



*Scientific Advice  
Mechanism (SAM)*

# Scientific Advice

to European Policy in a Complex World

*Group of Chief Scientific Advisors  
Scientific Opinion No.7, Sep. 2019*

Independent  
Expert  
Report

Research and  
Innovation

## Scientific Advice to European Policy in a Complex World

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EUROPEAN COMMISSION

Chief Scientific Advisors – SAM, EGE  
INDEPENDENT SCIENTIFIC ADVICE FOR POLICY MAKING

# Scientific Advice

## to European Policy in a Complex World

***Group of Chief Scientific Advisors***

*Scientific Opinion No.7, Sep. 2019*

*(Supported by SAPEA Evidence Review Report No. 6)*

*Brussels, 26 September 2019*



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<sup>1</sup> SAPEA brings together knowledge and expertise from more than 100 academies and learned societies in over 40 countries across Europe. Funded through the Horizon 2020 programme of the EU, the SAPEA consortium comprises Academia Europaea (AE), All European Academies (ALLEA), the European Academies Science Advisory Council (EASAC), the European Council of Academies of Applied Sciences, Technologies and Engineering (Euro-CASE) and the Federation of European Academies of Medicine (FEAM).

<sup>2</sup> <https://esaforum.eu/members-2/>

## Executive Summary

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### Why should I care about the topic?

This opinion should be of interest to those who want to know (more) about:

- what the architects of the EC scientific advice system (the College) can do concretely to set in motion further improvements of the system;
- how scientific advisors and policy makers can best work to define a clear mandate and questions for scientific advice;
- when and how to include stakeholders and the public in science advice;
- how to achieve clarity about values and interests which may be affecting scientific advice, and how to manage them;
- how to optimise EC rules on conflicts of interest to ensure the impartiality of experts without needlessly losing valuable expertise;
- how to boost the reliability and usefulness of expert consultation by reducing bias and arbitrariness;
- how to ensure that the evidence that is collected and used for policy is of high quality;
- how to deal with different uncertainties in scientific evidence and advice;
- how to communicate scientific advice effectively, including uncertainties, gaps and divergent scientific views.

This opinion recommends ways to generate high quality scientific advice for European policy.

In setting that goal, we base our work on the following fundamental principles, informed by evidence and experience:

- High-quality science is the bedrock of good scientific advice; scientific advice needs to employ effective methods for analysis of the scientific evidence.
- Scientific advisors are intermediaries between science and policy; hence they need to demonstrate their trustworthiness in the eyes of policymakers, the public, the scientific community and all others involved in the process, as a prerequisite for doing their work well.
- Scientific advice needs to be a transparent and impartial process, and to have a clear mandate to ensure that science is separate from politics;

To achieve that goal we have adopted the following recommendations:

## **Recommendation 1: Engage early and regularly**

### Clarify boundaries between science, scientific advice, and politics

Values, beliefs, opinions and competing interests are integral to society and politics. To be trusted and credible, scientific evidence and its analysis must, as much as possible, be clearly differentiated from such factors when advising on policy decisions.

Science (and scientific advice) themselves are not completely value-free but scientific advice must not be driven by partisan interests and stealth issue advocacy.

The boundaries between science, scientific advice, and policy – and thus the mandate for scientific advice – must be clear. However, they are often not clearly predetermined. In fact they can be contested – by policymakers, the public or scientists: e.g. it may be subject to some debate whether scientific advice should offer policy options. The boundaries need to be agreed and set in dialogue – when the questions for scientific advice are defined together with policymakers, and when the decision is made on how to involve the public and stakeholders in scientific advice are made.

### Define together the questions for scientific advice

Scientists and policy makers should define the questions for policy advice together, involving stakeholders and the public, to ensure robust and high-quality science advice. As evidence emerges, these questions often need to be refined in an iterative approach.

When defining together the questions for science on complex policy issues, using simple conceptual aids can make a difference.

Integrating foresight and horizon scanning into scientific advice is important for complex policy issues. These methods can help capture early warnings: lessons from the past include e.g. the cases of ozone-depleting gases and BSE. Foresight can help the timeliness of the scientific advice on complex emerging issues.

When policy issues informed by science are socially controversial, scientific advice should involve stakeholders. Involving members of the public that are directly affected should also be considered. To work well and avoid becoming an unclear mixture of science and politics, stakeholder and public involvement in scientific advice must have a clear purpose, follow clear principles, and combine deliberation with analytical rigour. A model developed by the US National Research Council is an example of good practice.

