***European Commission* v. *Bilbaína and Others*: The Fine Line Between Procedural and Substantive Review in Cases Involving Complex Technical-Scientific Evaluations.**

Case C-691/15 P, *European Commission* v. *Bilbaína de Alquitranes SA and Others*, Judgment of the Court of Justice (Sixth Chamber) of 22 November 2017, EU:C:2017:882.

1. Introduction.

What the last years have witnessed is a gradual – albeit discontinuous – watering down of EU-wide precautionary risk governance, and a greater emphasis being placed on evidence-based regulation; in other words, the rise of the latter "soul" of EU risk regulation[1] has ultimately caused the former to shrink. A precautionary approach to the governance of uncertain public health and environmental risks postulates a prudential risk assessment,[2] whereby due consideration is given to the relevant margins of scientific uncertainty. The risk manager shall then take into account the results of the risk assessment phase, the overarching tenets of the precautionary principle[3] and any other legitimate factors ("OLFs") at stake;[4] against this backdrop, the risk manager is called upon to politically weigh and balance all relevant interests and identify the intended level of public health and environmental protection. Evidence-based risk regulation, on the other hand, is grounded on a positivist approach to science; this paradigm privileges a more circumscribed focus on what science has proved and established, and postulates a thorough scrutiny of the soundness of the scientific evidence substantiating regulatory measures.[5]

Unsurprisingly, the case law of the CJEU in this field is inconsistent and rather erratic.[6] On the one hand, the Court's rulings have traditionally adhered to a procedural standard of review.[7] On the other

[1] On the "dual" nature of EU risk regulation, and on the coexistence of an "evidence-based" and "precautionary" soul therein, see Alemanno, "Case C-79/09, *Gowan Comércio Internacional e Servicos Lda* v. *Ministero della Salute*, Judgment of the Court of Justice (Second Chamber) of 22 December 2010" 48 *CML Rev* (2011) 1329, 1329-1330; and Alemanno, "Risk Versus Hazard and The Two Souls of EU Risk Regulation: A Reply to Ragnar Lofstedt" 2 *EJRR* 169, 169-170.

[2] On the notion of "prudential" risk assessment, and the – arguably, formalistic – distinction between "prudential" risk assessment and "precautionary" risk management, see COM(2000) 1 Final, Communication from the Commission on the Precautionary Principle, p. 12, section 5.

[3] See COM(2000) 1 Final, Communication from the Commission on the Precautionary Principle, *supra* note 2, at 12, stating that the precautionary principle shall apply *"when scientific uncertainty precludes a full assessment of the risk and when decision-makers consider that the chosen level of environmental protection or of human, animal and plant health may be in jeopardy*"; at 13, section 5.1., on the appreciation of scientific uncertainty; and at 16, section 6.2., on the triggering factor for the application of the precautionary principle. See also Recitals (8) and (21) and Articles 5(1) and 7(1) of Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety, O.J. 2002, L 31, the General Food Law (hereafter, "GFL"). Article 7(1) maintains that "*In specific circumstances where, following an assessment of available information, the possibility of harmful effects* [on health] *is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of* [health] *protection chosen in the Community may be adopted* […]".

[4] Notably, in this perspective, see recital (19) and articles 5, 6(2), 6(3) and 7(2) of the GFL, *supra* note 3. Article 6(3) maintains that "*risk management shall take into account the results of risk assessment* […]*, other factors legitimate to the matter under consideration, and the precautionary principle where the conditions laid down in article 7(1) are relevant* […]".

[5] For a detailed account see *infra*, section 5., and particularly notes 199 and 200.

[6] For the same view, see Janssen and Van Asselt, "The Precautionary Principle in 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), pp. 197-200; Dąbrowska Klosinska, "Risk, Precaution And Scientific Complexity Before

hand, the post-*Pfizer*[8] partial "scientification" of the Court's review[9] has resulted in the coexistence of different strands of case law, along the continuum spanning from a deferential standard of scrutiny, to a more thorough and intrusive review of the scientific evidence relied upon.

Bilbaína is peculiar because of its structural ambiguity: a close look at this case testifies that it deserves special attention. Do the General Court and the Court of Justice in this case focus on the Commission's duty to take "all relevant factors" into account in the decision-making process, or do they rather scrutinise the scientific soundness of the assessment methodology applied? Is the standard of review deployed in the case under comment an authentically procedural one? If the Commission complied with its procedural obligations, as laid out by the General Court and the Court of Justice, would it still be in a position to enact the same precautionary categorisation? And, crucially, does this case epitomise a latent shift away from a *procedural* review[10] of the Commission's duty of *good administration*, to a *substantive* review[11] of the Commission's duty to adhere to an *evidence-based model* of risk regulation?

2. The Factual and Legal Background.

As expressly acknowledged in the Opinion of the Advocate General[12] and in the Judgment of the Court of Justice,[13] a range of highly complex technical-scientific matters lie at the heart of this case. In case T-689/13[14] the eighteen applicants – suppliers or downstream users of "pitch, coal tar, high-temperature" (EC No. 266-028-2, hereafter, "CTPHT") – successfully challenged the Commission's classification of CTPHT as an Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) substance.[15] The aquatic toxicity level of CTPHT had been assessed and categorised in accordance with the provisions of Regulation 1272/2008 on the Classification, Labelling and Packaging of Substances and Mixtures (hereafter, "CLP Regulation");[16] the applicants in the case were market actors facing a range

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the Court of Justice of the European Union", in Gruszczynski and Werner (eds.), *Deference In International Courts and Tribunals* (OUP, 2014), p. 208; Janssen and Rosenstock, "Handling Uncertain Risks: An Inconsistent Application of Standards?" 7 *EJRR* (2016) 144, 146 and 154.

[7] Inter alia, see Case C-77/09, *Gowan Comércio International e Servicos LDA* v. *Ministero della Salute*, EU:C:2010:803; Case C-343/09, *Afton Chemical Limited* v. *Secretary of State for Transport*, EU:C:2010:419; and Case T-333/10, *ATC and Others* v. *Commission,* EU:T:2013:451 – despite the Court's decision that the initial ban manifestly disregarded the limits of the Commission's discretion for specific procedural reasons. Looking at less recent case law, see Case C-68/86, *United Kingdom* v. *Council,* EU:C:1988:85*;* Case C-331/88, *Ex Parte Fedesa and Others*, EU:C:1990:391; Case C-405/92, *Établissements Armand Mondiet SA* v. *Armement Islais SARL*, EU:C:1993:906; Case C-157/96, *Ex Parte National Farmers' Union and Others,* EU:C:1998:91; Case C-180/96, *United Kingdom* v. *Commission,* EU:C:1998:192; Joined Cases C-154 and C-155/04, *Ex Parte Alliance for Natural Health and Others* v. *Secretary of State for Health*, EU:C:2005:449. On the Court's – originally – deferential standard of review, see also Vos, "The European Court of Justice in the Face of Scientific Uncertainty and Complexity", in Dawson, De Witte and Muir (eds.), *Judicial Activism at the European Court of Justice* (Edward Elgar, 2013), pp. 145-149.

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

[9] For the same view see Lee, *EU Regulation of GMOs* (Edward Elgar, 2008), pp. 84-87; Vos, op. cit. *supra* note 7, pp. 152 ff.; Dąbrowska Klosinska, op. cit. *supra* note 6, pp. 205 ff.; Anderson, "Contrasting Models of EU Administration in Judicial Review of Risk Regulation" 51 *CML Rev* (2014) 424, 432 ff.

[10] That is, a *procedural* review of the Commission's duty to take *"all relevant factors"* into consideration in the *application* of the summation method – see *infra*, sections 3. and 4.1.

[11] That is, a *substantive* review of the *scientific soundness* of the Commission's decision to *use* the summation method – see *infra*, sections 3. and 4.1.

[12] Opinion, paras. 1, 62 and 79.

[13] Judgment, paras. 43 and 44.

[14] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, EU:T:2015:762.

[15] For a definition of "Acute Aquatic Toxicity", see Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the Classification, Labelling and Packaging of Substances and Mixtures, Amending and Repealing Directives 67/548/EEC and 1999/45/EC, and Amending Regulation (EC) No. 1907/2006, O.J. 2008, L 353 (hereafter, "CLP Regulation"), Annex I, point 4.1.1.1.(a); for a definition of "Chronic Aquatic Toxicity", see Annex I, point 4.1.1.1.(g).

[16] *Supra* note 15.

of procedural burdens and economic costs, as a result of the Commission's classification of CTPHT.[17] This substance is a residue from the distillation of high-temperature coal tar,[18] used in the manufacturing of aluminium, carbon, graphite and steel.[19] Crucially, it is among the substances of unknown or variable composition, complex reaction products or biological materials, defined as "UVCB substances";[20] in other words, CTPHT cannot be straightforwardly identified by its chemical composition.

Back in 2010, pursuant to Article 37 of the CLP Regulation,[21] the Netherlands had submitted a technical dossier to the European Chemicals Agency (hereafter, "ECHA")[22] proposing that CTPHT should be classified as an Aquatic Acute 1 and Aquatic Chronic 1 substance.[23] Upon the submission of comments and observations by all concerned parties, the dossier was forwarded to the ECHA Risk Assessment Committee;[24] one year later the latter adopted its own opinion,[25] confirming the proposal of the Netherlands. On these grounds the Commission enacted Regulation (EU) No. 944/2013 of 2 October 2013,[26] classifying CTPHT as an Aquatic Acute 1 and Aquatic Chronic 1 substance.[27]

The applicants sought the partial annulment of the Regulation, alleging in their three pleas in law, respectively, a breach of the REACH Regulation,[28] a breach of the CLP Regulation and an infringement of the principle of equal treatment; a manifest error of assessment; and a breach of the principle of transparency and of the rights of defence.[29]

In its Judgment, the General Court devoted special attention to the second part of the second plea in law,[30] whereby the applicants lamented a manifest error of assessment as a result of the Commission's choice to use and apply the summation method for the assessment of CTPHT's toxicity for aquatic organisms.

The Netherlands and the ECHA Risk Assessment Committee had concurred in the view that the aquatic toxicity of CTPHT could not be effectively assessed through the Water Accommodated

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[17] See the labelling and packaging requirements laid out in the CLP Regulation, *supra* note 15; as well as the obligations set out in Article 3 and Annex III of Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the Inland Transport of Dangerous Goods, O.J. 2008, L 260.

[18] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, paras. 1 to 8, quoting the CLP Regulation, *supra* note 15, Annex VI, Tables 3.1. and 3.2.

[19] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, paras. 1 to 8.

[20] Ibid.

[21] CLP Regulation, *supra* note 15.

