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Master Working Paper

2023/1

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On the discretion of EU Institutions in science-based policymaking: the case of nuclear energy in the Complementary Climate Delegated Act to accelerate decarbonisation

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Published in Maastricht, November 2023

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This paper is to be cited as MCEL Master Working Paper 2023/2

The present Master's thesis focuses on the legal implications of the inclusion, through the Complementary Climate Delegated Act to accelerate decarbonization (CDA), of nuclear energy-related activities among those disciplined by the EU Taxonomy Regulation. The adoption of the CDA has been met with strong criticism by Member States, NGOs, and Civil Society, as it has been argued that the scientific evidence behind that measure could have been both insufficient and assessed through an incorrect method of assessment. Indeed, as regard nuclear energy-related activities, the act found its scientific basis in a report by the Joint Research Centre (JRC) on the compatibility of nuclear energy with the Do No Significant Harm (DNSH) principle as defined in Article 17 of the Taxonomy Regulation. That report has been, in turn, the object of two separate reviews, one from the Group of Experts as defined in Article 31 of the EURATOM Treaty and one from the Scientific Committee on Health, Environmental, and Emerging Risks (SCHEER). Ultimately, while true that, in the adoption of science-based measures, Institutions enjoy a widely recognized discretion, the SCHEER review highlighted some possible incompatibilities between the completeness of the scientific data and the adequacy of the assessment method relied on by the JRC, and the DNSH principle, thus opening the door for an assessment by the Court through the so-called manifest error of assessment test.

Therefore, starting from the finding of the SCHEER, the present thesis tries to hypothesize how a possible action by a Member State, against the adoption of the CDA, insofar as it includes nuclear energy-related activities among those disciplined by the EU Taxonomy Regulation, could be structured and what approach the Court could apply to reach a final judgement, based on relevant case-law. Specifically, the present work makes a comparison between the initial protective approach of the Court toward the discretion of the Institutions in cases dealing with science-based measures, such as Bayer, and the more aggressive one of the latest jurisprudence, such as GWS Powder, and tries to reach a hypothetical conclusion as regard an eventual judgement by the CJEU concerning the inclusion of nuclear energy-related activities among those regulated by the Taxonomy Regulation through the CDA.

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Chapter 1: Introduction

Since the 70s, science-based policymaking in the EU has become growingly relevant.[1] From the Complementary Climate Delegated Act to accelerate decarbonisation[2] to the proposal for science-based criteria for endocrine disrupting chemicals[3], from the latest[4] evolutions in the field of agriculture and food safety[5] to the growing openness of the European Commission toward Carbon Capture and Storage (CCS)[6], the European Union[7] appears to be always more determined to affirm itself as one of the leading science-policy actors on an international level. This seems even truer when considering the impressing[8] legal, political, and technical objectives the Union introduced to reach the ambitious objective of climate neutrality by, at the latest, 2050 set out in European Climate Law.[9]

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[1] D. Guéguen, V. Marissen, *Science-based and evidence-based policy-making in the European Union: coexisting or conflicting concepts?*, *Collège d'Europe Department of European and Governance Studies*, 2022, p. 7.

[2] *Commission Delegated Regulation (EU) 2022/1214 of 9 March 2022 amending Delegated Regulation (EU) 2021/2139 as regards economic activities in certain energy sectors and Delegated Regulation (EU) 2021/2178 as regards specific public disclosures for those economic activities*. Also known as CDA, the act adds specific nuclear energy and gas energy activities to the list of the economic activities covered by the EU Taxonomy Regulation so that they can be qualified as "sustainable" (please improve my additional explanation) (*Regulation (EU) 2020/852 on the establishment of a framework to facilitate sustainable investment*).
EU taxonomy: Complementary Climate Delegated Act to accelerate decarbonisation, European Commission website, link:
https://finance.ec.europa.eu/publications/eu-taxonomy-complementary-climate-delegated-act-accelerate-decarbonisation_en#details

[3] P. Holdorf, M. Fehling, *How will the Commission act on endocrine disruptors?*, *Fleishman Hillard*, link:
https://fleishmanhillard.eu/2020/05/how-will-the-commission-act-on-endocrine-disruptors/

[4] Not universally well received.

[5] For instance, the European Commission extended the EU authorization for the use of the herbicide glyphosate until the end of 2023 (*Commission Implementing Regulation (EU) 2022/2364 of 2 December 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance glyphosate*). The measure has been subjected to strong critiques. Specifically, the herbicide has been the object of several medical studies as regards the incidence of cancer in humans as a result of exposure to the chemical compound, leading to different opinions on the subject. For instance, both the EPA (the U.S. Environmental Protection Agency) and the EFSA (the European Food Safety Authority) agree that "*there is no evidence that glyphosate causes cancer in humans*" (*Does glyphosate cause cancer?*, *City of Hope*, 2021), while, pursuant to a research conducted by the Department of Environmental & Occupational Health Sciences of the University of Washington, exposure to glyphosate increases the risk of non-Hodgkin lymphoma by 41% (*Can Roundup cause cancer?*, *Interdisciplinary Center For Exposures, Diseases, Genomics and Environment*, 2020).
B. Brzezinski, *Glyphosate license extended to end of 2023*, *Politico*, 2023.

[6] *Carbon capture, storage and utilization*, *European Commission, Energy*, link:
https://energy.ec.europa.eu/topics/oil-gas-and-coal/carbon-capture-storage-and-utilisation_en

[7] With a particularly strong impetus by the Commission.

[8] Both in aim and complexity.

[9] Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 ('European Climate Law'), which codifies the objectives set out by the European Green Deal for EU's economy and society to become climate neutral by the year 2050 and introduces intermediate targets of net reduction of greenhouse gas emissions by at least 55% by 2030 compared to 1990 levels.
European Climate Law, European Commission website, link:
https://climate.ec.europa.eu/eu-action/european-green-deal/european-climate-law_en

Nevertheless, fast-paced and constant scientific evolutions and discoveries call for an even faster and, foremost, necessary evolution of the EU science-based policymaking process.[10] This might prove to be one of the toughest challenges the Union will have to face in the near future.[11] As science has increasingly become the subject of political debate[12], the adoption of controversial measures[13] and the frequent reliance on delegated and implementing acts of the Commission in science-based policymaking paint the picture of an EU which ever more often struggles to justify to sceptical Member States and private actors its decision in technical fields and arguably appears to occasionally experiences difficulties in properly justify the scientific evidence relied on in the adoption of science-based measures in cases of scientific uncertainty or conflict between experts.[14] The latter issue[15] poses a fundamental yet complex question: What degree of freedom do EU Institutions enjoy when adopting science-based policy in situations of scientific uncertainty?

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[10] On the challenges posed by EU science-based policymaking and the necessity of its evolution, an interesting opinion is that of former MEP Julie Girling, according to which *"The European Union, and the rest of the world, face a number of critical challenges. There are issues around resource efficiency, energy independence, climate change and food security which need to be dealt with. These new challenges need new policy ideas, or new products and processes to be introduced. Many of the solutions to these challenges will come from scientific and technological advances but many such scientific advances are met with fear and confusion – they are believed to pose risks to public health, or the environment. In some cases, such concerns are absolutely justified, but in others, they are not"*.
J. Girling, *The Role of Science in 21st Century EU Policy-Making*, *Symposium on the European Commission's Chief Scientific Advisor*, 2014, p.1.

[11] *Ibid*.

[12] Nuclear energy, for instance, represents a perfect example of this trend. The reaching of an agreement on March 30th between the European Parliament, the Commission, and the Member States on the revision of the Renewable Energy Directive (*Directive (EU) 2018/2001 of the European Parliament and of the Council of 11 December 2018 on the promotion of the use of energy from renewable sources*), which opened the door to the inclusion of nuclear-derived hydrogen – however, under very strict conditions – is the result of months of political debate between nuclear-energy sceptic MSs (Austria, Denmark, Germany, Ireland, Luxembourg, Portugal, and Spain) and the so-called pro-nuclear coalition (France, Bulgaria, Croatia, Czechia, Hungary, Poland, Romania, Slovakia, Slovenia).
F. Simon, *Seven countries reject nuclear-derived hydrogen from EU renewable law*, *Euractiv*, 2023.

[13] The adoption of the Complementary Climate Delegated Act to accelerate Decarbonisation (CDA), which will be the main focus of the present thesis, represents a clear example of the point made above.
Ibid.

[14] On this point, the Bellio judgement (ECLI:EU:C:2004:212) – in which the Court upheld the right of the EC to implement a "zero tolerance" policy with regard to the contamination of animal feed by materials that possibly contained the agent responsible for Bovine Spongiform Encephalopathy (BSE, also known as Mad Cow Disease), although there was uncertainty among the scientific community on the minimum amount of infected material necessary to transmit the disease to humans – represents an interesting ruling on the possible course of action the EU legislator can adopt when dealing with situations of scientific uncertainty. The ruling, alongside other relevant case-law, will be further examined in the next Chapters of the thesis.
E. Vos, *European Risk Governance: Its Science, Inclusiveness and its Effectiveness*, *Academia*, 2008, p. 58.

[15] Which will be the main focus of the present thesis.

The main objective of this work will be to try to find further insights to answer this question by specifically examining one of the most recent and truly controversial developments in EU science-based policymaking: the introduction of nuclear energy-related activities among those listed in the EU Taxonomy Regulation[16] through the Complementary Climate Delegated Act to accelerate decarbonisation of the Commission.[17] Not objected by neither the Parliament nor the Council[18], the CDA[19] has almost immediately been met with strong scepticism as regard the scientific basis for such a measure by several Member States[20] and NGOs[21], following the perplexities expressed by part of the scientific community[22] as to whether the EC's decision to adopt that act could be considered in line with the scientific findings on the compatibility of nuclear energy with the "*Do No Significant Harm*" (DNSH) principle provided for by Article 17 of the Taxonomy Regulation.[23] Indeed, during the risk assessment phase, which preceded the drafting procedure of the act, the initial (non-binding) report provided by the Joint Research Centre (JRC) of the Commission[24] had been the object of two distinct reviews, a favourable one by the Group of Experts on radiation protection and waste management under Article 31 of the EURATOM Treaty, and a more sceptical one by the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER).[25]

Focusing on this interesting example[26], the present dissertation will, thus, try to answer the following research questions: What are the general criteria for EU science-based policymaking

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[16] Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment.

[17] From now on, the "CDA". Published on February 2nd, 2022, the act also involves natural gas, which will not, however, be covered by this thesis.

[18] Which were given until July 11th to object against the Delegated Act.

[19] Which has entered into force in and has been applied since January 1st, 2023.

[20] In particular, Germany, Austria, Denmark, Luxembourg, and Portugal raised some relevant doubts as regards to the compatibility of nuclear energy with the "*Do No Significant Harm*" principle (DNSH) as developed by Article 17 of the Taxonomy Regulation, and even formed an "anti-nuclear alliance" at the COP26 *"to keep nuclear out of the EU's green finance taxonomy"*.
N. J. Kurmayer, *Five EU countries form anti-nuclear alliance at COP26*, *Euractiv*, 2021.

[21] A. Tidey, *Taxonomy: 12 NGOs launch challenge against EU's bid to label nuclear and gas as green*, *Euronews*, 2022.

[22] See, among others: *Two EU reports on nuclear sustainability not entirely on the same page*, *NuclearNewswire*, 2021.

[23] A topic which would require an in-depth analysis of scientific data and which, thus, will not be examined in the present thesis.

[24] The in-house science and knowledge service of the Commission.

[25] Note: by the time the present thesis was being written, the SCHEER review became unavailable online due to a technical malfunctioning of the Commission's website. After a round of e-mails with several members of the Commission (Mr. Daniel Sheridan Ferrie – Spokesperson for the Commission; Miss Aikaterini Apostola – Press officer; and Miss Silvia De Iacovo – Policy assistant), the review has been made available online again.

[26] The merits of which will not be analysed by this thesis, as they would require a quite advanced level of scientific knowledge.

and what are the limits to the Institutions' discretion when adopting science-based measures in situations of scientific uncertainty or conflict between experts? Does the introduction of the Complementary Climate Delegated Act to accelerate Decarbonisation complies with said criteria and limits? How could the Court approach an action against the adoption of that measure?

The present thesis will be structured in three main parts: Chapter 2 will focus on the analysis of relevant EU primary and secondary legislation[27] and CJEU case law[28], while also considering selected soft law measures[29], to define the criteria applicable to EU science-based policymaking and delineate the limits laid out by those sources to the discretion the Institutions enjoy when adopting science-based measures;[30] Chapter 3 will focus on the analysis of the procedural genesis of the CDA, with a focus on the aspects connected to nuclear energy, concentrating on the political and procedural steps which led to its adoption and on the scientific findings of the SCHEER on the compatibility of nuclear energy with the DNSH principle;[31] Chapter 4 will provide a final assessment as regards to the compatibility of the adoption of the CDA with the criteria highlighted in Chapter 2 in light of the criticalities underlined in the SCHEER report, basing the argumentation on the concept of "manifest error of assessment".[32] Specifically, the last Chapter will try to envision the possible content of an

[27] By focusing, in particular, on Article 114(3) TFEU, Article 191(2-3) TFEU, on Regulation 2020/852 (EU Taxonomy Regulation), and on Commission Delegated Regulation 2021/2139 (Supplementing Regulation (EU) 2020/852 of the European Parliament and of the Council by establishing the technical screening criteria for determining the conditions under which an economic activity qualifies as contributing substantially to climate change mitigation or climate change adaptation and for determining whether that economic activity causes no significant harm to any of the other environmental objectives).

[28] By focusing, in particular, on the Pfizer Animal Health SA v Council of the European Union judgement (case T-13/99) of 2002 the parallel Alpharma v. Council (case T-70/99), and on the Bellio F.lli Srl v Prefettura di Treviso judgement of 2004 (case C-286/02). The arguments of the Court in the two cases will be analysed in depth in Chapters 3 and 4 of the present thesis.

[29] By focusing, in particular, on the Science and Society Action Plan (2002) and on the Commission Communication on the Collection and Use of Expertise (2002). The content of both documents will be further analysed in Chapters 3 and 4 of the present thesis.

[30] The normative sources quoted in the thesis have been extrapolated by the sectorial literature, news articles, and institutional web pages quoted in the foot notes of the present work. All the quoted normative and jurisprudential instruments have been analyzed in depth before being quoted.

