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The Precautionary Principle and Management of Uncertainties in EU Law on Chemicals

by

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Table of Content

1. Introduction
2. The risk analysis framework
2.1. Risk assessment
- 2.1.1. Risk assessment as a prerequisite for the taking of precautionary action
- 2.1.2. Taking into account uncertainties
- 2.1.3. Jurisprudential requirements regarding the quality of the risk assessment
- 2.1.4. Exclusion of hypothetical considerations
- 2.1.5. Taking into account the multi-faceted effects of hazardous substances
- 2.1.6. Setting the level of protection

2.2. Risk management
- 2.2.1. Scientific opinions: a necessary but not sufficient condition for risk regulation
- 2.2.2. Acceptable risk
  - 2.2.2.1. Weighing of interests and high level of protection
  - 2.2.2.2. Balancing economic and environmental interests
  - 2.2.2.3. Zero risk and zero tolerance
- 2.2.3. Precautionary procedures
- 2.2.4. Substitution principle

3. Judicial review of the risk management process
3.1. Introductory remarks

3.2. Judicial restraint in reviewing the exercise of the discretionary power

3.3. Stricter interpretation of the marketing requirements

3.4. Testing the proportionality of the precautionary measure
- 3.4.1. Adequacy, necessity and weighing of interests tests
- 3.4.2. Proportionality in the light of the duty of re-examination
- 3.4.3. Proportionality and countervailing risks
- 3.4.4. Proportionality, cost-benefit analysis, and impact assessment

4. Conclusion

1. Introduction

Hazardous substances [1] inevitably affect health and workers' safety, consumer and environmental protection, aspects that cannot easily be dissociated from each other.[2] Aiming at reducing health and environmental risks, the chemicals policy has historically been related to a general preference for a certainty-seeking regulatory style in which a formal, science-based, and standardized risk assessment (RA) has been singled out as the predominant tool for decision-making. However, while RAs draw extensively on science, data are often incomplete

*The author would like to thank his colleague Jeffrey McNeill for reviewing his text.

[1] In this section, the term 'hazardous substances' is used as a convenient shorthand form to refer generically to a broad category of substances or mixture of substances, whether solid, liquid or gas, which are likely to cause significant acute (immediate) or chronic (long-term) adverse effects to the environment or humans. These terms include, among others, chemicals, insecticides, biocides, fungicides, rodenticides, petroleum products, and toxic materials.

[2] L. Krämer, *EU Environmental Law* 8th ed (Sweet & Maxwell, 2016) 224.

and results may be unclear or contradictory.[3] Indeed, as it is difficult to establish causal links between exposure to chemicals and health or environmental effects, there is generally a significant degree of uncertainty in estimates of the probability and magnitude of adverse effects associated with a chemical agent. The variety and complexity pathways of dispersion in the environment, and the bio-accumulation in the food chain are likely to compound these uncertainties. In addition, chemical substances have different properties which may give rise to risks of a different nature.[4] As the result of limited knowledge, it is difficult to provide conclusive evidence of a threat to human health or to the environment. Last, nature does not reveal its secrets quickly: [5]long latency periods may conceal hazards for decades.

In particular, endocrine disrupting substances (EDS) mimicking hormones have challenged the scientific belief that high doses produce more serious effects than low ones.[6] Contrary to Paracelsus' belief, the dose is thus only one of the factors that make the poison.[7] Consequently, there is no threshold below which the probability of disrupting effects is considered to be negligible. It comes therefore as no surprise that the uncertainty surrounding the causes and effects of hazardous substances has served to favour the recognition of the PP.

EU policy regarding the placing on the market of hazardous (or chemical) substances was established in the early days of the environmental debate. It consists of a complex regulatory system made up of an intricate network of regulations and several features of the resulting risk regulatory framework need to be explained before focusing on the precautionary principle (PP).

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[3] The assessment of the carcinogenicity of the active substance glyphosate is a case in point. In March 2015 the IARC of the World Health Organisation (WHO) published its monograph on that substance, concluding that glyphosate should be classified as 'probably carcinogenic to humans'. In the course of the EU RA of that substance, both EFSA and ECHA concluded that 'glyphosate is unlikely to pose a carcinogenic hazard to humans'. In light of the diverging view between EFSA/ECHA and IARC, the Commission decided to extend the approval period of glyphosate for 5 years (Commission Implementing Regulation (EU) 2017/2324 of 12 December 2017 renewing the approval of the active substance glyphosate; see Case T-125/18 *Associazione GranoSalus* [2019] T:2019:92). The opposing views of IARC and the two EU agencies can be explained by their diverging methodologies. Firstly, whilst the IARC looked at both glyphosate –the active substance – and the plant protection products (e.g. Roundup™), the EU assessments, on the other hand, considered only glyphosate, on the grounds that Member States are responsible for authorising each plant protection product that is marketed in their territories. Secondly, whilst IARC only considered published studies, the EU agencies also took into consideration studies submitted by applicants as part of their dossiers that were not in the public domain. These divergent methodologies explain the differences in how EFSA/ECHA and IARC weighed the available data. E.g. Communication from the Commission on the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides" C(2017) 8414 final. In *Pilliod et al. c Monsanto Company, et al.,* the California Superior Court held that Roundup's alleged risk of NHL was 'known or knowable in light of the generally recognized and prevailing scientific and medical knowledge'.

[4] Case C-419/17P *Deza* [2019] C:2019:52, para 37.

[5] C Cranor, *Toxic Torts* (CUP, 2006) 216.

[6] The restrictions placed on several active substances in pesticides having potential endocrine disruptive effects have been challenged in court. This was the case of Fenarimol (Case C-333/08 *Gowan* [2010] C:2010:803) and Flusilazole (T-31/07 *Du Pont de Nemours* [2013] T:2013:167). In *Gowan*, AG Mazak held that in cases of non-existing 'established and undisputed methodologies', the 'analysis necessarily entails choices of a political and social nature'.

[7] A Gides and AM Soto, 'Bisphenol A: contested science, divergent safety evaluations' in EEA Report No 1/2013 (Luxembourg, 2013) 217 and 219.

Firstly, the PP is entangled in a web of varied, fragmented, and complex regulations that harmonize the procedures related to the placing on the market of substances. Although they all aim to reduce the impacts of hazardous substances, specific reasons preclude adopting a single regulation to replace them. In effect, some substances are designed to be toxic and are released widely in the environment (pesticides and biocides), others are included in products that come into contact with the human body or are directly ingested (cosmetics and food additives), whereas others are designed to be biologically active in small doses (pharmaceuticals and veterinary medicines).

Secondly, given that all these sectors are product-related, it comes as no surprise that the EU institutions have favoured regulations adopted pursuant to Article 114 TFEU.[8] In sharp contrast with other environmental sectors, these regulations increase the centralization of the decision-making process. The preference of regulations based on the Treaty provision fostering the functioning of the internal market could be explained by the fact that the more flexible nature of a directive entails a genuine risk of market fragmentation. Given the completeness of their procedures,[9] these regulations lead to a total or a complete harmonization that constraints the Member States' room for manoeuvre.[10]

Thirdly, although these harmonising measures were initially motivated primarily by a desire to complete the internal market, the EU institutions have only recently begun to address environmental concerns. In effect, there has been an incremental evolution toward a more preventive regulatory approach based on approved lists at the EU level of substances and Member State authorization. The EU lists are compiled according to the level of 'significant' health and environmental risk that the substances pose, coupled with the authorization of products by national authorities and the mutual recognition of these authorizations. Post-market measures may also be adopted to prevent unsuspected risks. Accordingly, these internal market regulations seek to strike a balance between a high level of protection of human health and the environment and the free circulation of substances in the internal market.[11]

[8] Internal market authorisation procedures are entangled with environmental issues. By way of illustration, studies of residues and reports of field trials submitted in connection with a procedure for extending the authorisation of a product in accordance with the legislation of plant protection products (Art 114 TFEU) are deemed to be 'environmental information' for the purpose of Art 2 of Directive 2003/4 on access to environmental information (Art 192 TFEU). In effect, this information 'concerns elements of the environment which may affect human health if excess levels of those residues are present' (Case C-266/09 *Stichting Natuur en Milieu* [2010] C:2010:779, paras 42-43).

[9] Both Regulation 528/2012 concerning the making available on the market and use of biocidal products, *OJ L 167, 1* (hereafter BPR) and Regulation 1107/2009 concerning the placing of plant protection products on the market, *OJ L 309, 1* (hereafter PPPR) confer an exclusive competence on the EU authorities concerning the assessment of the active substances found in these products. See Case T-31/07 *Du Pont de Nemours*, above, para 203.

[10] N. de Sadeleer, *EU Environmental Law and the Internal Market* (OUP, 2014) 157-161, 291, 304, 353, and 358-382.

[11] REACH, Art 1(3); PPPR, Art 1(3), and BPR, Art 1. It must be noted that the European Commission is not empowered to undermine the equilibrium sought by the EU lawmaker. See Case T-521/14 *Sweden v Commission* [2015] T:2015:976, para 72.

Fourthly, this web of regulations on the one hand, empowers the Commission to adopt implementing acts in accordance with the comitology procedure[12] and, on the other hand, delegates significant administrative tasks, in particular in the realm of risk assessment, to two EU agencies. The regulatory decisions in chemicals policy, such as those relating to the registration, authorization, restrictions, classification, and labelling under REACH and CLP Regulations,[13] are backed by the opinions of the European Chemicals Agency (ECHA), whereas the assessment of the active substances in pesticides is subject to the opinions of the European Food Safety Agency (EFSA). The interaction between these two agencies (risk assessment), the regulatory committees, and the Commission (risk management) is testament to one of the paradigms of 'administrative constitutionalism'.[14]

At this stage, we have to turn on to the status of the PP in this regulatory web. This calls for three observations.

Firstly, most EU legislation on hazardous substances displays regulatory features that are permeated by precaution or prudence. We highlight in this section how the pesticides, biocides, and REACH regulations flesh out some elements of the PP. Whereas several of these regulations refer expressly to the PP, others ignore it. By way of illustration, REACH and the PPPRs alike refer to the principle,[15] whilst the CLP Regulation does not mention it. In addition, the EU is party to a number of MEAs that do proclaim the principle.[16]

Secondly, since the PP is binding on the EU institutions and on the Member States when their measures fall within the scope of secondary law, EU courts may be called on to review the consistency of measures on hazardous substances with the principle. Needless to say, the case law encompasses a wide range of disputes as well as different types of actions. The compatibility of a domestic precautionary measure with either primary law,[17] secondary law, or soft law (Communication on the PP) is likely to be reviewed either in an infringement case,[18] in a preliminary ruling proceeding,[19] in an action for annulment. Regarding the references for a preliminary ruling, in interpreting ambiguous provisions of secondary law in light of the PP, the CJEU has been constantly honing its scope. With respect to direct actions, the principle acts as a shield and as a sword. The PP can act as a sword: among the different grounds for reviewing risk decisions, claimants regularly invoke in their actions for annulment the breach by the EU institutions of the PP requirements.[20] It acts as a shield when the EU institutions rely on it with the aim of justifying the soundness and the reasonableness of their risk decisions adopted in face of uncertainty. On another note, the extent to which

[12] Accordingly, various rules of secondary law define the PP further in connection with the Commission's implementing powers.

[13] REACH; Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures [2008] OJ L353/1(hereafter, CLP Regulation).

[14] E. Fisher, *Risk Regulation* (Hart, 2010).

[15] REACH, Arts. 1(3) and 3 as well as recitals 9 and 69 and PPPR, Art 1(4).

[16] The EU is party to the 2001 Stockholm Convention on Persistent Organic Pollutants (POPs) that lays down the PA as its main objective (Preamble, eight recital; and Art 4, Art 8(7)) and to the 2001 London IMO Convention on the Control of Harmful Anti-fouling Systems on Ships, which establishes a precautionary mechanism to prevent the potential future use of other harmful substances in anti-fouling systems (Art 6(3) and (5); preamble, fifth recital).

[17] TFEU, Art 34-36.

[18] Ibid, Art 258.

[19] Ibid, Art 267.