## **Recommendation 2: Ensure the quality of the scientific evidence**

### Use the full scope of good science

All good quality science that can contribute to the issue at hand should be considered. This includes natural sciences, engineering, medicine, social sciences and humanities.

For broad and complex scientific questions, it is usually helpful to set up multidisciplinary expert panels and encourage interdisciplinarity (building links between disciplines).

### Ensure rigorous synthesis of scientific evidence

Comprehensive and rigorous synthesis of the best available evidence is the foundation of good scientific advice. A range of recognised synthesis methods exist. They have diverse applications (e.g. a 'scoping review' is relatively quick and useful for defining the problem at the outset). The choice between methods involves trade-offs e.g. between speed and rigour, and is influenced e.g. by the purpose of the synthesis, its policy importance, as well as the time and resources available.

General criteria of good evidence synthesis include comprehensiveness, transparency of methods, an iterative approach (to reframe the questions as work progresses), and aiming to reduce biases to the maximum extent possible under the method chosen.

Judging the quality of individual pieces of evidence included in the synthesis requires appraising them against the quality criteria for the study design used (e.g. randomised controlled trials, surveys, or qualitative research), next to the general criteria of high-quality science.

Scientific advisors and policymakers should only commission scientific evidence synthesis from bodies which apply rigorous standards. For evidence commissioned directly by policy departments, this can be made a part of the terms of reference. The teams doing evidence synthesis should bring together synthesis methodology experts and topic experts. Evidence synthesis reports should be peer-reviewed by experts who are not involved in the immediate advisory process.

### Ensure rigour in expert consultation

Expert consultations can be part of evidence synthesis for policy and can be very helpful e.g. when there are important gaps in the available evidence. However, experts can be subject to cognitive biases. A number of approaches, ranging from very formal and resource-intensive methods to quick and informal, are available to reduce that bias. The choice depends e.g. on the type of knowledge needed, the complexity of the question, and the time and resources available. Highly formal methods are mainly used for risk assessment.

Unstructured expert consultation (i.e. simply gathering experts, and asking them to debate and produce a consensus opinion) carries risks of bias and unreliability. A number of straightforward changes, e.g. in how experts are selected and how they deliberate, can improve the reliability of rapid and informal consultation methods.

### Refine the approach to conflicts of interest

Refinements in the policy of assessing and managing conflicts of interest (COIs) are suggested in the following areas (1) clarity of selection criteria, including excellence criteria and the expertise profile needed, and a transparent selection process; (2)

clarity of criteria used to exclude experts due to a COI, with a margin for case-by-case assessment, (3) consistency in the public disclosure of interests, including comparable scrutiny of both impartial experts and interest representatives, (4) better understanding of bias, based on the latest science.

### Codify good scientific advice and consider oversight of its implementation

Developing a single set of principles and good practices common to all scientific advice bodies in the European Commission is recommended. This could be achieved e.g. through an EC Code of Practice for Scientific Advice, accompanied by a living toolbox of good practices and methods designed for collaborative use with policymakers and the public. The toolbox could build on the approaches, methods and tools highlighted throughout this Opinion while adapting them to EC use and continually updating them.

Architects of the EC scientific advisory system should consider entrusting a body with a lead in developing the set of principles and guidance, and entrusting it with oversight of the implementation.

## Recommendation 3: Analyse, assess and communicate uncertainties

### Use the most suitable uncertainty analysis approaches

Some uncertainties in scientific evidence are 'technical' (e.g. related to limitations in available data) or 'methodological' (e.g. related to the reliability of expert judgement). An example of a question which involves such uncertainties is 'What are the risks to human health due to the possible presence of substance X in food products?'

Technical and methodological uncertainties can be measured and expressed as probabilities, which involves statistical data analysis and/or expert judgement. The choice of a method involves trade-offs between rigour, the time and resources available, and should take into consideration the importance of the question to be assessed. The European Food Safety Authority (EFSA) has produced extensive guidance on the use of these methods, which is suitable for use beyond the field of food safety.

Other uncertainties are 'epistemic' (e.g. about the sources of knowledge that are needed to address the issue) or 'societal' (e.g. whether the question is the 'right' one). Analysing them should be part of the early deliberation with policymakers (and the public when appropriate). Several tools are available, including mini-checklists and questionnaires, and an uncertainty matrix, as used e.g. by the Netherlands Environmental Assessment Agency (PLB). 'Pedigree analysis' is a method to reduce the arbitrariness of some such judgements through the use simple ordinal scales (0-4) combined with verbal descriptions.

