scenarios, the Commission had incurred a manifest error of assessment. On the one hand, it noted that the pursuit of a high level of protection and the precautionary principle are enshrined in the Treaties and in relevant legislation, so that the Commission was entitled to take into consideration these data.¹²⁶ On the other hand, the GC's review of the duty to take all relevant factors at stake is still at the heart of the examination; in this respect, it found that although the EU risk assessment report took account of the worst case scenario, it also took into consideration the normal conditions of use.¹²⁷ Ultimately, this is the basis and justification for the final finding that the decision was not vitiated by a manifest error.¹²⁸

5.3 Reconnecting Manifest Errors of Assessment, Administrative Discretion and Precautionary Risk Management

The cases in this group follow the *Pfizer* and *Alpharma* line of reasoning, wherein the analysis of manifest errors of assessment is set against the backdrop of the notions of scientific uncertainty (as opposed to hypothetical risk), precautionary risk management and the overarching tenets of the precautionary principle. In some of these cases, complaints alleging a failure to take all relevant factors into account and complaints on manifest errors of assessment in scientific matters are kept distinguished; in the analysis of the latter complaints, the Court largely resorted to the precautionary principle. In other cases, review of whether the risk manager took all relevant factors into account is ultimately absorbed in the Court's review of manifest errors of assessment in scientific matters; the latter form of review is explicitly set against the background of the precautionary principle.

Overall, in all cases in this strand, the Court did not quite focus on checking whether the procedural preconditions for the risk manager's exercise of discretion had been complied with (the "all relevant factors" test). Rather, like in *Pfizer* and *Alpharma*, it drew a clear association between *administrative discretion* and *precautionary risk management*. Review of compliance with proportionality is analysed separately, having regard to the risk management measures at issue rather than their scientific substantiation.¹²⁹

Case T-392/02 *Solvay*, another case on the withdrawal of additives used in animal feed, mirrors *Pfizer* and *Alpharma*. The applicants alleged, inter alia, breaches of law, manifest errors and misapplication of the precautionary principle, in so far as they claimed that the withdrawal was based on a purely hypothetical approach to risk.¹³⁰ The GC closely followed the line of reasoning in the "twin" *Pfizer* and *Alpharma* cases, interpreting the notion of a manifest error

¹²⁵ Para 50.

¹²⁶ Para 62.

¹²⁷ Para 59.

¹²⁸ For another example, see Case T-115/15, *Deza v. ECHA*, EU:T:2017:329 ("*Deza I*"). The Appeal was dismissed in Case C-419/17 P, *Deza v. ECHA*, EU:C:2019:52.

¹²⁹ In this strand, see also Case T-201/13, *Rubinum v. Commission*, EU:T:2015:311, and the Opinion of A.G. Mengozzi in Case C-680/16, *August Wolff and Remedia v. Commission*, EU:C:2018:819.

¹³⁰ Case T-392/02, *Solvay Pharmaceuticals v. Council*, EU:T:2003:277, para 27. The case was not appealed.

of assessment against the broader backdrop of persisting uncertainty and precautionary risk management.¹³¹

In Case T-326/07 *Cheminova* the applicants sought the annulment of a 2007 Commission Decision on the (non-)inclusion of an active pesticidal substance in the relevant Annex to Directive 91/414. The applicants complained, inter alia, that the Commission had failed to take into account all information, data and studies, so that its finding that scientific information was insufficient was unsubstantiated,¹³² and that the decision was not based on the latest science.¹³³ After an examination of whether all data provided by the applicants had been taken into account, the GC ultimately based its reasoning on the precautionary principle¹³⁴ and concluded that “the applicants have not shown that the evidence available to the Commission would have dispelled all reasonable doubt as to malathion’s harmful effects”.¹³⁵ The same occurred in Case T-71/10 *Xeda*, which also regarded the withdrawal of authorisation for a pesticidal active substance. The applicants challenged the EFSA’s conclusion that a number of concerns remained and that it was impossible to perform a reliable exposure assessment, due to the absence of data or insufficiency of the available data, again arguing that this conclusion rested on a hypothetical approach to risk.¹³⁶ The conclusion of the GC’s assessment, conducted in light of the precautionary principle,¹³⁷ was that the applicant had not proven any manifest errors of appraisal.¹³⁸ Similar considerations apply to T-31/07 *Du Pont de Demours*, where the applicant also sought damages and the GC engaged in a thorough analysis of the boundaries of precautionary risk management.¹³⁹