[22] See Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Establishing a European Chemicals Agency (ECHA), amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 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 (hereafter, "REACH Regulation").

[23] As well as a Carcinogenic 1A (H350), Mutagenic 1B (H340) and Toxic for Reproduction (H360FD) substance; Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 3.

[24] Article 76(1)(c) REACH Regulation, *supra* note 22.

[25] On the grounds of a detailed technical analysis, referred to in Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission* as "background document", and of a document listing the specific answers of the Netherlands to any observations on its technical dossier. See Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission,* para. 6.

[26] Commission Regulation (EU) No. 944/2013 of 2 October 2013 Amending, for the Purposes of its Adaptation to Technical and Scientific Progress, Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures, O.J. 2013, L 261.

[27] See Article 1(2)(a)(i) and Article 1(2)(a)(ii) and Annexes II and IV of Commission Regulation (EU) No. 944/2013, *supra* note 26.

[28] *Supra* note 22.

[29] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 18.

[30] In the other three parts of their second plea in law the applicants submitted a manifest error of assessment, respectively, in so far as UV irradiation testing was required, without having standardised test methods established and without taking account of the inert inherent properties of CTPHT; in so far as the classification and multiplication factors for the single components of CTPHT were included in the dossier on CTPHT, rather than in separate ad hoc dossiers; and in so far as the studies and information provided by the applicants had not been taken into account. See Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 20.

Fraction (hereafter, "WAF") approach, advocated by the applicants.[31] For this reason, the Netherlands and the ECHA Committee both opted for the application of the – alternative – summation method;[32] this postulates that the relevant substance is regarded as a *mixture*, and that the *single constituents* are analysed separately in accordance with their aquatic toxicity effects.[33] Thus, the 16 polycyclic aromatic hydrocarbon (hereafter, "PAH") constituents of CTPHT were the object of a separate assessment:[34] CTPHT was accordingly classified as a (H400) and (H410) substance. It is worth noting that the summation method is liable to provide an *overestimation* of the aquatic toxicity of a mixture: analysing the level of *water solubility* and *availability to aquatic organisms* (bioavailability) of every single toxic chemical constituent gives an overview of the worst case scenario.[35] However, and conversely, the assessment of UVCB substances as a whole – as advocated by the eighteen applicants – is in fact likely to result in an *underestimation* of their aquatic toxicity; indeed, scientific uncertainty persists as to the behaviour of the single toxic constituents of UVCB substances once in contact with water.[36]

In the second part of the second plea in law the eighteen applicants claimed that the Commission had disregarded that the 16 PAH components, when bound together in CTPHT, have a very low level of water solubility and a low level of bioavailability; hence, the applicants maintained that the Commission had manifestly erred in its assessment of CTPHT's level of aquatic toxicity.

The General Court concurred with them, ruling that the Commission had committed a manifest error of assessment by failing "to comply with its obligation to take into consideration all the relevant factors and circumstances".[37] Specifically, the General Court maintained that neither the Commission nor the ECHA had been able to establish that, in basing their classification of CTPHT "on the assumption that all of the PAHs present in that substance dissolved in the water phase and were thus available to aquatic organisms, [they had taken] into consideration the fact that, according to point 1.3. of the [Risk Assessment Committee's] background document […], the constituents of CTPHT were released from CTPHT only to a limited extent, and that the substance was very stable".[38] Moreover, the General Court added that the Commission had manifestly erred in its presumption that the 16 PAH *constituents* – representing 9.2% of the CTPHT mixture – could all dissolve in water, disregarding the finding that the maximum rate of water solubility of CTPHT as a *whole substance* is 0.0014%.[39]

Against this background, the General Court concluded that the Commission had incorrectly applied the summation method, and had manifestly erred in its assessment of CTPHT's toxicity to aquatic organisms; accordingly, it partially annulled Commission Regulation (EU) No. 944/2013 of 2 October 2013, in so far as it classified CTPHT as an Aquatic Acute 1 and Aquatic Chronic 1 substance.

In case C-691/15 P the Commission, supported by the Netherlands, Germany and Denmark, sought to have the Judgment of the General Court set aside; the Commission submitted three grounds of appeal.

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[31] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 7.

[32] As laid out in Annex I, part 1, of the CLP Regulation, *supra* note 15.

[33] Ibid.

[34] Thus, upon attributing a coefficient factor to all PAHs, the results of the multiplications were summed up to identify the level of aquatic toxicity of the CTPHT mixture. See Annex I, part 1, of the CLP Regulation, *supra* note 15.

[35] See *infra*, section 4.2. and 4.3.

[36] See *infra*, section 4.2. and 4.3.

[37] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 30. At para. 24 of the Judgment the General Court – quoting Case C-343/09, *Afton Chemical Limited* v. *Secretary of State for Transport*, para. 34, and Case T-93/10, *Bilbaína de Alquitranes SA and Others* v. *European Chemicals Agency (ECHA)*, EU:T:2013:106, para. 77 – maintains that "the EU authorities which have adopted the act must be able to show before the EU Courts that, in adopting the act, they actually exercised their discretion, which presupposes the taking into consideration of all the relevant factors and circumstances of the situation that the act [is] intended to regulate". Case C-343/09, *Afton Chemical Limited*, in turn, referred to Case C-310/04 *Spain* v. *Council*, EU:C:2006:521, at para. 122. For a more detailed overview of this point see *infra*, section 4.1.

[38] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 32.

[39] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 34.

In the first ground, the Commission claimed that the General Court had violated its duty to state reasons – enshrined in Articles 36 and 53 of the Statute of the CJEU.[40] The Commission contended that the decision is vitiated by a lack of reasoning, in so far as the arguments of the General Court are ambiguous and inherently contradictory: specifically, the Commission pointed to the fact that the Judgment is unclear as to whether the Regulation was partially annulled because of the *use* of the summation method, or because of an error in its *application.*[41]

Drawing on the argument developed in the first ground of appeal, the second ground is structured in two parts. In the first part of the second ground of appeal, the Commission alleged an error of law in so far as the General Court partially annulled the Regulation because of the Commission's decision to *use* the summation method.[42]

In the second part of the second ground of appeal,[43] alternatively, the Commission alleged an error of law in so far as the General Court partially annulled the Regulation because of the Commission's incorrect *application* of the summation method. In this specific regard the Commission underlined that, despite the General Court's finding that the Commission should have taken account of the characteristics of CTPHT as a *whole substance* in its *application* of the summation method, the *choice*, *use* and *application* of this methodology in fact postulate an analysis of the mixture's *components*. In this light the General Court's argument that the Commission should have given due consideration to the inert inherent features of CTPHT as a whole substance,[44] as well as to its 0.0014% maximum rate of water solubility,[45] is inconsistent with the very use and application of the summation method – which postulates the analysis of CTPHT as a mixture, and the calculation of the maximum rate of water solubility of its single components. The Commission thus concluded that "it is important only to ascertain, using the summation method, whether the thresholds set by the Regulation No. 1272/2008 are met, without the Commission having any margins of discretion whatsoever in that regard. The General Court therefore erred in law in criticising the Commission for not taking into consideration factors that are not prescribed by the summation method […]".[46]

Finally, in its third ground of appeal, the Commission argued that the General Court had exceeded the limits of judicial review, going beyond the review of a manifest error of assessment.[47] The Commission highlighted that it had adopted Regulation (EU) No. 944/2013 on the basis of a broad range of scientific evidence, which justified its use and application of the summation method.[48] It thus argued that the General Court, by picking and choosing the data on the low solubility of CTPHT as a whole substance to invalidate the Commission's classification, had disregarded the rest of the available scientific evidence, distorted the evidence in the case and directly substituted its own assessment for that of the Commission.

3. The Opinion of Advocate General Bobek and the Decision of the Court of Justice.

[40] See Opinion, para. 30, and Judgment, para. 19.
[41] See Opinion, para. 30, and Judgment, paras. 19 and 20.
[42] Opinion, para. 42, and Judgment, para. 28.
[43] Opinion, paras. 42 and 43, and Judgment, para. 28.
[44] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 32.
[45] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 34.
[46] See the Judgment, para. 30 – reporting the Commission's argument.
[47] Opinion, paras. 97 and 98, and Judgment, para. 57.
[48] Ibid.

In the words of the Advocate General, this case "concerns the reconciliation of complex scientific assessments with the requirement of legality of administrative action";[49] the fundamental question of law thus attains to the discretion of the Commission "in cases in which the legislation has laid down a list of relevant factors to be taken into account in the course of [a technical-scientific] assessment".[50] The following sub-sections analyse the arguments of the Advocate General and the decision of the Court of Justice by specific reference to the three grounds of appeal.

3.1. The First Ground of Appeal.

Starting off from an analysis of the first ground of appeal, the Advocate General claimed that the decision of the General Court is clear and unequivocal in ruling that the Commission *applied* the summation method in an incorrect manner.[51]

The Advocate General specifically focused on the General Court's finding that the Commission had committed a manifest error of assessment by failing to comply with its obligation to take into consideration "all the relevant factors and circumstances" – i.e., in this case, the low solubility of CTPHT as a *whole substance* – that would allow it to correctly assess the chemical properties of the *constituents* of CTPHT,[52] as mandated by the *summation method*. Thus, the Advocate General inferred, the contested Judgment clearly referred to the Commission's incorrect *application* of the summation method, rather than to its decision to *use* it.[53]

In this light, the Advocate General argued that the General Court had not breached its duty to state reasons.[54] The Court of Justice concurred with the views of the Advocate General and rejected this ground of appeal as unfounded, arguing that the Judgment of the General Court is clear and unequivocal in holding that the Commission manifestly erred in its application of the summation method.[55]

3.2. The Second Ground of Appeal.

Building on his Opinion on the first ground of appeal, the Advocate General directly turned to the second branch of the second ground of appeal – whereby the Commission alleged an error of law in so far as the General Court held that the Commission had incorrectly applied the summation method.[56]

To begin with, the Advocate General carefully scrutinised the Commission's argument. The Commission claimed that, when applying the summation method, it had no discretion to take into account any evidence other than that provided for in the CLP Regulation.[57] Drawing on this premise, the Commission argued that it had not committed any error of assessment in the application of the

