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Science-based and evidence-based policy-making in the European Union: coexisting or conflicting concepts?

Daniel Guéguen & Vicky Marissen

About the authors

Daniel Guéguen, a lawyer and graduate of Sciences-Po Paris, has devoted almost his entire career to European public affairs. He has been a leader of professional associations and then a consultant. Today he is an Associate Partner at EPPA, visiting professor at the College of Europe, author, and editorialist.

Vicky Marissen, lawyer, graduated from the University of Antwerp and the Institute of European Studies of the ULB. She has devoted her entire career to European public affairs. Currently Partner at EPPA and Director of the European Training Institute, visiting professor at the College of Europe, and author.

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Contact details:

daniel.gueguen@coleurope.eu
vicky.marissen@coleurope.eu

Abstract

Precaution-innovation, the risk-hazard relationship, science-based and evidence-based policy-making are all complex issues that lie at the heart of major European themes: agriculture, food, health, environment, energy, etc. The first objective of this Research Paper is to explain clearly these different concepts, their interaction and how they apply *in concreto*. The authors analyse in depth the strengths and weaknesses of the current EU set-up. After highlighting the progress made with the Better Regulation package, they observe that the processes put in place in the drafting phase of legislative or regulatory proposals often suffer from a lack of harmonisation and from interpretations that can thwart the required objectivity. To remedy this, the authors make concrete proposals, including implementation of good practices, creation of an administrative code, and publication of impact assessments prior to publication of the corresponding legislative proposal. In conclusion, they insist that in order to strengthen the role of science in European governance, the creation of a pro-science climate at all levels of the institutions, business circles and civil society is urgently needed.

INTRODUCTION

From modest beginnings as a six-member trading bloc, the European Union (EU) has seen its competences gradually expand into a broad range of economic, environmental and societal affairs. Whether on food, medicine or transport, the EU now enjoys the power to regulate issues impacting the citizen's daily life in fundamental ways. With such power comes a heightened responsibility to ensure that EU action across these diverse policy areas is evidence-based and founded on high standards of scientific evaluation. In our current era, the need for solid science has never been greater. Not only is it a crucial aid to EU decision-making; science is regarded as an indispensable tool for stimulating European innovation and technology in the face of strong competition from the United States and China. Moreover, science will have to play a vital role in the realisation of the Green Deal as the EU works towards the goal of net carbon neutrality by 2050.

Speaking at the launch of the European Innovation Council in 2021, European Commission President Ursula von der Leyen claimed Europe to be "a powerhouse of science".[1] Over the past two decades, however, the EU has experienced difficulties in translating science into policy. A conservative, precaution-based approach to assessment has taken hold, hindering access to innovative products and techniques. In key sectors affecting human and animal health and the environment, a series of controversies, fuelled by intense media coverage, have placed the EU-level regulatory framework under significant strain. Disputes over fossil fuels, food quality and safety, tobacco, genetically modified organisms (GMOs) and plant protection products in particular have polarised Member State governments, poisoned relations between economic stakeholders and civil society, and weakened the Internal Market. Major decisions are being taken via opaque, complex procedures, while doubts persist as to whether the Commission has the expertise to assess

[1] Opening speech at the European Innovation Council Launch Ceremony, 18 March 2021. Link: https://ec.europa.eu/commission/presscorner/detail/en/speech_21_1241

objectively the real-world impacts of new initiatives. Although the broader notion of 'evidence-based decision-making' has gained traction, notably via the use of impact assessments, the argument can be made that science is becoming increasingly subjective and politicised, a trend that risks eroding public trust in the EU, undermining its legitimacy as well as its capacity to address the daunting challenges mentioned above.

If the Union truly aspires to be a "powerhouse of science", then there is an urgent need for reflection and frank debate among its citizens on how scientific assessment is conducted at EU level and how those assessments are validated by policy-makers. Consideration must be given to any and all options for remedying the defects identified including, if necessary, adaptation of the relevant structures, decision-making processes, methodologies and practices that govern scientific evaluation. Moreover, the question of if and how 'science-based' and 'evidence-based' decision-making can reinforce each other requires in-depth discussion.

The purpose of this Research Paper is threefold: (i) provide a critical analysis of the EU framework of scientific risk assessment and risk management, with a particular focus on bodies active in the fields of human medicines, food, feed, chemicals and the environment; (ii) explore the significance of evidence-based decision-making, including what it precisely entails, how it is applied in practice, and how it can co-exist with science-based decision-making; and (iii) offer operational considerations on how evidence-based and science-based decision-making can be further integrated into the EU decision-making process.

I. DIAGNOSTIC

This section will begin with a discussion on what the term 'science' implies in the context of EU governance. Following a brief historical overview of the EU's approach to science-based regulation, we will identify the key features of the current process of scientific decision-making, with a focus on the role of decentralised EU agencies and scientific committees,

explore emblematic cases that have exposed problems in the system, and discuss tensions between the over-arching principles that influence the process.

What do we mean by 'science'?

The term has been defined most succinctly by the UK-based Science Council as "the pursuit and application of knowledge and understanding of the natural and social world following a systematic methodology based on evidence".[2] Therefore, at a very basic level, science consists in a discipline and a method for creating new knowledge. A key characteristic of the scientific process is its objective nature and the expectation that research will be carried out according to the highest standards of impartiality and excellence, continually subject to peer review, and ultimately utilised in the interests of societal progress.

Of course, there is a difference between theory and practice. First of all, perfect objectivity in science is quite rare, since the research process can be influenced by the values and preferences of the researcher.[3] But when science passes through the prism of public policy and governance, the range of factors liable to dilute the 'ideal of objectivity' multiplies. Parkhurst has discussed the different forms of bias that can affect the use of evidence in policy, in particular "technical bias" (where evidence is not handled in line with best scientific practice) and "issue bias" (where debates in the democratic arena promote certain forms of evidence in a way that marginalises other considerations).[4] He indicates that "pieces of evidence can be manipulated or they can be presented faithfully to their findings", and that "research designs can be valid and rigorous or they can be created on flawed scientific foundations to achieve a pre-desired conclusion."[5] In truth, the belief that policy-making can ever be fully objective is an illusion. As Parkhurst puts it: "policymaking fundamentally

[2] Science Council, 'Our definition of science', link here.
[3] Wilholt, 'Bias and values in scientific research', *Studies in History and Philosophy of Science Part A*, Vol 40 Issue 1, March 2009, pp. 92-101.
[4] Parkhurst, *The Politics of Evidence: From evidence-based policy to the good governance of evidence*, Routledge, Abingdon, Oxon, UK (2017), pp. 42-43.
[5] *Ibid.*, p. 8.

involves competition between multiple social goals and the pursuit of social values".[6] This necessarily leads to a difficult discussion on which social interests prevail. A minimum of transparency in decision-making and good governance, along with accountability for the decisions ultimately taken, will be important factors underpinning the choice made based on evidence.

Furthermore, the reality is that scientific research in the modern era has often been carried out with a view to promoting specific political, economic and/or societal goals: commercial expansion, military development, etc. A particularly relevant example is the response to climate change, as we witness huge resources being poured into research at national, regional and global level to develop the technology necessary to mitigate the effects of climate breakdown and achieve a fundamentally political objective of shifting society towards cleaner, more renewable forms of energy. To this end, the EU has put forward a wide-ranging policy agenda called the 'Green Deal'.[7] Although widely accepted that the Green Deal must be based on science, ultimately it is subject to the EU's legislative procedure, an intensely political process where horse-trading between different centres of power – rather than the objective evidence – is the determining factor. Even before concrete proposals have been put on the table, a range of actors – the political leaders within the European Council, the European Parliament, civil society and the media – regularly work to promote their own interests by influencing the orientation of policy initiatives in the upstream phase. In some instances, this process has had a discrediting impact on EU policy-making overall: in particular, the preparation of the screening criteria for 'taxonomy', the EU legal framework for encouraging investors to switch to environmentally sustainable activities, has confronted criticised from all sides for being driven predominantly by politics rather than the scientific evidence, especially in relation to the status of nuclear energy and gas under that framework.

[6] Parkhurst (2017), p. 8.
[7] European Commission, 'Communication from the Commission: The European Green Deal', COM(2019) 640 final, 11 December 2019.

It is equally important to note the difference between 'science' stricto sensu, and 'science-based decision-making' as practised at EU level. Independent agencies such as the European Food Safety Authority (EFSA) which provide risk assessment to the European Commission, although staffed by scientific experts, are not actually engaged in original scientific research; rather, their role involves compiling and evaluating research carried out by others.[8] Therefore, it may be said that they occupy a kind of intermediate position between 'science' and 'governance'. Similarly, when the Commission conducts impact assessments, a crucial step in the EU rule-making process, it is not creating its own evidence as such, but is gathering evidence generated by others and interpreting that evidence according to its own policy priorities.

Furthermore, the increasing interaction between science and governance can result in the science itself being called into question. Across different countries, interest groups and sections of the public, one encounters conflicting visions of how society and the economy should be structured. As these debates become more heated, each side tends to engage in cherry-picking by promoting the scientific opinions which appear to validate their ideological position, while reflexively dismissing those studies which contradict it.