However, the triad of cases which best mirrors the “twin” decisions in *Pfizer* and *Alpharma* consists of *Dow Agrosciences*,¹⁴⁰ *Sepro Europe*¹⁴¹ and *Bayer CropScience II*.¹⁴² All these cases involved challenges to withdrawals of authorisations for pesticidal active substances. In *Dow Agrosciences*, like in previous cases, the applicants challenged the Commission’s departure from the positive results of the EFSA’s risk assessment; the GC rejected this line of argument.¹⁴³ Further, they alleged manifest errors of assessment in that the Commission had not taken all factors into account¹⁴⁴ and its findings were not scientifically substantiated.¹⁴⁵ Part

¹³¹ See paras. 121 to 124 and 137 to 167. See also Case T-177/02, *Malagutti v. Commission*, EU:T:2004:72, paras. 50 to 55 (not appealed).

¹³² Case T-326/07, *Cheminova and Others v. Commission*, EU:T:2009:299, para 94 (not appealed).

¹³³ Paras. 158 et seq.

¹³⁴ Para 166.

¹³⁵ Para 171.

¹³⁶ Case T-71/10, *Xeda International and Pace International v. Commission*, EU:T:2012:18, paras. 64 et seq. The Appeal was dismissed in Case C-149/12 P, *Xeda International and Pace International v. Commission*, EU:C:2013:433.

¹³⁷ Paras. 69 to 78.

¹³⁸ Para 120.

¹³⁹ Case T-31/07, *Du Pont de Demours (France) and Others v. Commission*, EU:T:2013:167, paras. 128 to 150 and 151 to 214 (not appealed).

¹⁴⁰ Case T-475/07, *Dow Agrosciences and Others v. Commission*, EU:T:2011:445. The Appeal was dismissed in Case C-584/11 P, *Dow Agrosciences and Others v. Commission*, EU:T:2013:281.

¹⁴¹ Case T-483/11, *Sepro Europe*, EU:T:2013:407 (not appealed).

¹⁴² Case T-429/13, *Bayer CropScience II*, cited *supra* note 97.

¹⁴³ Case T-475/07, *Dow Agrosciences and Others v. Commission*, EU:T:2011:445, para 87, and case law cited therein. In this respect, see also *Pfizer*, *Bayer CropScience I* and *Gowan*.

¹⁴⁴ Paras. 100 et seq.

¹⁴⁵ Paras. 138 et seq.

of the analysis of whether all factors had been taken into consideration was absorbed in the GC's review of the scientific substantiation of the measures, against the backdrop of the notion of precautionary risk management.

Moreover, in this case, the GC added a further specification. After an analysis of the precautionary principle and political role of EU risk managers in the determination of the threshold of acceptable risk,¹⁴⁶ it held that “in order to establish that the Commission committed a manifest error of assessment [...] such as to justify the annulment of a decision [...] the [scientific] evidence adduced by the applicant must be sufficient to make the factual assessments used in the decision *implausible*” (emphasis added).¹⁴⁷ This reference to “implausibility” bears a close resemblance to the finding of Advocate General Jääskinen in Case C-77/09 *Gowan* that risk management measures could only be rendered invalid by *flagrant inconsistency* with a risk assessment “based on an undisputed methodology leaving no room for scientific uncertainty”.¹⁴⁸ *Gowan*, a preliminary ruling on the validity of restrictions on a pesticidal active substance, also involved a decision departing from the positive results of a risk assessment.¹⁴⁹ However, in *Dow Agrosciences*, this finding is more clearly and explicitly set in the context of precautionary risk management. The procedural analysis of the Opinion in *Gowan*, on the other hand, set the notion of manifest error of assessment and “flagrant inconsistency” against the background of the risk manager’s broad discretionary powers.¹⁵⁰ The centrality of the of the precautionary principle is even clearer in *Sepra Europe*.¹⁵¹ Finally, in *Bayer CropScience II*, the GC powerfully reasserted the connection between the interpretation of manifest errors of assessment and the need to safeguard precautionary risk management. The amendment of the conditions of approval of neonicotinoids, highly controversial pesticidal active substances, was at stake in this case. The GC conducted a thorough preliminary analysis of the precautionary principle,¹⁵² technical-scientific risk assessment,¹⁵³ the determination of the level of risk deemed unacceptable,¹⁵⁴ risk management,¹⁵⁵ the burden of proof¹⁵⁶ and the scope of judicial review,¹⁵⁷ including a reference to the “plausibility” criterion mentioned in *Dow AgroSciences*.¹⁵⁸