[20] Ibid, Art 263.

national authorities are bound by the principle can be gauged by the sheer number of preliminary ruling requests[21]and action for infringement.[22]

Thirdly, the EU courts have been applying similar tests for reviewing precautionary measures in health as well as in hazardous substances disputes. According to the GCt, the PP is a general EU law principle that empowers the EU institutions 'to take appropriate measures to prevent specific potential risks to public health and safety.[23] However, one needs to draw a dividing line between, on the one hand, the cases discussed below and, on the other, genuine environmental cases (climate change, waste management, water and nature conservation). With respect to health issues[24] that do prevail in the hazardous substances sector, scientific knowledge is far more advanced than for the environmental sector. Conversely, with respect to environmental cases, the obligation to take account of the most salient scientific findings does not warrant strict rules of evidence.[25] Given that there is no demarcation between genuine health disputes and disputes regarding hazardous substances, we also refer to these health cases.

The following table highlight the coexistence of the PP and the principle of substitution in several of the regulations we comment upon.

Substances	**Acts**	**Regulatory approach**	**Precautionary Principle**	**Principle of substitution**
Existing and new substances	Regulation 1907/2006	Registration, evaluation, authorisation and restriction of chemicals (REACH)	Articles 1(3) and 3	Art 60(4)
Substances and mixtures	Regulation 1272/2008	Classification, labelling and packaging (CLP)		
Pesticides	Regulation 1107/2009	Placing on the market	Art 1(4)	
Pesticides	Directive 2009/128	Use	Art 2(3)	
Biocides	Regulation 528/2012	Placing on the market	Art 1(4)	Art 50
Cosmetics	Regulation 1223/2009	Product safety	Art 19(d)	Art 4(2) (c)
Carcinogens	Directive 2004/37	Protection of workers from the risks related to exposure to carcinogens at work	Art 11	Art 4
Food	Regulation 178/2012	General principles of food law (GFL)	Art 6	

[21] Ibid, Art 267.
[22] Ibid, Art 258-260.
[23] Cases T-429/13 and T-451/13 *Bayer* [2018] T:2018:624, para 109.
[24] For instance, the PP is expressly defined in Art 7 of the Regulation (EC) No 178/2002 laying down the general principles and requirements of food law (hereafter the General Food Regulation or 'GFL').
[25] As stressed by AG Kokott, with respect to subject areas where the PP has not been defined further in connection with the Commission's implementing powers, 'the obligation to take account of the latest scientific findings does not …warrant strict rules of evidence'. AG Kokott' opinion in Case C-343/09 *Afton* [2010] C:2010:419, para 34.

Since environmental issues are peripheral to the regulation of pharmaceuticals,[26] food and feed additives, as well as cosmetics, the case law related to these substances is commented on in as much as it sheds new light on risk assessment and risk management obligations. [27]

2. The risk analysis framework

As far as EU law is concerned, the PP is located within the broader context of risk analysis, which comprises a three-step process: risk assessment, risk management and risk communication. First, the probability of the occurrence of harm is determined using a RA procedure, in which experts examine both hazard and exposure - generally by mathematical modelling - in order to calculate an acceptable or tolerable level of contamination or exposure.[28] Once the RA procedure has been completed, a risk management decision must be taken by politicians. Given that that most members of the public share a different understanding of the term risk, risk communication explores the ways in which expert assessments could be communicated to the public so that the tension between public perceptions and expert judgement could be reduced.

Generally speaking, the EU institutions consider the PP merely as a risk management tool that has nothing to do with RA.[29] Nonetheless, we show below that precaution permeates the two stages of the risk analysis. In fact, the EU Courts' reasoning rests on a two-step approach that mirrors the transversality of precaution on the grounds that the principle constitutes 'an integral part of the decision-making processes leading the adoption of any measure for the protection of human health'. [30]

Moreover, as discussed below, the PP implies neither less scientific assessment nor diminished political responsibility. Rather, the EU courts both reinforce and nuance the role played by scientists in decision-making. They strengthen the importance of science by insisting on the requirement to carry out a systematic RA. By contrast, they also loosen this linkage in two ways: on the one hand, by recognising the limits of scientific expertise and, on the other, by obliging EU institutions, 'while dealing with the first component of the risk assessment', clearly to define the political objectives at issue. In other words, risk

[26] That said, synthetic oestrogens used in contraceptive pills can have serious impacts on aquatic wildlife. See S Jobling and B Metz, 'Ethinyl Oestradiol in the aquatic environment' in *EEA Report 1/2013* , above, 279-307.

[27] The case-law has been influenced by the high number of health disputes. Needless to say, the two spheres, whilst related, are far from being similar. The PP has been construed by courts in the field of health protection, and in particular food safety, with a view to avoiding unduly restrictive practices. All in all, it is doubtful whether the lessons from the case law relating to health safety, in particular with respect to the obligation to carry out RAs, are really relevant in the resolution of all environmental cases.

[28] This division of powers harks back to the 1983 report of the US National Research Council, *Risk Assessment in the Federal Government: Managing the Process* 5-8 (1983).

[29] The Commission's Communication on the PP reflects the belief that precaution is chiefly a question of the political business of deciding how safe is safe: 'The principle, which is essentially used by decision-makers in the management of risks should not be confused with the element of caution that scientists apply in their assessment of scientific data' (summary, para 4). By the same token, according to the GFL, the PP intervenes exclusively as a risk management tool (Art 7).

[30] Case C-236/01 *Monsanto Agricoltura Italia* [2003] C:2003:431, para 133.

management presupposes that the authorities determine from the outset 'the level of protection which they deem appropriate for society'.[31]

Last, account must be made of the fact that the manner in which the EU applies the principle must be consistent with the WTO SPS discipline.

This analysis provides an empirical basis for further discussion in section 4 on how risk assessment and risk management procedures could be conceptualized in a different manner.

2.1. Risk assessment

In this sub-section we explore what experts must know before decision-makers can reach the conclusion whether or not it is appropriate to regulate a hazardous substance.

2.1.1. Risk assessment as a prerequisite for the taking of precautionary action

Risk can be taken seriously provided that appropriate methodological tools are available. The verification of the serious nature of a hypothesis should be undertaken using a specific technique which is recognised as a means of risk assessment. Regarding this obligation, the EU courts clearly stress the need to perform a RA 'which is as complete as possible given the particular circumstances of the individual case'.[32] Thanks to this assessment, the institutions should be able to examine, 'carefully and impartially, all the relevant facts of the individual case'.[33] The 'detailed assessment of the risk',[34] 'presupposes, in the first place, the identification of the potentially negative consequences for health' of the product or the substance.[35] This scientific process consists in the traditional four stages approach: the identification and characterisation of a hazard, the assessment of exposure to the hazard and the characterisation of the risk.[36] What matters is that the object of the RA is 'to appraise the degree of probability of harmful effect on human health'.[37] Without going into the details of RA methodology, we discuss briefly how the EU courts have been interpreting this requirement to new and existing substances such as chemicals, pesticides and biocides.

This calls for a closer analysis of the two-fold task whose components are complementary:[38]
(i) the obligations related to the performance of a scientific assessment of the risk (2.1.2 to 2.1.5),
(ii) the determination of the level of risk deemed to be unacceptable (2.1.6).

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[31] Case C-473/98 *Toolex* [2000] ECR I-5681, para 45; Case T-13/99 *Pfizer*, above, para 151.
[32] Case C- 236/01 *Monsanto Agricultora Italia*, above, para 113; Case T-13/99 *Pfizer*, above, paras 155-156; Case E-3/00 *EFTA Surveillance Authority v Norway* (2000-2001)EFTA Ct. Rep. 73. In that regard, the incomplete analysis of the relevant scientific evidence is apt to vitiate the measure. See Cases C-405/09P, *Netherlands v Commission* [2008] ECR I-8301, para 77.
[33] See, inter alia, Case C-269/90, *Technische Universität München* [1991] C:1991:438, para 14; C-326/05 P, *Industrias Químicas del Vallés* v *Commission* [2007] C:2007:443, para 77; C-405/07 P, *Netherlands* v *Commission*, [2008] C:2008:613, para 56; and C-77/09 *Gowan*, above, para 57
[34] Case C-192/01 *Commission v. Denmark* [2003] ECR I-9693, para 47.
[35] Case E 3-00 *EFTA Surveillance Authority* v *Norway*, above, para 30; Case C-236/01 *Monsanto Agricoltura Italia*, para 113; and Case C-192/01 *Commission v Denmark,* above, *para* 51.
[36] Case T-429/13 and T-451/13 *Bayer*, above, para 113. See also GFL, Art 3(11). In its Communication on the PP, the Commission defines the four components of a risk assessment.
[37] Case C-192/01 *Commission c. Denmark*, above, para 48.
[38] Case T-13/99 *Pfizer*, above, para 149.

2.1.2. Taking into account uncertainties

It may be impossible to carry out a complete RA where such investigations operate at the frontiers of scientific knowledge, the regulators facing a dilemma. On the one hand, they may be tempted to require better risk assessments by requiring the experts to conduct additional research and by refining their techniques. On the other, the quest for sound science is likely to come at the price of continued exposure to hazardous substances as the regulation is deferred.

Rather than rendering the principle nugatory, the EU courts consider the need to take preventive measures with a view to protecting the environment and human health despite the lingering uncertainties. Indeed, the scientific RA is not required to provide the EU institutions with conclusive scientific evidence of the reality of the adverse consequences of the hazardous substances being released into the environment or the seriousness of the potential adverse effects that may result.[39] The Court of Justice of the EU (CJEU) and the General Court (GCt) alike express the view that 'where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the PP justifies the adoption of restrictive measures'.[40]

It comes as no surprise that scientists usually do not acknowledge that their studies are inconsistent, incomplete, uncertain or insufficient. In fact, the implementation of precautionary measures arises mostly within conflictual contexts.[41] Obviously there is not a single scientific view on the existence and the extent of the suspected risk.[42] Those controversies are exacerbated by the fact that some Member States are increasingly distrustful of the findings of the EU's scientific committees and seek to adhere to the findings of their own scientific bodies to support their protective measures.[43] Accordingly, numerous cases (antibiotics in feed,[44] BSE,[45] or chemicals) ruled by the CJEU and the GCt illustrate the

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[39] Case T-31/07 *Du Pont de Nemours*, above, para 140.

[40] Case C-192/01 *Commission v Denmark*, above, para 52; Case C-343/09 *Afton*, above, para 171. See also E-3/00 *EFTA v. Norway*, above, para 31. In virtue of Art 7(1) of the GFR, 'in specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Union may be adopted, pending further scientific information for a more comprehensive risk assessment'. If follows that the provisional risk management measures 'can only occur after the assessment of available information, as provided for in Art 6 of that regulation, has been carried out and has revealed scientific uncertainties regarding the possible harmful effects on health of a food or a substance added to a food'. Case C-282/15 *Queisser Pharma* [2017] C:2017:26, para 55; AG Bobek' opinion, para 50.

[41] In that respect, see the line of reasoning of AG Poiares Maduro in case C-41/02 *Commission v Netherlands* [2004] ECR 1-11357, para 33.

[42] 'The mere expression of a view by the rapporteur Member State at a particular stage of the evaluation procedure on the identification of a safe substance cannot therefore be regarded as sufficient to give rise to certainty on the part of the applicants that that problem had been completely resolved' (Case T-75/06 *Bayer CropScience* [2008] ECR II-2081, para 164).

[43] J Scott and H Vos, 'The Juridification of Uncertainty: Observations of the Ambivalence of the Precautionary Principle within the EU and the WTO' in Ch Joerges and M Dehousse (eds) *Good Governance in Europe's Integrated Market* (OUP, 2002) 271.

[44] Typical in this respect is the ban on virginiamycin which was not based upon a single RA highlighting a specific risk to human health. The EC institutions justified their ban invoking a Danish

tensions arising between different scientific bodies, or between a scientific advisory council and an EU institution.