A very recent example is illustrative. The EU needs to decide whether to renew glyphosate's licence, which expires at the end of 2022. In view of this upcoming decision, the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) issued a scientific opinion in May 2022 which confirms that "classifying glyphosate as a carcinogen is not justified."[9] However, shortly after that opinion was adopted, a report published by the NGO HEAL (Health and Environment Alliance) accused ECHA of ignoring certain scientific studies involving tests on mice which, it claimed, showed that glyphosate poses a risk of causing "malignant lymphomas" in humans. In that report, Prof. Christopher Portier also

[8] See for example the infographic here.
[9] Press release, 'Glyphosate: no change proposed to hazard classification', ECHA/NR/22/10, 30 May 2022, link here.

argued that the EU agencies' use of industry studies as the main basis for their own observations set a pro-glyphosate tone.[10] These statements undermined ECHA by painting it as biased. ECHA responded by indicating that their experts evaluated "in detail" the tumours found in the animal studies and also evaluated input submitted by Prof. Portier. The experts "considered the strength of the statistical evidence and the biological relevance of the findings" but "agreed that the findings in the many studies in rats and mice, as well as the epidemiology studies, provide insufficient evidence for classification for carcinogenicity".[11] But beyond this response, there is relative silence with regard to defending the work of ECHA, notably from the European Commission. This situation perpetuates the sense of 'doubt' currently surrounding the independent agencies and the scientific nature of decision-making. It is one aspect which must be addressed to reinforce science and evidence-based decision-making at EU level, a point we will discuss later in this Paper.

The stance based on '*my* science is more valid than *your* science', most familiar in the fields of tobacco, fossil fuels and plant protection, has the ultimate effect of rendering science subjective rather than objective, weakening its credibility and even generating 'anti-science' attitudes among the public.[12] In the European sphere, the divide has manifested itself in the growing distrust between industry stakeholders and civil society groups on issues affecting public health and the environment. A crucial phenomenon in this respect has been the upsurge in social and environmental activism, including a number of well-organised non-governmental organisations (NGOs) which, through effective communication and extensive grassroots networks, have managed to impact the direction of EU policy. The European Citizen's Initiative (ECI), a mechanism of participatory democracy introduced by the Treaty of Lisbon,

[10] Report 'How the EU Risks Greenlighting a Pesticide Linked to Cancer', June 2022.
[11] POLITICO Pro Morning Agri and Food 'Grain blame game — Glyphosate debate heats up — Food packaging risks', 9 June 2022.
[12] Note the contrasting opinions in 'Glyphosate approval: stakeholders squabble over who has the science right', Euractiv, 8 December 2021, link here. For an analysis of 'anti-science' perspectives, see Mede, 'Legacy media as inhibitors and drivers of public reservations against science: global survey evidence on the link between media use and anti-science attitudes', *Humanities and Social Sciences Communications* 9, 40 (2022).

has played an important role in this regard. In particular, an ECI was submitted to the Commission in October 2017, entitled "Ban glyphosate and protect people and the environment from toxic pesticides". Although failing to achieve its primary objective, it influenced the Commission's decision to propose a reform of the transparency and governance of the scientific process within EFSA.[13]

All the elements mentioned above demonstrate that when we speak of 'science' in an EU context, the discussion is really about how the results of scientific research are interpreted and applied by the various actors involved in policy-making, and by society at large. A key challenge, therefore, is to ensure that science is used as objectively as possible, rather than dominated by the vagaries of public opinion, ideological conflict, and other subjective considerations. Another challenge is how to reconcile scientific evidence with other forms of evidence, and with the various political, societal and other non-scientific factors that inform the process of governance.

How the EU's approach to science has evolved to what it is today

As EU competences have expanded, so has the role of science in European policy-making. As early as the 1970s, the institutions saw the need to establish scientific committees tasked with providing expert opinion and advice to the Commission in the field of consumer health and food safety, e.g. the Scientific Committee on Food. This network of committees was formalised by a Decision of 1997 which emphasised the importance of "sound and timely scientific advice...based on the principles of excellence, independence and transparency."[14] Although those committees were composed of specialised experts in the relevant discipline

[13] Link here. See also the Commission's response to the Initiative: C(2017) 8414 final, 12 December 2017.
[14] Commission Decision 97/579/EC of 23 July 1997 setting up scientific committees in the area of consumer health and food safety.

(and generally chaired by one of them), the Commission played a crucial role in their operation: it appointed the members, convened meetings and provided administrative support.

Numerous developments in the 1990s heralded a fundamental change in this system. At the level of primary law, the Treaties of Maastricht and Amsterdam injected more onerous wording into internal market policy, requiring the Commission to ensure "a high level of protection" in the areas of health, safety, environmental protection and consumer protection, while "taking account in particular of any new development based on scientific facts".[15] Furthermore, the mishandling of the BSE crisis, coupled with revelations of mismanagement which brought about the resignation of the Santer Commission in March 1999, exposed serious weaknesses in the EU's scientific-regulatory regime, intensifying the pressure for reform.[16] A key turning point was the publication of the White Paper on European Governance in 2001, in which the Commission advocated the creation of "further autonomous EU regulatory agencies…with a degree of independence" and having the "ability to draw on highly technical, sectoral know-how…".[17]

The political momentum generated by the White Paper resulted in the establishment of the European Food Safety Authority in 2002 and later the European Chemicals Agency in 2007. In the pharmaceutical field, although the European Agency for the Evaluation of Medicinal Products had existed since 1995, that body was in 2004 re-named the European Medicines Agency (EMA) and saw its centralised powers significantly upgraded. As a result, the EU found itself in a new paradigm where scientific risk assessment in key sectors would be carried out not by the Commission services, or bodies directly controlled by them, but by

[15] That wording was retained in Article 114(3) TFEU.
[16] Chalmers, Davies & Monti, *European Union Law* (2nd Edition), Cambridge University Press (2001), p. 66.
[17] European Governance – A White Paper, COM(2001) 428 final, 12 October 2001, pp. 19-20. See also an earlier Commission White Paper on Food Safety (COM (1999)719 final) which called for the creation of an independent authority responsible for scientific advice and risk communication regarding food safety.

decentralised authorities enjoying structural independence from the EU institutions and direct funding from the EU budget.

EU science-based decision-making today

Overview

Science-based decision-making at EU level is structured around two distinct, consecutive stages: 'risk assessment' and 'risk management'.

Risk assessment was defined most aptly in 2002 by the General Court of the European Union as "a scientific process consisting in the identification and characterisation of a hazard, the assessment of exposure to the hazard and the characterisation of the risk".[18] Applied across multiple EU policy areas, risk assessment may be conducted by a number of different actors, and the more complex the issues have become, the more the Commission has relied on bodies outside its own departments. In public health in particular, the key characteristic of risk assessment is that it is entrusted to agencies and/or scientific committees of experts, whose task is to provide the EU institutions (usually the Commission) with independent, objective advice on scientific and technical issues, e.g. the safety of a chemical substance, or the efficacy of a medicinal product.

Risk management consists of the decisions adopted by policy-makers based on risk assessment. While the risk assessor estimates the magnitude of the risk, the risk manager determines what level of risk is acceptable to society and takes appropriate measures. For instance, they may choose to eliminate the risk entirely (e.g. banning the product) or mitigate it (e.g. setting performance standards).[19] In an EU context, the risk managers are in most cases the European Commission acting under the supervision of Member State governments (the

[18] Case T-13/99, Pfizer Animal Health v Council, paragraph 156.
[19] Better Regulation Toolbox (November 2021 edition), pp. 104-5 provides an indicative list of potential risk management measures.

European Parliament may also participate if the adoption of primary legislation is required). Risk management therefore allows for a broader range of factors beyond the strictly 'scientific' to be taken into account, including political, societal, ethical and economic considerations.

This division of labour is intended to reconcile two competing pressures. On the one hand, entrusting risk assessment to independent experts is perceived as the best way to ensure the highest possible standards of quality and objectivity in the scientific advice. On the other hand, leaving the final decision to risk managers, rather than the risk assessors, can be said to satisfy the demands of democratic legitimacy, since it guarantees that such measures are taken by those actors who are accountable to the public.[20] The rationale underlying the system has been summed up by one academic as follows: the risk assessors discuss facts, while the risk managers discuss values.[21] We believe it may be even more accurate to say that risk managers discuss 'interests'.

Risk assessment and risk management are supplemented by a third component (although not a procedural phase): **risk communication**. This refers to the practice of communicating and explaining to the public the existence of risks and hazards, the basis of risk assessment findings and the rationale for risk management decisions.[22] The approach of the EU institutions to risk communication in recent years, particularly the Commission, has left much to be desired. Attempts to explain to the public the risks and hazards associated with files such as glyphosate, endocrine disruptors and neonicotinoids have been incoherent, overly complicated and, in some cases, totally lacking. This has contributed to damaging public trust in science.