### Communicate uncertainties and diverging scientific views

Where there are uncertainties in scientific evidence or advice, provide clarity about what is known, partially known, unknown, and unknowable. As an ethical imperative, uncertainties, gaps and limitations in available knowledge should always be clearly communicated in the least ambiguous and most comprehensive way achievable. Clarify the reasons for diverging scientific views whenever possible.

For uncertainties expressed as probabilities, numerical and verbal expressions should be combined (e.g. '70% certain i.e. likely ') to reduce ambiguity, and their technicality should match the main audience and be expressed in a clear way. EFSA provides extensive guidance in that respect.

Expert panels and evidence reports should aim at consensus, but not at the expense of the rigour of the deliberation. Dissenting views should be documented and explained. Legitimate scientific dissent can be useful to policy – for example, it may offer 'early warnings' on the importance of the problem or minority scientific views.

### Explain the path from evidence to the advice

The reasoning applied by scientific advisors when bridging the gap between evidence and policy options or recommendations should be explained. This should include the assumptions made and normative positions taken, as well as the limitations and uncertainties encountered.

Scientific advisors should consider expressing (through consensus – where achievable) their confidence that their recommendations contribute to achieving the stated policy objective. For this, approaches modelled on the 'pedigree analysis' may be considered.



# *Introduction*



## 1. Introduction

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### 1.1. Why this opinion and for whom

This Scientific Opinion, hereafter 'the Opinion', has been produced by the European Commission's Group of Chief Scientific Advisors, hereafter 'the Scientific Advisors'.

Under President Juncker, the European Commission (EC) has committed to putting better regulation principles and scientific evidence at the heart of policy-making. It asserted that 'high quality scientific advice, provided at the right time, greatly improves the quality of EU legislation and therefore contributes directly to the better regulation agenda'<sup>3</sup>. To this end, in 2015, the EC set up the Group of Chief Scientific Advisors, as well as the Regulatory Scrutiny Board, both of which make use of independent expertise.

We, the Scientific Advisors, have taken up our role because we are convinced that the use of scientific evidence and advice in policy is necessary for the functioning of democracies, and for our societies to thrive and face the challenges of the coming decades. Among other legitimate inputs into decision-making, science has a special role due to the rigorous and comprehensive nature of knowledge that it offers. Defending this role of scientific evidence and advice as a core value is particularly urgent and important now that scientific uncertainty is often exploited to manufacture a general distrust of science or to pursue narrow interests and agendas that ignore evidence.

As the new College of Commissioners will take office in November 2019, we have looked back on roughly three and half years of experience in advising the 2015-2019 College. Our reflections and experience have led us to the conclusion that use of scientific evidence and advice in Commission policymaking can and should be further strengthened.

In working on this Opinion, we took into account insights from practice by listening to the experiences of other practitioners of scientific advice – those advising the Commission, international organisations or national governments. We have also considered the evidence from the scholarship on scientific advice, representing various schools of thought. All that evidence together has revealed concrete areas where our own practice too can be further improved – and these are also reflected in the Opinion.

The societal issues that EU policies seek to address – such as climate change, biodiversity and pollution; ensuring nutritious, healthy and sustainable food; societal transformations due to the rise of artificial intelligence and other next-generation digital technologies – are highly complex. The scientific evidence which is called upon to help address such problems is often equally complex, and typically contains various kinds and degrees of uncertainty that are inherent to science.

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<sup>3</sup>[https://ec.europa.eu/research/sam/pdf/c\\_2015\\_6946\\_f1\\_commission\\_decision\\_en\\_827417.pdf](https://ec.europa.eu/research/sam/pdf/c_2015_6946_f1_commission_decision_en_827417.pdf)

One of the aims of science advice to policy is to provide a reliable and trusted guide through all these layers of complexity and uncertainty. Our ambition is to contribute to that aim through this Opinion.

We are addressing in particular:

- Policymakers at the highest levels of the European Commission, including the College of Commissioners as the architects of the possible future changes to the scientific advisory system in the EC;
- EC policymakers at expert level (in policy departments) who rely on scientific evidence and advice in their work;
- Members of the Regulatory Scrutiny Board;
- Members of EC scientific advisory bodies and expert groups;
- Scientists who are – or are interested in working as – experts contributing to scientific evidence that underpins scientific advice to European policies.