[49] Opinion, para. 1.
[50] Ibid.
[51] Opinion, paras. 30 to 41.
[52] Opinion, paras. 33 and 34. Para. 33, quoting para. 30 of Case T-689/13, refers to the Commission's failure to "take due account of the proportion in which the 16 PAH constituents are present in CTPHT and their chemical effects".
[53] Opinion, paras. 34 to 40, referring to Case T-689/13, paras. 31 to 34.
[54] Opinion, para. 40.
[55] Judgment, paras. 26 and 27. At para. 22 of the Judgment the Court, quoting Joined Cases C‑204/00 P, C‑205/00 P, C‑211/00 P, C‑213/00 P, C‑217/00 P and C‑219/00 P, *Aalborg Portland and Others* v. *Commission*, EU:C:2004:6, para. 372, and Case C‑50/17 P, *Universidad Internacional de la Rioja* v. *EUIPO* (Order of 1 June 2017, not published) EU:C:2017:415, para. 12, maintains that "It follows from settled case‑law of the Court that the obligation of the General Court to state reasons requires it to disclose its reasoning clearly and unequivocally, in such a way as to enable the persons concerned to ascertain the reasons for the decision taken and the Court of Justice to exercise its power of review".
[56] Opinion, paras. 42 and 43.
[57] Opinion, para. 44.

summation method, as this specific methodology does not allow the Commission to take the overall solubility of CTPHT into consideration.[58]

The Advocate General noted that, in accordance with the duty of good administration enshrined in settled case law, the Commission is under an obligation to take into consideration "all the relevant factors and circumstances of the situation which the act [is] intended to regulate", examining "carefully and impartially all the relevant aspects of the individual case".[59]

The Commission held that the low solubility of CTPHT is not a relevant factor "because the summation method does not identify as relevant";[60] moreover, the Commission claimed that it had "no discretion to determine what constitutes a relevant factor"[61] when applying the summation method. Symmetrically, the Advocate General considered the crux of this ground of appeal to lie in the relevance of the low solubility of CTPHT as a whole substance, and in the margins of the Commission's discretion in the application of the summation method;[62] he thus went on to assess "whether solubility as a whole is a relevant factor that must be considered in the context of the summation method",[63] and "whether the Commission has any discretion to identify relevant factors beyond those listed"[64] in the CLP Regulation, taking them into consideration when applying the summation method.[65]

The Advocate General found that the assessment of the former matter is under the exclusive jurisdiction of the General Court, which had considered the low aquatic solubility of CTPHT to be a "relevant factor";[66] he then turned to an analysis of the latter question, and answered it in the affirmative. To begin with, and in general terms, he disagreed with the view that the Commission enjoys a broad discretion as regards the choice and use of the appropriate assessment methodology, but no discretion at all in its application.[67] Building on this premise, the Advocate General developed four specific arguments on the Commission's discretion in the application of the summation method.[68] First,[69] he found that the wording of Annex I to the CLP Regulation[70] supports the view that all available data should be applied, when appropriate, "for the purposes of classifying the aquatic environmental hazards of the mixture".[71] Thus, the Advocate General noted that although the CLP Regulation[72] does not provide for the use of criteria other than those listed in its provisions, it does not expressly prohibit the consideration of other factors which may be relevant to the classification process.[73]

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[58] Opinion, paras. 45 to 50. Further than that, the Commission also claimed that it had not committed any error of assessment in assuming that all the PAH components dissolved in water, and that it had in fact taken into account the proportion and the chemical effects of all the constituents of CTPHT, in accordance with the summation method.

[59] Opinion, para. 53, "The Commission has an obligation to take into consideration all the relevant factors and circumstances of the situation which the act was intended to regulate. That obligation can be clearly traced back through the Court's case law to the more general duty of good administration, which entails a duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case […]". In this respect, the Advocate General cites Case C‑269/90, *Technische Universität München*, EU:C:1991:438, para. 14; and Case C‑505/09 P, *Commission* v. *Estonia*, EU:C:2012:179, para. 95. See also *supra*, note 37; for a detailed overview of this point see *infra*, section 4.1.

[60] Opinion, para. 56.

[61] Ibid.

[62] Opinion, para. 50.

[63] Opinion, para. 54.

[64] Opinion, para. 59.

[65] Opinion, paras. 61 to 95.

[66] See Opinion, para. 55, citing Case C-199/13 P, *Polyelectrolyte Producers Group and Others* v. *Commission* (Order of 27 March 2014), EU:C:2014:205, paras. 33 to 36. See also Opinion, para. 104.

[67] Opinion, para. 66.

[68] Opinion, paras. 73 to 93.

[69] Opinion, paras. 73 to 76, and Judgment, para. 41.

[70] See Annex I, point 4.1.3.1. of Regulation 1272/2008, *supra* note 15.

[71] Opinion, para. 73, and Judgment, para. 41.

[72] See Annex I, point 4.1.3.5.5. of Regulation 1272/2008, *supra* note 15.

[73] Opinion, paras. 73 to 75. See also Judgment, para. 39.

Secondly,[74] and with reference to the broader context and international origins of the CLP Regulation,[75] he highlighted that the highly complex technical-scientific nature of the processes dealt with in the Regulation sheds light on the inherent limits of all methodological criteria, calling for the integration and consideration of any other "relevant factors" into the assessment and final classification of aquatic toxicity.

Thirdly,[76] he stressed the need to look beyond the individual case: he then went on to underline that even though the Commission's "error of assessment" in this case had resulted in the most severe hazard classification, the opposite may occur, and the Commission's alleged "inability to take into account other relevant factors [may] ultimately lead to a lower hazard classification than might otherwise be justified".[77] A thorough scrutiny of the Commission's duty to take "all relevant factors" into consideration, he suggested, is of great importance: yet, "if there is indeed discretion, it must be accepted that such discretion can cut both ways. If highly important, relevant factors come to light that make it appear that a hazard classification is too high, those factors must also be considered as part of the main assessment".[78]

Finally,[79] the Advocate General made a very brief reference to Case T-93/10 *Bilbaína* v *ECHA*[80] and Appeal Case C-287/13 P.[81] Relying on the Court's finding in Case C-287/13 P that the Commission was not precluded from applying the summation method to assess the bioaccumulative properties of CTPHT, even though Annex XIII of the REACH Regulation did not expressly provide for the use of this assessment methodology, the Advocate General remarked that there is nothing in Annex I to the CLP Regulation which precludes the identification of any other "relevant factors" that the Commission shall take into consideration. This, the Advocate General suggested, lends support to the argument that the Commission had a discretionary power to take all "relevant factors" into account when applying the summation method.

The Advocate General concluded that "as a matter of law, the Commission did have discretion to identify other relevant factors in the course of applying the summation method, without breaching the CLP Regulation".[82] It thus held that the General Court did not err in law in ruling that the Commission had incorrectly applied the summation method, and proposed that the Court should reject the second ground of appeal.[83]

The Court of Justice concurred with the Advocate General's Opinion. The Court specifically focused on the question "whether the Commission, when it applies the summation method in order to determine whether a UVCB substance comes within the categories of chronic or aquatic toxicity, is required to limit its assessment solely to the factors expressly referred to in [the CLP Regulation], excluding any other factor, or, on the contrary, whether it must, under its duty to act diligently,

[74] Opinion, paras. 76 to 80, and Judgment, paras. 42 to 44.

[75] See Opinion, para. 76, where the Advocate General quotes Recital 6 to the CLP Regulation: "This Regulation follows various declarations whereby the Community confirmed its intention to contribute to the global harmonisation of criteria for classification and labelling, not only at UN level, but also through the incorporation of the internationally agreed GHS criteria into Community law". The Advocate General further remarks that the tiered approach to aquatic hazard classification reflects the approach taken at the international level, under the Globally Harmonised System of Classification and Labelling of Chemicals ("the GHS").

[76] Opinion, paras. 81 to 85.

[77] Opinion, para. 81. See also the Opinion, at paras. 83 and 92, and the Judgment, at para. 46.

[78] Opinion, para. 84.

[79] Opinion, paras. 86 to 92.

[80] Case T-93/10, *Bilbaína de Alquitranes SA and Others* v. *European Chemicals Agency (ECHA)*, EU:T:2013:106. For a more detailed comment on this case see *infra*, section 4.3.

[81] Case C-287/13 P, *Bilbaína de Alquitranes SA and Others* v. *European Chemicals Agency (ECHA)*, EU:C:2014:599. For a more detailed comment on this case see *infra*, section 4.3.

[82] Opinion, para. 93.

[83] Opinion, para. 96.

examine other factors […]":[84] the "other factors" the Court referred to are of course the inert inherent features of CTPHT as a whole substance[85], and its 0.0014% maximum rate of water solubility.[86]
First, the Court started off by assessing whether the Commission's discretion was limited in the application of the summation method and in the consequent assessment of CTPHT's aquatic toxicity. Relying on the arguments of the Advocate General, the Court concluded that "when it applies the summation method […] the Commission is not required to limit its assessment solely to the factors expressly referred to in […] Annex I […] to the exclusion of any other factors":[87] rather, and "in accordance with its duty to act diligently, the Commission is required to examine carefully and impartially other factors which […] are nevertheless relevant".[88]
Secondly, the Court maintained that the question whether the low solubility of CTPHT as a substance may be regarded as a "relevant factor" that the Commission should have taken into due consideration "is a question of the legal characterisation of facts coming within the jurisdiction of the Court in the course of its review in appeal".[89] Drawing on this finding, the Court ruled that the low aquatic solubility of CTPHT as a whole substance was in fact a "relevant factor" that the Commission should have taken into due consideration.[90]
On these grounds, the Court upheld the General Court's ruling that the Commission had manifestly erred in its assessment of the aquatic toxicity of CTPHT, in so far as it had failed to consider the inert inherent features of CTPHT as a whole substance[91] as well as its 0.0014% maximum rate of water solubility.[92] Thus, the second ground of appeal was rejected as unfounded.[93]

3.3. The Third Ground of Appeal.

Finally, the Advocate General analysed the third ground of appeal, whereby the Commission argued that the General Court had exceeded the limits of judicial review, going beyond the review of any manifest error of assessment and directly substituting its own scientific assessment for that of the Commission.[94] The Advocate General contended that the Commission had relied on an incorrect interpretation of the decision,[95] and claimed that "the contested Judgment does not say that, if the Commission had taken the solubility of CTPHT as a whole into account, it would have inevitably trumped all other factors. The General Court concludes only that the Commission committed a manifest error of assessment by failing to consider the solubility of CTPHT as a whole".[96] Thus, it proposed that the third ground of appeal should also be rejected.

[84] Judgment, para. 33.
[85] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 32.
[86] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 34.
[87] Judgment, para. 47.
[88] Ibid.
[89] Judgment, para. 49. For a different view on this point see the Opinion, paras. 55 and 104.
[90] Judgment, paras. 50 to 56.
[91] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 32.
[92] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 34.
[93] Judgment, paras. 54 and 55.
[94] See the Opinion, at para. 97, and the Judgment, at para. 57.
[95] Specifically, when assessing the third ground of appeal, the Advocate General develops three points; for a detailed analysis see the Opinion at paras. 102 to 107.
[96] Opinion, para. 107. See also the Opinion, at para. 94: "Moreover, I note that at no point does (or indeed could) the General Court hold that if, hypothetically, the Commission had taken the low solubility of CTPHT into account, it would have committed a manifest error in going on to classify CTPHT as Aquatic Acute 1 or Aquatic Chronic 1. Rather, it is the Commission's objective failure to take that element into account in its reasoning, as confirmed by the General Court, which resulted in the partial annulment of the contested regulation", commented *infra*, in section 5.