[20] COM(1999) 719 final, p. 15.
[21] Alemanno, 'Science and EU Risk Regulation: The Role of Experts in Decision-Making and Judicial Review' *Young Researchers Workshop on Science and Law: Scientific Evidence in International and European Law*, 31st May – 1st June 2007, ISUFI, Lecce, Italy, p. 7.
[22] See the definition contained in Regulation 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, Art. 3(13).

The EU – via the adoption in 2019 of a new Regulation amending the General Food Law –[23] has embedded stronger rules on risk communication and calls for the development of an integrated framework by EU food safety risk assessors and risk managers at EU and national level, notably the development of a "General plan for risk communication". The results of this reform are still to be assessed, but if the plan and its implementation genuinely proves of added value, it would require further extension into sectors beyond food and feed.

Risk assessment: the main actors

Three decentralised EU agencies play a vital role in the area of public health:

- The **European Food Safety Authority (EFSA)** is responsible for risk assessment under the EU legislation on Plant Protections Products (PPPs), Maximum Residue Levels of pesticide substances (MRLs), Food Contact Materials (FCM) and Contaminants in Food and Feed. Applications for authorisation or requests for assessment are assigned to one of EFSA's ten Scientific Panels composed of independent scientific experts, each having its area of expertise, or to the EFSA Scientific Committee for horizontal issues. The panel typically entrusts the assessment to a specialised working group which analyses the relevant scientific information, produces a draft and submits it to the competent panel which adopts the report by a majority of its members.[24]

- The **European Medicines Agency (EMA)** is responsible for risk assessment under the EU legislation on human and veterinary medicinal products. In the context of the centralised procedure for granting marketing authorisation, the Committee for Human Medicinal Products (CHMP) plays a leading role, assisted by the

[23] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC.
[24] An overview of the EFSA process is available here.

Pharmacovigilance Risk Assessment Committee (PRAC) which advises on risk management plans. At the end of the evaluation process, the CHMP adopts a scientific opinion on whether the product should be authorised.[25]

- The **European Chemicals Agency (ECHA)** conducts risk assessment under the EU legislation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Classification, Labelling and Packaging of substances and mixtures (CLP), Biocidal Products, and the Export and Import of Hazardous Chemicals (PIC). Under the complex legal frameworks of REACH and CLP, a number of expert committees may play a role. For identifying Substances of Very High Concern, for example, ECHA's Member State Committee (MSC) conducts analysis, carries out consultations and issues an opinion (referral to the Commission takes place only if the MSC fails to reach unanimous agreement). For individual authorisations, the Risk Assessment Committee (RAC) evaluates the risk posed by the substance while the Committee for Socio-Economic Analysis (SEAC) assesses the socio-economic impacts as well as the availability and feasibility of alternative substances.

Although we have historically seen an evolution towards creating and relying on decentralised agencies for scientific opinions, there are some exceptions involving scientific committees which remain under the direct supervision of the Commission:

- The **Scientific Committee on Health, Environment and Emerging Risks (SCHEER)**. The product of a merger in 2016 between two pre-existing scientific committees,[26] SCHEER provides risk analysis on general cross-cutting issues

[25] For human medicinal products, an overview of the EMA process is available here.
[26] The Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).

affecting consumer safety and public health that do not fall directly under the remit of the decentralised agencies (e.g. antimicrobial resistance);

- The **Scientific Committee on Consumer Safety (SCCS)** carries out risk assessment under the EU legislation on Cosmetic Products, Toy Safety and General Product Safety.

Both SCHEER and SCCS have been reproached for not being sufficiently independent and being managed directly by the Commission. In the case of SCHEER, that has notably led to criticism by stakeholders as to the biased nature of some scientific advice (e.g. on e-cigarettes).

Reflecting the spirit of the 2001 White Paper, the Commission's over-arching approach has involved a gradual transfer of risk assessment duties from its scientific committees to the independent agencies. For instance, analysis of workers' exposure to dangerous chemicals and recommendations on associated limits used to be conducted by the Scientific Committee on Occupational Exposure Limits (SCOEL); in 2019, that responsibility was handed over to ECHA's Risk Assessment Committee (RAC). Furthermore, in its Fitness Check of EU chemicals legislation, the Commission noted concerns around the potential for divergence between the opinions of bodies like SCHEER and EFSA.[27] Building on these findings in its 2020 Chemicals Sustainability Strategy, the Commission gave a concrete commitment that it will:

> rationalise the use of expertise and resources by proposing the reattribution of technical and scientific work on chemicals performed under the relevant pieces of legislation to European agencies, including work of the SCHEER and SCCS.[28]

A horizontal legal proposal in this regard is currently under preparation, and may be published over the course of 2022 in parallel with amendments to sectoral legislation (e.g.

[27] Commission Staff Working Document: Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries, SWD(2019) 199 final/2, PART 1/3, 18 July 2019, pp. 76-8.
[28] Commission Communication: Chemicals Strategy for Sustainability: Towards a Toxic-Free Environment, COM(2020) 667 final, 14 October 2020, p. 16.

cosmetics).[29] These proposed changes, emblematic of a long-standing trend of entrusting scientific risk assessment to independent authorities at EU level, should be viewed as a positive development.

In addition, it is worthwhile to mention two other EU-level bodies on which the Commission relies for scientific input on general policy initiatives:

- The **Joint Research Centre (JRC)** is the Commission's science and knowledge service responsible for providing independent scientific advice to support EU action at all stages of the policy cycle. Its activity is structured around 10 thematic areas including climate change, food security, and digital transformation, and it enjoys its own facilities and infrastructure to carry out scientific research, particularly in the field of nuclear safety.[30] It receives funding from the EU's framework programme for research and innovation (Horizon 2020) and the Euratom Research and Training Programme. As a separate Directorate-General (DG), the JRC carries out its tasks in line with the political priorities set by the Commission President and, to that end, has its own resources (including over 2,700 staff members) and strategic work plan. The JRC recently provided an opinion on the place of nuclear energy in the EU taxonomy framework, which concluded that there is no science-based evidence that nuclear energy does more harm to human health or to the environment than other electricity production technologies already included in the EU taxonomy as activities supporting climate change mitigation.[31] Although the Commission took this opinion into account when preparing its delegated act on the subject, it has not diminished the political

[29] 'State of the implementation of the actions announced under the Chemicals Strategy' (Nov 2021), p. 12, link here.
[30] 'Science Areas', link here.
[31] Abousahl et al., 'Technical assessment of nuclear energy with respect to the "do no significant harm" criteria of Regulation (EU) 2020/852 ('Taxonomy Regulation')', EUR 30777 EN, *Publications Office of the European Union*, Luxembourg, 2021, ISBN 978-92-76-40538-2, doi:10.2760/207251, JRC125953.

controversy surrounding the inclusion of nuclear energy within the scope of taxonomy; and

- The **Scientific Advice Mechanism (SAM)** provides independent scientific advice directly to the European Commissioners rather than to the Commission services. Established in 2015, the SAM is composed of two parts: (i) the Group of Chief Scientific Advisors (GCSA), consisting of seven independent scientists appointed in their personal capacity; and (ii) the Scientific Advice for Policy by European Academies (SAPEA), a consortium which gathers expertise in a broad range of disciplines from over 100 academies and societies across Europe. The GCSA and the SAPEA cooperate closely and are assisted in their work by a secretariat from the Commission's DG for Research and Innovation. Advice may be prepared upon request by the Commissioners or following a proposal from the GCSA themselves. For instance, the SAM has delivered scientific opinions on responses to future pandemics, cybersecurity and glyphosate.[32]

Risk assessment: transparency standards

As mentioned before, a central concern of the scientific decision-making process is the elimination of bias. To this end, mechanisms have been put in place to guarantee the openness and objectivity of the work carried out by the EU's scientific agencies.

The experts who sit on the various EFSA/EMA/ECHA scientific panels and committees come from a wide spectrum of backgrounds, including Member State authorities, national public research institutes, universities, self-employed and retired scientists.[33] The basic principle, enshrined in EU legislation, is that they are obliged to act independently, in the public interest, and free from any external influence.[34] To ensure this, the agencies operate

[32] A list of scientific advice published by the SAM is available here.
[33] See for example EFSA Press Release of 15 May 2018, 'Experts named for EFSA scientific panels', link here.
[34] See for example Regulation 178/2002, Art. 37(2).

a 'conflict of interests' policy whereby its scientific experts are required (i) to submit an annual declaration of financial interests; and (ii) to declare at the beginning of each meeting any interest which might be prejudicial to their independence regarding a point on the agenda.[35] Furthermore, each authority has its own internal process for screening conflicts of interests and taking mitigating measures, which range from letters of reprimand to dismissal from the relevant panel or committee. That said, the three EU agencies differ in their implementation of these rules: EMA adheres to a highly 'automatic' decision-making system in terms of the consequences of breaching interest rules, whereas the EFSA regime is more discretionary.[36]

Despite these safeguards, the alleged links between agency experts and industry stakeholders have remained a substantial point of contention, particularly regarding the procedure for approval of active substances.[37] Questions have also been raised about the extent to which authorities like EFSA base their risk assessments on scientific studies supplied by industry, to the exclusion of data from other sources.[38] This criticism spurred the Commission to propose a significant reform of EFSA's transparency (mentioned above), which provides that:

- Citizens have automatic access to, and are to be consulted on, all studies and information submitted by industry in the risk assessment process (subject to confidentiality in duly justified cases);
- EFSA is to be notified of all commissioned studies to ensure that companies applying for authorisations submit all relevant information and do not hold back unfavourable studies;

[35] See for example Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Art. 63(2).
[36] Vos, Athanasiadou & Dohmen, 'EU Agencies and Conflicts of Interest', Study commissioned by the Petitions Committee of the European Parliament, January 2020, pp. 57-63.
[37] See for example the report of Corporate European Observatory, 'Recruitment Errors', 11 June 2017.
[38] See for example the Report of the European Parliament Special Committee on the Union's authorisation procedure for pesticides (PEST), 18 December 2018 (A8-0475/2018).