¹⁴⁶ Paras. 143 et seq.

¹⁴⁷ Para 152, citing Case T-380/94, *AIUFFASS and AKT v. Commission*, EU:T:1996:195, para 59, and Case T-308/00, *Salzgitter v Commission*, EU:T:2013:30, para 138. In judicial review of EU risk regulation, see also the references to “implausibility” in Case T-257/07, *France v. Commission*, EU:T:2011:444, paras. 86, 99, 109 and 214, and Case T-201/13, *Rubinum*, cited *supra* note 129.

¹⁴⁸ Opinion of A.G. Jääskinen in Case C-77/09, *Gowan*, EU:C:2010:432, para 74.

¹⁴⁹ Even though, in *Gowan*, the relevant positive assessment had not been conducted at EU level but by the rapporteur Member State.

¹⁵⁰ Opinion of A.G. Jääskinen in Case C-77/09, *Gowan*. Compliance with the precautionary principle was analysed in greater detail in the Judgment of the Court, under the umbrella of proportionality (paras. 68 to 79); however, the notion of a “manifest” error of assessment was still analysed against the backdrop of the risk manager’s duty to take all relevant factors into account (see paras. 55 to 57), as in *Afton Chemical*.

¹⁵¹ Case T-483/11, *Sepra Europe*, paras. 38 to 62.

¹⁵² Case T-429/13, *Bayer CropScience II*, paras. 109 to 111.

¹⁵³ *Ibid.*, paras. 112 to 121.

¹⁵⁴ *Ibid.*, paras. 122 to 124.

¹⁵⁵ Paras. 125 and 126.

¹⁵⁶ Paras. 137 to 142.

¹⁵⁷ Paras. 143 to 147.

¹⁵⁸ Para 145.

It is in this light that the GC examined all the applicants' complaints on alleged manifest errors of assessment, including the failure to take all relevant studies and data into due consideration, under the umbrella of the precautionary principle and scientific uncertainty. Just like in *Pfizer* and *Alpharma*, the complaints alleging manifest errors of assessment and those alleging misapplication of the precautionary principle were examined together. Indeed, with unprecedented clarity, the GC stated in paragraph 336 that "the answer to the question whether, given the Commission's *discretion* in relation to risk management, *certain scientific knowledge* and information supported the conclusion that the conditions of approval were no longer satisfied and that the approval of the substances covered had to be amended is [...] influenced by the *precautionary principle*".¹⁵⁹ This is the clearest possible acknowledgment of the need to draw a connection between the notions of manifest error of assessment, political-administrative discretion, scientific uncertainty and precautionary risk management; this is what the Court did in this case, rejecting the applicants' complaints one by one.

5.4 From Procedural Review of "All Relevant Factors" to Quasi-Substantive Review

This final sub-section analyses cases where the Court has applied a quasi-substantive standard in its review of EU precautionary measures challenged by the applicants for being too restrictive.¹⁶⁰ This standard, which crosses the fine line between procedural and substantive review, is "quasi-substantive" in a twofold sense. First, it expands on review of compliance with the procedural preconditions for the exercise of administrative discretion. In this sense, it cannot be properly defined as a "substantive" standard. Secondly, it is "quasi-substantive" in its effects. As the analysis shows, the Court's scrutiny of the evidence relied upon by the risk manager and its examination of whether it was taken into due consideration in the final decision might indirectly constrain administrative discretion. The suggestion that specific assessments should be conducted or specific factors should be taken into account pertains to the relevant procedural obligations of the risk manager; the Court does not *directly* pick and choose the evidence which should substantiate the final measures, nor does it conclude that conducting certain assessments or taking some evidence into account should result in a specific regulatory measure. However, employing a quasi-substantive standard may *indirectly* yield the same result. This is liable to impact on precautionary risk management.