The Court adhered to the interpretation of the Advocate General, and explicitly argued that the third ground of appeal is based on "an erroneous reading of the Judgment […]".[97] Specifically, the Court contended that the General Court had not substituted its own assessment of the relevant technical-scientific evidence for that of the Commission, because the General Court's review had exclusively focused "on the procedural question of determining whether the Commission, in classifying CTPHT, complied with its obligation to take into consideration all the relevant factors and circumstances".[98] Against this backdrop, the third ground of appeal was also rejected and the appeal was dismissed.

4. Comments: The Blurred Boundaries Between Procedural and Substantive Review.

The following sub-sections endeavour to sketch out a few comments on this very complex case. Sub-section 4.1. argues that the Courts' unilateral focus on the Commission's procedural margins of discretion and procedural duty to take "all relevant factors" into consideration is misleading, and fails to capture what is truly at stake in the case. Indeed, and as anticipated since the introductory section, *Bilbaína* perfectly exemplifies how the boundaries between a *procedural* review of the Commission's duty to take "all relevant factors" into consideration and a *substantive* review of the scientific soundness of the evidence relied upon are inherently blurred.
Building on this finding, sub-section 4.2. claims that the procedural framing of this case turns out to obscure the substantive implications of the adoption of different scientific methodologies. At the heart of this case, in fact, lies the Commission's choice to draw on a *prudential* risk assessment, and opt for a *precautionary* classification of CTPHT's level of aquatic toxicity.
Sub-section 4.3. turns to a concise analysis of the antecedent[99] of the case under comment. Whilst the thread running between *Bilbaína I* and *II* is certainly the attempt to outline the boundaries of the Commission's discretion, framing its duty to take "all relevant factors" into consideration, the two cases in fact reach diametrically opposite conclusions. Not only this makes it impossible to reconcile the decisions in *Bilbaína I* and *II*, but it also detracts from the consistency of the standard of review.
Finally, section 5. sketches out some conclusive remarks, focusing on the far-reaching implications of the standard of review outlined in this case.

4.1. From Manifest Error of Assessment to Scientific Soundness?

What is truly at stake in Cases T-689/13 and C-691/15 P, beyond the technical-scientific terminology and the complex references to different assessment methodologies? And how did the Court of Justice outline the scope of its review? Two irreconcilable interpretations of the issues at stake in this case are put forward by the General Court, Advocate General and Court of Justice, as opposed to the Commission.
The Judgment of the Court of Justice is very specific in its framing of the questions of law underlying the case, and so is the Advocate General's Opinion. The review of the Court of Justice directly targets the Commission's margins of discretion in the application of the summation method, and focuses on whether the Commission fulfilled its duty to act diligently, taking "all relevant factors" into consideration.[100] This is understood as a form of procedural review, whereby the Court of Justice

[97] Judgment, para. 58.
[98] Ibid.
[99] Case T-93/10, *Bilbaína de Alquitranes SA and Others* v. *ECHA*, and Case C-287/13 P, *Bilbaína de Alquitranes SA and Others* v. *ECHA*.
[100] See *supra*, section 3., and specifically notes 37 and 59.

ascertains whether the General Court erred in law in holding that the Commission, by failing to take into consideration the overall solubility of CTPHT as a whole substance, committed a manifest error of assessment when applying the summation method.[101]

Indeed, throughout their Judgments, both the General Court and the Court of Justice emphasise the allegedly procedural nature of the scrutiny in *Bilbaína*. To begin with, the Courts stress that – in accordance with settled case law – "where the EU authorities have a broad discretion, in particular as to the assessment of highly complex scientific and technical facts in order to determine the nature and scope of the measures which they adopt, review by the EU courts must be limited to verifying whether there has been a manifest error of assessment […]".[102] Accordingly, the Courts "cannot substitute their assessment of scientific and technical facts for that of the authorities on which alone the FEU Treaty has conferred that task".[103] Further than that, the General Court does also expressly mention that the "broad discretion of the EU authorities, which implies limited judicial review of its exercise, applies not only to the nature and scope of the measures to be taken but also, to some extent, to the findings of the basic facts".[104]

Whilst drawing on these premises, the General Court and the Court of Justice still underline that the exercise of the Commission's discretion is not excluded from review by the Court; the Courts must therefore scrutinise whether the Commission complied with its duty to act diligently, in accordance with the principle of good administration,[105] by examining "carefully and impartially all the relevant facts of the individual case on which that assessment was based".[106] As expressly maintained by the General Court, the EU authorities "must be able to show before the EU Courts that, in adopting the act, they actually exercised their discretion, which presupposes the taking into consideration of all the relevant facts and circumstances of the situation";[107] thus, the Commission's ability to prove that it has taken "all relevant facts and circumstances" into consideration becomes a precondition for the Commission's exercise of its discretion.

The General Court, the Advocate General and the Court of Justice are all unequivocally committed to this procedural framing and interpretation of the issues at stake in *Bilbaína*. Although the reasoning of the Advocate General and of the Court is very clear, and appears to fully justify their conclusions, the assessment of CTPHT's classification through the *procedural* lens of a review of the Commission's

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[101] See *supra*, section 3.2.

[102] See the General Court in Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 23. See also the Judgment under comment, para. 34, "if the Commission is to be able to classify a substance pursuant to Regulation No. 1272/2008, account being taken of the complex scientific and technical assessments which it must undertake, it must be recognised as enjoying a broad discretion", where the Court of Justice quotes Case C-326/05, *Industrias Químicas del Vallés* v. *Commission*, EU:C:2007:443, para. 75, and Case C-15/10, *Etimine*, EU:C:2011:504, para. 60. On the broad discretion of the Commission in cases involving complex technical-scientific evaluations see already Case C-331/88, *Ex Parte Fedesa and Others*, para. 14; Case C-157/96, *Ex Parte National Farmers' Union and Others,* para. 39; and COM(2000) 1 Final, Communication from the Commission on the Precautionary Principle, *supra* note 2, p. 15, section 5.2.2. For an overview on the "legislature's political responsibilities and the correspondingly narrowed scope for judicial review" in EU risk regulation see Anderson, op. cit. *supra* note 9, pp. 431 ff.; see also Türk, *Judicial Review in EU Law* (Edward Elgar, 2009), pp. 136 and 145.

[103] See the General Court in Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 23, quoting Case C-15/10, *Etimine*, para. 60; Case C-199/13 P, *Polyelectrolyte Producers Group and Others* v. *Commission*, para. 26; and Case T‑93/10, *Bilbaína de Alquitranes and Others* v *ECHA*, para. 76.

[104] See Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 24; Case T‑93/10, *Bilbaína de Alquitranes and Others* v *ECHA*, para. 77; and Case C-287/13 P, *Bilbaína de Alquitranes SA and Others* v. *ECHA*, para. 20. See also the Opinion of Advocate General Kokott in Case C-343/09, *Afton Chemical Limited*, at para. 34, quoting – inter alia – Case C-326/05, *Industrias Químicas del Vallés* v. *Commission*, *supra* note 102, para. 77, and Case C-425/08, *Enviro Tech (Europe)*, EU:C:2009:625, para. 62; and the decision of the Court of Justice in Case C-343/09, *Afton Chemical Limited*, at para. 33.

[105] Judgment, para. 35; see also para. 33, and the Opinion, at para. 53 – as reported *supra* at note 59.

[106] Judgment, para. 35, quoting Case C-269/90, *Technische Universität München*, para. 14, Case C-326/05, *Industrias Químicas del Vallés* v. *Commission*, para. 77; Case C‑405/07 P, *Netherlands* v. *Commission*, EU:C:2008:613, para. 56; and Case C-77/09, *Gowan Comércio*, para. 57.

[107] See the General Court in Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 24. See *supra*, note 37, for further details.

discretion is misleading. In other words, the unilateral focus on the Commission's discretion in the application of the summation method fails to capture what is truly at stake in the case; this is what the Commission – rightfully – pointed at. In fact, this case perfectly epitomises the blurred boundaries between a *procedural* review of the Commission's duty to take "all relevant factors" into consideration, and a *substantive* review of the scientific soundness of the evidence relied upon.

In its second ground of appeal the Commission clearly explained that, despite the General Court's ruling that the Commission should have taken account of the characteristics of CTPHT *as a whole substance* in its *application* of the summation method, the *choice*, *use* and *application* of this methodology in fact postulate an analysis of the mixture's *components*. This casts light on how the General Court's argument is inconsistent with the very *use* and *application* of the summation method – which postulates the analysis of CTPHT as a mixture, and the calculation of the maximum rate of water solubility of its single components.

Arguing that the low solubility of CTPHT as a whole substance is a "relevant factor" that the Commission should have taken into consideration in its *application* of the summation method, in practice, implies a direct shift from the *use* of the summation method to the *use* of a different methodology; in other words, and crucially, requiring the Commission to take account of CTPHT's low solubility in its *application* of the summation method is tantamount to requiring the Commission to *use* the different methodology advocated by the applicants. It is then worth getting back to the first ground of appeal, whereby the Commission rightfully lamented the opaqueness of the General Court's reasoning as to whether the Regulation was partially annulled because of the *use* of the summation method, or because of an error in its *application*.[108] In fact, if the low solubility of CTPHT as a whole substance is held to be a "relevant factor", any distinction between a review of the *procedural* application of the summation method and a review of its *substantive* use is plainly elusive.

On these grounds the boundaries between the *procedural* review of the Commission's alleged *manifest error of assessment*, and the *substantive* review of the *scientific soundness* of the methodology and evidence relied upon, get increasingly blurred.

This ultimately results in a breach of the Commission's broad discretion, as applying "not only to the nature and scope of the measures to be taken but also […] to the findings of the basic facts",[109] and into a direct contradiction of the Courts' own acknowledgment that in cases of high technical-scientific complexity "review by the EU courts must be limited to verifying whether there has been a manifest error of assessment […]",[110] and the courts "cannot substitute their assessment of scientific and technical facts for that of the authorities on which alone the FEU Treaty has conferred that task".[111] From this perspective this case exemplifies how, as rightfully noted, the increasing "scientification" of the Court's review[112] expands on the scrutiny of the Commission's compliance with all relevant procedural guarantees, and on the procedural assessment of the plausibility of the final decision.[113] In this case, indeed, the Court's allegedly procedural review of the Commission's duty to take "all relevant factors" into account results in an indirect substantive scrutiny of the scientific soundness of the assessment methodology used.