[31] It is worth noting that, however, the analysis of the content of the reports and reviews quoted in the present thesis will only amount to the necessary element to build up the legal argumentation of this work. A substantive analysis of the scientific content of such reports and reviews would require a degree of scientific knowledge concerning nuclear energy that the author of the present thesis does not possess.

[32] The concept will be defined in Chapter 4 of the present thesis.

action brough in front of the Court by a Member State to challenge the adoption of that act[33] and the possible approach the Judges might adopt to deal with such an action.[34]

[33] In so far as it led to the inclusion of nuclear energy-related activities within those listed in the Taxonomy Regulation.

[34] With an argumentation based on relevant case-law selected from the literature taken under exam in the Chapter.

Chapter 2: The principles of science-based policymaking: between case-law and codification

The EU's approach to science-based policymaking[35] has gone through several evolutionary phases over the past fifty years. The first scientific committees in the areas of consumer health and food safety were established by the institutions already in the 1970s[36] and their network was later formalized in 1997 through Commission Decision 97/579/EC.[37] Furthermore, a growth in prosperity in the EU, the evolution of internal market policy[38], and the recurring adoption by Member States of restriction on trade, justified on the ground of protection of health on the basis of Article 36 EC[39], led to the introduction of more severe requirements as regard the protection of health, the environment, and consumers[40], and to the first instances of further defined principles on the role of science in EU policymaking in the Maastricht and Amsterdam Treaties. Indeed, in 1992, the Maastricht Treaty[41] introduced the requirement of ensuring a high level of human health *"in the definition and implementation of all Union policies and activities"* in Article 152[42], and that Community environmental policy aimed to a *"high level of protection",* and, for that purpose, it takes account of *"available scientific and technical data"*. Furthermore, the requirement that the Commission takes as a base "*a high level of protection*" in its proposals concerning health, safety, environmental protection and consumer protection and takes account "*in particular of any new development based in scientific facts*", which is

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[35] A concept which should not be confused with that of "science" *stricto sensu*. Indeed, the latter, pursuant to the definition coined by the UK-based Science Council ("*the pursuit and application of knowledge and understanding of the natural and social world following a systematic methodology based on evidence*") entails an activity of original research which is, however, not necessarily part of science-based policymaking.

[36] For instance, the Scientific Committee on Food, the first scientific committee composed of independent scientists to assist the European Commission in the field of food safety, was established in 1974 and maintained its functions until they were transferred to the European Food Safety Authority in 2003.

[37] *Commission Decision of 23 July 1997 setting up Scientific Committees in the field of consumer health and food safety*. The discipline at hand is today laid out by Commission Decision 2008/721/EC setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC.

D. Guéguen, V. Marissen, *Science-based and evidence-based policy-making in the European Union: coexisting or conflicting concepts?*, *Collège d'Europe Department of European and Governance Studies*, 2022, p. 7.

[38] A. Alemanno, *The Shaping of European Risk Regulation by Community Courts*, *The Jean Monnet Program*, 2008, p. 4.

[39] Today Article 36 TFEU.

A. Alemanno in E. Vos, *European Risk Governance: Its Science, its Inclusiveness and its Effectiveness*, *Connex*, 2008, p. 37.

[40] On this point: *"EU regulation relies on modern science to keep citizens and the environment safe. From the food we buy, the medicines we take, to a multitude of products we purchase every day, the assumption is that they are safe. A thriving internal market relies on such assumption. It is also the foundation of the EU regulatory state"*.

M. Weimer, M. Morvillo, *Op-Ed: "Out of balance – Why the CJEU 'modern' approach to reviewing EU agency science has gone too far (CWS Powder, joined cases T-279/20, T-288/20 and T-283/20)*, *EU Law Live*, 2023.

[41] Which, in Article 3(1), elevated a *"high level of health"* to the status of general objective of the EC Treaty.

[42] Today Article 168 TFEU.

today laid out in Article 114(3) TFEU, can be traced back to Article 95(3) of the Amsterdam Treaty[43]. Moreover, a key turning point in the development of science-based policymaking is represented by the publication of the White Paper on European Governance[44] in 2001[45], in which the Commission highlighted the necessity to create *"further autonomous EU regulatory agencies in clearly defined areas"*[46] which *"should operate with a degree of independence"*[47] and have *"the ability to draw on highly technical, sectoral know-how"*[48].

Nevertheless, while true that, to a limited degree, a codification of principles generally applicable to science-based policymaking as a whole exists, the creation of a EU general normative framework on science-based policymaking has proven quite complex, considering that the process involves numerous bodies which acts following different methods depending on the subject, and that, when dealing with science-related factors, the EU is called to find a middle ground between the necessity to attain a high level of protection of human health and consumer's interests and preserving the proper functioning of the internal market.[49] As a result, the established general elements of modern science-based policymaking are the product not of consistent legislative pushes but rather of a conspicuous amount of CJEU case law.[50]

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[43] Furthermore, Article 95(5) TEC (today, Article 114(5) TFEU), requires that Member States, when they deem necessary to introduce a national measure concerning the protection of the environment which derogates from European harmonisation legislation, must provide for *"new scientific evidence"*. Therefore, it could be argued that the rationale behind the scientific discipline introduced by the Amsterdam Treaty was not necessarily the protection of human health, but rather the need of resisting Member States' protectionism, in order to allow the establishment of the internal market.
A. Alemanno in E. Vos, *European Risk Governance: Its Science, its Inclusiveness and its Effectiveness*, *Connex*, 2008, p. 39.

[44] Officially known as "*European Governance – A White Paper"*, this Commission's document, which is the result of over six years of research conducted by academic researchers and European Commission civil servants, lays out five principles of "good governance": openness, participation, accountability, effectiveness, and coherence. The main aim of the document was to confer a kind of democratic legitimacy to both the Commission civil servants and experts alike.
E. Bertrand, *The European Commission's White Paper on European Governance (2001)*, *Encyclopédie d'histoire numérique de l'Europe*, 2020.

[45] Indeed, the influence of the White Paper led not only to the establishment of several European specialists' bodies but, also, to the affirmation of the current scientific risk assessment model employed by the EU, one not conducted directly by the Commission's services or bodies under their control, but rather by sectorial authorities structurally independent from EU institutions and not directly funded with EU budget. Among these, the European Food Safety Authority in 2002 and the European Chemical Agency in 2007.
D. Guéguen, V. Marissen, *Science-based and evidence-based policy-making in the European Union: coexisting or conflicting concepts?*, *Collège d'Europe Department of European and Governance Studies*, 2022, p. 8.

[46] *European Governance – A White Paper*, COM(2001) 428 final, 2001, pp. 19-20.

[47] *Ibid*.

[48] *Ibid.*

[49] A. Alemanno, *The Shaping of European Risk Regulation by Community Courts*, *The Jean Monnet Program*, 2008, p. 6.

[50] *Ibid*.

Modern EU science-based policy is composed of two main procedural phases[51]: risk assessment and risk management.

2.1. Risk Assessment

A unified definition of risk assessment[52] can be found in the case-law of the Court of Justice. Specifically, the *Pfizer* and *Alpharma* cases define this phase as a *"scientific process consisting in the identification and characterisation of a hazard, the assessment of exposure to the hazard and the characterisation of the risk"*.[53] In the absence of a unified legislative instrument, risk assessment has been divided through the case-law of the Court, in four steps, hazard identification, hazard characterization, assessment of exposure to the hazard, and risk characterization, a structure which has been further delineated by sectorial EU bodies' and non-binding acts. In particular, a specific definition for each of these four stages can be found in Annex III to the *Communication from the Commission on the precautionary principle*.[54]

Hazard identification is defined as the process of *"identifying the biological, chemical or physical agents that may have adverse effects. A new substance or biological agent may reveal itself through its effects on the population (illness or death), or on the environment and it may be possible to describe the actual or potential effects on the population or environment before the cause is identified beyond doubt"*.[55] Under this definition the process entails the

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[51] Followed by a third non-procedural phase called "risk communication", which, however, will not be covered in-depth by the present thesis. This process can be described as entailing the communication and explanation to the public of the existence and nature of eventual risks and hazards, the reasoning behind risk assessment finding, and the basis of risk management decisions (a definition that can be derived from Article 3(13) of Regulation 178/2002). It is relevant to notice, that, as attempts to properly enact risk communication in the past have not led to effective results and have contributed, according to some academics, to the damage of *"public trust in science"*, the EU has been calling for the introduction of stricter rules as regards to the criteria to be followed in this phase. In this context, some of the most relevant efforts are, for instance, those made in the food safety area, with the so called Transparency Regulation (Regulation 2019/1381), which, in Article 8c, calls for the introduction of a general plan for risk communication, and, at the request of the Commission, has been complemented by the publication of four separate reports which provide further insight from social research and map existing risk communication structures and best practices by EU Member States food safety authorities (*Scientific report of EFSA on Technical assistance in the field of risk communication; Mapping the coordination and cooperation mechanisms of risk communication on feed/food safety in the EU; Catalogue of Communication Tools and Dissemination Guidelines: Benchmarking current practice in EU and Members State bodies; Engagement Toolkit: Methods, tips and best practices to design effective participatory processes*).
D. Guéguen, V. Marissen, *Science-based and evidence-based policy-making in the European Union: coexisting or conflicting concepts?*, *Collège d'Europe Department of European and Governance Studies*, 2022, p. 10.

[52] Resulting from the merging of the elements highlighted in the legal sources quoted at the beginning of the Chapter.

[53] See: Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, par. 156; and Case T-70/99, *Alpharma Inc. v Council of the European Union*, ECLI:EU:T:2002:210, par. 169.

[54] Commission of the European Communities, *Communication from the Commission on the precautionary principle*, Brussels, 2.2.2000.

[55] *Communication from the Commission on the precautionary principle*, *Annex III*, p. 28.

analysis and identification of established or possible inherent health hazards[56] connected to the potential risk, a requirement which can be found in the case-law of the CJEU as well. For instance, in *Commission v. Denmark*[57], the Court asserted that *"a proper application of the precautionary principle presupposes, in the first place, the identification of the potentially negative consequences for health of the proposed addition of nutrients, and, secondly, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research"*.[58]

Once the agents with potential detrimental effects have been identified, the nature and severity of those effects must be assessed through a quantitative and qualitative analysis amid the hazard characterization phase. In this stage *"a relationship between the amount of hazardous substance and the effect has to be established"*.[59] Demonstrating said relationship is, however, oftentimes a complex[60] task, as, for instance, the causal link cannot always be established beyond doubt.[61]

The third step – assessment of exposure to the hazard – requires the evaluation, from a quantitative and qualitative point of view, of the probability of exposure of an organism, a system, a population, or of the environment at large to the hazard subject of study[62], a definition embraced by the Court in the four *Vitamin* cases as well.[63] For instance, in *Commission v. Denmark*, the Court asserted that *"the object of the risk assessment to be carried out by the*

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[56] To this day, there is not a universal definition of "hazard" yet, but rather several definitions depending on the specific area. For instance, in the *EU general risk assessment methodology* (Ch. 3.2., p. 7), defines "hazard", or "danger", as *"the property (including aspects of poor performance) of the product that might result in harm"*. Another example can be found in Article 3(14) of the General Food Regulation (*Regulation (EC) No 178/2002*), which states that *"" hazard" means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect"*. Furthermore, the terms "hazard" and "risk" should not be confused. Pursuant to the definition laid out by the EFSA, "hazard" refers to something that has the potential to cause harm, while "risk" refers to the likelihood of a hazard causing harm.
On the distinction between "hazard" and "risk", see: *Hazard vs. Risk*, *EFSA*, 2016, link:
https://www.efsa.europa.eu/sites/default/files/images/infographics/hazard-vs-risk-2016.pdf

[57] One of the four so called *Vitamin* cases concerning national administrative practices subjecting marketing of enriched foodstuff produced in other MSs to the proof that the enrichment meets a nationally defined need of the population (Case 192/01 Commission v Denmark ECLI:EU:C:2003:492; Case C-24/00 Commission v France ECLI:EU:C:2004:70; Case C-270/02 Commission v Italy ECLI:EU:C:2004:78, and Case C-41/02 Commission v Netherlands ECLI:EU:C:2004:762).

[58] Case 192/01 Commission v Denmark [2003] ECLI:EU:C:2003:492, par. 51.

[59] *Communication from the Commission on the precautionary principle*, *Annex III*, p. 28.

[60] Or occasionally impossible.
Ibid.

[61] *Ibid*.

[62] *Ibid.*

[63] A. Alemanno, *The Shaping of European Risk Regulation by Community Courts*, *The Jean Monnet Program*, 2008, p. 19.

Member States is to appraise the degree of probability of harmful effects on human health from the addition of certain nutrients to foodstuffs and the seriousness of those potential effects"[64], a position also underlined in paragraph 55 of *Commission v. France* and paragraph 49 *Commission v. Netherland*.[65]

Finally, the Communication defines risk characterization as the *"qualitative and/or quantitative estimation, taking account of inherent uncertainties, of the probability, of the frequency and severity of the known or potential adverse environmental or health effects liable to occur"*.[66] Therefore, the lasts step of risk assessment aims at establishing, through a qualitative and/or quantitative analysis, the probability that a potential or known adverse effect of the agent under study on an organism, system, population, or on the environment at large may occur. The results of this phase may translate into a wide range of findings: from risks which potentially entails a major impact on health or the environment, but which are not likely to materialize, to risks with a minor impact but whose occurrence is highly probable.[67]

Once defined the four steps of risk assessment, it is necessary to determine who are the subjects responsible for the process. While the initial case-law of the Court indicated the Institutions as the responsible actors for risk assessment[68], in later rulings, the judges acknowledged the increasing complexity of scientifical and technical assessments and recognized the necessity to entrust that phase to actors with specialized scientific and technical expertise.[69] Indeed, in *Pfizer*, the Court asserted that *"it is appropriate to point out, first, that,*

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[64] Case 192/01 Commission v Denmark [2003] ECLI:EU:C:2003:492, par. 48.

[65] Moreover, a concrete example of the results of the assessment of exposure phase, can be also found in par. 46 of the *Solvay Pharmaceuticals* case65, in which the Judges stated that *"… as both the ADI*65 *and the human exposure to Nifursol residues (including metabolites) cannot be established, the safety of Nifursol cannot be ensured"*.
Case T-392/02 Solvay Pharmaceuticals BV v Council of the European Union, ECLI:EU:T:2003:277, par. 46

[66] *Communication from the Commission on the precautionary principle*, *Annex III*, p. 28.