Artogodan, the first case under analysis in this section, may in its own right be defined as the only instance of "substantive" review of the scientific evidence underlying risk management measures; under a different reconstruction, the GC simply found that the measures at stake

¹⁵⁹ Para 336.

¹⁶⁰ This section does not examine cases where acts deemed too restrictive were annulled for procedural breaches which are ultimately unrelated to the *evidence* procedurally relied upon; examples are Case T-125/96, *Boheringer v. Council and Commission*, EU:T:1999:302; Case C-326/05 P, *Industrias Químicas del Vallés*; Case T-344/00 *CEVA and Pharmacia Enterprises v. Commission*, EU:T:2003:40 (on liability of EU institutions, overturned on appeal); Case T-273/03, *Merck Sharp & Dohme and Others v. Commission*, EU:T:2006:36. A couple of early decisions blur the boundaries between an analysis of procedural breaches and the Court's indirect suggestion that the measures were scientifically unsubstantiated; see Case C-212/91, *Angelopharm v. Freie und Hansestadt Hamburg*, EU:C:1994:21; and Case T-120/96, *Lilly Industries v. Commission*, EU:T:1998:141.

were in breach of proportionality. *ICdA*, *BASF* and *Bilbaína II*, on the other hand, exemplify the impact of a non-deferential application of the “all relevant factors” test. In these cases, the Court drew on the “all relevant factors” standard to conduct an intrusive examination of the relevant evidence.

In *Artegodan*, the applicants sought the annulment of a string of Commission Decisions on the withdrawal of marketing authorisations for medicinal products containing a range of anorectic agents. Despite the inability to establish a causal link, use of these anorectic agents had long been associated with a range of uncertain health risks; in this respect, no new scientific evidence had become available since the original authorisations. However, “accumulated scientific knowledge acquired over the years”¹⁶¹ had proven that the therapeutic efficacy of these substances was very limited. On these grounds, drawing on the Opinion of the relevant Scientific Committee, the Commission determined that the risk/benefit balance was no longer positive and withdrew the authorisations.¹⁶²

The GC argued that the precautionary principle requires withdrawal of an authorisation “where new data give rise to serious doubts as to either the safety or the efficacy of the medicinal product in question and those doubts lead to an unfavourable assessment of the benefit/risk balance of that medicinal product”.¹⁶³ After this acknowledgment, quite surprisingly, it found that the Committee’s Opinion did not make any reference to “new scientific data or information which [...] would explain the development of [medical] consensus”¹⁶⁴ and concluded that changes in clinical and therapeutic practices could not justify the withdrawals in the absence of new scientific evidence.¹⁶⁵

This decision lends itself to a twofold reading. If regard is had to the GC’s finding that the development of medical consensus cannot qualify as “new” scientific evidence, *Artegodan* exemplifies the impact of a substantive standard of review. Ultimately, the GC scrutinised the “quality” of the scientific data underlying the measures and selected the specific type of scientific evidence that the Commission could rely upon. In the face of persisting uncertainty on the health risks posed by anorectic agents, and in light of the re-assessment of their benefits, the Commission had clearly taken the view that their use no longer met the threshold of acceptable risk. The GC’s decision *directly* impacted on this – *discretionary* and *precautionary* – evaluation.

An alternative reading suggests that, while pointing to the “novelty” of the relevant scientific evidence, the GC in fact tacitly scrutinised whether the measures complied with the principle of proportionality. From this different angle of analysis, the GC targeted the risk management measures and the level of protection that the measures pursued. Under this reconstruction, the GC implicitly suggested that the withdrawals were in breach of proportionality. Ultimately, this does not change the final result. As argued in the second section, and as this case arguably shows, proportionality review will still encroach on the determination of the intended level of

¹⁶¹ 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*, cited *supra* note 42, para 39.

¹⁶² Paras. 38 et seq.

¹⁶³ Para 192.

¹⁶⁴ Para 210.