[108] Judgment, paras. 19 and 20.
[109] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 24; and *supra*, note 104.
[110] See *supra*, note 102, in detail.
[111] See *supra*, note 103, in detail.
[112] See *supra*, note 9.
[113] Dąbrowska Klosinska, op. cit. *supra* note 6, pp. 205 and 208.

4.2. The Substantive Implications Beneath the Procedural Surface: The ECHA's Prudential Risk Assessment and the Commission's Precautionary Classification of CTPHT.

If the Court's interpretation fails to capture what is truly at stake in the classification of CTPHT, what lies underneath the procedural surface? The procedural framing of this case, in fact, obscures the substantive implications of the adoption of different assessment methodologies. The use and application of different models for risk assessment has a significant impact on any ensuing technical-scientific classification and/or on risk quantification.[114] There is nothing monolithic, neutral or objective about – allegedly – "sound" science;[115] whilst in-built scientific bias is almost impossible for lay people to detect, different scientific methodologies reflect a plurality of diverging approaches to the qualification or quantification of complex risks. This is quite apparent from the case of CTPHT: the applicants supported the use of the WAF approach, resulting in a low aquatic toxicity index for CTPHT, whereas the ECHA chose to apply the summation method, with a very different outcome.

From this perspective the Commission, by deferring to the ECHA Risk Assessment Committee's choice to use and apply the summation method, did in fact exercise its discretion, concurring with the ECHA's decision to undertake a prudential assessment[116] of CTPHT's aquatic toxicity. Despite the Commission's rather unfortunate argument about its own lack of discretion, whereby it claimed that "it is important only to ascertain, using the summation method, whether the thresholds set by the Regulation No. 1272/2008 are met, without the Commission having any margins of discretion whatsoever in that regard",[117] the Commission in fact *implicitly* exercised its discretion by referring to the results of a prudential risk assessment, by using them to underpin the categorisation of CTPHT, and by refusing to give any substantial weight to the data on the low water solubility of CTPHT as a whole substance. In other words, in the face of persisting scientific uncertainty and of incomplete, inconclusive and insufficient scientific data,[118] the Commission chose to rely on the ECHA's *prudential* risk assessment, and opted for a *precautionary* classification of CTPHT's level of aquatic toxicity.

At the heart of this case, then, lies the Commission's choice to adopt a precautionary approach to the governance of the uncertain risks posed by UVCB substances. This is apparent from a careful reading

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[114] As rightfully noted by Majone the choice of one model of assessment, rather than another – for instance the use of a linear, rather than a threshold model for a dose-response function – is critical to the relevant classification of a substance, or to the quantification of a risk. In this perspective, the determination of technical experts may in fact pre-empt decision-making by risk managers. On this point, see Majone, "Foundations of Risk Regulation: Science, Decision-Making, Policy Learning and Institutional Reform" 1 *EJRR* (2010) 5, at 10.

[115] The denigrators of the precautionary principle refer to a "neutral" and "objective" sound science approach, as opposed to "politicised" precautionary approaches to the governance of uncertain risks. See inter alia Graham and Wiener, *Risk v. Risk. Trade-Offs in Protecting Health and the Environment* (Harvard University Press, 1997); Sunstein, *Laws of Fear. Beyond the Precautionary Principle* (CUP, 2005); Pollack and Shaffer, *When Cooperation Fails. The International Law and Politics of Genetically Modified Foods* (OUP, 2009); Pollack and Shaffer, "The EU Regulatory System for GMOs", in Everson and Vos,
(eds.) *Uncertain Risks Regulated* (Routledge, 2009), 269 ff.; Wiener, "The Rhetoric of Precaution", in Wiener, Rogers, Hammitt and Sand (eds.) *The Reality of Precaution. Comparing Risk Regulation in the United States and Europe* (Routledge, 2011); Sunstein, "Precautions Against What? Perceptions, Heuristics and Culture", ibid. For an advocacy of evidence-based approaches in EU law, see Alemanno, op. cit. *supra* no. 1; Alemanno, "The Shaping of European Risk Regulation by Community Courts" (2008) *Jean Monnet Working Paper No. 18/2008*; Alemanno, "The Fabulous Destiny of Bisphenol A (BPA)" (2010) 1 *EJRR* 397; Alemanno, "The Science, Law and Politics of Neonicotinoids and Bees. A New Test Case for the Precautionary Principle" (2013) 4 *EJRR* 191.

[116] See *supra*, note 2.

[117] See the Judgment, para. 30 – reporting the Commission's argument.

[118] See COM(2000) 1 Final, op. cit. *supra* note 2, p. 7, section 1, defining a situation of *scientific uncertainty* – warranting the adoption of a precautionary approach – as a situation where scientific information is *insufficient*, *inconclusive* or *uncertain*, and where the potential risk may be *inconsistent* with the *chosen level of protection* of the relevant values at stake. See also *supra*, note 2 and note 3. In the case law see explicitly, inter alia, Case C-157/96, *Ex Parte National Farmers' Union and Others,* para. 64, *supra* note 7; Case C-180/96, *United Kingdom* v. *Commission,* para. 100, *supra* note 7; and, more recently, Case C-333/08, *Commission* v. *France*, EU:C:2010:44, paras. 92 and 93.

of the decisions of the General Court and of the Court of Justice. The applicants, on the basis of the scientific studies carried out by CTPHT producers,[119] advocated the use of the WAF approach:[120] the ECHA, however, disagreed for a plurality of reasons.

First, as documented by the ECHA Risk Assessment Committee's background document,[121] many of the PAH constituents of CTPHT are phototoxic; the impact of CTPHT on aquatic species should have been tested in the presence of UV irradiation, but all studies based on the WAF approach were performed in the absence of UV irradiation.[122] This made all the scientific data collected through the application of the WAF approach incomplete and insufficient to fully evaluate the aquatic toxicity of CTPHT as a whole substance, and scientific uncertainty persisted as to the reliability of these studies.[123] Secondly, all the studies performed by CTPHT producers through the application of the WAF approach had been carried out with a single loading.[124] Finally, the summation method was held to be the most suitable to apply in so far as it also takes into account the persistence and bioaccumulation potential of a mixture.[125]

In the light of the highly complex interpretational problems triggered by UVCB substances, whose chemical composition is unknown or variable and whose reactions depend on the behaviour of each component of the mixture,[126] the ECHA opted for the summation method because this would – ultimately – result in a prudential risk assessment. Indeed, the General Court noted that by applying the summation method the ECHA could "attach more weight to the highly toxic constituents of CTPHT"[127] and that, by assuming that all the PAH constituents of CTPHT dissolved in the water phase and were available to aquatic organisms, it could provide "an overestimation of the toxicity of CTPHT [to be] regarded as the worst case scenario";[128] in a similar vein, the Court of Justice remarked that the summation method gives due consideration to the fact that "Acute 1 and Chronic 1 components contribute to the toxicity of the mixture even at a low concentration".[129]

From this perspective the Commission, in choosing to align to the results of the ECHA's prudential risk assessment, exercised its discretion to opt for a precautionary classification of CTPHT's levels of aquatic toxicity: precautionary decision-making, thus, lies at the heart of this case.

What conclusions are we to draw from these reflections? On the one hand, the substantive rationale and substantive implications of the ECHA's risk assessment and of the Commission's categorisation of CTPHT are completely obscured by the Courts' procedural review of the Commission's duty to take "all relevant factors" into consideration. Not only this does not do justice to the Commission's precautionary approach to the governance of the uncertain environmental risks posed by CTPHT; but also, it simultaneously shifts the focus onto the Commission's alleged procedural breach of its duty of good administration.

On the other hand, however, it is worth noting that the Commission did neither at the General Court nor at the appeal stage ever refer to its discretionary power to draw on the ECHA's prudential assessment and enact a precautionary classification of CTPHT's level of aquatic toxicity. Whilst the

[119] The first nine applicants (Bilbaína de Alquitranes SA, Deza a.s., Industrial Química del Nalón SA, Koppers Denmark AS, Koppers UK Ltd, Koppers Netherlands BV, Rütgers Basic Aromatics GmbH, Rütgers Belgium NV and Rütgers Poland Sp. Zoo) in Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, are all producers and/or suppliers of CTPHT.

[120] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 25.

[121] See specifically point 7.6.

[122] See the Opinion, para. 17, and Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 27.

[123] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 27.

[124] Opinion, para. 17.

[125] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 27.

[126] On the specific problems of classification as to biodegradation, bioaccumulation, partitioning behaviour and water solubility see the Judgment at para. 43.

[127] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 7.

[128] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 31.

[129] Judgment, para. 4.

incompleteness, inconclusiveness and insufficiency of the scientific data[130] obtained through the use of the WAF approach warranted the use of the summation method, the Commission did not venture to suggest that taking the low solubility of CTPHT as a whole substance[131] into consideration as a "relevant factor" would ultimately run counter to the prudential risk assessment performed by the ECHA, and result in a departure from the Commission's precautionary approach to the classification of CTPHT.[132]

Had the Commission clearly spelled out the substantive impact of the use and application of different scientific methodologies, it could have expressly argued that taking the low solubility of CTPHT as a whole substance into account is plainly inconsistent with the ECHA's prudential approach to risk assessment,[133] and with the achievement of the level of environmental protection deemed to be appropriate.[134] In turn, this would have arguably reconnected to the crucial issue of the Commission's discretion, as applying "not only to the nature and scope of the measures to be taken but also […] to the findings of the basic facts".[135]

Although it is hard to envisage whether this argument could have benefited the Commission, or strengthened its position in the case,[136] it is still worth noting that the latter is completely silent on the prudential nature of the ECHA's assessment, as well as on the precautionary classification of CTPHT as a (H400) and (H410) substance. A close look at the Judgments confirms that any such reference is missing in *Bilbaína*: the precautionary principle is nowhere to be found.