[67] A. Alemanno, *The Shaping of European Risk Regulation by Community Courts*, *The Jean Monnet Program*, 2008, p. 19.

[68] A relevant example could be found in the *Denkavit* case, as quoted in the *Pfizer* case. Indeed, in par. 154 of the latter, the Judges stated that *"the Court of Justice has already had occasion to note that in matters relating to additives in feedingstuffs the Community institutions are responsible for carrying out complex technical and scientific assessments"*68, which refers to par. 20 of the former judgement (*"In those circumstances the Commission cannot be blamed for having waited until it was fully informed before adopting a decision on a matter as complex as the presence in feeding-stuffs of substances which might prove to be undesirable from the point of view of human or animal health"*).
See: Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, par. 154; and Case 14/78 Denkavit Commerciale Srl and Denkavit Nederland BV v Commission of the European Communities, ECLI:EU:C:1978:221, par. 20.

[69] For instance, in the Angelopharm GmbH v Freie Hansestadt Hamburg case, concerning the danger to health posed by chemical substances in cosmetic products, the Court asserted that *"the Commission is not in a position*

when a scientific process is at issue, the competent public authority must, in compliance with the relevant provisions, entrust a scientific risk assessment to experts who, once the scientific process is completed, will provide it with scientific advice".[70] Furthermore, the relevance of the role of experts in the risk assessment phase has been not only further stressed but, most of all, turned into a requirement by the Court in *Angelopharm*, which essentially established the obligations for institutions to demand technical and scientific advice from experts whenever a decision for which they lack the necessary knowledge is to be taken.[71] Therefore, today, the main tasks connected to risk assessment have been allocated to three categories of actors[72]: decentralized EU agencies; Scientific Committees; the Joint Research Centre (JRC), and the Scientific Advice Mechanism (SAM).

EU agencies can be defined as bodies of the European Union and the Euratom, with their own legal personality, set up for an indefinite period, and distinct from EU institutions. The main tasks of the over thirty decentralized agencies are aiding the Union implement its policy and supporting it by providing it with technical expertise when required.[73] Agencies carry out risk assessment operations in the limit of their mandate and the agency or agencies involved in the process will vary depending on the nature of the risk to be assessed.[74] Finally, these bodies operate through a different range of acts, which can be, in specific instances and for specific

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to carry put assessments of this kind (scientific and technical assessments which must themselves be based on the results of the latest international research and which are frequently complex)".
Case C-212/91 Angelopharm GmbH v Freie Hansestadt Hamburg ECLI:EU:C:1994:21, pars. 31-32.

[70] Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, par. 157.

[71] Case C-212/91 Angelopharm GmbH v Freie Hansestadt Hamburg ECLI:EU:C:1994:21, par. 34 (*"The Scientific Committee, however, has the task of assisting the Community authorities on scientific and technical issues in order to enable them to determine, from a fully informed position, which adaptation measures are necessary"*) and 37 (*"he Commission cannot successfully argue, as it did during the oral procedure, that consultation of the Scientific Committee is necessary only when authorization of the use of a substance in the manufacture of cosmetic products is envisaged"*).

[72] Which enjoy different levels of independence from the EU institutions.

[73] *Types of institutions and bodies*, *EU*, link:
https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/types-institutions-and-bodies_en

[74] For instance, the European Centre for Disease Prevention and Control (ECDC) carries out the risk assessment when the possible threat is of *"biological origin and consists of infectious diseases or antimicrobial resistance and healthcare-associated infections"* or of an unknown origin. The European Food Safety Authority (EFSA) is involved in the case of serious cross border threats to health.
Risk assessment, *European Commission*.

bodies, binding[75] or semi-binding[76], but are usually non-binding.[77] As specified in paragraphs 199-201 of the *Pfizer* judgment, scientific advice provided by the agencies – but also by the other experts' bodies –, as it derives from bodies which lack both democratic legitimacy and political responsibilities, is not recognized any binding power, therefore leaving the Institutions a certain degree of freedom[78] to disregard experts' opinions.[79]

In cases in which the risk assessment falls totally or partially outside the mandate of a specific EU decentralized Agency, the procedure is usually allocated to actors which are under the direct supervision of the Commission: The Scientific Committee on Health, Environmental and Emerging Risk (SCHEER) and the Scientific Committee on Consumer Safety (SCCS).[80] The former provides the Commission, on a request its services, with opinions relating to the health, environment, and emerging risks area.[81] The latter provides the Commission, on a request by

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[75] For instance, pursuant to Article 77 of Regulation 1139/2018 (*Regulation (EU) 2018/1139 of the European Parliament and the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91*), the European Union Aviation Safety Agency (EASA) has the power to issue airworthiness and environmental certifications for aircrafts.

[76] A notable example of a semi-binding act can be found in Articles 10 and 15 of Regulations 1093/2010, 1094/2010, and 1095/2010 (which establish the three supervisory financial authority of the EU – respectively, the European Banking Authority, the European Supervisory Authority, the European Securities and Markets Authority), which lay down the enactment of Regulatory Technical Standards by the three supervisory financial authorities for the adoption of delegated and executive acts by the Commission (which enjoys very limited discretion to deviate from such standards).

[77] Soft law acts.

[78] Notwithstanding the specific procedural obligations for risk managers introduced by the Court, which will be analysed in the present Chapter.

[79] A conclusion which has, also, been reached by the Court in the *Bellio* and *Motte* cases (both cases will be further analysed in Chapter 4) and, to a certain degree, in the *EC Communication on the collection and use of scientific expertise*, which states that *"Within the institutional framework, the Commission is politically responsible for its initiatives; it must not appear to 'hide behind' expert advice. Instead, the Commission must be capable of justifying and explaining the way expertise has been involved, and the choices it has made based on advice. In a similar way, accountability also extends to the experts themselves"*.
See: COM (2002) 713 final, *Communication from the Commission on the Collection and use of expertise by the Commission: Principles and Guidelines*, pp. 9 – 10.

[80] It is, however, relevant to specify that, due to the fact that they are directly managed by the Commission (which has led to the Committees being accused of producing biased scientific advice), the European Commission's new approach has been gradually shifting toward the transfer of risk assessment operations from these Committees to decentralized agencies.

[80] D. Guéguen, V. Marissen, *Science-based and evidence-based policy-making in the European Union: coexisting or conflicting concepts?*, *Collège d'Europe Department of European and Governance Studies*, 2022, p. 13.

[81] Specifically, the SCHEER plays a pivotal role in the production of scientific advice relating to, among others, antimicrobial resistance, new technologies, fertility reduction, the risks related to pollutants in the environmental media and physical or biological factors or changing physical conditions which may have adverse effects on the environment at large.
Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), *European Commission*, link:

the Commission services, with opinions on health and safety risks[82] as regard non-food consumer products and services.[83]

Finally, the Commission can rely on the Joint Research Centre (JRC) and the Scientific Advice Mechanism (SAM) to receive scientific and technical advice as regard general policy initiatives. The JRC is the Commission's science and knowledge service, which provides scientific and technical advice in support of all the stages of the EU policy cycle.[84] The SAM is composed by a team of scientific advisors which provide expertise directly to European Commissioners rather than tot the Commission at large.[85] In the past, the SAM has delivered advice on subjects such as the Biodegradability of plastics in the open environment, microplastic pollution, and the COVID-19 pandemic.

Once established that the Commission has a requirement to refer to experts for the fulfillment of risk assessment operations, and defined the role of the different actors which might assist the EU in that task, it is relevant to refer to the guidelines laid out in the EC Communication on the Collection and Use of Expertise by the Commission and the Commission Decision setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment.[86] In particular, through these specific acts, the Commission has introduced the requirement that scientific advice must be in compliance with the principles of *excellence, independence, and transparency*[87], which, under the former Communication on

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https://health.ec.europa.eu/scientific-committees/scientific-committee-health-environmental-and-emerging-risks-scheer_en

[82] Of a chemical, mechanical, biological, or physical nature.
Scientific Committee on Consumer Safety (SCCS), *European Commission*, link:
https://health.ec.europa.eu/scientific-committees/scientific-committee-consumer-safety-sccs_en

[83] Products such as cosmetic products, toys, and textiles; Services such as artificial sun tanning and tattooing.
Ibid.

[84] It operates in thirty-three different portfolios, including green transition, sustainable materials, digital transition, and international cooperation, sustainable, and trusted connections. Furthermore, the Centre operates through its own facilities and infrastructure to conduct scientific and technical research and is one of the main reference actors in the field of EU nuclear energy research.
JRC science and knowledge activities, *EU Science Hub*, link:
https://joint-research-centre.ec.europa.eu/jrc-science-and-knowledge-activities_en

[85] More precisely, the Mechanism is structured in two parts: the Group of scientific advisors (GCSA), which is composed by seven advisors, appointed in their personal capacity, which act independently and in the public interest; and the Scientific Advice for Policy by European Academics (SAPEA), a consortium which pool technical and scientific expertise from over one-hundred societies and academic institutions across the Europe.
Group of Chief Scientific Advisors, *Research and innovation*, *EU*, link:
https://research-and-innovation.ec.europa.eu/strategy/support-policy-making/scientific-support-eu-policies/group-chief-scientific-advisors_en

[86] *Commission Decision of 5 August 2008 setting up and advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC*.

[87] See: COM (2002) 713 final, *Communication from the Commission on the Collection and use of expertise by the Commission: Principles and Guidelines*, p. 9; and *Commission Decision of 5 August 2008 setting up and advisory*

the collection and use of expertise are to be considered parts of two separate macro-criteria: *Quality*[88] and *Openness*[89].

Starting from the first macro-criterion, the aforementioned Communication states that *"the Commission should seek advice of an appropriate high quality"*[90], based on three principles: excellence, independence, and pluralism. Under that instrument, the first sub-criterion can be highlighted as the main component of quality of scientific expertise, which, *"in many cases… can be based simply on the excellence of scientists"*[91], founded on the endorsement of the scientific community and, ideally, on that of experts with practical know-how as well, and on the number and impact of refereed publications. As regard the principle of independence, the Communication, while firstly acknowledges the impossibility for an individual to be *"entirely independent"*, states that *"experts should be expected to act in an independent manner"* and aims to *"minimize the risk of vested interests distorting the advice proffered by establishing practices that promote integrity, by making dependencies explicit and by recognizing that some dependencies – varying from issue to issue – could impinge on the policy process more than others"*.[92] Finally, pluralism entails taking into account multi-disciplinary and multi-sectoral expertise, minoritarian and non-conformist views, as well as third factors, such as gender, cultural, and geographical perspectives.

As regard the second macro-criterion, the Communication states that *"the Commission should be open in seeking and acting on advice from experts"* and identifies the principle of transparency as a *"key precondition for more accountability for all involved"*.[93] Furthermore, the Communication specifies that transparency entails the adoption of a *"strategy for proactive communication… in which the Commission should constantly seek ways to better publicize and explain its use of expertise to interested parties and the public at large"*, a commitment

structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC, Article 12.

[88] Which includes excellence and independence.

[89] Which includes transparency.

[90] *Communication from the Commission on the Collection and use of expertise by the Commission: Principles and Guidelines*, p. 9.

[91] *Ibid*.

[92] *Ibid.*

[93] The latter criterion is of particular importance in relation to the characterization of issues, the selection of experts, and the way results of risk assessment are handled.
Ibid.

which, moreover, implicates, first the necessity to adopt a language accessible to non-experts and general principles for public access to documents.[94]

The principles of *excellence, independence*, and *transparency* have been embraced and further articulated by the case-law of the CJEU as well. In particular, firstly, in both *Pfizer*[95] and *Alpharma*[96] the Court recognized that, in the context of consumer health, scientific advice shall be based on those three principles. Moreover, these criteria, through a consistent number of judgements, have translated into a set of procedural requirements for risk assessors to facilitate the transition from risk assessment to risk management. Indeed, referring once again to *Alpharma*, the Judges have further articulated this connection between the two phases, by stating not only that scientific advice provided to the competent authority must be *"sufficiently reliable and cogent… to allow it to understand the scientific question raised and decide upon a policy in full knowledge of the facts"*[97], but, most importantly, that risk assessment must enable those authorities to determine, on the basis of the best available scientific data (BAS)[98] and the most recent results of international research, whether the level of risk is beyond the threshold to be considered acceptable for society, whether preventive measures are necessary[99], and, ultimately, what measure appears to be the most appropriate to prevent the risk from concretizing.[100] Moreover, a relevant articulation of the positions established in *Alpharma*, can be found in *Olivieri*.[101] The case revolved around the authorization by the Commission of a new treatment for anemia, a measure challenged by prominent hematologist,

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[94] Which have already been established. In particular, disclosure of information should be in compliance with Regulation 1049/2001 regarding public access to European Parliament, Council and Commission documents, and Regulation 1045/2001 regarding data protection.
Ibid.

[95] Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, par. 159

[96] Case T-70/99, *Alpharma Inc. v Council of the European Union*, ECLI:EU:T:2002:210, par. 172.

[97] *Ibid*, par. 175.

[98] A definition which refers to *"the best information currently available that is derived from a valid scientific process or scientific sources that have been adopted by a majority of the scientific community at large"*. The term *"available"* has been further clarified by the Court in the *Mirepoix* case – concerning the harmful effects of pesticides residues for human health –, in which the Judges stated that *"the authorities of the importing member are obliged to review the prohibition on the use of a pesticide or a prescribed maximum level if it appears to them that the reasons which led to the adoption of such measures have changed […] as a result of the discovery of a new use of a particular pesticide or as a result of further information becoming available through scientific research"*.
See: *Best available science definition*, *Law Insider* and Case C-54/85, *Ministère public against Xavier Mirepoix*, ECLI:EU:C:1986:123, par. 16.

[99] Two points which will be further analysed later in the Chapter.

[100] Case T-70/99, *Alpharma Inc. v Council of the European Union*, ECLI:EU:T:2002:210, par. 176.

[101] Case T-326/99, *Nancy Fern Olivieri v Commission of the European Communities*, ECLI:EU:T:2000:102.