¹⁶⁵ Paras. 211 and 220.

protection and lower it. *Artegoda*n has remained an isolated “anomaly” in the case law of the Court.¹⁶⁶

In a different vein, *International Cadmium Association (“ICdA”)*¹⁶⁷ shows an expansion of the Court’s review under the “all relevant factors” test. While the GC nominally followed a procedural standard of review, the effects are quasi-substantive in nature. This case involved a challenge to a 2011 amendment to Annex XVII (Cadmium) of REACH. By this amendment, cadmium and its compounds (including cadmium pigments) could no longer be used in articles or mixtures produced from plastic;¹⁶⁸ this significantly expanded the pre-existing restrictions, extending their scope from mere restrictions on use in PVC to encompass use in *all* plastic materials.¹⁶⁹ The GC annulled the Commission Regulation on the grounds of an alleged failure to take into due consideration the behaviour of cadmium pigments (as opposed to cadmium) in plastic materials (as opposed to the more circumscribed case of PVC). In this sense, the GC allegedly applied a procedural standard of review, pointing to a procedural failure to conduct an individual risk assessment and thus concluding that the Commission had incurred a manifest error.

Yet, a careful analysis of the case shows that the Commission had adduced some evidence on the behaviour of cadmium pigments in all plastic materials. For instance, the Commission referred to a 2000 report identifying a link between the presence of cadmium in the environment, on the one hand, and the incineration of (any kind of) plastic containing cadmium pigments, or leaching of plastic waste from incinerators, on the other. In a similar vein, the Commission relied on a further study on the behaviour of cadmium and cadmium pigments in landfills. However, the GC found that these studies could not reach specific conclusions as to the precise sources of cadmium detected in landfills,¹⁷⁰ including the presence of cadmium pigments in plastic materials other than PVC.¹⁷¹ In other words, the GC found that these scientific studies were not sufficiently cogent or specific.

The standard of scrutiny employed in *ICdA* crosses the line between procedural review of compliance with the obligation to take all factors into account, and substantive review of the quality and specificity of the scientific evidence relied upon. Cadmium and its pigments are non-threshold carcinogens and pose high public health and environmental risks; in light of exposure from multiple sources (waste incineration and landfills, steel production, oil and coal combustion, traffic), the measure challenged in this case was part of a broader EU risk reduction strategy. Clearly, technical difficulties may come into play if specific evidence on the behaviour of cadmium pigments in each and every type of plastic disposed of in landfills or incinerated is to be provided. Would it be possible at all to conduct as specific a risk assessment as the GC suggested? If this proved impossible, by requesting a specific standard for the scientific substantiation of the measures, the GC would indirectly limit the risk

¹⁶⁶ The Appeal was dismissed in Case C-39/03 P, *Commission v. Artégoda and Others*, EU:C:2003:418. However, the ECJ upheld the annulment of the acts due to the Commission’s lack of competence to adopt the decisions at issue; it did not assess the Commission’s plea in law relating to the interpretation of the conditions for withdrawal of the authorisations.

¹⁶⁷ Case T-456/11, *International Cadmium Association and others v. Commission*, EU:T:2013:594 (not appealed).

¹⁶⁸ Para 17.

¹⁶⁹ Paras. 4 et seq.

¹⁷⁰ Paras. 55 and 56.

¹⁷¹ Para 70.

manager's discretionary choice to enact precautionary measures in a case involving a highly hazardous substance. As already explained, this is typical of quasi-substantive review.

In *BASF*,¹⁷² on the other hand, the applicants challenged a Regulation amending the conditions of approval for the pesticidal active substance fipronil. The applicants alleged a misapplication of the precautionary principle¹⁷³ in so far as the Commission had not conducted an impact assessment, analysing the economic costs and benefits of alternative risk management options, as allegedly mandated by point 6.3.4 of the Communication on the Precautionary Principle.¹⁷⁴ The GC noted that the Communication does *not* specify the format or scope of the evaluation of any advantages and disadvantages associated with risk management measures; in particular, the risk manager does *not* appear to be under an obligation to produce a written assessment report.¹⁷⁵ The GC thus remarked that the requirements of the Communication are satisfied where the authority concerned has “[...] acquainted itself with the effects, positive and negative, economic and otherwise, to which the proposed action [...] may lead”.¹⁷⁶ However, it also added that the corollary of the discretion conferred on the administration is an obligation to exercise that discretion by taking *all relevant factors* into consideration;¹⁷⁷ on these grounds, it found that the Commission “was *obliged*, pursuant to the precautionary principle, to carry out an impact assessment” (emphasis added).¹⁷⁸ After this preliminary examination, the GC went on to assess whether the Commission had conducted such analysis. It found that absence of any written record of an impact assessment suggested that such assessment had not been carried out at all.¹⁷⁹ It thus annulled the Commission’s Regulation.