Hence, a situation in which the PP is applied by definition coincides with a situation in which scientific uncertainty persists.[46] However, it is not entirely clear what the EU courts had in mind in referring to insufficiency, inconclusiveness and imprecision. This means that the factors triggering precautionary action are still open to debate.[47]

A further observation must be made. The EU courts clearly link insufficiency of knowledge with uncertainty as a triggering factor of precautionary measures. In other words, insufficient evidence fosters uncertainty. In that respect, attention should be drawn to the fact in interpreting Article 5(7) of the SPS Agreement, the WTO Appellate Body (AB) took the view that the application of the safeguard clause enshrined in that provision, which previously was deemed to reflect the PP,[48] 'is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence'.[49] As a result, under the SPS Agreement, a precautionary measure could not be triggered by uncertainty *per se* but exclusively by insufficient results.

2.1.3. Jurisprudential requirements regarding the quality of the risk assessment

As a matter of course, the lawmakers offer no guidance on what should be the most reliable scientific evidence available which need to be gathered when the experts are coping with scientific uncertainty. Thus, a particularly significant question arises for risk assessors and risk managers alike: how much information is needed in order to reach a precautionary decision? No easy answer can be given to this question. At first glance, the open-textured terms 'reasonable grounds for concerns' set out in the Commission Communication leave a

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study on laboratory rats providing new evidence on the transfer of antibiotic resistance from animals to human beings, whereas the Scientific Committee for Animal Nutrition (SCAN) contended with the scientific results of that study. The GCt took the view that the EU institutions were not bound to follow the Committee's opinion on the account that the institutions were sufficiently well informed to conclude that the Danish study on live rats could be considered as major fresh scientific evidence enabling the introduction of a precautionary measure. See Case T-13/99 *Pfizer* , above, para 298.

[45] Another case in point is the Court's judgment in *Commission v France*, in which the CJEU condemned the French BSE ban that had been unilaterally imposed. On one hand, France argued that the Commission had not taken into account the minority opinions within the ad hoc scientific committee, whilst on the other hand, the Commission contended that the French could rely only on the scientific opinion of their own national experts. Although the French authorities had founded their justification of the prohibition on imports of British beef on the precautionary principle, the CJEU, in a judgement of 13th December 2001, did not accept this argument. Finding against France, the Court held that a Member State could not invoke its own scientific expertise and ignore RA which had been carried out by the Commission in conformity with EU law. See Case C-1/00 *Commission v France* [2001] ECR I-9989, para 88.

[46] Cases T-429/13 and T-451/13 *Bayer*, above, para 116.

[47] According to the Commission, the following factors are deemed to be relevant to trigger a precautionary measure: 'the absence of proof of the existence of a cause-effect relationship, a quantifiable dose/response relationship or a quantitative evaluation of the probability of the emergence of adverse effects following exposure'. E.g. Commission's Communication on the PP, para 6.2.

[48] *European Communities – DS 26 Measures concerning meat and meat products (hormones)*, AB, Doc WT/DS 26 & 48/AB/R (16th January 1998), para 62.

[49] *Japan-Measures affecting the importation of apples*, DS 245, para 184.

lot of discretion to the EU institutions. Thus far, some lessons can be drawn from the case law.

Ratione materiae, the risk management decision has to based 'on the most reliable scientific data available' [50] or on a 'sufficiently reliable and cogent information' allowing the authority to understand the ramifications of the scientific question raised.51 This detailed assessment of the risk52 must reckon on 'solid and convincing evidence which, while not resolving the scientific uncertainty, may reasonably raise doubts as to the safety and/or efficacy of the … product'. 53 By way of illustration, the failure to take into consideration key studies regarding the link between a substance and Parkinson's disease vitiates the authorisation.[54] Last, the 'reliable scientific evidence' should rely upon recommendations made by international, 55 EU, 56 or national scientific bodies.[57]

Ratione temporis, the risk management decision must be backed up by the scientific data available at the time 'when the precautionary measure was taken'. 58 Moreover, references to the latest international research 59 as well as new evidence 60 on the subject enhance the quality of the decision.61 In particular, restrictions placed on approved substances require the existence of 'new scientific and technical data'.[62]

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[50] Case C-236/01 *Monsanto*, above, para 113; Case C-192/01 *Commission v. Denmark*, above, para 51; Case C-616/17 *Blaise* [2019] C:2019:800, para 94; Case T-13/99 *Pfizer*, above, paras 196-197. Under the Art 5(7) SPS safeguard clause, which mirrors precaution, the measure adopted provisionally must be based on the available pertinent information, including that from the relevant international organisations as well as from SPS measures applied by other Members.

[51] Case T-13/99, *Pfizer*, above, para 162; Case T-70/99 *Alpharma* v *Council* [2002] T:2002:210, paras 173 to 176 ; Case T-257/07 *France* v *Commission* [2011] T:2011:444, para 77; see also, to that effect, Cases T-429/13 and T-451/13 *Bayer*, above, para 117.

[52] Case C-192/01 *Commission* v *Denmark*, above, para 48; and case C-514/99 *Commission* v *France* , above, para 55; case C-42/02 *Commission v Netherlands*, above, para 48.

[53] Case T-74/00 *Artegodan* [2006] T:2006:286, para 192.

[54] T-229/04 *Sweden v. Commission* [2007] ECR I-2437, para 110.

[55] Case T-13/99 *Pfizer*, paras 300-310. In its case law on food additives, the CJEU has been stressing that Member States should rely upon the results of international scientific research and in particular the work of the Community's Scientific Committee on Food. Another case in point is *Toolex*, where the CJEU highlighted that evidence has been gathered by the IARC, set up by the WHO, as to the risk of cancer entailed by the use of the substance trichloroethylene.

[56] As far as national restrictions placed on hazardous substances are concerned, the Commission must take into account the opinion of the EU scientific committee when assessing the proportionality of a Member State's measure providing for more stringent standards than the ones laid down under a directive, calling into question the validity of the EU standards (Case C-3/00 *Denmark v Commission* [2003] ECR II-2643 paras 109-115).

[57] Likewise, national epidemiological studies are also relevant to substantiate the risk (Case C-473/98 *Toolex* , above, para 43). Although the risk management is not subject to the same principles and rules in the US as it is in the EU 'since the legal and political frameworks are different', the RA concerning exposure to acrylamide may also be founded on data from the US. See Case C-199/13 P, *Polyelectrolyte Producers* [2014] C:2014:205, paras 38-42.

[58] Case T-13/99 *Pfizer*, above, para 145.

[59] Case C-236/01 *Monsanto*, above, para 113; Case C-42/02 *Commission v Netherlands*, above, para 49; Case C-192/01 *Commission v. Denmark*, above, para 51; Case C-473/98, *Toolex*, above, para 45; Cases C-154/04 and C-155/05 *Alliance for Natural Health* [2005] ECR I-6451, para 53.

[60] Case T-74/00 *Artegodan*, above, para 194.

[61] Of particular importance is the new evidence gathered by Member States' authorities while assessing requests to depart from EU internal market rules in accordance with Art 114 (5) TFEU.

Furthermore, the RA should be undertaken in 'an independent, objective and transparent manner'.[63] Accordingly, the competent public authority should entrust this task to scientific experts [64] who, on completion of the scientific process, provide it with scientific advice, [65] which, in the interest both of consumers and industry, should be based on 'the principles of excellence, independence and transparency'.[66] Nonetheless, in light of the uncertainty inherent in assessing public health risks …, divergent assessments of those risks can legitimately be made, 'without necessarily being based on new and different scientific evidence'.[67]

Accordingly, the assessors are called upon to investigate as thoroughly as possible and with an appropriate methodology those risks with which they are confronted. In so doing, they should be able to reduce any lingering uncertainties and provide the risk managers with a sufficient scientific basis on which they can endorse their safety measures. Rather than formulating firmly established truths, their task is to formulate and transform the remaining uncertainties into functional estimates upon which decisions can be adopted. Therefore, precaution requires the application of the most rigorous scientific criteria with a view to characterizing uncertainties, filling gaps in knowledge, and furthering research. As a result, it could not be argued that precaution in EU law is anti-scientific.

Failure to deliver new scientific evidence which was not already considered at the time of the adoption of the relevant EU threshold is bound to lead to a rejection of the derogation request. On the contrary, a request for maintaining more stringent national measures pursuant to Art 114 (4) TFEU does not require new scientific evidence (Case C-3/00 *Denmark v Commission*, above, para 62).

[62] PPPR, Art 21(1). Against this background, the GCt ruled that peer–reviewed studies employing an innovative methodology provide the regulators with new knowledge on the effects of neonics on bees. In addition, these studies were deemed to be new on the account that they had been published after the submission of the dossier at the time of the fist approval. See Joined Cases T-429/13 and T-451/13 *Bayer* , above, paras 172, 178 and 179.

[63] Case T-31/07 *Du Pont de Nemours*, above, para 141; Joined Cases T-429/13 and T-451/13 *Bayer*, above, paras 115-117.

[64] Indeed, the institutions are not empowered to entrust a purely advisory body with the duty to perform the risk assessment. E.g. Case T-13/99 *Pfizer*, above, para 289.

[65] The CJEU's decision in *Monsanto* requires that the identification of a health risk posed by a novel food should normally be carried out by 'specialized scientific bodies' charged with assessing the risks inherent in novel food (Case C-236/01, *Monsanto*, above, paras 78-79 and 84*)*. See also Case T-13/99 *Pfizer*, above, para 157.

[66] Case T-31/07 *Du Pont de Nemours* [2013] T:2013:167, para 141. In *Pfizer,* those principles were applied to the Scientific Committee for Animal Nurtition (SCAN) (para 209) and to the Standing Committee. Whereas SCAN abided by those principles, the Standing Committee was not considered by the GCt as an independent scientific body in light of the principle of transparency (para 287). See Case T-13/99 *Pfizer* , above, para 159. Last, it should be stressed that those principles are enshrined in the GFL (Recitals 18, 32 to 36, and Art 6(2)).

[67] E.g. Case C-3/00 *Denmark v Commission* , above, para 63. See P Wennerås, P. 'Fog and Acid Rain Drifting from Luxembourg over Art 95(4)' (2003) *EELR* 169-178. By the same token, in *Pfizer*, the GCt acknowledged that the EU institutions could pay heed to different Member States' reports rather than exclusively the opinion of the appointed scientific body (para 308). In Case T-521/14, the GCt held that a scientific consensus is not required to establish the scientific criteria determining the endocrine disrupting substances in virtue of Art 5(3), of Regulation n° 528/2012. As a result, the Commission is free to favour one scientific approach to the detriment of another one (Case T-521/14 *Sweden v Commission* [2015] T:2015:976, para 73).

2.1.4. Exclusion of hypothetical considerations

It is settled case law that a preventative measure cannot properly be based on a purely hypothetical consideration of the risk, founded on mere conjecture which has not been scientifically verified.[68] Simply put, basic scientific knowledge is necessary. By way of illustration, a generalised presumption of a health risk must be supported by scientific evidence explaining the need to adopt a pre-marketing authorisation scheme.[69]

Risks qualified as residual - that is speculative risks founded upon purely speculative factors and without a basis in science – are thus excluded from the scope of application of the principle. It follows that there must exist a threshold of scientific plausibility. In this way the EU courts aligned themselves with the findings of several decisions handed down by the WTO AB, which has ruled against the PP's application to hypothetical risks. [70]

That said, it should be noted that the concept of 'hypothetical risk' is fraught with controversies. As has been held by the CJEU, these terms must not be interpreted too broadly. If it were the case, many precautionary measures would be precluded. In *Solvay Chemicals*, the CJEU held that a Council decision highlighting the difficulties faced by the scientists to determine the extent of the risk did not amount to a 'purely hypothetical risk'. [71] Likewise, the restrictions placed on the use of an active substance of a plant protection product cannot be considered to be based on purely hypothetical considerations when the EU institutions reckon upon different pieces of evidence such as scientific studies and reports and the ongoing work of the OECD.[72]

2.1.5. Taking into account the multi-faceted effects of hazardous substances

In *Pfizer*, the GCt stressed that the authority must give particular consideration to 'the severity of the impact on human health were the risk to occur, including the extent of possible adverse effects, the persistency or reversibility of those effects and the possibility of delayed effects as well as of the more or less concrete perception of the risk based on available scientific knowledge'.[73] Likewise, the CJEU has also stressed in other cases that it could be appropriate to take into consideration the cumulative effect of the presence on the market of several sources, including both natural and artificial, of a particular nutrient and of the possible

[68] Case T-13/99 *Pfizer*, above, para 143; Case T-229/04 *Sweden* v *Commission*, above, para 161. See also case C-36/01 *Monsanto Agricoltura* , above, para 106; Case C-192/01, *Commission v Denmark* , above, para 49; Case C-42/02 *Commission v Nederland*, above, para 52; Case T-392/02 *Solvay Pharmaceuticals*, para 129; Case C-282/15 *Queisser Pharma* , above, para 60; Joined Cases T-429/13 and T-451/13 *Bayer* , above, para 116; Case E-3/00 *EFTA Surveillance Authority v Norway* , above, para 29. By the same token, the CJEU held that studies on hypothetical emissions of an active substance found in a biocide are not subject to disclosure in virtue of Directive 2003/4/EC on public access to environmental information (Case C-442/14 *Bayer CropScience and Stichting De Bijenstichting* [2015] C:2016:890, para 90).