Dr. Nancy Olivieri[102], who doubted the scientific assessment which led to the authorization and sought its annulment. While true that, ultimately, the action pursued by the applicant was deemed inadmissible by the Judges, the ruling still introduced a relevant requirement on risk assessment, by stating the duty of the Institutions to take into account the opinions deriving from third parties.[103] Furthermore, in paragraph 68, the case[104] introduced a further obligation for risk assessors, by requiring that competent authorities are at all time up-to-date with the evolution of the scientific data on which specific risk assessment procedures are founded.[105]

2.2. Risk Management

Risk management can be identified as the set of procedures in which the conclusion reached through the risk assessment phase are translated into concrete measures to address the identified risk. In the EU, this process is mainly allocated to the Commission, which acts under the supervision of the Member States' governments, but occasionally also involves the European Parliament and the Council of the European Union.[106] In contrast to the risk assessment phase, the second phase of science-based policymaking does not solely take into account purely scientific elements, but incorporates considerations of a political, social, and

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[102] Which led the clinical trials on the new treatment covered by the case but was removed by the manufacturer from authorization process in the United States.

[103] *"Nevertheless, the Court notes that none of the provisions of the applicable Community rules prohibits the Commission, prior to granting a marketing authorisation, from following a procedure during which persons other than the applicant for marketing authorisation are able to submit their observations so as to enable it to fulfil its duty to check, in the interest of public health, that all the information relating to the scientific evaluation of the product in question, whether it be favourable or unfavourable to the product, has indeed been made available to it. The fact that those rules do not contain any provision to that effect cannot prevent the Commission from obtaining information from a third party where such a course of action is indispensable in order to safeguard public health"*.
Ibid, par. 73.

[104] *"That provision implies that the Community institutions must ensure that their decisions are taken in the light of the best scientific information available and that they are based on the most recent results of international research"*.
Ibid, par. 68.

[105] This latter principle is of particular relevance in reference to the subsequent risk management phase, as emphasized in par. 40 of the *Agrarproduktion Staebelow*, in which the Court asserted that *"when new elements change the perception of a risk or show that that risk can be contained by less restrictive measures than the existing measures, it is for the institutions and in particular the Commission, which has the power of legislative initiative, to bring about an amendment to the rules in the light of the new information"*.
Case C-504/04, *Agrarproduktion Staebelow*, ECLI:EU:C:2006:30, par. 40

[106] Specicially, the European Parliament and the Council of the European Union will also be involved in the process in those cases in which the measure implemented on the basis of the results of risk assessment must be adopted through Ordinary Legislative Procedure (OLP).
D. Guéguen, V. Marissen, *Science-based and evidence-based policy-making in the European Union: coexisting or conflicting concepts?*, *Collège d'Europe Department of European and Governance Studies*, 2022, p. 9.

economic nature into the process as well[107], except when differently provided.[108] This can be explained as a consequence of the democratic legitimacy which characterizes the Commission, which not only enjoys a certain degree of freedom in disregarding non-binding scientific advice provided by experts through risk assessment, but, is also allowed to introduce regulatory measures which don't respond exclusively to scientific concerns, but to rather political and/or democratic ones as well.[109] However, before the Commission is actually called to determine which instrument to introduce in order to deal with the identified risk, it must conduct an evaluation of the degree of risk deemed acceptable to society, a matter on which the Court of justice have ruled extensively.

Indeed, the role of European institutions in the definition of the acceptable degree of risk[110] can be, once again, traced back to the *Pfizer* case, which states that "*it is for the Community institutions to determine the level of protection which they deem appropriate for society"* and that *"the level of risk deemed unacceptable will depend on the assessment made by the competent public authority of the particular circumstances of each individual case"*.[111] Furthermore, the case established some indicative criteria to be, *inter alia*, taken into account to make such a determination:[112]

- The severity of the impact on human health in case of occurrence of the risk
- The extent of possible adverse effects and their persistency or reversibility.

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[107] This was confirmed in pars. 200 and 201 of the *Pfizer* case, in which the Court stated the Commission may disregard scientific advice provided by experts, that *"that finding can also be justified on grounds of principle relating to the political responsibilities and democratic legitimacy of the Commission"*, and, ultimately, that *"scientific legitimacy is not a sufficient basis for the exercise of public authority"*. Furthermore, a similar definition has also been developed by the Organisation for Economic Co-operation and Development in the *Description of selected key generic terms used in chemical hazard/risk assessment*.
See: Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, pars. 200-201, and *Description of selected key generic terms used in chemical hazard/risk assessment*, *OECD*, 2003, p. 17.

[108] For instance, recital 13 of Regulation 726/2004 (*Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 Marc 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency"*) states that *"In the interest of public health, authorisation decisions under the centralised procedure should be taken on the basis of the objective scientific criteria of quality, safety and efficacy of the medicinal product concerned, to the exclusion of economic and other considerations"*.

[109] . Alemanno, *The Shaping of European Risk Regulation by Community Courts*, *The Jean Monnet Program*, 2008, pp. 59-60.

[110] A task which is, however, also conducted by Member States (see, for instance: Case C-293/94, *Brandsma*, ECLI:EU:C:1996:254; Case 174/82, *Sandoz BV*, ECLI:EU:C:1983:213). However, the role of Member States in risk management will not be analysed in the present thesis.

[111] Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, pars. 151 and 153.

[112] *Ibid*, par. 153. The same criteria have been also re-established in par. 166 of *Apharma*.

- The possibility of delayed effects as of the more or less concrete perception of the risk based on available scientific knowledge.

The determination of the minimum degree of risk acceptable must, therefore, be conceived as a case-by-case evaluation, notwithstanding the duty of EU institutions to still ensure a *"high level of human health protection"*, under Article 168(1) TFEU.[113]

Once the level of risk deemed acceptable for society is defined, the Commission, or the other institutional actors involved, will be called to determine which measure must be implemented in order to contain the risk. However, in order to do so risk managers are, as already underlined, required not only to consult scientific experts pursuant to the *Angelopharm*[114] case-law, but to duly take into account the results of the risk assessment phase.[115] This requirement has been better explained in the order of the judge hearing the application for interim measures in the Court in the *France v. Commission* case.[116] In that order, the Court suspended certain relevant provisions of a Commission Regulation introducing less restrictive measures as regard to the surveillance and eradication of certain forms of spongiform encephalopathies, on the ground that, firstly, the measure adopted by the Commission failed, *"without justification"*, to take into account some relevant points raised by the EFSA in its opinion[117] and, secondly, that the alleged violation of the precautionary principle[118] by commission of an error in the risk

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[113] Which, however, pursuant to the *Safety-High Tech* case, should not be interpreted as "*highest degree of protection possible"* from a technical point of view. Indeed, as ruled by the Court in the case, *"whilst it is undisputed that Article 130r(2)* (today Article 191(2) of the TFEU) *of the Treaty requires Community policy in environmental matters to aim for a high level of protection, such a level of protection, to be compatible with that provision, does not necessarily have to be the highest that is technically possible"*, a conclusion reiterated in par. 166 of *Alpharma* as well
Case C-284/95, *Safety High-Tech Srl v S. & T. Srl*, ECLI:EU:C:1998:352, par. 49.

[114] See: Case C-212/91 Angelopharm GmbH v Freie Hansestadt Hamburg ECLI:EU:C:1994:21, pars. 34 and 37, as quoted in p. 10 of the present thesis.

[115] Which, as asserted in *Pfizer*, must *"enable the competent authority to decide, in relation to risk management, which measures appear to be appropriate and necessary to prevent the risk from materialising"*.
Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, par. 163.

[116] Concerning the introduction by the Commission of less restrictive measures for the surveillance and eradication of certain forms of spongiform encephalopathies than those required by Regulation 999/2002 (*Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies*).

[117] *"In that regard, it must be stated that recital 9 in the preamble to Regulation No 727/2007 expressly refers to the conclusions of the aforementioned opinion but conceals a part of it which seems to call in question the Commission's dual premise on which the contested provisions are based, namely, that TSEs other than BSE cannot be transmitted to humans and that the discriminatory tests are reliable"*.
(Order of the judge hearing the application for interim measures), ECLI: ECLI:EU:T:2011:444, pars. 72.

[118] A subject which will be further analysed later in the Chapter.

management phase[119], would have required and in-depth analysis on the merits of the adoption of the contested measure by the Court.

However, while true that the case-law of the Court establishes a duty for risk managers to consult experts' advice and to take it duly into account, the institutions still enjoy some freedom in disregarding scientific and technical expertise, which, as previously underlined, lacks the democratic legitimacy to be given binding force. The modalities through which the institutions are allowed to depart from experts' advice have been defined by the Court in *Pfizer*: *"To the extent to which the Community institution opts to disregard the opinion, it must provide specific reasons for its findings by comparison with those made in the opinion and its statement of reasons must explain why it is disregarding the latter"*.[120] Furthermore, the specific reasoning offered by risk managers not to follow scientific and technical advice provided by the competent actors in the risk assessment procedure must be of a *"scientific level at least commensurate with that of the opinion in question"*, a requirement which the institution may fulfil by means of a supplementary opinion from the same experts involved in the first phase or of *"other evidence*" with an at least commensurate probatory value to that of the scientific or technical opinion at hand.[121]

Therefore, taking into consideration the considerable degree of freedom which risk managers enjoy in disregarding scientific advice, it could be wondered what principles have been devised by the Court case law to assess the discretion of the Institutions in cases of scientific uncertainty or conflicting opinions among experts, as in the case of the CDA. In these circumstances, the precept that the data gathered through risk assessment should be sufficient to allow risk managers to determine the degree or risk acceptable for society and to adopt the necessary measures to deal with the identified risk will be less cemented than in cases of absolute or quasi-absolute scientific certainty.[122] In case of lack of universal scientific consensus, it could, then, be stated that the action of risk managers will be necessarily precautionary in nature and that, thus, modern EU risk management finds in the precautionary

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[119] The lack of consideration of parts of the EFSA opinion.

[120] Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, par. 199.

[121] Furthermore, experts' advice can be disregarded fully or partially. In the latter case, the Institution *"may also avail itself of those parts of the scientific reasoning which it does not dispute"* when providing the specific reasons for such a departure.
Ibid.

[122] M. D. Rogers, *Risk management and the record of the precautionary principle in EU case law*, *Journal of Risk Research*, 2011, p. 469.

principle (PP) one of its main general principles[123], a precept also confirmed by the Commission Communication on the precautionary principle, adopted in 2000.[124]

While true that PP finds recognition in EU primary law through Article 191(2) TFEU[125], that provision does not lay out a definition for that principle, quoting it only once, and appearing to limit its scope solely to the environment. A more specific denotation has been provided by the aforementioned Communication on the precautionary principle, which delineates PP as an approach to risk management which presupposes that *"potentially dangerous effect deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty"*.[126] In such circumstances, risk managers will, then, be required to implement an appropriate approach, which can range, *inter alia*, from no action at all, to the introduction of either binding or non-binding measures.[127]

It can, therefore, be asserted that the precautionary principle introduced a right to act for institutions in situations of scientific uncertainty, a conclusion validated by the case-law of the CJEU. Indeed, starting from the *Sandoz* case of 1983 – in which the Judges, without explicitly referring to the PP as such yet, established that *"in so far as there are uncertainties at the present state of scientific research it is for the Member States, in the absence of harmonization, to decide what degree of protection of the health and life of humans they intend to assure,*

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[123] *Ibid*.

[124] *"The precautionary principle should be considered within a structured approach to the analysis of risk which comprises three elements: risk assessment, risk management, risk communication. The precautionary principle is particularly relevant to the management of risk"*.
Commission Communication on the precautionary principle, recital 4.

[125] *"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, that environmental damage should as a priority be rectified at source and that the polluter should pay"*.

[126] *Communication from the Commission on the precautionary principle*, recital 4.

[127] Notwithstanding that, when, after the risk management phase, the introduction of a measure is deemed necessary, the measures introduced should be, *inter alia*, *proportional* (a measure tailored to the chosen level of protection. Pursuant to par. 411 of *Pfizer*, in the context of risk management, proportionality entails: that measures adopted by Community institutions should not exceed the limits of what is suitable or appropriate in order to attain the legitimate objective pursued by the legislation in question; where there is a choice between several appropriate measures recourse must be had to the least onerous method; that the disadvantages caused must not be disproportionate to the aims pursued), *non-discriminatory* (comparable situations should not be treated differently and different situations should not be treated in the same way), *consistent* (the measure should be of comparable scope and nature to those already taken in equivalent areas in which all scientific data are available), *examining costs and benefits* (there should be a comparison between the long and short term costs and benefits to the EU deriving from either action or no action), and *subject to review in light of new scientific data* (measures based on PP should be maintained so long as scientific information is incomplete of inconclusive). These criteria have been further analysed by the Court in the *Vitamins* line of case and codified, for the first time at EU level, in Article 7 of the General Food Regulation (Regulation 178/2002).
Ibid, recital 6.

having regard however for the requirements of the free movement of goods within the Community"[128] – the precautionary principle has been gradually integrated in the Court's jurisprudence.[129] The principle was explicitly referred to for the first time by the Court of First Instance in the *Bergaderm* case, in which the judges stated: *"By the second limb of that ground of appeal, the appellants dispute the reference to the precautionary principle in paragraph 66 of the contested judgment"*.[130] Subsequently, the nature of PP was further delineated in *Alpharma*, in which the Court asserted that *"the fact that it is impossible to carry out a full scientific risk assessment does not prevent the competent public authority from taking preventive measures, at very short notice if necessary, when such measures appear essential given the level of risk to human health which the authority has deemed unacceptable for society… In such a situation, the competent public authority must therefore weigh up its obligations and decide either to wait until the results of more detailed scientific research become available or to act on the basis of the scientific information available. Where measures for the protection of human health are concerned, the outcome of that balancing exercise will depend, account being taken of the particular circumstances of each individual case, on the level of risk which the authority deems unacceptable for society"*[131], hence, officially

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[128] On this point, see also *Hejin* (Case 94/83, *Criminal proceedings against Alber Hejin BV*, ECLI:EU:C:1984:285), *Mirepoix* (Case C-54/85, *Ministère public against Xavier Mirepoix*, ECLI:EU:C:1986:123), and *UK v Commission* (*Case C-180/96*, *United Kingdom of Great Britain and Northern Ireland v Commission of the European Communities*, ECLI:EU:C:1998:192).
Case 174/82, *Criminal proceedings against Sandoz BV*, ECLI:EU:C:1983:213, par. 16.