- The Commission may ask EFSA to commission additional studies and may perform fact-finding missions to verify that studies are in compliance with applicable standards.

Since the Regulation only entered into application on 1 July 2022, it remains to be seen whether these reforms will strengthen the objectivity of scientific assessment within EFSA. The improved rules on transparency at risk assessment level will only be beneficial if risk managers support the agency experts and the overall process, and avoid situations where politics takes the upper hand in the adoption of the final decision.

Risk management: deciding on the basis of risk assessors' opinions

The scientific opinions of EFSA, EMA, ECHA, SCHEER or SCCS do not, by themselves, produce legal effects. They require a formal decision of the Commission, to which the agency/committee forwards its opinion. This adoption process (formerly known as 'comitology') consists of two categories of measure: implementing acts and delegated acts. Since delegated acts are used far less for decisions related to risk assessment, we will focus on the process for adoption of implementing acts, its advantages as well as its flaws.

The Commission is required to submit each draft implementing act for scrutiny by a committee composed of Member State representatives (civil servants from the relevant ministries in the national capitals). Following discussion and possible amendments, the committee – which the Commission chairs – votes by qualified majority (QM). With a QM in favour of the draft, the Commission can move forward and adopt the implementing act. In the event of a QM opposing the draft or a so-called 'no opinion' (no QM in favour or against), the Commission has the option of re-drafting the measure and submitting it to the Member State committee or taking the same draft to the Appeal Committee, a committee composed of

attachés from the Member States' Permanent Representations, for a second vote.[39] This step necessarily makes the discussions far more political than those held in the initial committee.

The lack of transparency in the workings of these committees has been criticised, especially the failure to publish systematically the names of the Member State officials attending meetings, the individual voting positions expressed by those Member States, and detailed minutes of the items discussed in each meeting.[40] Moreover, these defects in the risk management process helped exacerbate two recent controversial files.

Glyphosate is the active ingredient in the herbicide 'Roundup', one of the most widely-used weedkiller products globally. Following an application for re-approval, EFSA delivered a scientific opinion in October 2015 concluding that glyphosate is "unlikely to pose a carcinogenic hazard to humans".[41] Its findings were consistent with assessments by various food safety authorities worldwide,[42] with the sole exception of an evaluation published in March 2015 by the World Health Organisation's International Agency for Research on Cancer (IARC), which deemed glyphosate "probably carcinogenic to humans".[43] Despite this imbalance in the expert consensus, the process was thrown into disarray by the decision of certain EU governments (including France and the Netherlands), backed by the European Parliament and a vigorous civil society campaign, to promote the IARC opinion as justification for opposing any re-approval for glyphosate. Within the Member State committee, seven EU countries abstained, preventing a QM from being reached. Although the Commission was entitled to adopt the draft, Health and Food Safety Commissioner Vytenis Andriukaitis refused

[39] The procedure is described in detail in Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, Art. 5 and 6.
[40] PEST Committee Report, paragraph 77; Report by Transparency International EU, 'Hiding a Forest Behind the Trees', February 2021, pp. 39-44.
[41] European Food Safety Authority, 'Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate', EFSA Journal 2015;13(11):4302, 12 November 2015.
[42] These included authorities in the United States, Canada, Japan and the United Nations' Food and Agriculture Organisation. See Url, 'Don't attack science agencies for political gain', *Nature*, 24 January 2018, link here.
[43] IARC Monographs Volume 112: evaluation of five organophosphate insecticides and herbicides, 20 March 2015.

to do so without a QM of countries in favour. Even after ECHA issued its own opinion in March 2017, which concluded that glyphosate should not be classified as carcinogenic based on the available scientific evidence,[44] the stalemate continued until November 2017 when Germany dramatically switched from 'abstain' to 'yes'. This finally enabled the Appeal Committee to deliver a QM in favour, paving the way for the adoption of a reduced 5-year renewal for glyphosate.[45]

GMOs have confronted a similar situation. Despite multiple positive opinions from EFSA regarding the safety of GM products for cultivation or for use in food and feed, final decisions on those applications were not adopted for several years due to strong divisions among Member State governments – many of whom oppose GMOs on various political, ethical and health-related grounds – generating repeated 'no opinions' in the Member State committee and in the Appeal Committee. At one stage, around 20 draft authorisations were left in limbo for an extended period of time. The Commission has been condemned by the EU courts and the European Ombudsman for its role in allowing such delays to occur.[46] In an effort to resolve these bottlenecks in the GM approval process, the European Parliament and Council adopted a Directive which allows individual Member States to prohibit unilaterally on their national territory the cultivation of GM products authorised at EU level.[47] The Commission then put forward another proposal based on the same mechanism, this time

[44] Press Release, 'Glyphosate not classified as a carcinogen by ECHA', ECHA/PR/17/06, 15 March 2017, link here.
[45] Commission Implementing Regulation (EU) 2017/2324 of 12 December 2017 renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.
[46] Case T-164/10, Pioneer Hi-Bred v Commission; Decision of the European Ombudsman closing the inquiry into complaint 1582/2014/PHP on the European Commission's handling of authorisation applications for genetically modified food and feed, Case 1582/2014/PHP, 15 January 2016.
[47] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.

applying to the use of GM food and feed.[48] However, in October 2015 the European Parliament formally requested the Commission to withdraw that proposal, citing concerns about the implications for the internal market and the European agriculture sector, and criticising the lack of an impact assessment.[49]

The glyphosate and GMO cases exposed significant flaws in the EU system of risk management. Despite clear expert opinions from EFSA and ECHA, the Commission, European Parliament and Member State governments undermined the authority of these scientific agencies by allowing equal (if not more) weight to be given to public opinion throughout the process. The reputation of the EU's scientific-regulatory system was damaged due to the commercial uncertainty caused for applicants involved in the respective processes. The controversies also shined a light on aspects of the implementing acts procedure, namely the rules on abstention and 'no opinion' which, for a long time, permitted both the Commission and the Member States to evade responsibility for taking a final decision.

How to reconcile competing concepts: risk-hazard, precaution-innovation

The operation of EU science-based decision-making may be framed as a constant and uneasy interaction between two pairs of concepts: the 'precautionary principle' and the 'innovation principle' on one hand, and 'risk' and 'hazard' on the other.

Precautionary principle vs. innovation principle

While no universal definition exists, the essence of the precautionary principle is that public authorities should not be precluded from adopting risk management measures to

[48] Proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory, COM(2015) 177 final, 22 April 2015.
[49] European Parliament Press release, 'Parliament rejects national GMO bans proposal', 28 October 2015, link here.

address a potential serious threat to human or animal health or the environment, even where there is a lack of scientific certainty regarding the presence or extent of that threat.[50] Application of the principle has taken various forms, including international agreements to phase out halocarbons, and full bans of all forms of asbestos.[51]

The precautionary principle enjoys the privilege of being firmly anchored in EU primary and secondary law. First integrated into the 1992 Treaty of Maastricht, it is currently enshrined in Article 191(2) of the Treaty on the Functioning of the European Union (TFEU), which states that EU environment policy "shall be based on the precautionary principle". However, its scope extends beyond the environmental sphere, as the concept is explicitly mentioned in numerous sectoral EU legislative acts, most notably the General Food Law, the REACH Regulation, the Biocidal Products Regulation and the PPP Regulation; regarding the latter three acts, their provisions are "underpinned" by the principle.[52] Furthermore, the Court of Justice of the European Union (CJEU) has addressed the precautionary principle in its case law, holding in particular that the EU institutions' discretion will not be questioned by the courts unless there was a manifest error or misuse of powers.[53] The rules governing the application of the precautionary principle derive primarily from CJEU rulings and have been consolidated in a non-binding Commission Communication which sets out the process as well as minimum standards to be respected, e.g. any precautionary measures adopted must be proportionate, non-discriminatory and regularly reviewed.[54]

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[50] See for example the formulation in Principle 15 of the 'Rio Declaration on Environment and Development' adopted during the United Nations Conference on Environment and Development, Rio de Janeiro, 3-14 June 1992 (A/CONF.151/26/Rev.1(vol.I)).

[51] 'The Precautionary Principle: Definitions, applications and governance', Report of the European Parliamentary Research Service (EPRS), December 2015, PE 573.876, pp. 14-15.