[69] Case C-333/08 *Commission* v *France*, above, para 97.

[70] *Hormones*, above, para 186; *Australia – DS 21 Measures concerning the importation of salmonids*, Appellate Body, Doc WT/DS18/AB/R (20 October 1998), para 129.

[71] Case T-392/02 *Solvay Chemicals*, above, para 135.

[72] Case C-333/08 *Gowan*, above, para 78.

[73] Case T-13/99 *Pfizer*, above, para153.

existence in future of additional sources which can reasonably be foreseen. 74 In this respect, the EU courts highlighted a particularly sensitive issue given that chemicals cannot be assessed in isolation. In addition, the authorities should request the assessors to emphasize in their studies the possibility of delayed adverse effects, along with the persistency, accumulation and reversibility of such adverse effects. Against this backdrop, they should look at multi-causal pathways and complex interactions.[75] Moreover, the specificity of the risk must be ascertained in the light of geographical, ecological, nutritional or societal particularities.76

Accordingly, this process should enhance the continuous dialogue between regulators and scientists.77 In this way the GCt and the CJEU alike reject the notion of compartmentalisation or demarcation which stems from traditional methods of risk analysis.[78] Lately, the CJEU has been offering some leeway to the Commission in including in the REACH procedures other data or methodologies that those strictly required. 79

[74] Case C-192/01 *Commission v. Denmark*, above, para 50; case C-42/02, *Commission v Netherlands,* para 50; *EFTA* v *Norway*, above, para 29. Regarding the obligation to take into account known the cumulative and synergistic effects in the assessment of an active substance, see Article 4(2) and (3) of the PPP Regulation.

[75] Let be noted that current testing regimes for chemicals are poorly designed to detect indirect effects. See Royal Commission on Environmental Pollution, 24th report, *Chemicals in Products* (London, 2003*)* 16.

[76] Regarding eating habits prevailing in a country and the nutritional need, see Case 174/84 *Commission v Germany* (*Reinheitsgebot*) [1987] ECR 1227 ; case C-192/01 *Commission v. Denmark*, above, para 54. According to the objectives of the PPPR 'Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children'. By the same token, TSCA 2016 requires the EPA to consider risks to susceptible subpopulations in all activities it undertakes.

[77] According to L Bergkamp, 'where risk assessors cannot provide the desired information, or can provide only relatively uncertain or ambiguous information, they should make that clear.' E.g L. Bergkamp, *European Community Law for a New Economy* (Intersentia, 2003) 511.

[78] In *Bayer CropScience,* the CJEU had to assess whether the information regarding the foreseeable emissions into the environment of the residues of the active substance glyphosate could be disclosed in accordance with Directive 2003/4/EC on public access to environmental information. The Court took the view that the information to be communicated encompasses 'studies which seek to establish the toxicity, effects and other aspects of a product or substance under the most unfavourable realistic conditions which could possibly occur, and studies carried out in conditions as close as possible to normal agricultural practice and conditions which prevail in the area where that product or substance is to be used' (Case C-442/14 *Bayer CropScience and Stichting De Bijenstichting* [2015] C:2016:890, para 91).

[79] Given the limits inherent in the methodological criteria for determining the classification of substances' hazards to the aquatic environment, the Commission is required to examine 'carefully and impartially other factors which, although not expressly referred to by the provisions of the regulation at issue, 'are nevertheless relevant' (Case C-691/15P *Commission v Bilbaína de Alquitranes SA* [2017] C:2017:882, para 44). Similarly, in the context of the identification of a substance as being of very high concern under Annex XV of REACH, the Commission can take into consideration other data than those relating to the hazards arising from the intrinsic properties of the substances concerned, such as those relating to human exposure reflecting the risk management measures in force. The substance must be identified in light 'of all the data available, …, having regard to the concerns to which their serious effects on health or on the environment give rise' (Case C-323/15P *Polynt SpA* [2017] C:2017:207, para 41).

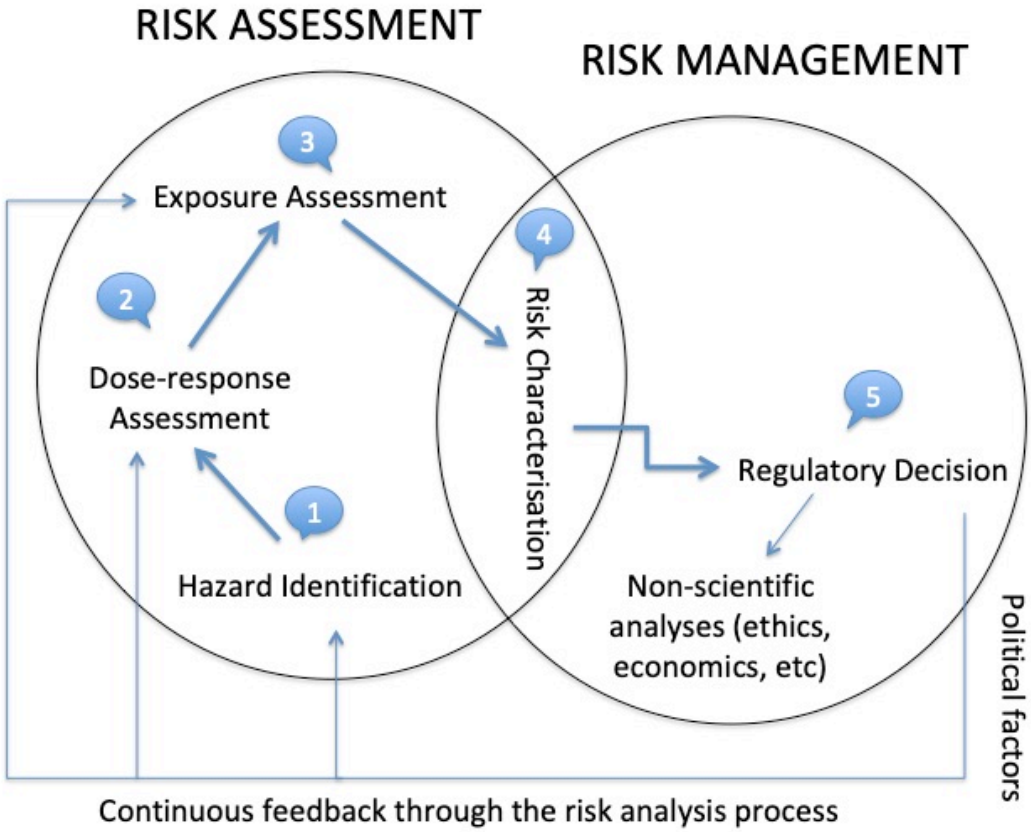
2.1.6. Setting the level of protection

What is considered an acceptable risk is not only a function of the strength of the evidence, but also of the authorities' vision of risk management, which may reflect the public's risk aversion and the pros and cons of alternatives. Accordingly, the determination of the level of risk deemed unacceptable for society is not a rule of thumb. It is settled case law that 'the responsibility for determining the level of risk which is deemed unacceptable for society lies, …, with the institutions responsible for the political choice of determining an appropriate level of protection for society. It is for those institutions to determine the critical probability threshold for adverse effects on public health, safety and the environment and for the degree of those potential effects which, in their judgment, is no longer acceptable for society and above which it is necessary, in the interests of protecting public health, safety and the environment, to take preventive measures in spite of the existing scientific uncertainty'.80 The question arises as to whether the regulator must determine that a risk is deemed to be unacceptable at one death in ten thousand or at one death in a million. Given that the determination of such safety threshold reflects ideological preference in order to privilege either human health or the economy, it cannot be deferred to scientists. Moreover, this obligation is subject to the constitutional requirements to ensure a high level of protection of public health, safety and the environment under treaty law.81

These requirements essentially amount to a reinvigoration of political decision-making, with decision-makers no longer being able to seek refuge behind a facade of scientific pseudo-certitudes presented by their own experts. They are now forced to show their hand and face up to the consequences of their choices. It falls to them alone to set at the outset the level of protection and thereby assume political responsibility. Thus the decision to act, or to refrain from doing so, now takes place within a political context: the determination of the acceptable level of protection.

[80] Case T-31/07 *Du Pont de Nemours*, above, para 145.

[81] Regarding the justification of restrictions on active substances in virtue of the high level of protection, see Case C-138/05 *Stichting Zuid-Hollandse Milieufederatie* [2006] ECR I-8339, para 43; Case C-326/05 P *Industrias Químicas del Vallés* v *Commission* [2007] ECR I-6557, para 74; Case T-334/07 *Denka International* v *Commission* [2009] ECR II-4205, para 92; Case T-31/07 *Du Pont de Nemours*, above, para 145; and Cases T-429/13 and T-451/13 *Bayer*, above, para 123.



2.2. Risk Management

As emphasized above, scientific uncertainty exists whenever there is no adequate theoretical or empirical basis for assigning probabilities to the occurrence or the extent of a risk. Having thus outlined the limits of scientific assessment, we come to the political phase of risk analysis, namely risk management.

In contrast to risk assessment, risk management is the public process of deciding how safe is safe enough. Indeed, societal, economic, traditional, ethical and environmental factors as well the feasibility of controls might appear as factors legitimising the regulation of a specific risk.82 Accordingly, preventative measures, can be adopted, at very short notice if necessary, 'where such measures appear essential given the level of risk to human health which the authority has deemed unacceptable for society'.83 Taking precaution seriously involves making judgments which, though they must be informed as far as possible by scientific assessment, may go beyond it. It follows that a risk management measure could be decided despite the fact that the risk assessors were unable to determine the probability of the

[82] *'Other legitimate factors'* may be taken into account by the risk manager. See GFL, recital 19 and Art 3(12); Regulation (EC) 1829/2003 on GM food and feed, Art 6(6). Likewise, the GCt and the CJEU and have upheld the right to balance different factors in a number of cases (Case C-180/96 P *UK* v *Commission* [1996] ECR I-3903; Case T-199/96 *Bergaderm* [1998] ECR II-2805; Cases T-344 & T-345/00 *CEVA Santé Animale* [2003], para 66). As far as WTO law is concerned, attention to 'other legitimate factors' such as taking into account the real use of the product is deemed to be admissible (AB, *EC: Measures Affecting the Prohibition of Asbestos and Asbestos Products* (WT/ D135/AB/R) paras 162 and 174).

[83] Case T-13/99 *Pfizer*, above, para 393.

occurrence of the risk. 84 That said, the restrictive measures have to be proportionate, non-discriminatory, objective, and consistent with similar measures already taken.[85]

Account must also be made of the fact that the discretionary powers of the authorities as regards the type of preventive measure must be exercised in a manner which is consistent with a range of constraints stemming from EU law, some of which were outlined above (e.g. risk assessment, consultation of scientific bodies), others which will be discussed below (proportionality, impact assessment).

The discussion will be structured in the following manner. It will start by considering the issue of the non-binding nature of scientific opinions (2.2.1), moving on to address the issue of which risks are deemed to be unacceptable (2.2.2). The next subsections will be dedicated to the precautionary procedures (2.2.3) and the pivotal role played by the principle of substitution (2.2.4).

2.2.1. Scientific opinions: a necessary but not sufficient condition for risk regulation

As discussed above, given that science is the cornerstone of precaution within the field of hazardous substances and other health issues, the decision making stage is not entirely separate from the scientific stage which is supposed to precede it.