[129] However, a major contribution to the evolution of the precautionary principle was that of the EFTA Court in case E-3/00 (*EFTA Surveillance Authority v Norway*), concerning the ban by the Norwegian authorities of fortified corn flakes, lawfully produced in other EEA States, on the ground of scientific uncertainty as regards to the effect of that product on the health of the Norwegian population. In that case, the Court – after declaring the ban unjustifiable on the basis of Article 13 EEA (*"The provisions of Articles 11 and 12 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between the Contracting Parties"*), as Norway did not bring forward sufficient arguments relating to any connection between the fortification of the corn flakes and the danger posed to public health – developed a first definition of the precautionary principle, by stating: *"When there is uncertainty as to the current state of scientific research, it is for the contracting Parties to decide what degree of protection of human health they intend to assure… This means that a risk management decision rests with each Contracting party. It is withing the discretion of the Contracting Party to make a policy decision as to what level of risk it consider appropriate"*. However, the Court specified that a *"purely hypothetical or academic consideration"* is not sufficient to trigger the application of the precautionary principle, which instead requires a *"comprehensive evaluation of the risk to health based on the most recent scientific information"*, a condition later partially disregarded by the CJEU.
See: Case E-3/00, *EFTA Surveillance Authority v Norway*, pars. 25 and 30, and A. Alemanno, *The Shaping of European Risk Regulation by Community Courts*, *The Jean Monnet Program*, 2008, pp. 47-48.

[130] Case C-352/98 P, *Laboratoires Pharmaceutiques Bergaderm SA and Jean-Jacques Goupil v Commission of the European Communities*, ECLI:EU:C:2000:361, par. 52.

[131] Case T-70/99, *Alpharma Inc. v Council of the European Union*, ECLI:EU:T:2002:210, pars. 173-174.

establishing the right of Institutions to act even in cases where scientific consensus has not been reached. Moreover, the principles laid out in *Alpharma* find further articulation in *Pfizer*. Indeed, in the latter ruling, the Judges specified that the precautionary principle cannot be used as a basis for the adoption of totally arbitrary precautionary measures, which must, instead, be based on *"sufficiently reliable and cogent information to allow it to understand the ramifications of the scientific question raised and decide upon a policy in full knowledge of the facts"* [132], therefore, asserting the principle that, even in cases of scientific uncertainty, the Institutions' actions must still take into account, to a certain degree, the data provided by risk assessors.[133] Furthermore, under the latter judgement, risk assessment has the double objective of enabling *"the competent public authority to ascertain, on the basis of the best available scientific data and the most recent results of international research, whether matters have gone beyond the level of risk that it deems acceptable for society"* and *"to decide, in relation to risk management, which measures appear to it to be appropriate and necessary to prevent the risk from materialising"*[134], two determinations which are fundamental for the Court to first define what level of risk has been deemed unacceptable for society by the relevant authority and, consequently, whether a precautionary measure is based on the *"data available at the time when the measure was taken"*.[135]

Ultimately, although not codified for the most part yet, it is clear that science-based policymaking has been disciplined through a copious amount of case-law. It can then be stated that, while true that the Institutions indubitably enjoy a high degree of discretion in the adoption of science-based measures, even in circumstances of scientific uncertainty, that discretion cannot translate in completely arbitrary measures which do not take into consideration the relevant scientific data and experts' advice.

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[132] Thus, taking the distance from the purely negative approach of the EFTA Court (*"purely academic or hypothetical considerations"*).
Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, par. 162.

[133] A similar conclusion was also reached in *Netherlands v Commission*, in which the Court stated that the adoption of science-based measures must be based on evidence that is "*actually accurate, reliable and consistent but also whether that evidence contains all the information which must be taken into account in order to assess a complex situation and whether it is capable of substantiating the conclusions drawn from it*".
Case C-405/07 P, *Kingdom of the Netherlands v Commission of the European Communities*, ECLI:EU:C:2008:613, par. 55.

[134] *Ibid*, pars.162-163.

[135] See: *Ibid,* par. 144 and A. Alemanno, *The Shaping of European Risk Regulation by Community Courts*, *The Jean Monnet Program*, 2008, p. 51.

Chapter 3: The Complementary Climate Delegated Act to accelerate decarbonisation

Completed the analysis of the criteria applicable to science-based policymaking, it is worth providing a brief reconstruction of the procedural genesis of the CDA, in order to highlight the aspects which might possibly appear in contrast with the elements highlighted in Chapter 2. The present Chapter will, thus, first focus on the timeline of the adoption of the CDA to then concentrate on the definition of nuclear energy-related activities provided by that measure and, briefly, on the content of the SCHEER review to the JRC report.

On 1 January 2023, the CDA came into force. The act was approved by the Commission on 2 February 2022.[136] The draft was formally adopted on 9 March 2022[137] and subsequently transmitted for the scrutiny period[138] to the European co-legislators[139], which were given until 11 July 2022 to object. On 6 July 2022, the European Parliament rejected a motion to oppose the inclusion of nuclear energy-related activities and natural gas-related activities within the list of sustainable economic activities.[140] In order to veto the Commission's proposal, the motion would have needed an absolute majority of 353 MEPs. However, out of 639 votes, only 278 MEPs voted in favour of the resolution, while 328 voted against and 33 abstained.[141] As the EC proposal was not objected by the Council of the European Union either by the given term, on 15 July 2022, the Complementary Act was published in the Official Journal and entered into force on 1 January 2023. The act complements the discipline established in the

[136] *EU taxonomy: Complementary Climate Delegated Act to accelerate decarbonization*, *European Commission*, link:
https://finance.ec.europa.eu/publications/eu-taxonomy-complementary-climate-delegated-act-accelerate-decarbonisation_en

[137] Date in which the document was made available in all EU official languages.

[138] After the adoption of a delegated act by the Commission, the Parliament and Council are usually granted two months to examine the act and formulate eventual objections. It is worth noticing that, however, such a term can come with a certain degree of flexibility, as the co-legislators may demand an extension of the given period. In case either one of the co-legislators objects to the delegated act within the given term, that act may not enter into force.
Implementing and delegated acts, *European Council/Council of the European Union*, link:
https://www.consilium.europa.eu/en/council-eu/decision-making/implementing-and-delegated-acts/#:~:text=Once%20the%20Commission%20has%20adopted,have%20two%20months%20for%20this.

[139] The Council and The European Parliament.

[140] *Taxonomy: MEPs do not object to inclusion of gas and nuclear activities*, *European Parliament*, 2022, link:
https://www.europarl.europa.eu/news/en/press-room/20220701IPR34365/taxonomy-meps-do-not-object-to-inclusion-of-gas-and-nuclear-activities

[141] *Ibid*.

Taxonomy Regulation[142] by including certain fossil gas activities[143] and nuclear energy-related activities among those deemed necessary to reach the climate neutrality objective[144] and introducing technical screening criteria for those two areas.[145]

Nuclear energy holds a peculiar position in the context of the climate objectives set by the EU for 2050.[146] Recital 5 of Commission Delegated Regulation 2022/1214 states that "*Renewables will play a fundamental role in meeting the climate and environmental goals of the Union. In that light, investments in renewables need to scale-up to meet the needs of the energy market of the Union for more renewable and clean energy*". In this context, however, nuclear energy-related activities do not fall under the definition of energy from renewable sources[147] but should, according to recital 6, be rather defined as low-carbon activities which

[142] Which establishes a precise framework on the concept of sustainability by exactly defining when a certain enterprise or company operates sustainably or in an "environmentally friendly" manner and can, hence, benefit from higher investments. To be classified as a sustainable economic activity pursuant to the EU Taxonomy Regulation, a company must fulfil four conditions: the economic activity contributes to at least one of the six environmental objectives set by the Regulation (Climate change mitigation, climate change adaptation, sustainable use and protection of water and marine resources, transition to a circular economy, pollution prevention and control, protection and restoration of biodiversity and ecosystems); the economic activity does "no significant harm" (DNSH) to any of the six environmental objectives; the economic activity complies with the technical screening criteria developed by the EU Technical Expert Group; the economic activity meets "minimum safeguards" such as the UN Guiding Principles on Business and Human Rights to not have a negative social impact.
EU Taxonomy Overview, *EU Taxonomy Info*, 2020, link:
https://eu-taxonomy.info/info/eu-taxonomy-overview#:~:text=The%20EU%20taxonomy%20regulation%20creates,should%20benefit%20from%20higher%20investments.

[143] Which, however, will not be covered by the present thesis.

[144] Although the inclusion of nuclear energy and natural gas-related activities has been conceived as a "transitional" measure

[145] Furthermore, the act amends both Delegated Regulation (EU) 2021/2139 (*Commission Delegated Regulation (EU) 2021/2139 of 4 June 2021 supplementing Regulation (EU) 2020/852 of the European Parliament and of the Council by establishing the technical screening criteria for determining the conditions under which an economic activity qualifies as contributing substantially to climate change mitigation or climate change adaptation and for determining whether that economic activity causes no significant harm to any of the other environmental objectives*) and Delegated Regulation (EU) 2021/2178 (*Commission Delegated Regulation (EU) 2021/2178 of 6 July 2021 supplementing Regulation (EU) 2020/852 of the European Parliament and of the Council by specifying the content and presentation of information to be disclosed by undertakings subject to Articles 19a or 29a of Directive 2013/34/EU concerning environmentally sustainable economic activities, and specifying the methodology to comply with that disclosure obligation*).

[146] Notwithstanding the fact that a reference to "*renewable forms of energy*" as a mean to "*improve the environment*" in the context of the establishment and functioning of the internal market was already present in Article 194 TFEU.

[147] laid out in Article 2, par. 2, point (1) of Directive (EU) 2018/2001 (*Directive (EU) 2018/2001 of the European Parliament and of the Council of 11 December 2018 on the promotion of the use of energy from renewable sources*), and referred to in Article 10(1), point (a) to (i) of Regulation (EU) 2020/852 (*Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment and amending Regulation (EU) 2019/2088*).

shall, in the absence of low-carbon alternatives at a sufficient scale to cover the energy demand in a reliable and continuous manner, be qualified under Article 10(2) of the Taxonomy Regulation. Therefore, under said provision nuclear energy-related activities fall within the category of economic enterprises which contribute "*substantially to climate change mitigation where it supports the transition to a climate-neutral economy consistent with a pathway to limit the temperature increase to 1.5 ^{0}C above pre-industrial levels, including by phasing out greenhouse gas emissions, in particular emissions from solid fossils fuels*", have greenhouse levels that correspond to the best performance in the sector or industry, do not hamper the development and deployment of low-carbon alternatives[148], and do not lead to a lock-in of carbon-intensive assets.[149] Furthermore, the new Delegated Act only includes a limited number of categories of nuclear energy-related economic activities among those already considered by the EU Taxonomy Regulation[150]:

- Research, development and deployment of advanced technologies ("Generation IV") that minimise waste and improve safety standards.[151]
- New nuclear plant projects with existing technologies for energy generation of electricity or heat ("Generation III+"), until 2045.[152]
- Upgrades and modifications of existing nuclear plants for lifetime extension purposes, until 2040.[153]

Nevertheless, while true that, in the CDA, these three types of nuclear energy-related economic activities are not classified within the same category as renewable energy sources, the decision to include them within the discipline set out by the EU Taxonomy Regulation, by recognising the compatibility of nuclear energy with the DNSH principle, arguably has the effect of enclosing these very activities in what could be defined as a "complementary" category

[148] Although, according to the Final Report of the Technical Expert Group on Sustainable Finance from March 2020, the generation of nuclear energy has near to zero green-house gas emissions in the energy generation phase.
Commission Delegated Regulation (EU) 2022/1214 of 9 March 2022 amending Delegated Regulation (EU) 2021/2139 as regards economic activities in certain energy sectors and Delegated Regulation (EU) 2021/2178 as regards specific public disclosures for those economic activities, recital 6.

[149] A carbon lock-in can be defined as a situation in which emission-intensive energy assets continue to be used although low-carbon and socially more beneficial assets exist.
L. Hancher, *How to approach the risk of carbon lock-in effects in state aid analysis?*, Lexxion, 2022.

[150] *Factsheet: EU taxonomy accelerating sustainable investments*, *European Commission*, link: https://finance.ec.europa.eu/publications/eu-taxonomy-complementary-climate-delegated-act-accelerate-decarbonisation_en

[151] As defined in Article 4.26 of Annex I and Annex II of Commission Delegated Regulation (EU) 2022/1214.

[152] As defined in Article 4.27 of Annex I and Annex II of Commission Delegated Regulation (EU) 2022/1214.

[153] As defined in Article 4.28 of Annex I and Annex II of Commission Delegated Regulation (EU) 2022/1214.

through which they are, however, essentially attributed the same relevance as renewable energy-related enterprises a choice which has been, so far, met with mostly sceptical reaction by several actors.[154] Among the Member States which expressed the most critical position as regard the compatibility of nuclear energy with the principle established in Article 17 of the Taxonomy Regulation, on 7 October 2022, Austria went as far as challenging the CDA in front of the CJEU. Indeed, the Vienna government brought forward several claims against the inclusion of nuclear-energy and natural gas-related activities, through an action divided in sixteen different pleas in law, two of which specifically concern the compatibility of nuclear energy-related activities with the DNSH principles.[155]

Concerns on the compatibility of those activities with that principle are, furthermore, shared by part of the scientific community. For instance, *inter alia*[156], the partially contrasting results of the SCHEER and Group of Experts reviews on the JRC comprehensive document concerning

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[154] See, for instance: N. J. Kurmayer, *Five EU countries form anti-nuclear alliance at COP26*, *Euractiv*, 2021; and A. Tidey, *Taxonomy: 12 NGOs launch challenge against EU's bid to label nuclear and gas as green*, *Euronews*, 2022.

[155] Specifically, the action id composed of eight pleas in law concerning nuclear energy and eight focusing on natural gas. Out of those focusing on nuclear energy, two specifically refers to the compatibility of nuclear energy-related activities with the DNSH principle:

- "*Third plea in law, alleging that the classification of nuclear energy as environmentally sustainable infringes the DNSH criterion in Article 17 and Article 19(1)(f) and (g) of Regulation (EU) 2020/852 and the precautionary principle under primary law. The Commission falls short of the level of protection required by Regulation (EU) 2020/852 and the requirements of proof. It fails to recognise the risks of a significant impairment of several of the protected environmental objectives due to severe reactor accidents and high-level radioactive waste. A significant impairment of the environmental objective of adaptation to climate change is also not ruled out with sufficient certainty. In addition, the requirement of a life cycle analysis is violated. At the very least, the contested regulation suffers from deficiencies in the investigation and in the statement of reasons with regard to the aforementioned point*".