4.3. Reconciling *Bilbaína I* and *Bilbaína II*: Taking "All Relevant Factors" Into Account?

As anticipated in section 3. the case under consideration, which will be referred to in this section as *"Bilbaína II"*, has one important antecedent. In case T-93/10[137] and appeal case C-287/13 P[138] (hereafter, *"Bilbaína I"*) the nine applicants/appellants, eight of which were also parties to *Bilbaína II*, sought the partial annulment of a 2010 decision of the ECHA[139] identifying CTPHT as a very persistent and very bioaccumulative ("vPvB") substance in accordance with Article 57(a), (d) and (e) of the REACH Regulation. The ECHA had opted for this classification of CTPHT upon a risk assessment conducted through the use and application of the summation method. The similarities between *Bilbaína I* and *Bilbaína II* are therefore quite clear: despite the difference in the legal basis for the adoption of the challenged decisions,[140] the applicants, the substance whose classification was at stake and the methodology used and applied by the ECHA are in fact exactly the same. The only

[130] See *supra*, note 118.
[131] See *supra* section 4.1. Requiring the Commission to take account of the low solubility of CTPHT as a *whole substance* in its *application* of the *summation method* is tantamount to requiring the Commission to *use* a *different methodology*.
[132] See *infra*, section 5. If the low solubility of CTPHT as a whole substance is identified as a "relevant factor" to be taken into account in the application of the summation method, it is hard to envisage the possibility for the Commission to enact – the same – precautionary classification of CTPHT.
[133] See *supra*, note 118.
[134] Ibid.
[135] Case T-689/13, *Bilbaína de Alquitranes SA and Others* v. *European Commission*, para. 24; and *supra*, note 104.
[136] The question is whether, if the Commission had explicitly referred to the *prudential* nature of the ECHA's risk assessment and to its own *precautionary* approach to the categorisation of CTPHT, the ruling would have been different. In a very different vein, at the core of the appeal is the argument that the Commission lacks *any discretion* in the *application* of the summation method – see *supra*, sections 2. and 3.
[137] Case T-93/10, *Bilbaína de Alquitranes SA and Others* v. *ECHA*, *supra* note 80.
[138] Case C-287/13 P, *Bilbaína de Alquitranes SA and Others* v. *ECHA*, *supra* note 81.
[139] The decision of the ECHA, published on 13 January 2010, to identify pitch, coal tar, high temperature (EC No. 266-028-2) as a substance meeting the criteria laid out in Article 57 of the REACH Regulation, see *supra* note 22.
[140] In *Bilbaína I* the legal basis for the classification of CTPHT as a vPvB substance is the REACH Regulation (see *supra*, note 22), whereas in *Bilbaína II* the legal basis is the CLP Regulation (see *supra*, note 15).

relevant difference lies in that the REACH Regulation, setting out the criteria for the identification of vPvB substances, did not make any explicit reference to the summation method.[141]

In *Bilbaína I*, the nine applicants challenged the ECHA's departure from the criteria expressly provided for in Articles 59(2) and (3) and Annexes XIII and XV of the REACH Regulation;[142] in other words, they challenged the ECHA's decision to use and apply the summation method, even though this assessment methodology was not provided for under the REACH Regulation.[143] Thus, the applicants contended that the ECHA had committed a manifest error of assessment.

In setting out the scope of its review the General Court emphasised the broad discretion of the EU institutions, in so far as they are able to show that they took into consideration "all the relevant factors and circumstances of the situation the act was intended to regulate".[144] To begin with, the General Court noted that "it cannot simply be held that the ECHA made a manifest error of assessment in taking the view that [CTPHT had] vPvB properties on the grounds that its constituents had such properties".[145] Although the REACH Regulation did not expressly provide for the use and application of the summation method, the Court found that it did not preclude that approach.[146] The opposite conclusion, the Court ruled, would not take into account the overarching aims of the REACH Regulation – and particularly the achievement of a high level of public health and environmental protection, the proper control of any risks posed by substances of very high concern and their progressive replacement by suitable alternative substances or technologies, whenever economically and technically viable.[147]

The General Court then went on to assess whether the ECHA's decision to use and apply the summation method was based on well-established practices rooted in EU legislation, and on scientific reasons.[148] In both respects, the General Court concurred with the ECHA's view. On the one hand, focusing on the relevance of the summation method under EU law, the General Court found that this methodology is explicitly provided for in Article 53(2) of the CLP Regulation.[149] On the other hand, and turning to an analysis of the ECHA's choice to use and apply the summation method, the General Court developed three considerations.

First, it found that the use and application of the summation method was suitable because "once in the environment the individual constituents of [CTPHT] will behave as independent substances [which] will release several PAHs with PBT or vPvB properties during use, for example by heating during processing or by leaching upon contact with water".[150]

Secondly, the Court noted that the analysis of UVCB substances as a whole[151] – rather than by reference to their single components – "does not lead to significant results for the great majority of substances, including CTPHT".[152] Crucially, the General Court expressly maintained that the persistence of UVCB substances cannot be properly assessed by using "biodegradation testing methods that measure […] the properties of the whole substance but do not provide information on its

[141] Unlike in the case of the CLP regulation, where the possibility to use and apply the summation method is expressly provided for in Article 53(2) and Annex I, point 4.1.3.2.
[142] Case T-93/10, *Bilbaína de Alquitranes SA and Others* v. *ECHA*, para. 74.
[143] For an exhaustive overview of the three pleas in law raised by the applicants see Case T-93/10, *Bilbaína de Alquitranes SA and Others* v. *ECHA*, paras. 67 ff.
[144] Case T-93/10, *Bilbaína de Alquitranes SA and Others* v. *ECHA*, para. 77.
[145] Case T-93/10, *Bilbaína de Alquitranes SA and Others* v. *ECHA*, para. 83.
[146] Ibid.
[147] Ibid., referring to Article 1(1) of REACH Regulation, *supra* note 22. See also para. 69, referring to Recital 1 of the Preamble to the REACH Regulation, and Title VII – particularly Article 55 – of the REACH Regulation.
[148] Case T-93/10, *Bilbaína de Alquitranes SA and Others* v. *ECHA*, para. 86.
[149] Case T-93/10, *Bilbaína de Alquitranes SA and Others* v. *ECHA*, para. 87; and indeed, the CLP Regulation is at issue in *Bilbaína II*.
[150] Case T-93/10, *Bilbaína de Alquitranes SA and Others* v. *ECHA*, para. 90.
[151] As the applicants advocated in both *Bilbaína I* and *Bilbaína II*.
[152] Case T-93/10, *Bilbaína de Alquitranes SA and Others* v. *ECHA*, para. 91.

constituents", [153] as "even if in such a test the whole substance might appear to be readily biodegradable, the presence of nonbiodegradable constituents cannot be ruled out".[154] Further than that, the General Court clarified that according to the ECHA "similar difficulties are encountered in bioaccumulation and toxicity testing for UVCB substances";[155] whilst the physical form of the substance considered as a whole[156] "may impede the release of its individual constituents to any significant extent if the substance is tested as such, in reality, after a certain time, PAH constituents will be released into the environment".[157] Thus, taking into consideration the features of the UVCB substance as a whole is liable to result in an under-classification of its actual bioaccumulation or toxicity level.[158]

Finally, and building on the above considerations, the General Court decided not to give any substantial weight to the applicants' argument on leaching, whereby they claimed that "all short term and chronic tests confirm that [the separate toxic constituents] are trapped in the high-molecular matrix [of CTPHT as a whole substance] and do not create toxic effects when, for example, they are in contact with water".[159] On these grounds, the General Court dismissed the applicants' plea on the ECHA's manifest error of assessment: the decision of the Court of Justice upheld the General Court's ruling.

What is the connection between *Bilbaína I* and *II*, and how to reconcile the rationale of the two cases? At the core of *Bilbaína I* was the issue of the Commission's discretionary power to depart from the criteria laid out in the REACH Regulation: the General Court and the Court of Justice found that the Commission – in its duty to take "all relevant factors" into account – was not precluded from using and applying the summation method, even though that assessment methodology was not expressly provided for under the REACH Regulation.

Bilbaína II marks another step and elaborates further on the duty of the Commission to take "all relevant factors" into account. In *Bilbaína II* the General Court and the Court of Justice held that the Commission, in its application of the summation method, was not precluded from taking the low aquatic solubility of CTPHT as a whole substance into account: moreover, and in accordance with its duty to consider "all relevant factors", it should have given due consideration to these data.

In this light, the thread running between the two cases is certainly the attempt to outline the boundaries of the Commission's discretion, and to frame its duty to take "all relevant factors" into consideration. As the Advocate General put it in in his Opinion in *Bilbaína II*, "if there is indeed discretion, it must be accepted that such discretion can cut both ways":[160] from this perspective it would appear that the Commission had a right to take "all relevant factors" into account in *Bilbaína I*, as much as a duty to do so in *Bilbaína II*. However, is this the case? Does this interpretation do justice

[153] Ibid.
[154] Ibid.
[155] Ibid.
[156] Rather than the physical form of the *constituents* of the *mixture* – which is the specific focus of analysis under the *summation method*.
[157] Case T-93/10, *Bilbaína de Alquitranes SA and Others* v. *ECHA*, para. 91. Indeed, it is worth noting that this is exactly what the Commission argued in *Bilbaína II* – namely, that it could *not* take the low water solubility of CTPHT as a whole substance into consideration when *applying the summation method*, because that would *distort* the entire risk assessment and result in the *use* and *application* of a *different methodology*.
[158] This is what lies at the heart of *Bilbaína II*, as argued *supra*, in section 4.2. Taking into account the low solubility of CTPHT as a whole substance is inconsistent with the methodological premises of the summation method and with a prudential risk assessment.
[159] Case T-93/10, *Bilbaína de Alquitranes SA and Others* v. *ECHA*, para. 94. This is *exactly the evidence on which the applicants relied* to have the Commission's decision in *Bilbaína II* invalidated by the General Court; on the other hand, and from a diametrically opposite perspective, the General Court in *Bilbaína I* decided to disregard it. The only relevant difference lies in that in *Bilbaína I* the applicants merely referred to the scientific studies at issue, without attaching them (see Case T-93/10, *Bilbaína de Alquitranes SA and Others* v. *ECHA*, para. 94), whereas in *Bilbaína II* they more thoroughly elaborated on their relevance for the assessment of CTPHT's aquatic toxicity (see *supra*, section 2).
[160] Opinion, para. 84. See also at para. 92: "if one accepts some degree of discretion as a matter of principle, one must accept that that discretion can cut both ways".