## 1.2. The approach

The work on this opinion started once the Commission endorsed our Scoping Paper<sup>4</sup>, published in February 2018.

A number of evidence sources underpin this Opinion, notably:

1. A scoping workshop<sup>5</sup> - June 2018;
2. Consultation meeting with scientific advice practitioners and EC policy makers - March 2019<sup>6</sup> (referenced in the Opinion as 'Practitioner Consultation').
3. The review report developed by the network of European academies of science – July 2019 (SAPEA, 2019);
4. A report published by the EC Joint Research Centre (JRC), *Understanding Our Political Nature. How to Put Knowledge and Reason at the Heart of Political Decision-Making* – July 2019 (Mair et al., 2019).

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<sup>4</sup> [https://ec.europa.eu/research/sam/pdf/meetings/hlg\\_sam\\_scoping\\_paper\\_science.pdf](https://ec.europa.eu/research/sam/pdf/meetings/hlg_sam_scoping_paper_science.pdf)

<sup>5</sup> [https://ec.europa.eu/research/sam/pdf/topics/masos\\_scoping\\_workshop\\_outcome.pdf](https://ec.europa.eu/research/sam/pdf/topics/masos_scoping_workshop_outcome.pdf)

<sup>6</sup> [https://ec.europa.eu/research/sam/pdf/topics/masos\\_consultation\\_meeting\\_summary\\_032019.pdf](https://ec.europa.eu/research/sam/pdf/topics/masos_consultation_meeting_summary_032019.pdf)



# *Recommendations*



## 2. Recommendations

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### 2.1. Engage early and regularly

#### 2.1.1. Clarify boundaries between science, scientific advice, and politics

**Ensure that scientific evidence and its analysis are differentiated from other factors which influence policy decisions such as interests, values, beliefs, and opinions.**

Scientific advice is a bridging and brokering activity that acts as an intermediary between science and policy (cf. SAPEA, 2019:56; Kowarsch et al., 2016; Pielke, Jr, 2007; Spruijt et al., 2014): it translates practical (societal) issues dealt with by policy into one or more technical (scientific) problems, which can be addressed by science, and then interprets the scientific answers to develop advice to policy (Ravetz, 1971).

Policy and politics are laden with values, opinions, ideologies and competing interests (Parkhurst, 2017; OECD, 2015; Prewitt et al., 2012;). Values and emotions strongly influence not only political behaviour but also perceptions of facts (Mair et al., 2019).

Scientific evidence and advice are not the sole basis for the decision-making process (Cairney & Oliver, 2017; Parkhurst, 2017; Boyd, 2013; SAPEA, 2019:41). In line with a core principle of scientific advice, i.e. the principle of representation, the authority to take final decisions about policies rests with 'democratically representative and publicly accountable officials' (Parkhurst, 2017:177).

Science (and scientific advice) cannot be completely free of values either, despite it being a noble ideal (Douglas, 2009; SAPEA, 2019:96-9; Slob & Staman, 2012; Jasanoff, 1987). For example, the crucial role attributed to science as a source of evidence for policies is ultimately a value position too (Mair et al., 2019). Such core value positions should be made explicit in science advice<sup>7</sup>.

Setting and clarifying the boundaries between science, scientific advice, and politics are fundamental to the impartiality of scientific advice and hence to establishing and maintaining the trust of all those involved (cf. Saner, 2016) – especially when scientific advisors intensely engage not only with scientific experts but also with policymakers and the public, as we recommend they do (see 2.1.2.).

However, particularly for complex policy issues, the boundaries are not usually clearly predetermined. In fact, they may be contested – by policymakers, interest groups, and scientists (Jasanoff, 1987).

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<sup>7</sup> See Mair et al., 2019:8 for an example of a normative statement to that effect.

For example, science is unlikely to give a definitive answer to the question such as 'should certain drugs be decriminalised or legalised' - since the policies in that area are strongly driven by values and ideological standpoints. This may lead some policymakers, as well as some scientists, to state that the question is 'not scientific'.

Conversely, others may claim that the debate can be 'depolicitised' and science can solve it based e.g. on the consideration of relative health risks alone. Decision makers may also have incentives to 'depolicitise' a controversial issue by assigning it to scientific committees (Parkhurst, 2017:71).