- "*Fourth plea in law, alleging that the technical assessment criteria laid down in the contested regulation are not capable of excluding significant adverse effects on the environmental objectives. The technical assessment criteria infringe the DNSH criterion in Article 17 and Article 19(1)(f) of Regulation (EU) 2020/852 and the precautionary principle under primary law. In this respect, too, the level of protection and the verification requirements are misunderstood, not only with regard to severe reactor accidents and high-level radioactive waste, but also with regard to normal operation. A significant impairment of the environmental objective of adaptation to climate change is not ruled out with sufficient certainty. Moreover, the technical assessment criteria provided for in Annex II of the contested regulation fall short of those in Annex I, without there being any justification for this. With regard to the technical assessment criteria, the contested regulation is, at the very least, vitiated by deficiencies in the examination and justification.*

Action brought on 7 October 2022 – Austria v Commission (Case T-625/22), link:
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62022TN0625&from=EN

[156] For instance, several concerns have been also moved by Redeker/Sellner/Dahs, the law firm representing the Austrian government. Indeed, as specified by a press release, as regards to nuclear energy, Austria's main concerns, among others, revolve around the compatibility of the latter with the DNSH principle, as allegedly "*nuclear energy does not meet the requirements laid down in the Taxonomy Regulation, including one very central criterion: green technologies must not cause any significant environmental damage according to the so-called "do no significant harm" principle. Reactor accidents such as Chernobyl or Fukushima, with their enormous damage to the environment and population, demonstrate that significant environmental damage is indeed caused by nuclear energy*".

the compatibility of nuclear energy with the DNSH principle has been stressed by the American Nuclear Society[157] in an article published in its official journal, NuclearNewswire.[158] According to the North American researchers, while the report from the Article 31 EURATOM Treaty Group is basically in full agreement with the conclusion reached by the JRC, the SCHEER's report expressed more scepticism, stating that *"there are several findings where the* [JRC] *report is incomplete and requires to be enhanced with further evidence"*.[159]

Ultimately, in light of the principles on which EU science-based policymaking is founded under the case law and instruments examined in Chapter 2, and of the arguments raised against the compatibility of nuclear energy with the DNSH principle, it could, hence, be questioned whether, from a purely legal perspective, the inclusion of nuclear energy-related activities among those regulated by the Taxonomy Regulation could be considered in contrast with the obligations institutions are required to fulfil in the risk assessment and risk management phases.

3.1. The SCHEER review of the JRC report on *Technical assessment of nuclear energy with respect to the "do no significant harm" criteria of Regulation (EU) 2020/852* ("Taxonomy Regulation")

As previously specified, the JRC report on the compatibility of nuclear energy-related activities with the DNSH principle has been the object of two separate reviews: one from the Group of Experts as defined by article 31 of the EURATOM Treaty and one from the SCHEER. While both of these reviews essentially agreed that the findings by the JRC[160] were in the main comprehensive, the SCHEER analysis highlighted some relevant points in which it is argued that the Joint Research Centre relied on either incomplete data or on an inadequate assessment method to reach its conclusions.

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[157] An international not-for-profit organization of scientists, engineers and industry professionals active in the promotion of nuclear engineering and related fields.
American Nuclear Society, link:
https://ans.tandfonline.com/

[158] *Two EU reports on nuclear sustainability not entirely on the same page*, *NuclearNewswire*, 2021

[159] Similar distrustful conclusions have also been reached, *inter alia*, by the report produced by law firm *Redeker/Sellner/Dahs* for the Austrian Federal Ministry on Climate Action, Environment, Energy, Mobility, Innovation, and Technology, and by Eurosolar (the European Association for Renewable Energy), which will be further analysed in Chapter 4 of the present thesis.
See: *Nuclear Power and the Taxonomy Regulation*, *Redeker/Sellner/Dahs*, 2021; and *EUROSOLAR's open letter on the EU taxonomy for sustainable activities*, *EUROSOLAR*, 2022.

[160] Which led to a positive conclusion as regard the compatibility of nuclear energy-related activities with the DNSH principle as defined in Art. 17 of the Taxonomy Regulation.

Specifically,[161] the Committee underlined that, referring to the JRC report, "*there are several findings where the SCHEER is of the opinion that the review is incomplete and needs to be enhanced with additional evidence or more in-depth consideration*".[162] In Particular, the SCHEER has argued that:[163]

- Concerning the DNSH principle, "*in many cases the findings (comparing nuclear power plant (NPP) to other energy generating technologies already in Taxonomy) are expressed as 'do less harm than at least one of the comparator technologies', which in the SCHEER view is different (not equivalent) to "do no significant harm"*".[164]

- Concerning the sustainable use and protection of water and marine resources[165], "*in the phases of mining and milling, although less water is used, potential contamination may be higher*"[166], and that more data is needed.

- Concerning the transition to the circular economy, the JRC provided insufficient evidence as regard to its conclusion referring to radioactive waste and waste recycling.[167]

- Concerning pollution prevention and control, the evidence relied upon by the JRC concerning the human toxicity potential (HTP) is scarce and the "*methodology being used differs amongst the studies and indicates that there is some variability*

[161] Without going into depth on the scientific elements of the aforementioned analysis, the Committee underlined that, referring to the JRC report.

[162] Scientific Committee on Health, Environmental and Emerging Risks, SCHEER, *SCHEER review of the JRC report on Technical assessment of nuclear energy with respect of the "do no significant harm" criteria of Regulation (EU) 2020/852 ("Taxonomy Regulation")*, p. 11, link:
https://mail.google.com/mail/u/0/#sent/QgrcJHrjCFDTQzWrNlJPrrsSlgsFwbWTGPQ?projector=1&messagePartId=0.1

[163] In the present Sub-Chapter, the specific points concerning which the SCHEER has underlined either the incompleteness of the data or the use of a wrong method of assessment by the JRC will be listed in the order they are addressed in the Committee's review.

[164] *ibid*.

[165] Although true that, concerning this specific point, the SCHEER has found itself to be generally in agreement with the JRC's findings ("*The JRC report finds that for nuclear energy, its impact on water consumption and potential thermal pollution of water bodies does not meet the DNSH, but that there are mitigating factors, which would allow the impacts to be appropriately addressed, including site selection, facility design and plant operation phases*").

Ibid.

[166] *Ibid.*

[167] *Ibid.*

amongst the studies thus making comparisons difficult (if not infeasible), without giving details".[168]

- Concerning the impact of radiation on the environment, the JRC report was vitiated by a lack of "*useful or detailed information*".[169]
- Concerning the impact of severe accidents, "*there are several findings, where the review is incomplete and requires to be improved with further evidence*".[170]
- Concerning the specific assessment on the current status and perspectives of long-term management and disposal of radioactive waste the JRC conclusions are based on an incomplete and non-comprehensive method of assessment and data.[171]

[168] *Ibid.*
[169] *Ibid.*
[170] *Ibid*, p. 12.
[171] *Ibid*, pp. 12-13.

Chapter 4: The CDA: manifest error of assessment?

Completed the analysis of the principles and criteria on which EU risk assessment and management are based, and of the genesis and content of the CDA, it is finally necessary to assess whether, it could be possible for a Member State to claim in front of the CJEU that, in the adoption of the Delegated Act at hand, the Commission exceeded the limits of the discretion attributed to EU Institutions when introducing science-based policy measures. Indeed, as assessed in Chapter 2, while true that the Institutions ultimately enjoy a broad degree of discretion when adopting science-based measures, even in situations of scientific uncertainty or conflict between experts[172], the freedom of risk managers is still limited by the duty to not only refer to experts for the fulfilment of the risk assessment phase[173], but to also take fully into account the findings of the experts.[174] Furthermore, as further specified in *Netherlands v. Commission*[175], the assessment of a complex situation, such as the inclusion of nuclear energy-related activities amongst those listed in the Taxonomy Regulation, must rely on factually accurate, reliable, and consistent data and must make sure that the available evidence contains all the information which must be taken into account in order to assess a

[172] Which appears to be the case for the adoption of the CDA.

[173] Case C-212/91 Angelopharm GmbH v Freie Hansestadt Hamburg ECLI:EU:C:1994:21, pars. 34 and 37.

[174] Still considering that, as previously noted in Sub-Chapter 2.2, in the part concerning the Precautionary Principle, in situations of scientific uncertainty, that evidence, will not necessarily reflect a universal scientific consensus, but will still need to be taken into account to, at least, be able to understand the ramifications of the scientific question raised and to decide upon a policy in the full knowledge of the facts.
Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, par. 162.

[175] And, as already noted, previously in *Pfizer* ("*So, where experts carry out a scientific risk assessment, the competent public authority must be given sufficiently reliable and cogent information to allow it to understand the ramifications of the scientific question raised and decide upon a policy in full knowledge of the facts. Consequently, if it is not to adopt arbitrary measures, which cannot in any circumstances be rendered legitimate by the precautionary principle, the competent public authority must ensure that any measures that it takes, even preventive measures, are based on as thorough a scientific risk assessment as possible, account being taken of the particular circumstances of the case at issue. Notwithstanding the existing scientific uncertainty, the scientific risk assessment must enable the competent public authority to ascertain, on the basis of the best available scientific data and the most recent results of international research, whether matters have gone beyond the level of risk that it deems acceptable for society (see* pars. *150 to 153 above). That is the basis on which the authority must decide whether preventive measures are called for.*
Furthermore, a scientific risk assessment must also enable the competent authority to decide, in relation to risk management, which measures appear to it to be appropriate and necessary to prevent the risk from materializing").
Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, pars. 162-163.

situation.[176] Therefore, violation of such duties could amount to sufficient ground for Member State to challenge the adoption of the CDA[177] in front of the CJEU.[178]

In order to conduct such an assessment[179], the present chapter will build its argumentation on a hypothetical scenario in which the conclusions of the SCHEER concerning the JRC findings have been met with general consensus by the scientific community and can thus be considered correct.[180] In such an ideal situation, it could be argued that a possible action in front of the Court of Justice claiming the incompatibility of the nuclear energy-related activities defined in the CDA with the DNSH principle brought by a Member State[181] could be based on the "manifest error of assessment" line of reasoning, in connection with "duty of care" principle.[182]

Starting from the latter, the "duty of care" principle can be understood as the "*duty of the administration to impartially and carefully collect and examine the information needed for its decision making*".[183] More specifically, in the context of EU science-based policymaking, such a principle has been understood, through relevant case law[184], as the duty of the administration to ensure that the risk assessment phase is "*carried out as thoroughly as possible on the basis*

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[176] Case C-405/07 P, *Kingdom of the Netherlands v Commission of the European Communities*, ECLI:EU:C:2008:613, par. 55.
From: Redeker/Sellner/Dahs, *Nuclear Power and the Taxonomy Regulation (On behalf of the Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation, and Technology – Final report)*, 2021, p. 30, recital 88.

[177] All the references to a possible challenge to the adoption of the CDA in the present thesis only refer to the elements concerning the compatibility of nuclear energy-related activities with the DNSH principle.

[178] As is already the case for Austria.

[179] Considering the impossibility for the present thesis to analyse in depth the scientific elements of the SCHEER report highlighted in Sub-Chapter 3.1.

[180] The in-depth analysis of the scientific content of the SCHEER report would require a degree of scientific knowledge that the author of the present thesis does not possess. The hypothetical scenario which will be discussed in the present Chapter is, hence, merely speculative and could be proved wrong by either the CJEU or by the scientific community not reaching consensus as regard the SCHEER conclusions in the future.

[181] The Chapter will focus on the possible course of actions Member States might take in front of the Court of Justice.

[182] The duty of care, with the duty to give reasons, and the right to be heard fall under the category of principles deriving from the right to a good adiminstration.
M. Morvillo, M. Weimer, *Who shapes the CJEU regulatory jurisprudence? On the epistemic power of economic actors and ways to counter it*, *Cambridge University Press*, 2022, p. 523.

[183] However, a first definition can be found in par. 13 of the *Detlef Nölle, trading as "Eugen Nölle" v Hauptzollamt Bremen-Freihafen* case (Case C-16/90, Detlef Nölle, trading as "Eugen Nölle" v Hauptzollamt Bremen-Freihafen, ECLI:EU:C:1991:402).
M. Morvillo, M. Weimer, *Who shapes the CJEU regulatory jurisprudence? On the epistemic power of economic actors and ways to counter it*, *Cambridge University Press*, 2022, p. 525.

[184] For instance, see: Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, par. 172, Case T-70/99; *Alpharma Inc. v Council of the European Union*, ECLI:EU:T:2002:210, pars. 183 and 211; Case T-75/06, *Bayer CropScience AG v Commission* ECLI:EU: T:2008:317, par. 250.
M. Morvillo, M. Weimer, *Who shapes the CJEU regulatory jurisprudence? On the epistemic power of economic actors and ways to counter it*, *Cambridge University Press*, 2022, p. 526.

of scientific advice founded on the principles of excellence, transparency and independence".[185] However, while true that, over the years, the Court has underlined the relevance of the duty of care as a procedural guarantee offering protection to individuals against administrative acts which might affect their legal sphere[186], the principle has been rarely used as a self-standing ground of review in front of the Judges, and has rather been relied on through the "manifest error of assessment" test[187], as explained in *Pfizer*:

"*It follows that in this case, in which the Community institutions were required to undertake a scientific risk assessment and to evaluate highly complex scientific and technical facts, judicial review of the way in which they did so must be limited. The Community judicature is not entitled to substitute its assessment of the facts for that of the Community institutions, on which the Treaty confers sole responsibility for that duty. Instead, it must confine itself to ascertaining whether the exercise by the institutions of their discretion in that regard is vitiated by a manifest error or a misuse of powers or whether the institutions clearly exceeded the bounds of their discretion*".[188]

Therefore, to assess whether a specific act is vitiated by a manifest error of assessment, the Court will have to check if all the relevant evidence available has been considered in an impartial and careful manner.[189] Furthermore, since *Pfizer*, the Court has developed a more thorough and articulated manifest error of assessment test revolving around a "plausibility requirement", which, in order for the Court to establish that an Institution committed a manifest error of assessment in assessing complex facts such as to justify the adoption of a contested measure, entails that "*the evidence adduced by the applicant must be sufficient to make the*

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[185] Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, par. 172.