However, whereas experts have scientific legitimacy, they have neither democratic legitimacy nor political responsibilities,86 and their opinions are non-binding.87 EU institutions cannot therefore be criticised in cases concerning complex and sensitive public health issues for having taken the time necessary to address the relevant scientific issues and, in particular, for having referred such issues for a second examination by the competent scientific committee even though the act is silent on this point.88 On another note, the institutions 'may disregard the conclusions' of the official opinion, 'even though, in some places, it relies on certain aspects of the scientific analysis in the opinion.'89 In other words, the institutions may avail themselves of those parts of the scientific reasoning which they do not dispute.

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[84] This approach is entirely consistent with the WTO AB's judgment in the *Hormones* case, where it rejected the inclusion of the word 'probability' in the panel's interpretation of the definition of risk assessment, considering that it introduced a quantitative dimension of the notion of risk and therefore implied a 'higher degree or a threshold of potentiality or possibility', whereas the word 'potential' in para 4 of Annex A of the Agreement only relates to the possibility of an event occurring (*EC– DS 26 Measures concerning meat and meat products (hormones)*, AB, Doc WT/DS 26 & 48/AB/R (16th January 1998), paras 183-184).

[85] Case C-343/09 *Afton Chemical*, above, para 61; Case T-31/07 *Du Pont de Nemours*, above, paras 142 and 149.

[86] Case T-13/99 *Pfizer*, above, para 201.

[87] Case C-405/92 *Armand Mondiet* [1993] ECR I-6136, paras 31-32; Case C-120/97 *Upjohn* [1999] ECR-I-223, para 47.

[88] Case C-151/98 P *Pharos* v *Commission* [1999] ECR I-8157, para 26; Case C-352/98 P *Bergaderm and Goupil* v *Commission* [2000] ECR I-5291, para 66. When the Commission finds itself facing a situation of continuing scientific uncertainty characterized by divergences between the scientific opinions adopted by the different consultative organs, it does not appear unreasonable for the Commission to await the adoption of a re-evaluation of the risks at stake. In such a situation, the Commission does not disregard in a clear and serious manner the limits of its discretion. Case C-198/03P, *Commission v CEVA Santé Animale SA* [2005] C:2005:445, paras 82-89.

[89] For instance, the Commission can depart from EFSA's scientific opinion inasmuch it can appropriately justify such departure. See Case T-13/99 *Pfizer*, above, paras 199-200.

The authority applying the PP thus enjoys considerable discretion regarding the methods of analysis. In *Gowan*, the CJEU held that in restricting the period during which a hazardous substance can be placed on the market, the Commission and the Council were not bound by the national report on the substance and the opinion of the EU scientific committee that has been validating this report. The institutions remained thus entitled to adopt different risk management measures from those proposed by the rapporteur.[90] Likewise, the PP allows the Commission to regulate substances in short deadline. Because this institution enjoys a broad discretion in placing restrictions on neonicotonoids,[91] it was fully entitled to take the view that the PP precluded 'the setting of a deadline…that would enable later scientific knowledge to be taken into account'.[92]

Some lawyers appear to have been fighting a rear-guard action in submitting constantly new studies that have on the face a certain platina of acceptability but that contribute little or nothing to the resolution of the lingering uncertainties. In so doing, they tend to delay the regulatory process. The Commission is empowered to rebut these studies in producing a credible demonstration that a scientific consensus as emerged on the contested issue. An indefinite postponement of the deadline for evaluating an active substance would run counter to the aim of the regulation.[93] By way of illustration, the GCt held that the completion of a guidance document would 'necessarily have delayed the Commission's becoming aware, however imprecisely, as risk manager, of the level of risk posed by the substance covered, and, as a result, the taking of a decision'.[94]

Last, the EU institutions are subject to specific obligations when deciding to set aside a scientific opinion in order to upgrade the level of protection. They 'must provide specific reasons for their findings by comparison with those made in the opinion and its statement of reasons must explain why it is disregarding the latter.' In addition, as a matter of procedure, 'the statement of reasons must be of a scientific level at least commensurate with that of the opinion in question'.95 The GCt has held that the obligation to state comprehensively the reasons is particularly strict in the event of scientific uncertainty.96 Given that understanding RA requires substantial expertise and resources, only few institutions and national agencies can generate new data in order to rebut the contested RA.

Although most of the scientific opinions do not bind the institutions, any unlawfulness of a requested opinion could be regarded as a breach of an essential procedural requirement, thereby rendering the institutions' decision unlawful. As a result, the courts may be called upon to review the formal legality of a scientific opinion, albeit restrictively (internal consistency, statement of reasons).97

[90] Case C-77/09 *Gowan*, above, para 60.
[91] A class of systemic water-soluble insecticides chemically related to nicotine.
[92] Joined Cases T-429/13 and T-451/13 *Bayer*, above, paras 306-310.
[93] Case T-75/06 *Bayer CropScience*, above, para 41.
[94] Ibid, para 301.
[95] Case T-13/99 *Pfizer*, above, para 199.
[96] Ibid, para 200.
[97] Ibid, paras 199-200.

2.2.2. Acceptable Risk

Since science is seen as a necessary but not sufficient condition for risk regulation, the political actors are allowed a significant degree of discretion in relation to the means of achieving safety objectives in the face of uncertainty. However, their room for manoeuvre is far from being unfettered.

2.2.2.1. Weighing of interests and high level of protection

The EU institutions and the Member States must ensure under Articles 114(3), 168(1), 169(3), and 191(2) TFEU an increased level of protection of human health, consumer protection and the environment. Given that this undefined constitutional requirement offers no guidance about actions to take in face of uncertainty, one is driven to the conclusion that the PP does not determine a general level of protection. It just makes it easier for institutions to enact preventive measures. On this matter, the GCt has held that: 'it is for the [EU] institutions to determine the level of protection which they deem appropriate for society'.[98]

- Accordingly, it is by reference to that level of protection that the EU institutions may be required to take preventive measures in spite of existing scientific uncertainty. Therefore, determining the level of risk deemed unacceptable involves 'the [EU] institutions in defining the political objectives to be pursued under the powers conferred on them by the Treaty'. This level needs not technically be the highest level possible.[99]
- Likewise, in the absence of harmonisation and insofar as uncertainties continue to exist in the current state of scientific research, it is for the Member States to decide on the desirable level of protection of human health and life.[100] This means that a risk-management decision rests with each Member State, which has discretion in determining the level of risk it considers appropriate, in accordance with the PP.[101]

Once it is shown that uncertainty persists in the current state of scientific research on the harmful effects for health of certain substances, the margin of discretion of Member States relating to the choice of the level at which they intend to guarantee the protection of public health is particularly large.[102] The EU courts have already stressed that the competent public authority has, when confronted by uncertainty, to undertake a balancing of its obligations and then decide either to wait until the results of more detailed scientific research became available, or to act on the strength of existing scientific knowledge. Where measures intended to protect human health are at issue, this balancing process depends on the level of risk determined by the authority 'as being unacceptable for society' within the context of the particular circumstances of each individual case.[103] Moreover, in contrast to many

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[98] Ibid, para 151.
[99] On the reasonableness of the obligation to ensure a higher level of environmental protection, see the Court's case C-284/95 *Safety Hi-Tech* [1998] ECR I-4301, para 49
[100] Case C-174/82 *Sandoz* [1983] ECR 2445, para 16; Case C-42/90 *Bellon* [1990] ECR I-4863, para 11; Case C-400/96 *Harpegnies* [1998] ECR I-5121, para 33; Case C-192/01 *Commission* v *Denmark* , above, para 42; and C-333/08 *Commission* v *France* [2010] C:2010:44, para 85. See also Case E-4/4 *Pedicel*.
[101] Case C-286/02 *Bellio F.lli Srl v Prefetura di Treviso* [2004] ECR I-3465, para 58.
[102] 29 April 2010, *Solgar Vitamin's France* C-446/08 [2010] C:2010:233, paras 35 and 36; and Case C-282/15 *Queisser Pharma*, above, para 60.
[103] Case T-13/99 *Pfizer*, above, para 161.

environmental agreements requiring either significant or irreversible risk,[104] the EU regulations structured around the PP refer to a risk without such criteria.[105] Accordingly, they offer a broader margin for manoeuvre to the institutions.

This reasoning is not devoid of legal consequences. One has to bear in mind that the level set out by the lawmakers is likely to vary significantly as it can be set either in qualitative or quantitative terms. This wide discretion entails the risk that at the end of the day a low level of protection shall belittle the recourse to the PP. In practice this means that the fact of the decision maker paying little heed to the level of protection would limit any subsequent recourse to this principle. Conversely, giving at an early stage the protection of health or the environment precedence over economic considerations would enhance the principle. That being said, this discretion is far from being absolute. Indeed, with respect to the enactment of environmental precautionary measures, the institutions are obliged to seek a high level of environmental protection.[106]

2.2.2.2. Balancing economic and environmental interests

Nonetheless, the level of environmental and health protection is not the only matter that the decision-makers have to take into consideration. Much importance is conferred to the socio-economic interests. However, a striking feature of the EU courts' case law is that 'the protection of the environment takes precedence over economic considerations, with the result that it may justify adverse economic consequences, even those which are substantial, for certain traders.[107]

As the courts are silent on what is meant by its assertion 'by giving precedence to the requirements related to the protection of those interests over economic interests', one could wonder whether that principle must be strictly applied. Put simply, is that principle of giving precedence uncompromising? It has nonetheless to be balanced with the principle of proportionality. For instance, in *Bellio F.lli Srl*, the CJEU took the view that even if the need to safeguard public health has been recognised as a primary concern, the principle of proportionality must be respected.[108]

That said, the question of the appropriate means for averting the manifestation of uncertain risks is an open-ended one. Indeed, the various judgments commented in this section do not address the issue of which measures are to be taken in light of the PP.

It is settled case law that it is for the institution concerned to determine the level of protection which it considers appropriate for society, depending upon the circumstances of the particular case.[109]

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[104] N de Sadeleer, *Environmental Principles* (OUP, 2002) 162-7.
[105] GFL, Art 5. See our previous developments on the level of protection experts have to take into consideration while carrying out their risk assessment.
[106] Case C-333/08 *Gowan* [2010], para 71.
[107] See, to that effect, Case T-392/02 *Solvay,* above, para 125; Case T-177/02 *Malagutti,* above, para 186; Case T-74/00 *Artegodan*, above, para 186; Case T-475/07, *Dow AgroSciences* [2011] T:2011:445, para 143; Case T-483/11 *Sepro Europe* [2013] T:2013:407, para 85; Case T-269/11, *Xeda International* v *Commission* [2014] T:2014:1069, para 138; Case T-584/13 *BASF Agro* [2010] T:2018:279, paras 55 and 168.
[108] Case C-286/02 *Bellio F.lli Srl*, above, para 60.
[109] Case T-13/99 *Pfizer*, above, paras 151 and 153.

2.2.2.3. Zero risk and zero tolerance

The adoption of a preventive measure 'cannot be made subject to proof of the lack of any risk, in so far as such proof is generally impossible to give in scientific terms since zero risk does not exist in practice'.110 Indeed, such measures may deemed to be disproportionate.[111] Within this context one can appreciate the significance both of the recognition by the AB of the WTO that the level of protection adopted within a risk management framework could itself aim at a zero risk,[112] and of the EFTA Court's admission that a precautionary measure could in exceptional circumstances be directed at a zero risk level.[113]

Does this reasoning necessarily imply that any policy designed to eliminate risk is undesirable? In our view, one has to distinguish zero risk from zero tolerance. [114]

We are of the view that nothing precludes the EU institutions from endorsing a 'zero tolerance' policy with regard to certain risk factors for which the producer cannot adduce proof that they are acceptable.[115] In particular, the concept of zero tolerance may, through the PP, result in the total ban of a substance provided that its potential risk is supported by elementary scientific data. Additionally, according to the CJEU's settled case law on the proportionality of national measures limiting the use of food additives, the determination of the extent to which Member States intend to guarantee the protection of the health and life of persons is - in the absence of an exhaustive harmonisation at EU level – at their own decision, although they must of course have given consideration to the requirements of the free movement of goods. The margin for manoeuvre reserved to the Member States specifically allows them to set a very high level of protection where technical knowledge is not certain.[116] As convincingly argued by T. Christoforou, the pursuit of a zero risk does not however mean

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[110] Case T-31/07 *Du Pont de Nemours* [2013], para 140; see also, to that effect, case T-392/02, *Solvay Pharmaceuticals*[2003] T:2003:277, para 130.