As the GC rightly noted in this case, the obligation to carry out an impact assessment is “no more than a specific expression of the principle of proportionality”.¹⁸⁰ Review of compliance with the obligation to conduct an impact assessment or review of whether risk managers have taken all relevant data into consideration would not be problematic if the Court were to adopt a deferential standard; however, they could be highly problematic if this were not the case. Arguably, it is not by mere coincidence that the Court’s traditionally deferential approach to proportionality review in EU risk regulation has gone hand in hand with a soft approach to the risk manager’s duty to conduct an impact assessment. Further, the Court has stressed in its case law that the results of an impact assessment do *not* bind the risk manager.¹⁸¹

On these grounds, an obligation to conduct an impact assessment, produce some proof thereof and reference relevant data and evaluations exposes the risk manager to the possibility of more intense proportionality review. In this very sensitive field, this could be problematic. Against this overall backdrop, the mere “procedural” findings of *BASF* are liable to have a quasi-substantive impact; on these grounds, this case qualifies under the quasi-substantive standard of review group of cases.

¹⁷² Case T-584/13, *BASF*, cited *supra* note 95. The case was not appealed.

¹⁷³ Paras. 146 to 150.

¹⁷⁴ Para 159. See *supra* section 1.

¹⁷⁵ Para 162.

¹⁷⁶ Para 163.

¹⁷⁷ Para 170.

¹⁷⁸ Para 172.

¹⁷⁹ Para 172.

¹⁸⁰ Para 170.

¹⁸¹ See inter alia Case C-343/09, *Afton Chemical*, para 30.

Finally, in *Bilbaina II*,¹⁸² the Court took an unprecedented stance on the risk manager’s duty to take all relevant factors into consideration, crossing the line between procedural and substantive review more clearly than ever before. Like in *ICdA*, the Court’s standard of scrutiny in *Bilbaina II* has expanded on the “all relevant factors” test. Yet, in *Bilbaina II*, the Court did not merely suggest that the relevant risk assessment was insufficiently cogent. Rather, it pointed to the Commission’s failure to take *one specific factor* into due consideration for the purposes of its final decision.

In Case T-689/13¹⁸³ the applicants challenged the classification of CTPHT as an aquatic acute 1 and aquatic chronic 1 substance under the CLP Regulation. More specifically, just like in *Bilbaina I*, they alleged a manifest error of assessment in so far as the Commission had referred to the results of risk assessments conducted through the – prudential – summation method; this method provides a calculation of the toxicity effects of the single constituents, resulting in an over-estimation of the relevant risks.¹⁸⁴ The applicants claimed that the Commission had disregarded the fact that the components of CTPHT, when bound together in the substance, have a very low level of water solubility and bio-availability. Taking this factor into account would have had the same effect as applying a different method, based on a calculation of the aquatic toxicity effects of the substance as a whole and yielding very different results. In fact, the Commission had relied on the ECHA’s finding that uncertainties persist as to the behaviour of the individual constituents of CTPHT when in contact with water. This led to the application of the summation method.

The GC found that the Commission had failed to comply with its obligation to take into consideration all the relevant factors and circumstances of the case, incurring a manifest error of assessment.¹⁸⁵ Specifically, it pointed to the Commission’s failure to take into consideration the stability and the low level of water solubility of the substance as a whole.¹⁸⁶ It thus concluded that the Commission had incorrectly applied the summation method.