[186] An approach developed by the Court in the *T.U. Munchen* case (Case C-269/90, Technische Universität München v Hauptzollamt München-Mitte, ECLI:EU:C:1991:438), but partially modified in the *Arizona Chemical* case (Case T-369/03, *Arizona chemical v Commission*, ECLI:EU:T:2005:458), in which the European judges made a clear distinction between procedures leading to administrative acts of individual application, as opposed to those of general application. In the former case, the duty of care principle is understood as a procedural guarantee to be invoked by individuals against discretionary acts which affect their legal sphere. In the second case, the Court defined the principle as an "*objective procedural guarantee arising from an absolute and unconditional obligation on the Community institution relating to the drafting of an act of general application and not the exercise of any individual right*" (See: *Arizona Chemical* case, par. 86). However, the distinction introduced by the CJEU in *Arizona Chemical* has been rarely applied, and the Court has instead settled for the so called *T.U. Munchen* approach even in cases concerning administrative acts of general application.
M. Morvillo, M. Weimer, *Who shapes the CJEU regulatory jurisprudence? On the epistemic power of economic actors and ways to counter it*, *Cambridge University Press*, 2022, p. 526.

[187] *Ibid*.

[188] Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, par. 169.

[189] M. Morvillo, M. Weimer, *Who shapes the CJEU regulatory jurisprudence? On the epistemic power of economic actors and ways to counter it*, *Cambridge University Press*, 2022, p. 527.

factual assessment used in the decision implausible".[190] Such an approach has, over the years, translated into the analysis of the accuracy, reliability, and consistency of the evidence/data relied on by the Institutions to adopt a specific measure, of whether that evidence/data contains all the necessary information to assess a complex situation, and whether it can substantiate the conclusions drawn from it.[191] Finally, the case-law covering alleged violation of the duty of care principle has principally focused on two main hypotheses:[192]

- Challenges to the completeness of the information on which the contested measure is based.
- Challenges to the choice of assessment methods relied on by the administration in the adoption of the contested act.

Both hypotheses represent an interesting perspective on the different approaches the Court has employed when dealing with different instances of alleged manifest errors of assessment. Indeed, while in the former case the Judges have historically proved themselves reluctant in "challenging" the discretion of the Institutions when adopting science-based legal instruments, in the latter, the latest jurisprudence of the CJEU switched to a much more "intrusive" approach, which does not solely focus on the principles deriving from the right to a good administration, but rather delves into the scientific substance behind the adoption of science-based measures, possibly painting the picture of a future general tendency of the Court. Such

[190] It is worth mentioning, however, that such an operation, in this case, requires an advanced technical/scientific knowledge on the compatibility of nuclear energy-related activities with the DNSH principle. For this reason, the argument which will be presented in the present Chapter will be based on the hypothetical assumption that the concerns expressed by the SCHEER and listed in Chapter 3 have been met with consensus by the scientific community.
Case T-475/07, *Dow AgroScience Ltd and Others v European Commission*, ECLI:EU:T:2011:445, par. 152.
From: M. Morvillo, M. Weimer, *Who shapes the CJEU regulatory jurisprudence? On the epistemic power of economic actors and ways to counter it*, *Cambridge University Press*, 2022, p. 527.

[191] Case C-405/07 P, *Kingdom of the Netherlands v Commission of the European Communities*, ECLI:EU:C:2008:613, par. 55.

[192] It is worth noticing, however, that such case-law, which will be analyzed in the next two Sub-Chapters, covers situations in which private actors have claimed in front of the CJEU a violation of the duty of care principle based on a manifest error of assessment by the Institutions, in reference to restrictive measures enacted by the latter. The thesis of the manifest error of assessment has, however, been embraced by Austria in its claims against the CDA, which will be analyzed in the present Chapter.
For the two hypotheses of manifest error of assessment, see: M. Morvillo, M. Weimer, *Who shapes the CJEU regulatory jurisprudence? On the epistemic power of economic actors and ways to counter it*, *Cambridge University Press*, 2022, pp. 529-533.
For the reference to the manifest error of assessment by Austria see: Action brought on 7 October 2022 – Austria v Commission (Case T-265/22); and Redeker/Sellner/Dahs, *Nuclear Power and the Taxonomy Regulation (On behalf of the Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation, and Technology – Final report)*, 2021, pp. 30, 31, 32, 77.

an argument will be further developed through the analysis of two cases: *Bayer*[193] and *CWS Powder*.[194]

4.1. Challenges to the completeness of the information on which the contested measure is based

As previously mentioned in Sub-Chapter 3.1, there are six points (points (ii) to (vii)) in which the SCHEER review highlighted the alleged use of insufficient data in the JRC report concerning several aspects connected to the compatibility of the nuclear energy-related activities defined by the CDA and the DNSH principle. For instance, *inter alia*, concerning the sustainable use and protection of water and marine resources, the Committee has denoted a partial lack of relevant evidence on the potential contamination levels during the mining and milling[195] phases (point (ii)), while, as regard to the impact of radiation on the environment, the experts of the SCHEER underlined the absence of "*useful or detailed information*" in the JRC report. Starting from the supposition that such findings are correct, it could then be argued that there could possibly be sufficient ground for a Member State to bring an action in front of the CJEU, claiming a manifest error of assessment deriving from either the incompleteness or lack of the necessary evidence in reference to the highlighted points. Indeed, such a thesis could be reinforced by referring, among others[196], to recital 88 of the technical report developed by law firm Redeker/Sellner/Dahs on behalf of the Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation, and Technology of Austria, on which the action brought by the Austrian government against the adoption of the CDA is based:

"*We note that so far none of the reports drawn up at the Commission's request has assessed whether there are technologically and economically feasible low-carbon alternatives to nuclear*

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[193] Case T-429/13, *Bayer CropScience v Commission of the European Communities*, ECLI:EU:T:2018:280.

[194] Joined Cases T-279/20, T-288/20, and T-283/20, *CWS Powder Coatings and Others v Commission.*

[195] Both phases concern the mining and extraction process of uranium. Specifically, milling refers to the crushing of uranium ore into smaller particles before the uranium can be extracted.
Uranium Milling, *Nuclear-power.com*, link:
https://www.nuclear-power.com/nuclear-power-plant/nuclear-fuel/nuclear-fuel-cycle/uranium-milling/

[196] For instance, recital 91 of the report, specifically concerning the Levelized Cost of Electricity (LCOE), states: "*Regarding existing capacities, on the other hand, it is often argued that nuclear power has very low LCOE, even considering the costs of refurbishments required for a lifetime extension. However, this position appears to be increasingly challenged since it does not (sufficiently) take into account external costs, such as long-term waste management, managing intermittency with other energy sources and nuclear accidents. In this respect, it should be noted that according to Recital 44 TR, the Commission should also take into account environmental, social and economic externalities when establishing technical screening criteria. However, so far none of the reports drawn up on the Commission's request has assessed the external costs related to nuclear power. Therefore, any delegated act referring to nuclear power as a transitional activity could be vitiated by a manifest error of assessment also in this respect*".
Redeker/Sellner/Dahs, *Nuclear Power and the Taxonomy Regulation (On behalf of the Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation, and Technology – Final report)*, 2021, p. 31, recital 91.

power. On this factual basis, any delegated act referring to nuclear power as a transitional activity in terms of Article 10(2) TR[197] *could be vitiated by a manifest error of assessment*".[198]

Pursuant to such an argument, the failure of the EC to take into account the proper data/evidence[199] would vitiate the correctness of the assessment and, therefore, require the Court to engage into a procedural review of the administration's findings[200] in light of the duty to care principle deriving from the right to a good administration.[201] Based on the material analysed above, therefore, it could be argued that, upon a first observation, an argument in front of the CJEU based on an alleged manifest error of assessment deriving from insufficient nature of the necessary data might represent a viable option to challenge the compatibility of the CDA with the DNSH principle. Indeed, as previously stated, when dealing with allegations of incomplete data/evidence behind the adoption of science-based measures, the Court has shown a rather protective approach toward the degree of discretion enjoyed by the Institutions. An example of such a tendency could be, for instance, found in the *Bayer* case.

The latter judgement focused on the ban on the sale of seeds treated with the active substances clothianidin, thiamethoxam and imidacloprid, used as plant protection products, by the Commission. Indeed, following several incidents between 2008 and 2009 which led to the

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[197] Taxonomy Regulation.

[198] Redeker/Sellner/Dahs, *Nuclear Power and the Taxonomy Regulation (On behalf of the Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation, and Technology – Final report)*, 2021, p. 30

[199] Which is usually in the form of studies submitted by the applicants during public consultation (which in the case of the CDA was absent) or other exchanges the Institutions.
M. Morvillo, M. Weimer, *Who shapes the CJEU regulatory jurisprudence? On the epistemic power of economic actors and ways to counter it*, *Cambridge University Press*, 2022, p. 528.

[200] In more recent years, the reviews of the Court in cases concerning science-based policymaking have, always more often, started to cover the substance of the scientific findings behind the adoption of risk-regulation measures by the Institutions. Such a tendency of the Court has become increasingly manifest with, among others, cases such as *Bilbaína de alquitranes* (Case C-691/15 P., *European Commission v Bilbaína de alquitranes, SA and Others*, ECLI:EU:C:2017:882) and *CWS Powder* (Joined Cases T-279/20, T-288/20, and T-283/20, *CWS Powder Coatings and Others v Commission*), giving rise to skepticism by the experts as regarding the scientific legitimacy of the Court vis-à-vis EU expert agencies.
M. Weimer, M. Morvillo, *Op-Ed: "Out of balance – Why the CJEU 'modern' approach to reviewing EU agency science has gone too far (CWS Powder, joined cases T-279/20, T-288/20 and T-283/20)*, *EU Law Live*, 2023.

[201] Defined in Article 41 of the ECHR: "*1. Every person has the right to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions, bodies, offices and agencies of the Union. 2. This right includes: (a) the right of every person to be heard, before any individual measure which would affect him or her adversely is taken;*
(b) the right of every person to have access to his or her file, while respecting the legitimate interests of confidentiality and of professional and business secrecy;
(c) the obligation of the administration to give reasons for its decisions.
3. Every person has the right to have the Union make good any damage caused by its institutions or by its servants in the performance of their duties, in accordance with the general principles common to the laws of the Member States.4. Every person may write to the institutions of the Union in one of the languages of the Treaties and must have an answer in the same language".

loss of several honeybees' colonies, different studies[202] found those substances to pose a threat to the bees' population. On the basis of these findings, the European Food Safety Authority (EFSA) then published its conclusions, confirming that the substances posed a relevant risk to honeybees which were exposed to them, but also underlined numerous areas of uncertainty, due to the lack of scientific data.[203] In light of these findings, the Commission introduced a prohibition[204] on the sale of seeds treated with those three plant protection products through Implementing Regulation No 485/2013.[205] The applicants[206] of the case lamented, *inter alia*, a manifest error of assessment on the part of the Commission, claiming that in coming up with the conclusions on which the contested Implementing Regulation was based, the EFSA failed to take into account "*important relevant scientific data*".[207] Ultimately, the Court rejected the allegation, claiming that the EFSA did in fact analyse the data mentioned by the applicants, but that the latter would have not had a significant impact on the outcome of the risk assessment.[208] The *Bayer* case represents a perfect example of what could be defined as the first "post-*Pfizer*" approach.[209] Indeed, the argumentation of the Court to deal with the applicants' claims, rather than analysing the substantive scientific data utilized by the Commission in the adoption of the contested measure, relies on procedural considerations to assess whether the obligations deriving from the duty to care principle had been respected in the adoption of the contested measure. For instance, a demonstration of this solely procedural

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[202] A first study on the effects of the mentioned plant protection products was that of the Apenet monitoring and research programme, in Italy, followed by two separate studies concerning thiamethoxam ("The Henry study") and imidacloprid ("The Whitehorn study"). Ultimately, these studies were incorporated in two separate risk assessments by the EFSA.
Joined Cases T-429/13 and T-451/13, *Bayer CropScience v Commission of the European Communities*, ECLI:EU:T:2018:280, p pars. 18 and 19.

[203] *Ibid*, pars. 26 and 27.

[204] As the three substances no longer satisfied the approval criteria laid down in Article 4 of Regulation 1107/2009 (Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 *concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC*.

[205] Implementing Regulation (EU) No 485/2013 *amending Implementing Regulation No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and dale of seeds treated with plant protection products containing those active substances*.

[206] Bayer CropScience AG (for Case T-429/13) and Sygenta Crop Protection AG (for Case T-451/13).

[207] Specifically, the applicants claimed the EFSA failed to take into consideration peer reviewed scientific literature (in this case the claim stated "*to examine in detail*"), certain existing studies, and monitoring data and risk mitigation measures.
Joined Cases T-429/13 and T-451/13, *Bayer CropScience v Commission of the European Communities*, ECLI:EU:T:2018:280, pars. 354-382.

[208] *Ibid*, pars. 369 and 380.

[209] "The modern approach".
M. Weimer, M. Morvillo, *Op-Ed: "Out of balance – Why the CJEU 'modern' approach to reviewing EU agency science has gone too far (CWS Powder, joined cases T-279/20, T-288/20 and T-283/20)*, *EU Law Live*, 2023.

approach could be found in paragraph 368 of the *Bayer* case[210]: "*Likewise, in the case of the Genersch (2010) study, the Commission states both in the defence and in the rejoinder in Case T-451/13 that that study did not concern thiamethoxam and could not therefore provide reliable information on the absence of risks posed by products containing that substance. Syngenta did not respond to that argument. In those circumstances, it must be held that it has not demonstrated that the failure to consider the Genersch (2010) study — a failure for which, moreover, the Commission acknowledges that EFSA should have expressly given reasons — could have had an impact on EFSA's Conclusions on thiamethoxam*".

In light of such considerations, it could be stated that the first post-*Pfizer* approach could be interpreted as entailing a form of "shield" for the discretion of the Institutions. Indeed, by not challenging the scientific evidence relied on by the Institutions in the adoption of science-based measures, the Court is arguably left with little space of manoeuvre, leading to what could be identified as a higher degree of protection of the freedom enjoyed by the EU Administration in those circumstances. Therefore, in the case of the adoption of the CDA, in light of protective approach developed in the case-law, it may initially be stated that an eventual action brought by a Member State against the adoption of that instrument, based on a claim of manifest error of assessment concerning the completeness of the data/evidence relied on by the Commission, might be met with a rather favourable ruling for the discretion of the latter. However, such a conclusion could arguably be disproved in the future, considering the more intrusive strategies employed by the CJEU in cases concerning the second category of manifest error of assessment.