to the issues at stake in both cases, and does it make the standard of review deployed by the Courts *consistent*? Whilst a connection exists, the two cases in fact reach *diametrically opposite* conclusions.
On the one hand, in *Bilbaína I*, the Courts ruled that the Commission, in taking "all relevant factors" into consideration, was not precluded from applying the summation method. Crucially, the General Court emphasised that testing CTPHT as a whole substance is likely to result in an under-classification of its toxicity level: moreover, it expressly clarified that whilst the physical form of the substance considered as a whole[161] "may impede the release of its individual constituents to any significant extent if the substance is tested as such, in reality, after a certain time, PAH constituents will be released into the environment".[162] Thus, the General Court did not give any substantial weight to the applicants' argument, whereby they claimed that that the Commission should have taken *the inert inherent properties of CTPHT as a whole substance* into consideration in its assessment.
On the other hand, in *Bilbaína II*, the Courts held that the Commission had committed a manifest error of assessment by failing to take "all relevant factors" into account: the "relevant factors" which the Commission had failed to take into consideration, however, were *the same inert inherent properties of CTPHT as a whole substance* that the Commission had actually decided to disregard in *Bilbaína I*.
Beyond the *procedural* surface, the decision in *Bilbaína II* marks a *substantive* U-turn: the shift is most apparent in these two cases, where the substance whose classification is at stake and the assessment methodology are exactly the same.[163] How to square the circle, then?
A closer look at *Bilbaína I* and *II*, in fact, testifies that not only in these two cases the Courts provided a diametrically opposite interpretation of the "relevant factors" at stake in the assessment of CTPHT; but also, and ultimately, they applied two different standards of review.
On the one hand, in *Bilbaína I*, the General Court opted for a deferential standard of review, limiting the scope of its scrutiny to the *procedural* review of any manifest error of assessment. Although the General Court did certainly engage with the substance of the relevant scientific evidence in the case, it ultimately concluded that the Commission's discretionary choice to use and apply the summation method was not an arbitrary one.[164]
On the other hand, in *Bilbaína II*, the General Court applied a much more intrusive standard of scrutiny, blurring the boundaries between the *procedural* review of any alleged manifest error of assessment and the *substantive* review of the scientific soundness of the summation method.[165] By identifying the low aquatic solubility of CTPHT as a "relevant factor" to directly take into account, as already explained, it ultimately tipped the balance in favour of the use and application of a different methodology, disregarding the Commission's choice to rely on a prudential risk assessment and enact a precautionary classification.[166]
Against this overall background, the review of the "relevant factors" that the Commission shall take into account turns out to be a more problematic – and potentially inconsistent – standard than it would appear at first sight. Who holds the authority to decide what is a "relevant factor" and whether this should be part of the Commission's assessment?

[161] Rather than the physical form of the *single components*, as assessed under the *use* and *application* of the *summation method*.
[162] Case T-93/10, *Bilbaína de Alquitranes SA and Others* v. *ECHA*, para. 91.
[163] In other words, throughout *Bilbaína I* and *Bilbaína II*, the position of the applicants and the position of the Commission stay unchanged. The applicants consistently called for the assessment of the inert inherent properties of CTPHT as a *whole substance*, resulting in a lower classification of its level of aquatic toxicity; the Commission, on the other hand, opted for a *prudential* risk assessment, through the *use* and *application* of the *summation method*, and for a *precautionary* classification of CTPHT's index of aquatic toxicity.
[164] The standard of review applied in *Bilbaína I* is ultimately the same deployed in Case C-326/05, *Industrias Químicas del Vallés* v. *Commission*, Case C-425/08, *Enviro Tech (Europe)*, and Case C-343/09, *Afton Chemical Limited*.
[165] See *supra*, section 4.1.
[166] See *supra*, section 4.2.

It is legitimate to conclude that if in cases involving complex technical-scientific assessments the Courts "cannot substitute their assessment of scientific and technical facts for that of the authorities on which alone the FEU Treaty has conferred that task",[167] the review of the "relevant factors" that the Commission ought to take into consideration turns out to be a slippery slope. As *Bilbaína I* and *II* clearly show, the review of the Commission's duty to take "all relevant factors" into account may underpin or undermine the use of one assessment methodology, enabling the courts to arbitrarily pick and choose different strands of scientific evidence in favour of either a precautionary[168] or an evidence-based[169] approach.

From this perspective, the only way forward to restore an authentically procedural standard of review in cases involving complex scientific assessments postulates a turn back to the review of the Commission's compliance with the relevant procedural conditions, the accuracy of fact-finding, and the existence of any manifest error of appraisal or misuse of power;[170] in other words, the Court's scrutiny must target the *rational consistency* between the scientific findings emerging from the technical risk assessment, on the one hand, and the final decision, on the other hand.[171] As Advocate General Kokott rightfully suggested in her Opinion in *Afton Chemical Limited*, "what matters is whether [an alleged] error of assessment [is] legally relevant";[172] whilst this postulates that the Commission's assessment should not be arbitrary or unsubstantiated, it certainly does not imply that it should be scientifically "sound".

One last point, hinted at in the case under comment, needs to be briefly addressed in this section. In paragraph 81 of his Opinion on *Bilbaína II*, as already mentioned, the Advocate General stressed the need to look beyond the individual case: he then went on to highlight that even though the Commission's "error of assessment" in *Bilbaína II* had resulted in the most severe hazard classification, the opposite may occur, and the Commission's alleged "inability to take into account other relevant factors [may] ultimately lead to a lower hazard classification than might otherwise be justified".[173] In other words, if it is true that discretion can be exercised in a way which facilitates precautionary regulation, it is equally true that it may result in low and insufficiently stringent standards. In this light, the Advocate General suggested, a direct scrutiny of the Commission's duty to take "all relevant factors" into consideration turns out to be all the more important.

Whilst the Advocate General certainly has a point, an intrusive review of whether the Commission has taken "all relevant factors" and all scientific evidence into account, as outlined in *Bilbaína II*, does not appear to be a solution to the potential problems posed by insufficiently stringent standards. In fact, as testified by the inconsistencies in *Bilbaína I* and *II*, the outcome of this test is unpredictable: as already mentioned, the Courts' identification and interpretation of the "relevant factors" at stake in a case may turn out to facilitate or obstruct a precautionary approach to the governance of uncertain risks. Further than that, and as *Bilbaína II* shows, the "relevant factors" test might as well pave the way for a quasi-substantive review of the scientific evidence relied upon, marking a further step towards the scrutiny of scientific "soundness".

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[167] See *supra*, note 103.

[168] As occurred in *Bilbaína I* – respecting the Commission's (precautionary) approach.

[169] As in *Bilbaína II* – through a "quasi-substantive" review of the scientific evidence relied upon by the Commission. For the far-reaching implications of this standard of review see infra, section 5.

[170] Crucially, in this perspective, see the Opinion of Advocate General Jääskinen in Case C-77/09 *Gowan*, at paras. 70 to 74, *supra* note 7; the Judgment of the Court in Case C-77/09 *Gowan*, at paras. 71 to 79, *supra* note 7; and the Opinion of Advocate General Kokott in Case C-343/09, *Afton Chemical Limited*, paras. 27 to 34, para. 85 and paras. 89 to 93, *supra* note 7.

[171] See specifically the Opinion of Advocate General Jääskinen in Case C-77/09 *Gowan*, at paras. 70 to 74, *supra* note 7, and the Opinion of Advocate General Kokott in Case C-343/09, *Afton Chemical Limited*, paras. 89 to 93, *supra* note 7.

[172] Opinion of Advocate General Kokott in Case C-343/09, *Afton Chemical Limited*, para. 30.

[173] Opinion, para. 81. See also the Opinion, at paras. 83 and 92, and the Judgment, at para. 46.

Once again, then, how to square the circle? Albeit overlapping, the Commission's margins of *procedural* discretion and the *substantive* value of precautionary public health and environmental protection are two different – and distinguishable – aspects.[174] This is apparent from an analysis of *Bilbaína II*, where the arguments on the Commission's broad discretionary power to take "all relevant factors" into account when applying the summation method[175] go hand in hand with a review of the scientific soundness of its decision, undermining the Commission's precautionary approach.[176] For this reason, demarcating the boundaries between the *procedural* dimension of the Commission's discretion, on the one hand, and the *substantive* value of the precautionary principle, on the other, may turn out to be helpful.

From this perspective, the precautionary principle ought to be appreciated in its self-standing substantive value – as acknowledged by the TFEU[177] and in the broader framework of EU risk regulation, EU environmental law and the EU regulation of chemicals.[178] To put it differently, the precautionary principle would come to be interpreted as an *inherent – substantive – limit* to the Commission's broad – *procedural – discretion* in cases involving complex technical-scientific assessments: the discretion of the Commission would then have to be exercised *in accordance with* the high standards of public health and environmental protection enshrined in the broader framework of EU risk regulation and environmental law.[179]

Whilst this could provide an alternative answer to the argument of the Advocate General, whereby he claimed that the scrutiny of the Commission's duty to take "all relevant factors" into consideration would limit the Commission's power to enact low and insufficiently stringent standard, re-framing the precautionary principle as an inherent *substantive* limit to the Commission's *procedural* discretion triggers an array of highly complex questions. How far can the precautionary principle inform judicial review, with a view to safeguarding the intended EU level of health and environmental protection and ensuring that protective standards are enacted?[180] Should the Commission be bound to ignore any risk

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[174] Although commentators usually assume that the two dimensions go hand in hand, drawing a *direct parallelism* between the latitude of the Commission's *discretion* and the Courts' adherence to a *procedural standard of review* – on the one hand – and a *precautionary* approach to EU risk regulation – on the other hand. See e.g. Anderson, op. cit. *supra* note 9; Fisher, *Risk Regulation and Administrative Constitutionalism* (Hart Publishing, 2007), on the Rational-Instrumental and Deliberative-Cooperative paradigms of administration in the field of risk regulation; Weimer, "Risk Regulation, GMOs and the Challenges to Deliberation in EU Governance: Politicisation and Scientification as Co-Producing Trends", in Joerges and Glinski (eds.) *The European Crisis and the Transformation of Transnational Governance: Authoritarian Managerialism Versus Democratic Governance* (Hart Publishing, 2014), 295 ff.; and Weimer and Pisani, "Expertise and Justification. The Contested Legitimation of the EU Risk Administration", in De Ruijter and Weimer (eds.) *Regulating Risks in the European Union. The Co-Production of Expert and Executive Power* (Hart Publishing, 2017). Nonetheless, and as *Bilbaína II* shows, a procedural review of the Commission's – broad – margins of discretion may as well go hand in hand with a thorough scrutiny of the scientific soundness of the evidence relied upon.

[175] At the *procedural* level.

[176] At the *substantive* level.

[177] See the Consolidated Version of the Treaty on the Functioning of the European Union, O.J. 2012, C 326, Article 191(2), "Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken […]".