Unsurprisingly, the Commission complained on appeal that the GC had violated its duty to state reasons and erred in law in annulling the Regulation because of the *use* of the summation method or, alternatively, because of its incorrect *application*;¹⁸⁷ as the Commission pointed out, taking the stability and solubility of the whole substance into consideration when applying the summation method was tantamount to applying a different method. Moreover, the Commission maintained that the GC had exceeded the limits of judicial review, going beyond the review of a manifest error of assessment.¹⁸⁸ Both Advocate General Bobek¹⁸⁹ and the ECJ took the view that the GC had neither erred in law,¹⁹⁰ nor exceeded the limits of judicial review.

¹⁸² For a detailed overview, see Leonelli, “The fine line between procedural and substantive review in cases involving complex technical-scientific evaluations: *Bilbaina*”, annotation of Case C-691/15 P, *European Commission v. Bilbaina de Alquitrans SA and others*, EU:C:2017:882, 55 CML Rev. (2018), 1217.

¹⁸³ Case T-689/13, *Bilbaina de Alquitrans SA and others v. European Commission*, EU:T:2015:762. For an analysis of *Bilbaina I*, see *supra* sub-section 5.2.

¹⁸⁴ Para 20. See also *supra* sub-section 5.2.

¹⁸⁵ Para 30.

¹⁸⁶ Paras 32 and 34.

¹⁸⁷ Case C-691/15 P, *European Commission v. Bilbaina de Alquitrans SA and others*, EU:C:2017:882, paras 19, 20 and 28.

¹⁸⁸ Judgment, para 57.

¹⁸⁹ See the Opinion of A.G. Bobek in *European Commission v. Bilbaina de Alquitrans SA and others*, EU:C:2017:646.

¹⁹⁰ Opinion, para 96, and Judgment, paras. 54 and 55.

On the latter point, they ultimately concurred that the Judgment did not imply “that, if the Commission had taken the solubility of CTPHT as a whole into account, [this] would have inevitably trumped all other factors”¹⁹¹ or resulted in a different classification of CTPHT.

Bilbaina II is hard to reconcile with *Bilbaina I*, where the GC and the ECJ found that the Commission was entitled to use the summation method and had taken all relevant factors into consideration in its application;¹⁹² the very same method was at stake in both *Bilbaina I* and *II*. Notably, the substance at issue (and most of the applicants) were also the same in the two cases. This shows the potential inconsistency of the “all relevant factors” test, in so far as the boundaries and nature of the “relevant” factors to be taken into account are open to interpretation.

More importantly, however, *Bilbaina II* perfectly epitomises the blurred boundaries between procedural review of whether all relevant factors have been taken into account, on the one hand, and substantive review of the “quality” and “soundness” of the scientific evidence relied upon, on the other. Both the Advocate General and the ECJ maintained that the findings of the GC related to procedural aspects, rather than the substance of the final decision. Under this reconstruction, the Judgment would not encroach on the risk manager’s discretion in the enactment of precautionary risk management measures. Yet, it is hard to see how the Commission could comply with its duty to take the characteristics of CTPHT as a whole substance into due consideration when applying the summation method. Ultimately, as the Commission argued, this implies the application a different method; the application of a different method, in turn, will yield different results and result in a different – non-precautionary – classification. Against this backdrop, the discretion of the risk manager is indirectly bound and precautionary risk management is undermined.

As this case shows, the expansion and non-deferential application of the “all relevant factors” test poses considerable challenges to the application of the precautionary principle. *Bilbaina II* might then turn out to be a sign of a structural problem, rather than an isolated deviation from the traditional standard of review.

6. Conclusions: from Proportionality and “All Relevant Factors” to a Greater Role for the Precautionary Principle

This article has conducted an analysis of challenges to EU precautionary risk management measures, enquiring to what extent the Court’s application of different standards may safeguard precautionary risk management and do justice to the key role and function of the precautionary principle. The analysis has identified two problematic aspects.

First, the overlapping analysis of the precautionary principle and proportionality in preliminary rulings does not do justice to the rationale for precautionary risk management, the aims pursued by the risk manager and the key role of the precautionary principle in EU risk governance. In cases where scientific uncertainty and a “*stricto sensu*” application of the precautionary principle are at stake, a contextual analysis of the two principles fails to address the scientific

¹⁹¹ See in particular the Opinion, para 107 and para 94.