4.2. Challenges to the choice of assessment methods relied on by the administration in the adoption of the contested act

For claims of manifest errors of assessment concerning the methods of assessment employed by the administration, the Court, in its latest jurisprudence, as previously noted, has been developing a more intrusive approach, which focuses on the substantial scientific elements behind the adoption of a science-based measure rather than a procedural review. Such a tendency appears to be quite fitting, considering that the analysis by the Court of this type of manifest errors entails, more than those concerning the completeness of scientific evidence, "*a dense intertwinement of scientific and legal considerations, whereby the Court reviews*

[210] Addressing the claim that the Commission did not take into consideration some relevant studies concerning the effect of the contested plant protection products.

whether the chose assessment method is allowed by the relevant legislation and correctly applied".[211]

In the case of the CDA, firstly, the SCHEER review highlighted, in the general considerations concerning the compatibility of nuclear energy-related activities with the DNSH principle and in points iii, and vi[212], that the JRC report might have been vitiated by errors concerning the methods of assessment used to reach its conclusions. Specifically, in its review, the SCHEER stated that "*for the DNSH criteria, in many cases the findings (comparing nuclear power plant (NPP) to other energy generating technologies already in Taxonomy) are expressed as 'do less harm than at least one of the comparator technologies', which in the SCHEER view is different (not equivalent) to "do no significant harm". For GHG*[213] *mitigation, there are other energy generating technologies, which outperform NPP, without the additional challenges of waste management. It is the opinion of the SCHEER that, in many cases, the comparison is quite superficial, without the necessary detail, e.g. the origin of impacts determined by the various phases of the life cycle for different energy generating technologies*"[214], hence claiming, beside the partial incompleteness of the data relied on by the JRC, the use of allegedly inadequate methods of assessment in its report. It could then be argued that, also in this instance, there might arguably be sufficient ground for a Member State to challenge the inclusion of nuclear energy-related activities among those listed in the Taxonomy by the CDA, claiming a manifest error of assessment concerning the method of assessment relied on in the adoption of that Delegated Act.

On this point, *CWS Powder* represents a relevant example of the approach the Court has used in its latest jurisprudence when dealing with similar circumstances.[215] The case concerned the

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[211] M. Morvillo, M. Weimer, *Who shapes the CJEU regulatory jurisprudence? On the epistemic power of economic actors and ways to counter it*, *Cambridge University Press*, 2022, p. 530.

[212] See pp. 37-38 of the present thesis.

[213] Greenhouse Gas.

[214] Scientific Committee on Health, Environmental and Emerging Risks, SCHEER, SCHEER review of the JRC report on Technical assessment of nuclear energy with respect of the "do no significant harm" criteria of Regulation (EU) 2020/852 ("Taxonomy Regulation"), p. 11, link: https://mail.google.com/mail/u/0/#sent/QgrcJHrjCFDTQzWrNlJPrrsSlgsFwbWTGPQ?projector=1&messagePartId=0.1

[215] Another notable example could be found in *Bilbaìna v Commission* (*Alquitranes, SA and Others v European Commission*, ECLI:EU:T:2015:767 – unavailable online (the information concerning this case will be extrapolated from the literature available (M. Morvillo, M. Weimer, *Who shapes the CJEU regulatory jurisprudence? On the epistemic power of economic actors and ways to counter it*, *Cambridge University Press*, 2022) and from the text of the appeal judgement to that case – Case C-691/15 P).

classification and labelling of Titanium Dioxide[216] as a category 2 carcinogen by inhalation. Specifically, following the adoption of an opinion on the matter by the Committee for Risk Assessment (RAC) of the European Chemical Agency (ECHA)[217], the Commission adopted Delegated Regulation 2020/217[218], which introduced the new harmonised classification and labelling of titanium dioxide as a category 2 carcinogen by inhalation.[219] In this case, the applicants[220], demanded that the contested measure be annulled, on the ground that, *inter alia*[221], the adoption of the measure by the Commission was vitiated by a manifest error of assessment, essentially alleging that the scientific conclusion reached by that Institution differed from that of the RAC, leading to a failure to comply with the requirements of the CLP Regulation.[222] Specifically, the assessment of Court focused on whether the Delegated Regulation at hand was based on "*reliable and acceptable studies, as required by Section 3.6.2.2.1 of Annex I to Regulation No 1272/*2008"[223] and whether it was based on the intrinsic

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[216] An inorganic chemical substance either found in nature or produced industrially and used for its colourant and covering properties in various products, such as paints, coating, materials, varnishes, plastics, cosmetics, laminated paper, medicinal products, and toys.
Joined Cases T-279/20, T-288/20, and T-283/20, *CWS Powder Coatings and Others v Commission*, par. 3.

[217] Based in turn, based on a dossier, submitted to the ECHA by the Agence nationale de sécurité sanitaire de l'alimentation, de l'environment et du travail (ANSES) (National Agency for Food, Environmental and Occupational Health and Safety, France), proposing the harmonised classification and labelling of titanium dioxide as a category 1B carcinogen by inhalation. On 31 May 2016, the dossier was then published, and several parties concerned submitted their comments within the prescribed period.
Ibid, pars. 4 and 5.

[218] Commission Delegated Regulation (EU) 2020/217 of 4 October 2019 *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 on classification, labelling and packaging of substances and mixture and correcting that Regulation*.

[219] See: *Ibid*, pars. 9-15.

[220] CWS Powder Coatings GmbH (first applicant, supported by the second applicants in Case T-279/20), Billions Europe Ltd, Ettengruber GmbH un Tiefbau, Ettengruber GmbH Recycling und Verwertung, and by TIGER Coating GmbH & Co. KG (second applicants, supported by Conseil européen de l'industrie chimique – European Chemical Industry Council (Cefic), the Conseil européen de l'industrie des peintures, des encres d'imprimerie et des couleurs d'art (CEPE), British Coatings Federation Ltd (BCF), American Coatings Association, Inc. (ACA), Mytilineos SA and Delfi-Distomon Anonymos Metalleftiki Etaireia) and the third applicants (not named in the case, supported by the second applicants, Sto SE & Co. KGaA and Rembrandtin Coatings GmbH).
Ibid, par. 16.

[221] The applicants also alleged a manifest error of assessment on the ground that the "*classification and labelling* (of a substance as carcinogenic) *do not relate to a substance that has the intrinsic property to cause cancer*", an argument which will note be covered in the present thesis.
See: *Ibid*, pars. 124-180.

[222] 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006*.

[223] Specifically, the applicants claim that the RAC Opinion was adopted on the basis of the "Heinrich Study", which had been considered by the competent French Authorities to be unreliable, considering that it had been "*conducted solely on female rats and had used a single excessive testing dose*".
Joined Cases T-279/20, T-288/20, and T-283/20, *CWS Powder Coatings and Others v Commission*, par. 50.

properties of titanium dioxide to cause cancer[224], as always required by the CLP Regulation.[225] The most relevant element of the *CWS Powder* ruling can be, perhaps, found in the fact that such a claim, which clearly entails an analysis of aspects concerning the substance of the scientific data analysed rather than procedural elements, has been officially approached by the Court as if it was a case of manifest error of assessment concerning whether the assessment method relied on by the Commission could be considered the correct one. However, as opposed to *Bayer*, the ruling in *CWS Powder* concretely focused, as it could be expected, on the substance of the scientific evidence relied on by the Commission rather than on a procedural review as seen in *Bayer*, ultimately leading the Court to annul the Delegated Regulation at hand "*as regards the contested classification and labelling*".[226] An interesting example to denote the different approaches by the Court in *Bayer* and *CWS Powder* could be, for instance, found in paragraph 151 of the latter: "*In the third place, the carcinogenicity hazard covered by the contested classification and labelling corresponds, according to the actual wording of the RAC Opinion, to 'particle toxicity', the reason for which is 'the deposited particles, but not solutes of [titanium dioxide] molecules'. Furthermore, it is apparent from the RAC Opinion that the development of tumors which was observed in rats was not triggered by the direct contact of titanium dioxide particles with epithelial lung cells, but by the high load of particles in the alveolar macrophages of the lungs and by the resulting significant impairment of particle clearance mechanisms, which led to marked and sustained inflammatory responses*".[227] Such a paragraph, which denotes a clearly different approach than the one adopted in *Bayer*, could be perhaps considered emblematic of the new direction the Court has taken lately when dealing with challenges concerning science-based measures. Indeed, by focusing on the scientific substance of an act, the Court seems arguably willing to pierce the "shield" consolidated by the first post-*Pfizer* case-law, thus arguably intruding into the sphere of the Institutions' discretion.

Therefore, while ultimately true that the case analysed in the present Sub-Chapter can be considered an exception to the rule, the latest jurisprudence here taken under exam lead to question whether the Court truly respect the discretion the Institutions enjoy when adopting

[224] Essentially, the capability of titanium dioxide to cause cancer on its own rather than to cause cancer under specific conditions.
M. Weimer, M. Morvillo, *Op-Ed: "Out of balance – Why the CJEU 'modern' approach to reviewing EU agency science has gone too far (CWS Powder, joined cases T-279/20, T-288/20 and T-283/20)*, *EU Law Live*, 2023.
[225] Joined Cases T-279/20, T-288/20, and T-283/20, *CWS Powder Coatings and Others v Commission*, par. 124.
[226] *Ibid*, par. 180.
[227] *Ibid*, par. 151.

science-based measures.[228] Indeed, the *CWS Powder* might arguably foreshadow the approach the CJEU could adopt when dealing with eventual actions brought forward by Member States[229] against the inclusion of nuclear energy-related activities among those listed in the Taxonomy Regulation through the adoption of the CDA. Indeed, it could be stated that, although so far only observed in cases relating to alleged manifest errors of assessment concerning the assessment methods employed by the Institutions, the intrusive approach developed by the Court in that ruling might be interpreted as a sign of the possible intention of the Judges to transition from the moderate first post-*Pfizer* approach to a new general and intrusive one, which might allow them to fully extend their review to those elements initially confined within the Institutions' discretion, regardless of the type of manifest error of assessment claimed. In fact, the aforementioned case could arguably suggest a newfound inclination of the Court to take the role of both ultimate Judge and technical/scientific expert, a tendency which might arguably not be solely limited to claims of inadequate assessment methods, but possibly also to those of insufficient scientific data/evidence. In such a scenario, it could, then, be hypothesized that an eventual action brought forward by a Member State against the inclusion of nuclear energy-related activities in the Taxonomy Regulation through that Delegated Act[230], might translate into a review by the Court which focuses more on the substantive technical/scientific elements behind the adoption of the contested measure rather than a procedural review.[231]

[228] M. Weimer, M. Morvillo, *Op-Ed: "Out of balance – Why the CJEU 'modern' approach to reviewing EU agency science has gone too far (CWS Powder, joined cases T-279/20, T-288/20 and T-283/20)*, *EU Law Live*, 2023.

[229] Such as the one by Austria.

[230] Which, as previously hypothesized might be based on claims of both types of manifest errors of assessment.

[231] An approach which, as previously noted, poses several issues concerning the role of the Court *vis a vis* that of the experts involved in the risk assessment phase. Such concerns will not be covered by the present thesis.

Chapter 5: Conclusions

The introduction of nuclear energy-related activities amongst those labelled environmentally sustainable by the Taxonomy Regulation through the CDA arguably represent one of the most interesting turn of events concerning the EU in the latest years. The intricated set of principles developed by jurisprudence on science-based policymaking and the lack of consistency in the CJEU case-law concerning that area[232] may amount to the development of some possibly truly controversial decisions by the Court, which always more often appear determined to depart from the merely procedural assessment methods that characterized the first post-*Pfizer* approach, to venture into the less domesticated field of in-depth scientific reviews. While true that Institutions are ultimately not bound by the scientific advice of the experts and enjoy a consistent degree of discretion in the adoption of science-based measures, limits[233] such as the duty to take into consideration all relevant data and that the assessment of a complex situation[234] must rely on factually accurate, reliable, and consistent data and must make sure that the evidence contains all the information which must be taken into account in order to assess that situation[235], still offer some space of manoeuvre to an increasingly more intrusive Court. Indeed, cases such as *CWS Powder*, which can still be considered an exception[236] to the previous jurisprudence, represent a clear departure from the more protective case-law of, *inter alia*, *Bayer*, *Pfizer*, and *Alpharma*, and a potential precedent for the CJEU to follow in future rulings. Therefore, it could be argued that a possible action brought forward by Member States against the adoption of the CDA, so far as it includes nuclear energy-related activities among those listed in the Taxonomy Regulation, and based on the claim of alleged manifest errors of assessment concerning either the assessment methods used and/or the incompleteness of the data relied on by the administration, could potentially lead to a highly technical judgement focusing on substantive scientific data rather than a procedural one. Therefore, in the hypothetical scenario in which the SCHEER findings have been met by consensus by the scientific community and can be considered correct, a more intrusive approach by the Judges could arguably translate in a ruling which favours the sceptical

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[232] M. Weimer, M. Morvillo, *Op-Ed: "Out of balance – Why the CJEU 'modern' approach to reviewing EU agency science has gone too far (CWS Powder, joined cases T-279/20, T-288/20 and T-283/20)*, *EU Law Live*, 2023.

[233] On this point, see Chapter 2 of the present thesis.

[234] Such as the inclusion of nuclear energy-related activities amongst those listed in the Taxonomy Regulation,

[235] Case C-405/07 P, *Kingdom of the Netherlands v Commission of the European Communities*, ECLI:EU:C:2008:613, par. 55.
From: Redeker/Sellner/Dahs, *Nuclear Power and the Taxonomy Regulation (On behalf of the Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation, and Technology – Final report)*, 2021, p. 30, recital 88.

[236] However, it could be argued that such a consideration of these two cases only derives from the fact that they are some of the latest cases in the field of science-based policymaking and, therefore, that, to be properly defined as "exceptions", they should be disproved by future case-law in this area.

positions expressed by Member States at the expenses of the discretion that has been historically enjoyed by the Institutions in the adoption of science-based measures, thus possibly leading to the annulment of those provisions of the CDA which include nuclear energy-related activities among those defined in the Taxonomy Regulation.

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