Another issue that may be contested concerns the question of whether scientific advice can formulate policy options, or even recommend some, without encroaching on policy and politics (see Box 1 for an extended example):

- (a) a minimalist role for scientific advice (as a 'science arbiter'; Pielke, 2007) is to synthesise, assess and present the evidence, and make it as relevant to the policy issue as possible - but stay clear of formulating any forward-looking options;
- (b) scientific advisors as 'honest brokers of policy alternatives' (Pielke, 2007) where scientific advice formulates alternative courses of policy action, based on the analysis of evidence (Pielke, 2007; WRR 2017b; GCSA UK 2010);
- (c) Scientific advisors formulating a recommendation - i.e. stating a preferred policy option among several considered, based on their reasoning and interpretation of evidence (WRR 2017b), while leaving the decisions to policymakers. This may involve multiple recommendations based on the 'if-then' reasoning (WRR 2017b).

The last role listed above tends to be the most contested. Some practitioners reject it outright as encroaching on the domain of politics (Boyd, 2013; see also Box 1). Others advise against it for socially controversial issues - because of the risk of scientific advice being perceived as siding with a value-driven preference and thus getting mixed up in the controversy (Tyler & Akerlof, 2019). Stirling (2010) advocates it in the form of 'plural conditional' advice for complex policy issues with high uncertainties.

Wherever the boundaries for scientific advice are drawn, they need to be clearly agreed at the start between policymakers, scientific advisors and experts (OECD, 2015:9-10; GCSA UK, 2010). Stakeholders and the public may also have a role where appropriate (see 2.1.2.). Scientific advisors - as credible and reflective intermediaries - have a prime role in facilitating the dialogue and analysis that are necessary for agreeing and setting the boundaries.

In the example of drug policy, this would practically mean to define the questions pertinent to the issue which scientific advice can usefully address in order to inform policy. This approach can include assessing relative health risks of various legal and illegal drugs ('science arbiter'), but also a comparison of the likely health, economic or crime-related costs and benefits of various options ('an honest broker of policy alternatives'), and even a review of relevant ethical considerations and dilemmas.

In the EC, developing policy options for major new policy initiatives is a core objective of impact assessments (IAs). These are drawn up by policymakers at

expert departmental level, rather than scientific advisors. However, they draw heavily on specialised scientific evidence and expert input<sup>8</sup> and are then evaluated by the Regulatory Scrutiny Board.

The Group of Chief Scientific Advisors, operating at a cross-departmental level and advising the College of Commissioners, has regularly been tasked with developing broad strategic recommendations to policy, next to occasionally acting as a 'science arbiter', e.g. through explanatory notes on complex and controversial topics<sup>9</sup>.

*There is a spectrum of legitimate roles for scientific advice in the EC. Defining them explicitly, ideally at the start of advisory work, is important for the clarity of its mandate. Concretely, this can be achieved by:*

*(a) scientific advisors, experts, and policymakers defining together the questions that scientific evidence and advice can address, including a decision on whether the formulation of evidence-supported policy alternatives is desired, and*

*(b) deciding together on the precise role and principles of involving stakeholders and the public in scientific advice.*

*2.1.2. contains guidance on both of the above dialogues.*

*NB. This recommendation does not in any way prevent any scientific or advisory body (e.g. national academies) from offering pro-active and unsolicited advice on EU policies without any need for defining the questions or the mandate with the policy clients. We are aware of national advisory models which emphasise distance rather than close collaboration, as a means of ensuring complete independence. They are a part of the plural advisory landscape in Europe and play a useful role within it. The co-creation model that we recommend for the EC is geared at facilitating the use of science advice developed by bodies enjoying frequent and direct access to EC policymakers, while ensuring its impartiality.*

### **2.1.2. Define together the questions to be addressed**

**Engage early and regularly with those requesting scientific advice to ensure the questions for advisors are properly defined.**

A systematic review of the barriers to and facilitators of the use of evidence by policymakers (Oliver et al., 2014) reveals that collaboration and relationship-building between scientists and policymakers are among the top five facilitators (next to the availability, clarity, relevance and reliability of research findings).