[178] See, inter alia, Consolidated Version of the Treaty on the Functioning of the European Union, O.J. 2012, C 326, Article 191(2), "The Commission, in its proposals […] concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection"; and COM(2000) 1 Final, Communication from the Commission on the Precautionary Principle, *supra* note 2, p. 8, section 2, "The search for a high level of health and safety and environmental and consumer protection belongs in the framework of the single market, which is the cornerstone of the Community", and p. 8, section 3, "The Community has consistently endeavoured to achieve a high level of protection, among others in environment and human, animal and plant health". On the relevance of the precautionary principle under EU environmental law, see Lee, *EU Environmental Law, Governance and Decision-Making*, 2nd ed. (Hart Publishing, 2014), chapters 1 and 2; on the EU Regulation of Chemicals, specifically, see Recital 1 of the Preamble to the REACH Regulation and Article 1(1) therein, *supra* note 22; and Recitals 1 to 4 of the Preamble to the CLP Regulation and Article 1 therein, *supra* note 15.

[179] For an understanding of the precautionary principle as a "sword", rather than as a mere "shield", see already Scott and Vos, "The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle Within the EU and the WTO", in Joerges and Dehousse (eds.) *Good Governance in Europe's Integrated Market* (OUP, 2002), 253 ff.

[180] See *supra* notes 2, 3 and 118.

assessment which is found to be insufficiently prudential, in so far as taking it into consideration would be inconsistent with the overarching tenets of the precautionary principle?[181] How would the Courts outline the boundaries of scientific uncertainty, or define the "prudential" nature of a risk assessment?[182] And when is precautionary risk management to be understood as "precautionary" enough?

Substantiating the precautionary principle in legal – rather than political – terms[183] appears to be just as hard as reviewing compliance with it. Indeed, this is the challenge posed by the deployment of the precautionary principle as a "sword", rather than a "shield".[184] Whilst certainly difficult, carving out a role for the precautionary principle as a "sword" could still be a promising way forward to judicially review whether public health and environmental standards are stringent enough, and comply with the high level of protection enshrined in the Treaties. In any case, it would still be a more promising way forward than the intrusive review of the Commission's duty to take "all relevant factors" into consideration, as specifically outlined in *Bilbaína II*.

5. Conclusions: From the Entrenchment of A Quasi-Substantive Standard of Review To The Gradual Demise of EU Precautionary Risk Regulation.

This section addresses one final but crucial aspect of *Bilbaína II*. As already explained, the Court of Justice rejected the third ground of appeal, whereby the Commission argued that the General Court had distorted the scientific evidence in the case and had abused the limits of judicial review.[185] The Commission explicitly maintained that the General Court, by picking and choosing the data on the low solubility of CTPHT as a whole substance to invalidate the Commission's classification, had disregarded the rest of the available scientific evidence and had directly substituted its own assessment for that of the Commission.[186] The Court of Justice, on the other hand, held that the General Court had not substituted its own assessment for that of the Commission, because the General Court had exclusively focused "on the procedural question of determining whether the Commission, in classifying CTPHT, complied with its obligation to take into consideration all the relevant factors and circumstances".[187]

Section 4.1. has showed how the standard of scrutiny outlined in *Bilbaína II*, in fact, lies at the crossroads between a procedural review of the Commission's duty to take "all relevant factors" at stake into account, and a substantive review of the scientific soundness of the summation method. This consideration triggers one further question: had the Commission directly taken the low solubility of CTPHT as a whole substance into consideration in the decision-making process,[188] would it have still been in the position to classify it as an Aquatic Acute 1 and Aquatic Chronic 1 substance? Had the Commission complied with its *procedural* duty to give due consideration to "all relevant factors",

[181] Ibid.
[182] Ibid.
[183] For the view that compliance with the precautionary principle raises "policy concerns which must be dealt with in political fora", and that "it is not for this or any other court to determine proper national or [EU] environmental policy", see the Opinion of Advocate General Sharpston in Joined Cases C-439/05 and C-454/05, *Land Oberösterreich and Austria v Commission,* EU:C:2007:285, para. 145. However, it is worth underlining that in this case the precautionary principle was *not* directly relevant to any of the legal issues at stake; in fact, the appellants were seeking the annulment of the Commission's Decision to reject Austria's request for a derogation on the grounds of (what is today) Article 114(5) TFEU.
[184] Scott and Vos, "The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle Within the EU and the WTO", op. cit. *supra* note 179.
[185] Judgment, para. 57.
[186] Ibid.
[187] Judgment, para. 58.
[188] In its "procedural" *application* of the summation method – see *supra*, section 3. and section 4.1.

as outlined by the General Court and upheld by the Court of Justice, would it have been allowed to reach the same *substantive* conclusion on the classification of CTPHT?

The Court of Justice is silent on this point, but the Advocate General is not. In his Opinion, the latter maintained that "I am in no way suggesting that, on the merits, the result arrived at by the Commission is unsustainable. I pass no judgment whatsoever on the (in)correct classification of CTPHT";[189] further than that, the Advocate General went on to clarify that "at no point does (or indeed could) the General Court hold that if, hypothetically, the Commission had taken the low solubility of CTPHT into account, it would have committed a manifest error of assessment in going on to classify CTPHT as Aquatic Acute 1 or Aquatic Chronic 1".[190] Thus, "it is the Commission's objective failure to take that element into account in its reasoning, as confirmed by the General Court, which resulted in the partial annulment of the contested regulation".[191] Nonetheless, is this truly the case? Is it fair to argue that the Commission could have reached the same exact *substantive* conclusions, upon *procedurally* taking the low solubility of CTPHT as a whole substance into direct account in its decision? To put it differently, is it plausible to envisage a *precautionary* classification in the absence of a *prudential* risk assessment? Whilst possible in theory, this is neither too convincing nor too feasible in practice.

It is reasonable to suggest that if the Commission had taken the low solubility of CTPHT into direct consideration, when applying the summation method, it would have *not* had any scientific evidence available to substantiate a precautionary classification. CTPHT would have appeared to be very stable, and its low solubility index would have *not* warranted its classification as an Aquatic Acute 1 and Aquatic Chronic 1 substance.[192] If the Commission had reached the same *substantive* – precautionary – conclusions, upon *procedurally* taking the low solubility of CTPHT into direct account, it would have arguably committed a manifest error of assessment. In that case, indeed, its final decision would have been arbitrary as well as rationally inconsistent with the scientific findings of the risk assessment.[193] On the grounds of these considerations, and getting back to the Advocate General's point, it is in fact legitimate to doubt that the Commission could have reached the same *substantive* conclusions, upon complying with the *procedural* obligations laid out by the Court.

This sheds further light on the far-reaching implications of the standard of review outlined in *Bilbaína II*.[194] This case provides a perfect example of what has been defined as an *"evidence-based judicial reflex"*:[195] a thorough, *quasi-substantive* review of the scientific evidence relied upon in the decision-making *process*, encroaching on the Commission's assessment of highly complex technical-scientific facts and indirectly constraining its discretionary decision-making power.[196] Against this backdrop, the Judgment in *Bilbaína II* epitomises a *latent shift away* from a *procedural* review[197] of the

[189] Opinion, para. 70.

[190] Opinion, para. 94.

[191] Ibid. However, and as explained in section 4.2., the Commission did *not* fail to procedurally take this element into account in its reasoning; rather, the ECHA's decision to resort to the summation method and the Commission's deliberate choice to rely on its results built on the acknowledgment that, in the face of persisting scientific uncertainty over the behaviour of CTPHT's single components, the data on the low solubility of the substance as a whole should have *not* been given any weight.

[192] Indeed, the data underpinning the Commission's precautionary classification resulted from the prudential decision to resort to the summation method – whose application *postulates* that the overall solubility of the substance should *not* be taken into account.

[193] See *supra*, section 4.3. and particularly notes 170 and 171.

[194] More specifically, on the implications of the – peculiar – framing and interpretation of the Commission's duty to take "all relevant factors" into account, as outlined in this case.

[195] For a definition and a positive view see Alemanno, "The Emergence of the Evidence-Based Judicial Reflex. A Response to Bar-Siman-Tov's Semi-Procedural Review", 1 *Theory and Practice of Legislation* (2013) 1.

[196] This runs against settled case law on the broad discretion of the Commission in cases involving complex technical-scientific evaluations; see *supra*, notes 102, 103 and 104.

[197] Of the Commission's *application* of the summation method, to assess whether it took *"all relevant factors"* into consideration – see *supra*, sub-section 4.1.

Commission's duty of *good administration*, to a *substantive* review[198] of the Commission's duty to adhere to an *evidence-based model of risk regulation*. Indeed, the development of an *"evidence-based judicial reflex"* paves the way for the entrenchment of evidence-based risk regulation, to the direct detriment of a precautionary approach; it is not a case that the advocates of evidence-based risk regulation in the EU have consistently called for a more thorough substantive review of the scientific evidence triggering the enactment of precautionary measures[199] and substantiating the level of protection which is deemed to be appropriate by the risk manager.[200]

Is there more to the Courts' decision in this case? Did any other factors play a specific role in this case? As the Court of Justice expressly noted in its Judgment, "trade in substances and mixtures is an issue relating not only to the internal market, but also to the global market, [and] enterprises should benefit from the global harmonisation of rules":[201] the Union "confirmed its intention to contribute to the global harmonisation of criteria for classification and labelling, not only at UN level, but also through the incorporation of the internationally agreed GHS criteria into [EU] law", and "should be at the forefront of this process to encourage other countries to follow and with the aim of providing a competitive advantage to industry in the Community".[202] The direct link between evidence-based risk regulation, regulatory convergence, the elimination of non-tariff barriers to trade and transnational market access undoubtedly had a role to play in the specific context of – the CLP regulation and – *Bilbaína II*. Regardless of whether this trend is positively or negatively appraised, it still needs to be confronted in analytical terms. This makes it all the more important to explore the direct and indirect impact of the CJEU's case law and to spell out that, as occurred in *Bilbaína II*, an allegedly procedural review is liable to have far-reaching substantive implications for EU risk regulation.

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[198] Of the Commission's decision to *use* the summation method – see *supra*, sub-section 4.1.

[199] Alemanno, "Case C-79/09, *Gowan Comércio Internacional e Servicos Lda* v. *Ministero della Salute*, Judgment of the Court of Justice (Second Chamber) of 22 December 2010", op. cit. *supra* note 1, at p. 1345 claims that otherwise "it will prove to be impossible for the Courts to judicially review any science-based measure […]". See also Janssen and Rosenstock, "Handling Uncertain Risks: An Inconsistent Application of Standards?", op. cit. *supra* note 6.

[200] Alemanno, ibid., pp. 1345 to 1347. See also p. 1330, where Alemanno draws a connection between the Commission's broad margins of discretion and the Courts' – traditionally – deferential review of the scientific substantiation of risk regulation, on the one hand, and the strengthening of "the dominance of the administrations over the citizens", on the other hand.

[201] See the Judgment, at para. 2 – quoting recitals 1 to 8 of the CLP Regulation.

[202] Ibid.