[111] Communication on the PP, n° 6.3.1, para 18. See Case T-13/99 *Pfizer,* above, para 145 ; Case T-70/99 *Alpharma,* above, para 158.

[112] *Hormones*, above, para 187.

[113] EFTA case E-3/00, above, para 23.

[114] Regarding the 'zero risk' imperative, see Case C-446/08 *Solgar Vitamin's France* [2010] I-3973.

[115] Case C-121/00 *Hahn* [2002] ECR I-9193, para 93; Case T-392/02 *Solvay Chemicals,* above, para 97.

[116] In *Melkunie*, the CJEU found that zero-tolerance towards the admissibility of pathogenic micro-organisms in food waste was admissible, falling under the protection of human health under Art 36 TFEU (Case 97/83 *Melkunie* [1984] ECR 2367, para 15). In *Walter Hahn,* the Court accepted that a Member State could opt for a tolerance level equal to zero regarding the presence of listeriosis in fish (Case C-121/00 *Walter Hahn* [2002], para 31). The GCt endorsed the same reasoning in its *Solvay Pharmaceuticals* as regards the prohibition of an additive to animal feedstuffs. In *Fedesa* - recognised as one of the earliest instances of the application of the PP - the Court upheld the validity of measures based on a desire to eradicate consumer risk (Case C-331/88 *Fedesa* [1990] ECR I-4023). By the same token, the zero tolerance approach consisting of the prohibition of any contamination, even accidental, by unauthorised substances in feedstuffs is proportionate (Case C-286/02 *Bellio F.lli Srl*, above, para 61). Taking account of the genuine risk that the intake of fluoride in food supplements will exceed the upper safe limit established for that mineral, a Member State may set the maximum amount of fluoride which may be used in the manufacture of food supplements at a zero level (Case C-446/08 *Solgar Vitamin's France*, above, para 47).

that one should seek to eliminate all risks; the aim is by contrast to limit their manifestation as far as possible.[117]

Finally, it could be argued that the decision to eliminate every risk is an issue involving purely political responsibility, and is as such one in relation to which judicial review should be highly deferential.

2.2.3. Precautionary procedures

The PP has steadily expanded its dominion in the field of secondary law. It has been fleshed out in a broad range of measures ranging from prior authorisation schemes,[118] pre-market system,[119] restrictions brought to a marketing license,[120] registration of chemicals,[121] to bans.[122] By way of illustration, the prior authorisation and approval procedures put in place by the PPPR (and, previously, by Directive 91/414) 'emanate from the principle'.123 By the same token, the obligation to register monomers 'satisfies' the PP as referred to in REACH Regulation.[124] What is more, recourse to the PP does not necessarily imply urgency.[125]

An authorisation scheme indiscriminately covering all hazardous substances without distinguishing possible categories or types of substances is not contrary to the provisions of GFL Regulation. However, the CJEU held that the risk analysis which the competent national authorities must carry out pursuant to Article 6 of that regulation must still clearly identify the common elements or characteristics of the substances concerned, whose real risk for human health cannot be excluded.[126]

2.2.4. Substitution principle

The EU has embraced an important element of the PP by recognising the substitution principle, according to which the mere existence of an alternative substance that appears to be less dangerous than the substance in question is sufficient basis for a prohibition. This principle can be found in both Directive 89/391/EEC regarding the health and safety of workers at work and Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens at work,[127] which require employers to eliminate or reduce risks by replacing one dangerous substance with another, less dangerous, substance.[128]

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[117] T Christoforou, 'The Regulation of GMOs in the EU : The Interplay of Science, Law and Politics', 41 (2004) CMLRev 637-709.
[118] This is the case of a regime of *prior approval* of the plant protection. See AG Sharpston' opinion in Case C-616/17 *Blaise*, above, para 50.
[119] Case C-333/08 *Gowan*, above, para 74
[120] There is no inconsistency between the grant of a temporary authorisation and the simultaneous pursuit of the same authorisation. See Case T-392/02 *Solvay Chemicals,* above, para 108.
[121] Case C-558/07 *S.P.C.M.*[2009] ECR I- 5783, para 54.
[122] The proportionality principle does not preclude the adoption of bans of hazardous substances in light of the PP. See Case T-13/99 *Pfizer*, above, para 457.
[123] Case T-31/07 *Du Pont de Nemours*, above, para 133.
[124] Case C-558/07 *S.P.C.M.,* above, para 54.
[125] Case T-392/02 *Solvay Chemicals*, above, para 135.
[126] Case C-282/15 *Queisser Pharma*, above, para 64.
[127] This Directive is an individual Directive within the meaning of Art 16(1) of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work.
[128] Art 4(1).

Moreover, the principle is enshrined in the BPR and PPPR alike[129] as well as in REACH.[130] The latter regulation calls on businesses applying for authorization for Substances of Very High Concern (SVHC) which cannot be adequately controlled 'to analyse the availability of alternatives'.[131] Substitution must be articulated with the obligation to grant the authorisation provided that the socio-economic benefits outweigh the health and environmental risks.[132] That being said, substitution does not apply either to all applications or to all substances.

The substitution principle can play an important role in assessing the proportionality of measures that distort the free movement of goods. For instance, the CJEU ruled in *Toolex* that a Swedish ban on the toxic substance trichloroethylene, a measure having an effect equivalent to a quantitative restriction within the meaning of Article 34 TFEU, was compatible with the Treaty in that it was necessary for the effective protection of the health and life of humans. In particular, the Court stressed that the system of individual exemptions to the Swedish ban appeared to be appropriate and proportionate in that 'exemptions are granted on condition that no safer replacement product is available and provided that the applicant continues to seek alternative solutions which are less harmful to public health and the environment'.[133] The Court stressed that those requirements were compatible with the 'substitution principle', which emerges *inter alia* from Directives 89/391/EEC and 90/394/EEC.

3. Judicial review of the risk management process

3.1. Introductory remarks

The PP is likely to be seen as a double-edged sword. On the one hand, in actions for annulment brought by private parties[134]against an EU measure aiming at limiting health or environmental risks, the institutions have been regularly invoking precaution to justify the soundness of their measures. On the other hand, in infringement cases brought by the Commission against Member States' health and environmental measures[135] hindering free trade in goods, the national authorities have also been invoking the principle as a shield.[136]

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[129] BPR, Art 4(2) c) and PPPR, Art 50. The European Commission is required to define a list of active substances in pesticides considered to be 'Candidates for Substitution' (CfS) that go through a comparative assessment.

[130] G Winter, 'Risks, Costs and Alternatives in EC Environmental Legislation: The case of REACH', in de Sadeleer, *Implementing Precaution*, above, 313-330. Where there are still uncertainties regarding the unavailability of alternatives for a dangerous substance used in varnishes and paintings, the applicant has not met the burden of proof of the absence of an alternative solution required by Article 60(4) REACH. Consequently, the authorisation cannot be granted by the Commission to the undertaking wishing to continue to use the substance. Moreover, the Commission must, in accordance with its duty of diligence, examine the condition concerning the unavailability of alternatives in greater detail. As long as the uncertainties related to the scientific assessment have not been dispelled, the Commission is not entitled to grant an authorisation, even a conditional one. Case T-837/16 *Sweden v Commission* [2009] T:2019:144, paras 79, 84, 85.

[131] Art 60(4). See also Recitals 12, 72, 73.

[132] Art 60(5).

[133] Case C-473/98 *Toolex* [2000] ECR I-5702, para 47.

[134] TFEU, Art 263(4).

[135] Ibid, Art 258.

[136]There has been increasing use of the PP by Member States to derogate from the principle of free movement of goods where the matter has not been harmonized or with a view to departing from internal market harmonization in virtue of Art 114(4) and (5) TFEU. See de Sadeleer, *EU*

To some extent, EU secondary law may also encourage the invocation of the principle by national authorities.[137] Nonetheless, the fact that the intensity of review exercised by EU Courts varies extensively calls for two observations.

Firstly, one needs to draw a dividing line between, on the one hand, the lawsuits brought by a private party against an EU act and, on the other hand, the actions for infringement of EU law brought by the Commission against Member States. With respect to cases regarding actions for annulment, the PP generates a review test of the adequacy of scientific evidence supporting the contested measure. In contrast, in adjudicating references for a preliminary ruling regarding the consistency of national restrictions placed on substances with harmonized rules, the CJEU resorts to precaution as an interpretative principle.

Secondly, the stricter approach endorsed by the EU courts with respect to hazardous substances can be explained by the fact that those cases chiefly deal with the placing on the market of products and substances where a fundamental principle of Treaty law,[138] the free movement of goods, is at stake.[139] In the genuine environmental cases (nature conservation, water and air pollution), the courts have to balance economic freedoms - i.e., the right to property, the freedom to pursue a trade or business- *vis-à-vis* an EU public interest -i.e., the objective of a high level of health's protection-. In contrast, in the health-related cases, the courts have to weigh an EU public interest – the free movement of goods enshrined in articles 34-36 TFEU- against a national public interest -the willingness to depart from EU harmonized standards according to Article 114(4)(5) TFEU or to maintain a measure impinging upon trade according to Article 36 TFEU or the rule of reason.[140] This may explain the more stringent requirements imposed by EU courts on the Member States' measures than on the EU institutions' acts.[141]

3.2. Judicial restraint in reviewing the exercise of the discretionary power

As regard the actions for annulment, it needs merely to be pointed out that the EU courts are fully aware of the difficulties of regulating either in controversial cases or where action is urgently needed. Regarding health and environmental risks, the courts have been stressing that the institutions enjoy a wide discretion in determining the scope of the precautionary measures according to the nature, the seriousness and the scope of the risk.[142] In particular,

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Environmental Law, above, 358-381. See in that effect, Case C-3/00 *Denmark v. Commission*, above; and Joined Cases T-366/03 and T-235/04 *Germany v. Austria* [2005] ECR II-4005.

[137] By way of illustration, pursuant to Art 1(4) of the PPPR (EC) No 1107/2009 'Member States shall not be prevented from applying the PP where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorized in their territory.'

[138] Case C-3/00 *Denmark v. Commission*, above.

[139] Opinion AG Poiares Maduro in Case C-41/02 *Commission v. Netherlands* [2004] ECR I-11375, at para 30. According to the Advocate General, 'the discretion that Member States are allowed as regards recourse to the precautionary principle is increasingly restricted the further they depart from scientific analysis and the more they rely on policy judgment', in particular in cases of lack of data on account of the novelty of the product or a lack of resources in conducting scientific research (para 33). The Court of justice did not address that issue.

[140] de Sadeleer, *EU Environmental Law*, above, 259-334.

[141] A Alemanno, *Trade in Food* (Cameron & May, 2007) 107.

[142] It is settled case law that only manifest and grave failure to have regard to the limits of the discretion conferred to the institutions can result in a sufficiently serious breach of a rule of law

where the EU institutions are called upon to make 'complex assessments', they enjoy a wide measure of discretion when they adopt risk management measures.[143] Simply put, the EU has a discretionary power corresponding to its political responsibilities.[144]

Therefore, the EU courts rightly show themselves to be little inclined to penalise institutions for any errors which they may have committed in their desire to safeguard the general interest. Hence, review must be limited in cases in which the institutions are required to undertake a scientific RA and to evaluate highly complex scientific and technical facts.[145] As discussed below, the review must be circumscribed to (1) the compliance with the relevant procedural rules, (2) the accuracy of the statement of facts, (3) and the existence of a manifest error of appraisal or misuse of powers.[146] In particular, though the review of the merits of the case is rather narrow, the EU courts must verify whether the institution complied with the procedural requirements laid down by the various regulations on chemicals. In that connection, they have to examine 'carefully and impartially, all the relevant facts of the individual case, facts which support the conclusions reached'.[147]

Before the 2000s, the EU courts endorsed a minimal review of both the EU institutions' and Member States' precautionary measures. The courts have shown judicial restraint as they are not entitled to substitute their assessment of the facts for that of the EU institutions on which the Treaty confers sole responsibility for that duty.[148] It comes thus as no surprise that the CJEU[149] and the GCt[150] alike have on various occasions rejected lawsuits founded on manifest errors of appraisal committed by the institutions when taking decisions which were not fully justified in the light of prevailing scientific knowledge. Applicants have thus rarely been successful in their challenge of an insufficient or an over-zealous precautionary measure.[151] In so doing, the courts gave the EU institutions much leeway.