[52] Regulation 178/2002, Art. 7; Regulation 1907/2006, Art. 1(3); Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, Art. 1(1); Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, Art. 1(4).

[53] Case T-74/00, Artegodan v Commission, paragraphs 173 and 201.

[54] Communication from the Commission on the precautionary principle, 2 February 2000, COM(2000) 1 final final.

By contrast, the innovation principle has its origins in a stakeholder initiative. First promoted in a 2013 letter[55] of the European Risk Forum (a platform of companies from the chemicals and energy industries), it was subsequently incorporated into the Commission's 'Better Regulation' agenda two years later. The objective of the innovation principle is to ensure that during the development, implementation and review of EU policy and legislative or regulatory measures, the impact on research and innovation is taken into account. Its basic thrust is that EU legislation should be 'future-proofed' to remove obstacles to adopting the newest innovative technology. Concretely, the innovation dimension may be assessed by EU decision-makers at any stage of the policy cycle, involving foresight and horizon scanning, impact assessment and/or 'innovation deals'.[56]

Unlike the precautionary principle, the innovation principle per se is not enshrined in EU primary law, although it could be implied from certain Treaty provisions, e.g. Article 3(3) of the Treaty on the European Union (TEU) requires the Union to "promote scientific and technological advance".[57] To date, it has not been addressed by the EU courts, and is explicitly mentioned in only one piece of binding primary legislation.[58] Otherwise, the innovation principle is found exclusively in non-binding instruments, in particular the 'Council Conclusions on Research and Innovation-friendly Regulation',[59] and the Commission's Better Regulation Toolbox which is intended as guidance for Commission officials engaged in policy-making.

The precautionary principle therefore holds a decisive advantage over the innovation principle due to their respective positions in the EU legal and regulatory architecture. Whereas

[55] Open letter by the European Risk Forum (ERF) to the Presidents of the European Commission, the European Council and the European Parliament, 9 October 2013.
[56] Better Regulation Toolbox, Tool #22 (Research and Innovation).
[57] See also Articles 39(1)(a) and 173 TFEU.
[58] Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013, Recital 6.
[59] 9510/16, Brussels, 27 May 2016.

the precautionary principle has evolved into a *de facto* constitutional principle, applied extensively over numerous decades and fleshed out in international, European and national law, the innovation principle is a comparatively recent phenomenon whose application at EU level, while encouraged, remains largely at the discretion of Commission civil servants.

The value of the innovation principle is clear and can generate societal benefits and progress. Its more active use in policy-making could be beneficial provided that regulators and decision-makers make efforts to explain clearly the principle of innovation to society and citizens. This will help to overcome the unfortunately widespread perception that 'innovation' is merely for the benefit of business and industry stakeholders, thereby allowing for a more rational and balanced approach moving forward.

Risk-based decision-making vs. hazard-based decision-making

When engaging in scientific assessment, there are two possible approaches. The first involves an evaluation that focusses on the potential to cause harm based on intrinsic properties, i.e. the 'hazard', and taking measures on that basis. The second goes a step further by assessing the 'risk' posed, i.e. the likelihood that a living being (or the environment) might actually suffer harm from the hazard.

For example, a chemical substance in a plant protection product could be found to be carcinogenic in its inherent properties, but might have a low probability of causing cancer in humans assuming no high levels of exposure. An evaluation based on risk would be more likely to lead to market approval for the substance (at least for certain uses), whereas a hazard-based assessment would more likely invoke its carcinogenic properties as justification for a general prohibition. From an applicant's perspective, a focus on hazard often shifts the burden of proof unfavourably, requiring it to present positive evidence that its substance does *not* cause any harm. The notion of hazard-based assessment is closely linked to the precautionary principle, since the very existence of a hazard may be used to justify the adoption of risk

management measures, particularly where there is a lack of scientific certainty about the real-world risk associated with that hazard.

The principle of comprehensive risk evaluation is enshrined in numerous EU legislative acts, and some employ a mixture of risk and hazard approaches: under REACH for example, a chemical can be added to the Candidate List of Substances of Very High Concern based on its intrinsic hazard, but might subsequently be authorised for a specific use following risk assessment. Nonetheless, there has been a growing drift over the past two decades towards the stricter hazard-based approach, notably in chemicals regulation. In addition to having strong support from civil society organisations and Member State governments like France and Sweden, it is understood that certain departments of the European Commission, e.g. the Directorate-General for Environment, favour this shift in emphasis. The fact that these legislative acts explicitly promote the precautionary principle (as noted above) provides a valuable hook for advocates of hazard-based assessment. In a 2018 Communication, the Commission suggested that the EU's strategy towards endocrine disruptors "should be based on the application of the precautionary principle and aim at…minimising overall exposure of humans and the environment…",[60] while a more recent Communication commits to proposing "legally binding hazard identification of endocrine disruptors".[61]

The risk-hazard dichotomy is also manifested at EU level in the distinction between two methods of risk management:

- **Generic risk considerations (GRC)**. Potential exposures and risks are considered generically, and pre-determined risk management measures (e.g. restrictions) are automatically triggered based on the substance's hazardous properties, without any assessment of exposure in specific situations or uses;

[60] Communication from the Commission: Towards a comprehensive European Union framework on endocrine disruptors, COM(2018) 734 final, 7 November 2018, p. 9.
[61] COM(2020) 667 final, p. 11.

- **Specific risk assessment (SRA)**. Each substance is assessed on a case-by-case basis with consideration not only of its hazards but equally the specific exposure scenarios for humans and/or the environment. Rather than being pre-determined, risk management measures are dictated by the outcome of the SRA.[62]

These two concepts are especially prevalent in EU chemicals regulation, sometimes co-existing within the same legislative framework, e.g. the EU Cosmetics Regulation employs SRA for establishing the list of authorised substances, while relying on GRC for substances classified as carcinogenic, mutagenic or toxic for reproduction (the latter are banned for use in cosmetic products subject to strict derogations).[63] In this context, the 2020 Chemicals Sustainability Strategy contained a commitment to extend the GRC approach further to cover a range of consumer products from toys to cosmetics, with the aim of protecting humans and the environment from exposure to chemicals which cause cancer or affect the endocrine system. As part of this reform, the Commission intends to define criteria for "essential use", thereby ensuring that the most harmful chemicals are permitted only where their use is absolutely necessary and no alternatives exist.[64] This may be interpreted as further evidence of the on-going shift at EU level towards a precautionary, hazard-based approach to regulation.

II. EVIDENCE-BASED DECISION-MAKING

Following our analysis of the existing system of science-based decision-making, this section will present the concept of 'evidence-based decision-making' and explain how these two concepts are complementary rather than contradictory.

[62] For a discussion of GRC and SRA, see SWD(2019) 199 final/2, PART 1/3, pp. 10-12.
[63] Ibid.
[64] COM(2020) 667 final, pp. 9-10.

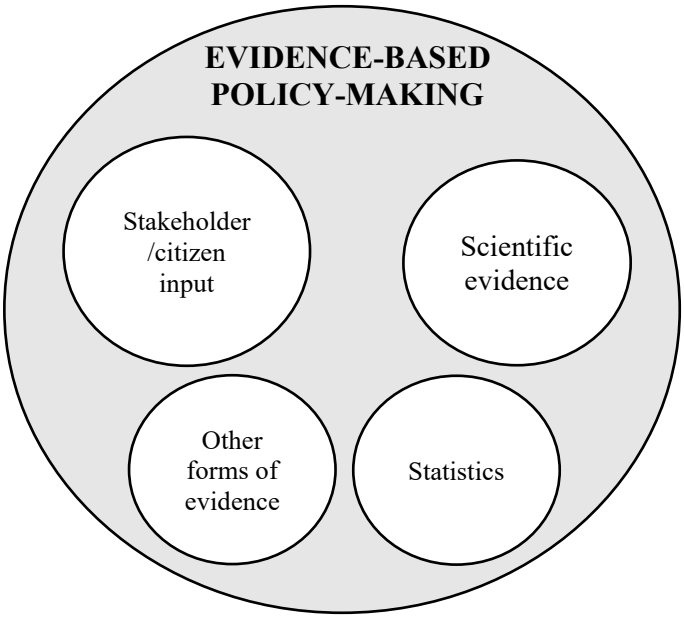
What is it and why is it important?

EU legislative and regulatory measures can be informed by multiple, diverse forms of 'evidence', including information and data not necessarily produced in the laboratory or via other strictly 'scientific' processes. In fact, it is common practice, in EU policy-making, to allow scientific and non-scientific factors to be given (near-)equal attention. For example, the General Food Law states that scientific risk assessment alone cannot, in some cases, supply all the information needed to take a decision, so "societal, economic, traditional, ethical and environmental factors" should also be taken into account.[65] The diversity of 'evidence' is something that the Commission itself has acknowledged in its own guidelines for its services, in which the principle of 'evidence-based' is embedded as a key dimension of the Better Regulation agenda and defined as follows:

> 'Evidence' refers to multiple sources of data, information and knowledge, including quantitative data such as statistics and measurements, qualitative data such as opinions, stakeholder input, conclusions of evaluations, as well as scientific and expert advice.[66]

It must be clarified that we do not view 'science-based' and 'evidence-based' as being in opposition, or as conceptually distinct. As the passage quoted above recognises, science is a form of evidence. That said, it is only *one kind* of evidence, alongside a number of other kinds that may feed into the policy-making process where appropriate: statistics, survey data, behavioural analyses, socio-economic data, input from affected stakeholders and citizens, etc. It may therefore be best to visualise 'scientific evidence' as a circle existing inside a larger circle representing the broader category of 'evidence-based policy-making'.