<sup>8</sup> Impact assessments address the likely economic, social and environmental impacts of each of the shortlisted options - which can be positive and negative; direct and indirect, intended and unintended [https://ec.europa.eu/smart-regulation/guidelines/docs/br\\_toolbox\\_en.pdf](https://ec.europa.eu/smart-regulation/guidelines/docs/br_toolbox_en.pdf)

<sup>9</sup> On glyphosate <https://ec.europa.eu/research/sam/index.cfm?pg=glyphosate>, and on new techniques in agricultural biotechnology <https://ec.europa.eu/research/sam/index.cfm?pg=agribiotechnology>

*A crucial way to help ensure that relevant questions are being addressed by scientific advice is to engage with policymakers from the very early stage (GCSA UK, 2010:5-6; KNAW, 2013:6; The Royal Society & Academy of Medical Sciences, 2018:14-15; Mair et al. 2019:64) with the purpose of defining the questions through reflective, nuanced and rigorous deliberation.*

This deliberative engagement is likely to mitigate an issue whereby scientific experts may consider that policymakers ask them the 'wrong' questions (Mair et al., 2019:64) whereas from the policymakers' perspective it is the scientists who may formulate the 'wrong' questions without being asked, and proceed to answer them (SAPEA, 2019:122).

The case study on badger culling as a response to bovine tuberculosis (Box 1) illustrates a number of issues that may go wrong in scientific advice, including a disputed scope of the problem to be addressed by science.

Lack of deliberative engagement can manifest itself in a number of problems that may lead to questions ending up 'wrong' from either perspective. These include in particular:

1. Unexamined assumptions (on all sides) about the types of questions that science can best answer or cannot answer - which may introduce an 'issue bias' into the process (Parkhurst, 2017:54-60).
2. The pressure to limit the above questions to assessing measurable risk (Stirling, 2010:1029) (see also 2.3.1.)
3. The fact that questions for scientific advisors may be defined from the perspective of a single departmental policy (e.g. food safety, environment, or agriculture) whereas they may be a part of a more complex and multifaceted issue (Cairney, 2016:28).
4. 'Blind spots' in how policymakers and/or scientific experts see a problem, which may have developed through deliberation with stakeholders and representatives of the public (Konig, Borsen, & Emmeche, 2017:13; OECD, 2015:9-10).
5. Insufficient understanding on the part of scientific experts of how policymaking and politics work (Mair et al., 2019:63; Tyler, 2013; Cairney, 2016:7-24) as well as insufficient scientific literacy among policymakers, including e.g. understanding the nature of scientific evidence (Mair et al., 2019:64) or interpreting scientific claims (Cairney, 2016:64-7; Sutherland et al., 2013).

Due to their role as intermediaries between science and policy, scientific advisors have a central and complex role in initiating and facilitating the deliberative dialogue, as well as mitigating all the issues listed above.

*The dialogue on problem definition typically needs to be iterative (Mair et al., 2019:69): as preliminary scientific evidence is gathered and analysed, the questions being addressed by scientific advice to policy may need to be refined again.*

### Box 1. Case study: the badger culling controversy (adapted from Montuschi, 2017)

In 1998, an Independent Scientific Review Group (ISG) in the UK reviewed the available evidence about the link between tuberculosis (TB) in badgers and in cattle and concluded that badgers are a significant source of infection in cattle. However, science was not able to say at the time whether culling badgers can be effective in combatting the spread of disease in cattle. To answer that question, a Randomised Badger Culling Trial took place between 1998 and 2007 overseen by the ISG. The resulting 2007 report concluded: 'although badgers do contribute to the disease in cattle, culling badgers is *not* the solution – and indeed it might even make things worse'.

The ISG took on a broad definition of the problem. Their report reads: '...while confirming its commitment to the scientific approach, the [committee] identified its core aim as being 'to present Ministers with a range of scientifically based policy options which will be technically, environmentally, socially and economically acceptable'. Accordingly, the ISG report included in its evidence base – besides wide natural science grounding in genetic, epidemiological, ecological and environmental studies – economic, social, practical and animal welfare issues that were deemed critical to assessing the effectiveness of culling as a measure of TB control.

In response, the government asked the Government Chief Scientific Advisor (GCSA) to assess the evidence provided by the ISG report. The brief to GCSA was to 'exclude economic and other practical issues'. The GCSA report reached a diametrically different conclusion than ISG, stating that culling badgers is 'the best option available at the moment to reduce the reservoir of infection in wildlife' – provided that it is properly carried out following an established protocol.