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capable of resulting in the EU's incurring non-contractual liability. See Case T-31/07 *Du Pont de Nemours*, above, para 156.

[143] Case C-180/96 *UK v Commission*, above, para 97; Case T-74/00 *Artegodan*, above, para 201; Case T-392/02 *Solvay Chemicals*, above, para 126; Case C-77/09 *Gowan*, above, paras 55 and 82; Case C-343/09 *Afton* , above, para 28; Case C-288/13P *Rüttgers* [2014].

[144] Case C-157/96 *NFU* [1998] ECR II-1211, para 61; Case C-331/88 *Fedesa*, above, para 14; Case C-368/89 *Crispoltoni* [1990] ECR I-3715, para 42; Case T-429/13 and T-451/13 *Bayer Crop Science*, above, para 506.

[145] Case T-13/99 *Pfizer*, above,, para 169; Case T-31/07 *Du Pont de Nemours*, above, para 154.

[146] Case C-333/08 *Gowan*, above, para 56.

[147] See, inter alia, Case C-269/90 *Technische Universität München*, above, para 14; Case C-333/08 *Gowan* , above, para 57.

[148] Case T-13/99 *Pfizer*, above, para 169.

[149] Case 174/82 *Sandoz* [1983] ECR 2445, para 17; Case C-331/88 *Fedesa* [1990] ECR I-4023, para 9; Case C-180/96, *UK v. Commission*, above, paras 99 and 100; and Case C-127/95, *Norbrook Laboratories Ltd* [1998] ECR I-1531.

[150] See Case T-199/96 *Bergaderm* [1998] ECR II-2805, paras 66 and 67. In the cases T-13/99 *Pfizer*, above, and T-70/99 *Alpharma*, above, the GCt noted that 'the legislature has a discretionary power which corresponds to the political responsibilities given to it by [Art 40 TFEU] and [Art 49 TFEU]'(para 412). The Court concluded that the adoption of the regulation in question did not constitute a manifestly inappropriate measure for the achievement of the pursued objective. See also Case T-257/07P *France v. Commission* [2011] T:2011:444, para 67.

[151] V Heyvaert, ''Facing the Consequences of the Precautionary Principle in EC Law' 31 (2006) *ELR* 185.

However, since the landmark *Pfizer* judgment, the courts' review has become much stricter. This shift can be explained by three factors:

- the influence of the US discourse on risk issues,152
- the influence of the WTO DSB case law after the *Hormones* decision,
- the 2000 Commission Communication on the PP that have been taken as an 'authoritative account' of the principle.153

Unsurprisingly, the case law has become rather erratic on the account that nowadays a procedural standard of review coexists with a more deferential standard of scrutiny.[154] The following table highlights the differences between a deferential and a more intrusive scientific Court's review.

Paradigm	**Evidence-based risk regulation paradigm**	**Prudential regulation paradigm**
Standard of Review	Procedural Standard of Review	Deferential Standard of Review
Scientification of the Court's review	Intrusive review of the scientific evidence underpinning the contested measure	Broad discretion of the decision-maker as regards the choice and use of the assessment methodology
Case law	*Gowan* (C-77/09) *Afton* (C-343/09) *Balbaina I* (C-287/13 P)	*Balbaina II* (C-691/15 P)

A stricter judicial review is likely to require more, rather than less, quantitative analysis. In addition, asking scientifically untrained judges to review the validity of RAs give them 'a complex and difficult task to assess the substantive merits of sciences'.[155] What is more, in placing more stress to ground regulatory measures on "good science" rather than on the need to provide effective protection in the face of uncertain risks, a strict judicial review is likely to render the PP nugatory.

3.3. Stricter interpretation of the marketing requirements

Likewise, the PP sheds new light on the duty to place on the market only products not endangering human health. In this respect, the *Paraquat* judgment handed down by the GCt is a case in point. Adjudicating an action for annulment lodged by Sweden against a Commission decision listing Paraquat – a highly poisonous chemical - under Annex I to Directive 91/414/EC[156] in spite of the hazards entailed by its use, the GCt stressed that the safety requirement had to be interpreted 'in combination with the precautionary principle'. It

[152] Fisher, *Risk Regulation*, above, 223.
[153] Ibid, 220. According to this author, the 2000 Commission on the PP accelerated the shift from a 'deliberative constitutive' paradigm to a 'rational instrumental paradigm'.
[154] GC Leonelli case note under Case C-691/15 P *Balbaina II* 55 (2018) *CMLR* 1217-1250.
[155] Cranor, *Toxic Torts*, above, 368.
[156] Paraquat is an active substance used in plant-protection products. Such active substances could be listed under Annex I to former Directive 91/414 (replaced by Regulation (EC) No 1107/2009) on pesticides inasmuch as the use of the product, 'in the light of current scientific and technical knowledge', had any harmful effects on animal health.

follows that 'in the domain of human health, the existence of solid evidence which, while not resolving scientific uncertainty, may reasonably raise doubts as to the safety of a substance, justifies, in principle, the refusal to include that substance in Annex I to Directive 91/414'.[157] The substance may be approved if it is established 'beyond a reasonable doubt' that its use will not have harmful health or environmental effects.[158]

In a challenge brought by the European Parliament and Denmark against a general exemption granted by the Commission for the use of a chemical hazardous substance known as a flame retardant, deca-BDE, in electrical and electronic equipment, the applicants argued that the conditions laid down by the EU legislature in Article 5(1) of Directive 2002/95 on the restriction of the use of certain hazardous substances in electrical and electronic equipment had not been met. They claimed that the decision at stake ran counter to the objective pursued by that legislature of establishing the principle of the prohibition of the components referred to in that directive. In analysing the preamble, the Court reached the conclusion that the intention of the legislature was to prohibit hazardous products referred to in the directive and to grant exemptions 'only in accordance with carefully defined conditions'.[159] The Court expressed the view in its *obiter dictum* that:

'Such an objective, in compliance with [Article 168 TFEU], according to which a high level of human health protection is to be ensured in the definition and implementation of all Community policies and activities, and in compliance with [Article 192(2) TFEU], according to which EU policy on the environment is to aim at a high level of protection and is based on the principles of precaution and preventive action justifies the strict interpretation of the conditions for exemption.'[160]

In this second judgment, the PP was not applied by the CJEU as a ground for annulment, but as an interpretative principle supporting a strict interpretation of the basic safety requirements laid down by the EU lawmaker.

Last but not least, these two judgments have thrown into relief the willingness of both the GCt and the CJEU to investigate in detail the scientific evidence underlying the contested decisions to list substances that pose significant risks. Therefore, these judgments are markedly at odds with previous case law according to which judicial review of scientific evidence has to be limited.

3.4. Testing the proportionality of the precautionary measure

The PP is intertwined with the principle of proportionality, which is one of the general principle of EU law. As a matter of fact, most of the important cases decided by the EU Courts with respect to precaution were brought by claimants averring that the contested regulation had been adopted in violation of the principle insofar as the measure in question was manifestly inappropriate for realising the pursued objective and that the institutions, which had a choice between various measures, had nonetheless not chosen the least restrictive one.

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[157] Case T-229/04 *Sweden v. Commission*, above, paras 161 and 224.
[158] The Court criticized the Commission for claiming that there were no indications of neurotoxicity associated with paraquat and of not considering in its studies the link between paraquat and Parkinson's disease. The active substance was not relisted after the GCt judgment.
[159] Case T-229/04 *Sweden v. Commission*, above, para 170.
[160] Cases C-14/06 and C-295/06 *EP v. Commission* [2008] ECR I-7441, paras 74 – 75.

3.4.1. Adequacy, necessity and weighing of interests tests

While the function of the proportionality principle is well understood, its modes of application still give rise to conflicting opinions. According to settled case-law, the principle of proportionality requires that measures implemented through EU provisions should be appropriate for attaining the objective pursued and must not go beyond what is necessary to achieve it.[161]

First, regarding the appropriateness of an EU harmonised measure, the Member State must demonstrate that the implementation of a precautionary measure is necessary in order to ensure that specific products (novel foods, food additives, enriched foodstuffs) do not present any danger for the consumer.[162] In *SPCM*, the CJEU held that the registration under REACH of monomers has to be regarded as a means of enhancing the protection of the public and professional down the supply chain.[163]

Second, the necessity test requires a comparison between the various measures which are capable of achieving the desired result, and that the one which causes the least inconvenience be retained. The *Pfizer* and *Alpharma* cases are illustrative of the central role which the necessity test occupies in determining the proportionality of a precautionary measure. The claimants had argued that the EU authorities should have waited, in line with the practice of Canadian and Australian authorities, for the scientific studies to show a sufficient likelihood of risk. As far as the violation of the necessity test was concerned, the GCt replied that

'the institutions cannot be criticised for having chosen to withdraw provisionally the authorisation of virginiamycin as an additive in feedstuffs, in order to prevent the risk from becoming a reality, and, at the same time, to continue with the research that was already under way. Such an approach, moreover, was consonant with the precautionary principle, by reason of which a public authority can be required to act even before any adverse acts have become apparent.' [164]

Furthermore, the GCt was persuaded that the use of such antibiotics is not 'strictly necessary in animal husbandry and that there are alternative methods of animal husbandry even if they can lead to higher costs for farmers, and ultimately, consumers'.[165] The court confirmed that the regulation satisfied the necessity test.

Third, with a few exceptions, the requirement to balance interests in a strict sense is, as is known, the least well-established test in the Court's jurisprudence.[166] Averring a violation of the proportionality test *stricto sensu*, *Pfizer* claimed that a withdrawal of a product's authorisation could not be considered proportionate in the absence of a serious and

[161] Case C-491/01 *British American Tobacco* [2002] ECR I-11453, para 122.
[162] Case C-174/82 *Sandoz* , above, para 18; Case C-42/90 *Bellon* [1990] ECR I-4863, para 14; Case C-400/96 *Harpegnies*, above, para 34; Case C- 236/01 *Monsanto Agricoltura Italia*, above, para 107. In the field of proprietary medicinal products, C-368/96 *Generics (UK) and Others* [1998] ECR I-7967, para 66.
[163] Case C-558/07 *S.P.C.M.*, above, para 49.
[164] Case T-13/99 *Pfizer*, above, para 444.
[165] Ibid, para 459.
[166] See T Tridimas, 'Proportionality in Community Law: Searching for the Appropriate Standard of Scrutiny' in Ellis, E. (ed.), *The Principle of Proportionality* (Hart, 1999) 66.

identifiable risk and of proof that the source against which the action was to be undertaken constituted the most probable explanation for the risk which that action was intended to confront. Where these conditions are not fulfilled, the balance should tilt in favour of the holders of the marketing authorisations. Due to the great importance accorded to the protection of human health [167] as contrasted with economic considerations, the GCt nonetheless found that the measure at stake was not disproportionate.

Other judgments highlight that the balance tilt in favour of the environmental and health interests.[168] Although not referring to the principle, the *Toolex* judgment provides the most striking evidence of a precautionary approach to the resolution of a conflict between the Commission and a Member State failing to abide by EU harmonized standards.169 The Court found that the Swedish regulation was appropriate and proportionate 'in that it offered increased protection for workers, whilst at the same time taking account of the undertakings' requirements in the matter of continuity'. [170] In particular, the Court rejected the Commission's argument according to which the desired objective could have been achieved through a least burdensome measure, the imposition of limit values on exposure to the chemical substance trichloroethylene. [171] In *Afton*, the Court was asked to rule on whether an EU limit for the presence of a metallic additive likely to cause air pollution in fuel complied with the principle of proportionality. The Court stressed that 'the [EU] legislature could justifiably take the view that the appropriate manner of reconciling the high level of health and environmental protection and the economic interests of producers of the substance' was to limit its content 'on a declining scale while providing for the possibility …. of revising those limits on the basis of the results of assessment'. [172]

3.4.2. Proportionality in the light of the duty of re-examination

The trend embedded within WTO and EU law requiring institutions to re-examine their precautionary measures in the light of new scientific information is particularly important in this respect. [173]Indeed, it is still possible for the authority to loosen the straightjacket of precaution when new elements show that the suspected risk does not constitute as important a risk as had initially been feared. *Pfizer* provided further insights into the assessment of the proportionality of a measure likely to be re-examined. Where such restrictions placed by way of the PP on the commercialisation of a product are not necessarily definitive, they thus

[167] Above 2.2.2.1.