¹⁹² See *supra* sub-section 5.2.

dimension in which the precautionary principle is embedded, the relevance of different forms of uncertainty and the pursuit of a high level of protection. Arguably, as noted in the fourth section, the analysis of the precautionary principle becomes “ancillary” to proportionality review. For this reason, as suggested in the second section, alleged breaches or misapplication of the precautionary principle should be examined autonomously, or in conjunction with questions surrounding manifest errors of assessment.

Secondly, in the context of direct actions for annulment, different strands of case law have differently framed the notion of administrative discretion and provided a different interpretation of legally relevant manifest errors of assessment. The *Pfizer* and *Alpharma* line of cases draws a clear connection between administrative discretion and precautionary risk management, emphasising that the risk manager is exercising his power to enact precautionary measures. Symmetrically, as the third and fifth sections have illustrated, the notion of a manifest error of assessment is interpreted against the background of the precautionary principle. Precautionary measures are thus effectively safeguarded. Further, the Court’s approach in this line of cases is more faithful to the rationale and overarching tenets of the precautionary principle, and reflects the institutional architecture of EU risk regulation.

By contrast, different strands of case law put the accent on (mere) administrative discretion. In these cases, the precautionary principle is hardly mentioned; a manifest error is associated with the risk manager’s failure to procedurally take all relevant factors into account. This failure to acknowledge the precautionary nature of risk management measures is hard to reconcile with the centrality of the precautionary principle under EU risk regulation. Further, as the fourth and fifth sections have demonstrated, the “all relevant factors” test is associated with a number of problems. Most importantly, a non-deferential application of this test can indirectly threaten precautionary risk management, resulting in quasi-substantive review and thus undermining the risk manager’s power to take precautionary action. The mere acknowledgment of the risk manager’s discretion is insufficient to safeguard precautionary risk regulation.

On these grounds, the Court’s different framing of the notion of administrative discretion and its different interpretation of manifest errors of assessment is by no means a mere issue of form or terminology. Rather, it has substantive implications. For this reason, it is all the more important that the Court follows the *Pfizer* and *Alpharma* strand of procedural review. The Court should always draw an explicit connection between administrative discretion and precautionary risk management; further, and crucially, it should always interpret the notion of a legally relevant manifest error of assessment in light of the precautionary principle.

As explained in the second section, EU institutions are neither bound to adhere to “sound” science, nor to refer to economic cost-benefit analysis and the results of impact assessment. At a minimum, EU institutions are fully entitled to take the precautionary principle into due consideration. Under a “maximalist” interpretation, the principle is an “inner limit” to the risk manager’s discretion. The complementarity of technical expertise and democratic legitimacy and the latter’s superiority shine through the precautionary principle. The principle enshrines a right to focus on ubiquitous uncertainties, with a view to pursuing enhanced levels of protection. In the face of scientific complexity, scientific pluralism and the evolutionary nature of scientific research, this is a perfectly legitimate regulatory choice; nor is recourse to the

precautionary principle, by any means, *a*-scientific.¹⁹³ The principle also suggests that *collective* public health and environmental stakes¹⁹⁴ should prevail over *individual* – trade and market access – rights, or at least be taken into due consideration. All of this lies at the heart of the notions of “intended level of protection” and “threshold of acceptable risk”.

Against this backdrop, the Court’s case law should closely focus on scientific uncertainty and the underlying tenets of the precautionary principle. In direct actions for annulment, the notion of a manifest error of assessment should always be interpreted in light of the precautionary principle. In preliminary rulings, the examination of the principle should not be “ancillary” to proportionality review. Precautionary risk management would then be effectively safeguarded, and the crucial role and value of the precautionary principle as a general principle of EU law would be more clearly and more fully acknowledged.

¹⁹³ As claimed by denigrators of the principle. For the most famous account of these criticisms, see Sunstein, *Laws of Fear. Beyond the Precautionary Principle* (CUP, 2005); and Sunstein, “Precautions against what? Perceptions, heuristics and culture”, in Wiener, Rogers, Hammitt and Sand (Eds.) *The reality of precaution. Comparing risk regulation in the United States and Europe* (Routledge, 2011).

¹⁹⁴ See *supra* section 1.