[65] Regulation (EC) No 178/2002, Recital 19.
[66] Better Regulation Toolbox, pp. 8-9.



One challenge associated with the 'evidence-based' category is that not all types of evidence necessarily operate on a level-playing field. In practice, when confronted with different forms of evidence, policy-makers will frequently prioritise certain forms at the expense of others. Parkhurst has discussed how calls for 'evidence-based policy-making' are often coloured by one's political and social values, ultimately leading to bias and the emergence of "hierarchies of evidence".[67] Unsurprisingly, given its rigorous methodologies and processes, scientific evidence is frequently placed at the top of that hierarchy, but Parkhurst notes that this is not a guarantee of positive societal outcomes since "evidence alone tells us nothing about [the] social desirability of that which is being measured".[68]

Pure scientific analysis is understandably (and often rightly) regarded by policy-makers as a compelling form of evidence in highly technical areas such as food safety and chemicals regulation. However, while risk assessment might, if taken in isolation, support the authorisation or restriction of a product, it does not allow for consideration of all the consequences of such a policy intervention. For example, a decision to prohibit the marketing of a substance, despite the assumed benefits for human health and/or the environment, might

[67] Parkhurst (2017), p. 4.
[68] *Ibid.*, p. 19.

produce unforeseen social or economic impacts, particularly where there is a lack of viable alternatives to the substance in question. As a result, general restrictions might cause undue disruption to downstream sectors, consumers and/or trade with third countries. In short, scientific evidence, when complemented by evidence of socio-economic impacts, is more likely to result in the optimal policy outcome, e.g. by combining a general restriction with mitigating measures whereby a substance can continue to be used in specific situations.

Combining science and socio-economic data: the example of RAC and SEAC

One area where the 'evidence-based' approach has been implemented at EU level is chemicals regulation. As mentioned previously, the European Chemicals Agency (ECHA) plays a vital role in overseeing the regulatory frameworks for REACH and CLP, and providing scientific opinions to the Commission on whether specific substances should be authorised for particular uses or be subject to restrictions.

In doing so, ECHA effectively divides the analysis between two entities. First, there is the **Risk Assessment Committee (RAC)**, which evaluates the risk that the substance in question poses to human health and the environment, assesses the effectiveness of risk management measures, and determines whether the proposed authorisation, restriction, or harmonised classification and labelling is appropriate. Secondly, there is the **Committee for Socio-Economic Analysis (SEAC)** whose role, intended to complement RAC's analysis, is to assess socio-economic factors and the availability, suitability and technical feasibility of the alternatives associated with the substance. In conducting its analysis, SEAC may require the applicant (or in the case of a proposed restriction, invite third parties) to submit comments and socio-economic data. The REACH Regulation outlines various elements that may form part of a socio-economic analysis, including:[69]

[69] Regulation 1907/2006, Annex XVI, 'Socio-economic analysis'.

- The impact on industry (manufacturers and importers) and other supply chain actors (e.g. downstream users);
- The impact on investment, research and development, innovation, one-off and operating costs, with consideration for general market and technology trends;
- Possible impacts on consumers, e.g. prices, product availability, changes in product composition or quality;
- Social implications, including for employment;
- The availability, suitability, and technical feasibility of alternative substances and/or technologies, and information on the potential for technological change in the sector concerned;
- Consequences for trade and economic development, in particular for SMEs and third countries, at local, regional, national or international level; and
- The costs and effectiveness of alternative risk management measures.

Essentially, the ECHA process allows the net benefits to human health and the environment of the proposed restriction or granted/refused authorisation to be compared directly with the net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole. Demonstrating the importance attached to socio-economic analysis in the procedure, the opinions of RAC and SEAC are prepared in parallel and published separately.

Some observers have highlighted challenges in the practice of socio-economic analysis, including potential under-estimation of future impacts on health and the environment.[70] Nonetheless, according to ECHA, the data suggests that the combined role of RAC and SEAC has been broadly successful in reducing the use of high-concern substances

[70] Arnold, 'Discounting Future Damage: Do Socio-Economic Assessments in EU Chemicals Policy Underplay Future Impacts?', The New Economics Foundation, September 2019.

and promoting substitution with alternatives, while allowing European businesses to stay competitive.[71]

Impact assessments: the key component of evidence-based policy-making

'Evidence-based policy-making' at EU level also manifests itself in the process of impact assessment. This is the practice whereby the Commission, prior to drawing up a proposal for a legislative or non-legislative initiative, assesses what the economic, environmental and/or social impacts of that initiative will be and "involves verifying the existence of a problem, identifying its underlying causes, assessing whether EU action is needed, and analysing the advantages and disadvantages of available solutions".[72] It is now regarded as a vital aid to EU decision-making that not only forms the cornerstone of the Commission's Better Regulation Guidelines but has also been integrated into the 2016 Inter-institutional Agreement on Better Law-making, which encourages the European Parliament and the Council to carry out an impact assessment whenever they make substantial amendments to a legislative proposal (although in practice, this is extremely rare).[73]

For the Commission, an impact assessment is in principle required for any initiatives included in the Annual Work Programme, including those entailing significant spending and where the Commission has a choice of policy options.[74] Impact assessment by the Commission is *not*, however, required for files on which the EU agencies have delivered a scientific opinion. A crucial component of the impact assessment process is stakeholder consultation: for a 12-week period, the public – potentially ranging from companies and SMEs directly impacted by the initiative, to public authorities, NGOs and individual citizens – are invited via a Call for Evidence (CfE) to provide, normally via questionnaire, their input on whether EU

[71] 'Socio-economic impacts of REACH authorisations', European Chemicals Agency, April 2021.
[72] Better Regulation Guidelines, p. 30.
[73] Interinstitutional Agreement of 13 April 2016 between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making, paragraphs 12-18.
[74] Better Regulation Guidelines, p. 30.

action is needed and, if so, what the best option(s) for achieving the objective are. It may be said that impact assessment and public consultation are the 'twin pillars' of EU evidence-based decision-making. Although it can be said that questionnaires are convenient tools to structure the input, it also has the disadvantage of curtailing responses, notably for citizens who may wish to express their views more freely and openly. Questionnaires are also perceived as 'orienting' replies, and hence risk steering a policy option. They should therefore be carefully formulated and should not in any way jeopardise the value of input by different type of respondents.

On average, the lead Commission department spends 12-18 months gathering evidence from stakeholders and various other sources (e.g. Eurobarometer surveys, Eurostat, the JRC, past fitness checks),[75] interpreting that evidence and converting the results into a draft impact assessment report. It evaluates the data via a very elaborate set of rules on how to perform analysis and data cleansing when assessing the input into consultations.[76] The latter process relies on IT tools as well as a 'human' check by the staff of the relevant Commission services when processing and analysing the contributions. Despite all these tools however, the actual uptake of contributions is not always clear and therefore generates doubt when decisions are ultimately adopted. It would be important to address the latter point carefully in order to create trust in decision-making and decision-makers.

The lead department is obliged to submit the draft impact assessment report to the Regulatory Scrutiny Board (RSB), a body composed of four Commission officials and three external experts whose function is, with the assistance of the Commission Secretariat-General, to evaluate the impact assessment and ensure it meets the minimum standards set down under the Better Regulation Guidelines. The RSB may issue (i) a positive opinion, (ii) a positive opinion with reservations, or (iii) a negative opinion. In principle, an impact assessment cannot

[75] The full list of potential sources of evidence is provided in the Better Regulation Toolbox, pp. 26-29.
[76] *Ibid.*, pp. 471-4.

be finalised unless it receives a positive opinion from the RSB, although the College of Commissioners has political discretion to take a decision to advance with an initiative even where the RSB has delivered two consecutive negative opinions.[77]

Despite the extensive guidance made available to its services, the Commission has received criticism regarding the quality of the impact assessment it produces. Most notably, a 2017 report of the Impact Assessment Institute (IAI) highlighted a number of shortcomings in the process, including: the adoption of legislative proposals without any impact assessment or justification for why one was not done; a tendency to undertake impact assessment without full neutrality, i.e. based on a pre-determined notion of what the outcome will be; and a failure to allow public scrutiny of the data underpinning impact assessments.[78]

Furthermore, it is clear from the RSB's own annual reports that some Commission departments are still struggling to comply fully with the guidelines: in 2020 for example, 19 of the 41 draft impact assessments (i.e. 46%) submitted to the RSB received a negative opinion.[79] The Annual Report for 2021 provides further interesting findings as to how the Board assesses certain flaws in the performance of impact assessments. While 2021 was an extremely busy year for the RSB in terms of evaluations and impact assessments, proportionally speaking the rate of negative submission was lower. Two key issues requiring attention were highlighted: assessment of the coherence of an initiative with other initiatives, and assessment of proportionality. Moreover, the RSB stated that negative opinions delivered on impact assessment were often related to the fact that the initiatives as such "had drawn their impetus from political commitments and target setting. The resulting impact assessments often lacked convincing evidence to demonstrate the existence and size of the problem."[80]

[77] This occurred for instance with the Proposal for a directive of the European Parliament and of the Council on the promotion of the use of energy from renewable sources (recast), COM(2016)767, 23 February 2017.
[78] 'A Year and a Half of the Better Regulation Agenda: What Happened?', Report of the Impact Assessment Institute, IAI-BR1½Yr-170130f, 30 January 2017.
[79] Regulatory Scrutiny Board Annual Report 2020, p. 11.
[80] Regulatory Scrutiny Board Annual Report 2021, p. 18.