[168] The regulation of PAH in food is not disproportionate, where the constested regulation is reckoning on an EFSA'opinion ascertaining the carcinegous and genocotix effects of these substances, in spite of the impossibility to set forth thresholds. Case T-14/16 *Apimab Laboratoires* [2018] T:2018:524, paras 167 and 168.

[169] Case C-473/98 *Toolex*, above, para 47.

[170] Ibid, para 47. That case arose from a challenge to the Swedish decision to ban the chemical substance trichloroethylene, which had been classified as a category 3 carcinogen under Directive 67/548/EEC on the classification of dangerous substances. Several scientists contended with that classification owing the hazards entailed by the use of the substance in question. Given that the EC committee was unable to reach agreement on an evaluation of that substance (Opinion of AG Mischo, delivered on 21 March 2000, para 63), the Swedish Government decided to ban the substance on the grounds that its use was endangering workers' health, and consequently, endorsed a more stringent approach than the one contemplated at the EC level.

[171] Case C-473/98 *Toolex*, above, para 47.

[172] Case C-343/09 *Afton*, above, para 64.

[173] As far as EU law is concerned, see GFL, Art 7(2); Communication on the PP, para 6.3.5. As to WTO law, see SPS Agreement, Art 5(7).

appear all the more appropriate.[174] The withdrawal of the authorisation for virginiamycin as a growth promoter thus constituted a provisional measure which was subject to the Community institutions' duty of re-examination.[175] Last, the CJEU held that by virtue of the GFL, the EU legislature was entitled to adopt 'provisional risk management measures necessary to ensure a high level of health protection and may do so whilst awaiting further scientific information for a more comprehensive risk assessment'. [176]

3.4.3. Proportionality and countervailing risks

In *Pfizer* and *Alpharma*, the claimants had highlighted the fact that the prohibition of the use of antibiotics as growth promoters would have significant negative effects on the environment, impacts which had not been taken into consideration by the EU institutions. The GCt replied that the contested regulation was founded 'on a political choice, in respect of which the institutions were required to weigh up, on the one hand, maintaining, while awaiting further scientific studies, the authorisation of a product which primarily enables the agricultural sector to be more profitable and, on the other, banning the product for public health reasons'. [177]

3.4.4. Proportionality, cost-benefit analysis, and impact assessment

Restrictions placed on chemicals entail costs. In contrast with US law, the obligation that a cost-benefit analysis (CBA) of a preventive measure be assessed is rarely stipulated in EU legislation.[178] This requirement gives rise to numerous questions.

As far as the third test is concerned, the GCt considered in *Pfizer* that a CBA was a particular expression of the principle of proportionality in cases involving risk management.[179]The assessment of the economic ramifications of the decision to withdraw made by the Danish and Swedish bodies nonetheless satisfied this requirement of the principle of proportionality. [180] The proportionality principle was not applied in an excessively strict manner. This seems to be confirmed by the recent *BASF Agro* judgment. The GCt held that the fact that the protection of the environment takes precedence over economic considerations does not preclude the obligation 'pursuant to the precautionary principle, to carry out an impact assessment' of the measures.[181] This is required in accordance with the Communication on the PP, which is a non-binding document. Such an obligation 'is ultimately no more than a specific expression of the principle of proportionality'.[182]

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[174] Case T-13/99 *Pfizer*, above, para 460.
[175] Ibid, para 460.
[176] Cases C-154/04 and C-155/05 *Alliance for Natural Health* [2005] C:2005:449, para 69.
[177] Case T-13/99 *Pfizer*, above, para 468.
[178] By way of illustration, with respect to the authorisation of SVHC substances, REACH requires that the socio-economic benefits outweigh the risks (Art 60(8)).
[179] Case T-13/99 *Pfizer*, above, para 468.
[180] Ibid, para 410. In contrast, the GCt ruled in 2015 that the listing criteria to identify endrocrine disrupting substances were not subject to an impact assessment under the BPR. See Case T-521/14 *Sweden v Commission*, above, para 74.
[181] Case T-584/13 *BASF Agro*, above, paras 163-169
[182] Ibid, para 170.

4. Conclusion

Despite the fact that the PP enables the adoption of risk reduction measures even where there is a suspicion of risk, assessment procedures regarding the placing on the market of hazardous substances still call for absolute certainty. In particular, unlike waste management policy, the RA procedures are cumbersome, time-consuming, and expensive, as they require analysis of an enormous quantity and variety of data. [183] In postponing the implementation of desirable risk reduction measures, an overly comprehensive and protracted RA process pays lip service to the PP. In fact, the more information that is required, the longer and more costly the RA is, and the longer it takes before the regulatory measures can be adopted.[184] The risk reduction measures achieved hitherto by the EU chemicals policy appear relatively modest in the context of the human and financial resources required by the assessment procedures.[185] In addition, in harmonising the marketing approval procedures and not the production of hazardous substances, the policy is not preventive enough.[186] In spite of the improvements brought by REACH, only a new regulatory paradigm will rectify the situation.

The PP should play a pivotal role in the assessment and regulation of hazardous substances. Indeed, in its report on chemicals, the Royal Commission on Environmental Pollution held that 'our failure to understand the interactions between synthetic chemicals and the natural environment, and most of all our failure to compile even the most basic information about the behaviour of chemicals in the environment, is a serious matter'.[187] With respect to a number of hazardous substances, current scientific knowledge is not such that a level can be established below which risks to health cease to exist. Given that indeterminacy and ignorance characterize the risks posed by a significant number of substances, the uncertainties are unlikely ever to be eliminated. Moreover, precaution is best implement through a systematic process of substitution that entails the replacement of hazardous substances with ones of lower hazard or a non-chemical alternative.[188]

The rationale of the various judgments commented upon above is the finding that scientific uncertainty constitutes the essence of the PP. The examination of these judgments demonstrates that the scientific expertise in dispute clearly lies on the frontiers of scientific knowledge.[189] Accordingly, the issue is not only how much information the decision-maker must gather before they can regulate, but also when they can regulate given the current state of scientific knowledge. In that context, it must kept in mind that the PP did not take root in virgin soil, as it exists alongside other general principles of EU law. Against this background, the EU courts have been developing a range of rather systematic tests for reviewing the

[183] In spite of the fact that problems continue to occur due to unforeseen risks, regulators continue to argue strongly that control must be on the basis of known risks.
[184] L Koch and N A Ashford, 'Rethinking the Role of Information in Chemicals Policy: Implications for TSCA and REACH' 5 (2005) *Elni Rev* 24.
[185] L. Krämer, *EU Environmental Law*, above, 243.
[186] In regulating the impacts of substances and not their production, the EU policy appears rather at odds with the principle that environmental damage should as a priority be rectified at source. M. Pallemaerts, *Toxics and Transnational Law* (Hart, 2003) 232.
[187] Royal Commission on Environmental Pollution, *Chemicals in Products*, above.
[188] Ibid, 97, 163.
[189] In contrast, the European Commission has approved potentially unsafe pesticides, thereby disregarding data gaps in the RA and ignoring concerns raised by the EFSA. See European Ombudsman Decision, Case 12/2013/MDC.

validity of precautionary measures. Moreover, whilst the US courts have been endorsing since the *Benzene* SCt Judgment a hard look review,[190] the EU courts are still more deferential.

The question arises as to whether the EU risk analysis model is rigid or flexible. Though much emphasis has been placed on the performance of a risk assessment, the requirements regarding the quality of the scientific expertise laid down by the EU courts are drafted in a somewhat convoluted manner. Accordingly, the RA methodology can be tailored according to the specificity of the hazardous substance. Moreover, though they play a central role, risk assessors don't have the final word. They have neither democratic legitimacy nor political responsibilities. Accordingly, the decision-makers are endowed with much leeway in determining the high level of protection. The determination of the acceptable risk involves not only the appraisal of an array of interests but also the different facets of the risk (cumulative, synergetic effects). Therefore, there is no one size-fits-all approach to risk analysis. In addition, comitology, the institutional device that controls the implementing powers of the Commission,191 offers ample room for deliberation and allow each Member State to put forward its own political agenda. Another illustration is the requirement to carry out an impact assessment that doesn't amount to a CBA.[192] Accordingly, in contrast to US law nothing precludes the determination of the acceptable risk in qualitative terms.

Against the background of the cases commented above, the debate on the acceptable level of protection must be more firmly rooted in each legal system's constitutional traditions. Although prevented from adopting a purely hypothetical approach to risk and orienting their decisions towards a level of 'zero risk',[193] EU institutions must still ensure under Articles 114(3), 168(1), 169(3), and 191(2) TFEU an increased level of protection of human health, consumer protection and the environment.[194] The incremental shifting of the burden of proof in EU law is testament to the willingness to flesh out these constitutional obligations.[195]

Last but not least, the PP blurs the dividing line between risk assessment and risk management. In effect, it is not very easy to trace the boundary between the scientific domain and the political approach to risk management, as there is no natural boundary between the two spheres which inevitably become intertwined at different stages in the decision-making process.[196] In reality, assessment and management overlap in a permanent reciprocal interplay. Accordingly, the assessment of a risk often results from a managerial decision; conversely,

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[190] *Industrial Union Dep't. AFL-CIO v. American Petroleum Inst.,* 448 U. S. 607, 656 (1980).
[191] TFEU, Art 291.
[192] Case T-584/13 *BASF Agro*, above, paras 170-172.
[193] Case T-13/99, *Pfizer*, above, para 145.
[194] On the reasonableness of the obligation to ensure a higher level of environmental protection, see the Court's case C-284/95, *Safety Hi-Tech*, above, para 49
[195] By way of illustration, it is the notifier who has to demonstrate that, on the basis of the information submitted to the EU authorities, the safety requirements laid down by the pesticides legislation are met. See Case T-31/07 *Du Pont de Nemours*, above, para 154. Under REACH, it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use in a way such substances that do not adversely affect human health or the environment (Recital 19 and Art 1(3) REACH).
[196] Royal Commission on Environmental Pollution, *Chemicals in Products,* above, 6, 8, 11, 33, 45, 46, 162. In the USA, the EPA was taking the view in 1997 that the RA and risk management must take place side by side, in order for the risk manager to be informed as to how the assessment has been carried out. See the Presidential and Congressional Commission on risk assessment and risk management, Final Report, vol. 2, 1997.

new assessments are made following management decisions. As a result, this separation is by no means watertight. It follows that the authorities should be afforded a certain leeway in taking into account other factors than the strict scientific evidence. Accordingly, the courts' review should be limited when authorities intervene in cases permeated with uncertainties.

To conclude with, in the absence of a more comprehensive and a swifter system of regulating hazardous substances, the replacement of expensive and cumbersome RA processes by more innovate methods, and without a more prominent role for substitution, the current regulatory systems are unlikely to prevent significant environmental impacts. By way of illustration, the risk reduction measures achieved hitherto by the EU chemicals policy appear relatively modest in the context of the human and financial resources required by the assessment procedures.[197] In addition, in harmonising the marketing approval procedures and not the production of hazardous substances, the policy is not preventive enough.[198] In spite of the improvements brought by REACH, only a new regulatory paradigm will rectify the situation.

[197] L. Krämer, *EU Environmental Law*, above, 243.

[198] In regulating the impacts of substances and not their production, the EU policy appears rather at odds with the principle that environmental damage should as a priority be rectified at source. M Pallemaerts, *Toxics and Transnational Law* (Hart, 2003) 232.