Furthermore, it noted: "The definition of options was the weakest element in impact assessments. Often the set of options was not complete and overly focusing on the predetermined (political) choice".[81] These findings are clear indicators that, on several occasions, impact assessment has been used not to assess various policy options but rather to underpin a political choice already made.

The Commission services rely heavily on impact assessment when determining policy choices, making it the cornerstone of evidence-based policy-making. Unfortunately, the impact assessment is only made public alongside the relevant proposal; there is no possibility of evaluating and potentially commenting on the impact assessment on a stand-alone basis. This practice should be re-assessed as means of emphasising the importance and value of impact assessment. Although, as noted previously, the 2016 Interinstitutional Agreement on Better Law-making explicitly refers to it, the efforts to encourage the European Parliament and the Council to perform impact assessments when introducing significant legislative amendments have so far proven quite unsuccessful. Yet again, genuine evidence-based decision-making would benefit from the mainstreaming of this activity by the legislators.

Finally, it should be emphasised that – although Better Regulation provides for it explicitly – we see very little impact assessment performed on delegated or implementing acts. Given the high impact these measures have on society, it would be advisable for the Commission services and its Secretariat-General to evaluate more carefully the performance of impact assessments for these measures as well. While it would admittedly prolong the decision-making process, it would also increase its credibility and generate higher trust in decisions taken.

[81] *Ibid.*, p. 17.

III. HOW TO FURTHER IMPROVE SCIENCE-BASED AND EVIDENCE-BASED DECISION-MAKING AT EU LEVEL

The preceding pages have demonstrated the complexity of the subject addressed in this Research Paper. We do not claim to propose a solution that would miraculously recognise 'science' as the one and only cornerstone of the European legislative corpus, nor do we offer a blueprint for how evidence-based and science-based decision-making can be ideally reconciled. We cannot deduce a purely legal solution consisting of constitutionalising the innovation principle or providing a precise definition of the boundaries between precaution and innovation, risk and hazard, etc.

We do, however, want to share some suggested actions that could be incorporated at EU level without the need for treaty change.

A logical starting point for introducing changes or integrating improvements concerning science and evidence-based decision-making at EU level would be to link them to discussions in the context of the Conference on the Future of Europe, its concluding report having been published in May 2022.[82] In our opinion, little should be expected from the work to come in the wake of the Conference. At this stage, a reform of the treaties is hardly feasible, and even if it were to take place, it is not certain that it would provide a valid solution to the question that interests us. Confirming these doubts over feasibility, on 9 May 2022 a group of 13 Member States published a non-paper on the outcome of and follow-up to the Conference on the Future of Europe in which they clearly indicate that they "do not support unconsidered and premature attempts to launch a process towards Treaty change. This would entail a serious risk of drawing political energy away from the important tasks of finding solutions to the

[82] Conference on the Future of Europe, Report on the Final Outcome, May 2022.

questions to which our citizens expect answers and handling the urgent geopolitical challenges facing Europe". [83]

In reality, science-based and evidence-based policy-making are multifactorial issues related to various spheres: political, administrative, economic, societal. These spheres interact with each other in an environment that is not necessarily oriented positively towards science and innovation. The COVID-19 crisis demonstrated again the resistance of a significant portion of the public to innovation, especially when it relates to genetics. It made us aware of an 'anti-science' climate in transgenerational layers of the population.

The problem is further complicated by the extraordinary complexity of EU decision-making processes, and it always comes back ultimately to the same question: who decides in the end? Politicians? The administration? Civil society? Business? This complexity often results in case-by-case management of files, leaving room for interpretation which, as such, is detrimental to scientific objectivity and administrative rigour. In the day-to-day operations of the European Union, there is a growing discrepancy between the balance of powers as set out in the treaties and the balance of powers as practised on a case-by-case basis. It can be seen that the Member States, the European Parliament and the European Commission are becoming very attentive to the messages being sent by civil society via non-governmental organisations, citizens' initiatives, petitions and social networks in general.

The much-needed neutrality and objectivity of the Commission are likely to suffer. To take the well-known example of glyphosate: if the Commission expects the requested studies to confirm the non-carcinogenic nature of the substance, will it propose an extension of the authorisation, or will it listen to the vox populi and take no action? The question is already

[83] Non-paper by Bulgaria, Croatia, the Czech Republic, Denmark, Estonia, Finland, Latvia, Lithuania, Malta, Poland, Romania, Slovenia, and Sweden on the outcome of and follow-up to the Conference on the Future of Europe, 9 May 2022, link here.

being asked by senior members of the European executive. In any case, EFSA announced in May 2022 a one-year postponement of its conclusions on glyphosate.

It is true that, in our view, science can only be promoted if all those involved in science take the trouble to promote it, talk about it, communicate with public opinion, and educate.

In June 2019, the EU adopted an amendment to its General Food Law in the shape of a new Regulation on the transparency and sustainability of the EU risk assessment in the food chain. One of the focal points of this revision relates to risk communication, requiring the development of a general plan which should ensure a coherent risk communication strategy throughout the risk analysis process, in combination with open dialogue amongst all interested parties. Unfortunately, the reform has not (yet) generated real change. Without many economic sectors being able to educate, train, or at least raise awareness, and to interest the end consumer in new technologies, innovation and technical progress, science will remain frozen in an environment of distrust and hostility. On the other hand, there may also be a need for non-governmental organisations to look inward, as there is a tendency to sow doubt about the validity of science according to who is doing it. This trend is also generating a great deal of distrust in science, scientists and scientific agencies. In between are the decision-makers who have a heavy responsibility to act appropriately within the law, on the basis of science and evidence, while taking into account the societal voice.

Our recommendations

In this conclusion, we attempt to put forward a set of principles on which possible changes and adaptations could be based, with the following objectives:

- A need for simplification;
- An obligation of transparency;

- A reduction in interpretation;
- A reduction in exceptions and derogations;
- A broad application of good practices;
- Administrative rigour.

Therefore, rather than talking about 'science-based policy-making', it would be better to talk about 'evidence-based policy making', a concept that is derived from Better Regulation and is broader than science. It involves the adoption of policies, legislation and regulatory acts on the basis of various elements (scientific, technical, economic, social, environmental, etc.), in particular through impact assessments, scientific evaluation and public consultations. Science must be seen as an element of evidence. Far from being in contradiction, the two are complementary to each other. The impact assessment method is interesting, but to make it even more credible – i.e. objective – the different components of this method will have to be improved.

Three options could be considered separately or jointly in order to make progress and develop evidence-based/science-based decision-making further:

1. A White Paper on Science and European legislation

The development of such a White Paper could be entrusted to a representative but limited group of five equal components: the European Commission, the Member States, the European Parliament, civil society, and business stakeholders. Even if it failed to reach an ideal solution, such an initiative could at least be expected to bring greater clarity and some progress in terms of simplification and harmonisation of rules.

2. The creation of an administrative code

One of the major weaknesses of the EU decision-making system that has surfaced over time is the case-by-case approach to files. This has been made possible by the complexity of

procedures, with the Commission's management in 'silos' granting considerable autonomy to officials and favouring a handling of processes that lacks uniformity.

The European Union has gradually developed ad hoc procedures in a number of thematic areas (e.g. competition, trade, access to EU documents). Furthermore, the Commission has a Code of Good Administrative Behaviour for its staff, which is a fragmented body of rules. Several years ago, discussions began on how to create a more consistent set of EU administrative procedures. With the Treaty of Lisbon, a new legal basis on administrative law was introduced.[84] The European Parliament has called for the adoption of a single European Administrative Procedure binding on EU institutions, bodies, agencies and offices including enforceable procedural rights for citizens when dealing with the Union's direct administration. On 15 January 2013, the Parliament adopted a resolution based on a legislative initiative report prepared by the Legal Affairs Committee, presenting detailed "recommendations to the Commission on a Law of Administrative Procedure of the EU."[85] While the Barroso II Commission did not respond by submitting a proposal, Commission Vice-President Timmermans, during his hearing before the Parliament in October 2014, did commit to examining the possibility of a European Law on Administrative Procedure. However, no follow-up was made. The European Parliament later adopted a "resolution for an open, efficient and independent European Union administration" in June 2016, asking the Commission to present a legislative proposal as part of its work programme for the year 2017.[86] The Commission did not see the necessity of such an initiative, and ever since, the EP has on regular occasions taken action to push the idea further, albeit without success.

[84] Article 298(1) TFEU, which provides that in carrying out their missions, the institutions, bodies, offices and agencies of the Union shall have the support of an open, efficient and independent European administration.
[85] European Parliament resolution of 15 January 2013 with recommendations to the Commission on a Law of Administrative Procedure of the European Union, P7_TA(2013)0004.
[86] European Parliament resolution of 9 June 2016 for an open, efficient and independent European Union administration, P8_TA(2016)0279.

The EU would benefit from such an Administrative Law to guarantee further coherence in the actions of its officials and to guarantee citizens clarity and legal certainty on what they can expect from the EU institutions.

3. Reinforcing the role of the Scientific Advice Mechanism (SAM) and the Joint Research Centre (JRC)

The Commission is more frequently relying on the input of these bodies in its policy-making, but the public is often not aware of their involvement, with the result that their input into the process is valued insufficiently, or not at all. While it is the purpose of neither the SAM nor the JRC to perform the role and responsibilities of ECHA, EMA and EFSA, the function of those agencies is more related to regulatory processes. The SAM and the JRC could make useful contributions to discussions regarding the precautionary principle and the innovation principle, and to the debates on hazard/risk-based decision-making and on generic risk considerations versus specific risk assessment.

4. Harmonising the functioning of ECHA, EMA and EFSA

For some years now, we have seen an increased concentration of responsibilities in the hands of three key agencies: ECHA, EMA and EFSA. Scientific committees have been abolished and their responsibilities have been transferred over to those agencies. As mentioned above, the latest example was SCOEL (Scientific Committee on Occupational Exposure Limits). Would it not make sense to evaluate whether the work of other scientific committees might be 'integrated' into such agencies? The Chemicals Sustainability Strategy is opening this door to a certain extent.

Furthermore, the functioning of those three agencies is not harmonised, and on this front progress could be made. The example of RAC and SEAC, the two key committees within ECHA, is in our view a very interesting set-up which allows for science (RAC) as well as

socio-economic factors (SEAC) to be taken into account, a combination resulting in a more holistic 'evidence-based' approach encompassing science.

Another problem that occurs from time to time is the fact that the opinions of the EU agencies are not always defended by the Commission, the Member States or the European Parliament, which ultimately raises questions regarding their reliance on the quality and scientific validity of those agencies' work. This is a slippery slope that results in a loss of faith in science, a loss of faith in decision-making, discussions about biased science, and so on.

In general, it should be compulsory for the Commission, the co-legislators (the European Parliament and the Council) and/or Member State governments to communicate publicly and with as much clarity as possible whenever they depart from the opinions on which they have to base their decisions. This should become a systematic obligation, applied when proposing or adopting legal acts.

5. Better Regulation: improving impact assessments

Better Regulation is a major tool that moves science-based policy-making towards evidence-based policy-making. This is an essential point, because scientific analysis is rightly confronted with various environmental, social, economic and societal parameters, all of which must be considered in order to reach a balanced decision or, one could say, a 'just order'.

Unfortunately, Better Regulation is facing serious difficulties in its application, which could be remedied. One of these concerns impact assessment. While the relevant Commission services are especially proud of how impact assessments are made, we have some suggestions for improving the process. The first is that the objective quality of an impact assessment is very much linked to the conditions under which it is carried out. How are the questions asked? Are they focused? Is the service provider in charge of the assessment competent, objective and neutral? Are stakeholders treated fairly and listened to? Based on a series of contacts, we have to conclude that the quality of the work is variable. Systematic practice does not exist.

As indicated above, the 2021 Annual Report of the Regulatory Scrutiny Board provides interesting findings as to how the RSB assesses certain flaws in the performance of impact assessments. Furthermore, if stakeholders feel that certain relevant input is not considered, the option of performing a 'counter-impact assessment' could be valid provided it is based on a solid methodology as to how the data is processed and analysed.

There has been an increase in the practice of 'upstream meetings' between the RSB and Commission departments that are in the very early stages of preparing the impact assessment. This has produced beneficial results, as it evidently gives the RSB a holistic view of assessments. In our view, it would be logical to make such upstream meetings obligatory, as the input provided by the Board is not only useful but also allows for greater coherence in the quality of the impact assessments.

A second major shortcoming of impact assessments is that they are published simultaneously with the corresponding draft legislative or regulatory act. The top hierarchy of the institutions, with whom we have had discussions, considers that any publication of impact assessments before the adoption of the proposal would undermine the Commission's monopoly of legislative initiative. We do not share this view. While it is true that dissociating the publication of the impact assessment from the proposal would tend to delay the latter, such an approach would ensure that the impact assessment fulfils its primary role, which is to objectify the choice between different policy options and not to validate a posteriori the policy decision already made by the Commission. This point seems essential to us.

Conclusion:

Improving existing arrangements will not be enough.
What is needed is the emergence of a 'pro-science' climate

The first observation a reader can make at the end of this Research Paper is the extraordinary complexity of the systems in place. If we wish to take a more positive view of the subject, we must recognise that, with successive treaty reforms and the adoption of the Better Regulation package, considerable progress has been made in ensuring greater rationality and transparency. This is not sufficient, however, because instead of simplifying, each layer of reform has been added on top of others, creating an incredible tangle that is impenetrable to non-specialists and where objectivity is no longer guaranteed. If there is an ambiguous concept, it is indeed that of 'objectivity'; the objectivity of some is not the objectivity of others. But at the very least, institutions and stakeholders should be treated fairly.

Having designed this Research Paper from a legal perspective, we supplemented it with a series of interviews with figures in institutions, professional associations and NGOs. These discussions were particularly enlightening as they demonstrate that, while significant improvements are possible, they will not be sufficient unless they are accompanied by broad communication efforts around science to integrate technological development into the core of current and future EU policies.

To sum up, the specific improvements to be made are the following:

- First, harmonise the operations of the EU agencies (EFSA, ECHA, EMA) through the extension of good practices, for example by transposing to EFSA and EMA two mechanisms specific to ECHA: the Risk Assessment Committee and the Committee for Socio-Economic Analysis, as these two bodies are perfectly in line with the evidence-based approach promoted by the Commission;

- Secondly, and failing the creation of a supervisory authority which would further complicate the system, we believe that the Joint Research Centre, which we consider to be under-used, and/or the Scientific Advice Mechanism could, in certain contentious cases such as glyphosate, perform the role of a scientific appeal or arbitration authority;
- The Better Regulation package, which introduced the concept of 'evidence-based', has many merits, but it suffers from an implementation that varies according to the case in question, and sometimes even amounts to a form of administrative arbitrariness. This is the case with impact assessments. Often criticised, their main flaw is that they are published simultaneously with the adoption of the corresponding draft legislative or regulatory act. This practice is problematic because it contradicts the primary role of an impact assessment, which is to provide options. According to the Commission, anticipating the publication of the impact assessment would undermine its monopoly of initiative, but that is not our view;
- Another weakness is the Commission's 'silo' management, which was initiated under the Commission Presidency of José Manuel Barroso and criticised by his successor, Jean-Claude Juncker, who tried unsuccessfully to eradicate it. Unfortunately, it is still in place. Leaving such autonomy to the Directorates-General generates a case-by-case management of problems according to each DG's own culture, with varying inclinations to dialogue, consultation or transparency. The creation of a European Administrative Code seems to us to be the only solution that would harmonise behaviour and procedures. The European Parliament has also echoed this.

These important, albeit common-sense, measures will not be enough to grant science the central role it ought to have, nor will evidence-based decision-making be unanimously recognised as *the* methodology to follow. In this respect, the interviews we conducted at the highest levels of the three EU institutions and with the leaders of professional associations

and representative NGOs were enlightening. Listening to them, the impression was that it is always the other party that is responsible and never oneself. The Commission criticises industry as too defensive and NGOs as too offensive, etc. Regardless of whom one speaks to in business or NGO circles, they all indicate that the Commission's practice is flawed in many respects: lack of transparency, failure to listen, subjectivity of decisions. NGOs are denounced by the business community as too activist and arrogant.

The responsibility for the current dissatisfaction is collective, and the faults attributed by some to others can very easily be returned to the sender.

- The Commission undoubtedly must harmonise its behaviour and abandon a bureaucratic style of management, the extreme complexity of which constitutes a major obstacle to good governance;
- The professional circles must learn that their high technical competence is not enough. They must anticipate, avoid being systematically defensive, and propose without fearing to oppose at times. They must learn to communicate;
- NGOs must no longer be ostracised by the business community, which in turn must offer solutions, information-sharing, visits to research centres and pilot projects.

In the European Union's long-term projects, and in particular the Green Deal, science, research and technology should be omnipresent, because tomorrow's world will not be the one we know today, nor the one we imagine based on our current knowledge. Governance and science must work in tandem. Evidence-based policy-making is an appropriate response, but its intellectual inventiveness cannot work without questioning its practical application.

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