The government decided to authorise culling in 2011. It stated that making predictions on the effectiveness and sustainability of culling badgers by the farming industry is 'a matter of judgement not of science' – suggesting that the earlier ISG report had ventured inappropriately into what should be the preserve of policymaking only. The ISG in turn criticised the narrow scope of the GCSA brief. The Chief Scientific Advisor (CSA) in the Department for Environment, Food and Rural Affairs (DEFRA) was of the view that 'unfortunately, some scientists have been drawn in to the public debate about which policy option is correct. If scientists start to say [that] then they are beginning to take the position of politicians and they devalue the scientific evidence they claim to present' (Boyd, 2013).

Unlike the GCSA earlier, however, the DEFRA CSA pointed out in 2013 that, because 'the epidemiology of bovine TB is fiendishly complex', several policy options are feasible based upon the evidence rather than a single one. In fact, several different policies were being pursued in different jurisdictions at the time (Boyd, 2013): next to proactive badger culling (England), they included badger vaccination (Wales); testing and vaccinating (Northern Ireland) and reactive badger culling (Republic of Ireland). Boyd argued that it would be inaccurate to suggest that, 'based upon the evidence, any of these policy options is more or less correct' and that 'all are possible even if the evidence suggests that some might be more successful than others' (Boyd, 2013).

Next to being a source of societal controversy and a dispute about the boundaries of scientific advice, the case was also subject to scientific controversy and dissent. The ISG accused the GCSA report of fundamental scientific errors in the use and interpretation of the data from ISG report, and making a case for badger culling without proper basis in evidence. Since the second report was authored by a government advisor and enthusiastically welcomed by the farming industry, accusations of a lack of impartiality also appeared.

Two badger culls took place in 2012/13 and 2014/15. Next to extensive social protests on animal-welfare grounds, stakeholder organisations opposed to culling, as well as a number of scientists, have contested the government claim that culling has been effective in reducing the prevalence of the disease. Today, while the policy is being continued, the government has moved towards a mix of interventions rather than insisting that culling is the single best option available. In 2019, DEFRA stated that: 'there is no single measure that will provide an easy answer to beating the disease. That is why we are pursuing a range of interventions to eradicate the disease by 2038, including tighter cattle movement controls, regular testing and vaccinations'<sup>10</sup>.

<sup>10</sup> <https://deframedia.blog.gov.uk/2019/03/18/bovine-tb-and-badger-culling/>

**When analysing a complex policy issue to define questions for scientific advice, take a systems perspective and consider the use of the best available aids.**

Defining the question for scientific advice should involve a rigorous analysis of the complex policy issue at hand. This is likely to help define aspects that can be most usefully addressed by scientific advice (Ansell & Geyer, 2017; Geyer & Rihani, 2010).

**Complexity** is a characteristic of a (natural or social) system where there are strong interactions among its elements, and where the cause-effect links between a multitude of interdependent variables are not fully understood or predictable (SAPEA, 2019:27-30; Geyer & Rihani 2010:16-52).

Examples of complex systems include a flock of birds, the human brain (OECD, 2009:5), traffic (OECD, 2017:15), climate patterns, large interconnected infrastructures (SAPEA, 2019:28), healthcare systems (Cairney, 2016:38) or educational systems (Snyder, 2013; OECD, 2017). Policymaking itself is a highly complex system (Mair et al., 2019:68; Cairney, 2016).

Features of complex systems of particular relevance to policymaking and scientific advice include:

- **emergence**: behaviour resulting from interactions at local level which restricts the behaviour of the whole system, thus making predictions of policy impact difficult. For complex policy issues, this implies that it can be useful to employ pilot schemes before big central policy roll-outs (Cairney, 2016:38-9; 75-6; OECD, 2009:6; Ansell & Geyer, 2017; Sanderson, 2009).
- **path dependence**: dependence on the initial decisions and conditions (e.g. resources historically committed to a policy; *ibid*: 38). In policy and scientific advice this often means that, as Tyler (2013) put it, 'starting policies from scratch is very rarely an option';
- the likelihood of some small actions having large effects, and large actions having small effects. In policymaking that may mean that certain issues are ignored or, conversely, disproportionate attention is paid to them in the policy agenda (Cairney, 2016:38).

**Box 2. Stacey diagram: a tool to facilitate the definition of questions for scientific advice for, with an application example**

The Stacey diagram is based on two axes: the degree of certainty, and the level of (political/societal) agreement on the issue in question (Ansell & Geyer, 2017; Geyer & Rihani, 2010).

It parses a complex policy issue into different zones, with differing scope for scientific expertise and advice. Ansell and Geyer (2017) provide a case study of drug policy in the UK<sup>11</sup>.

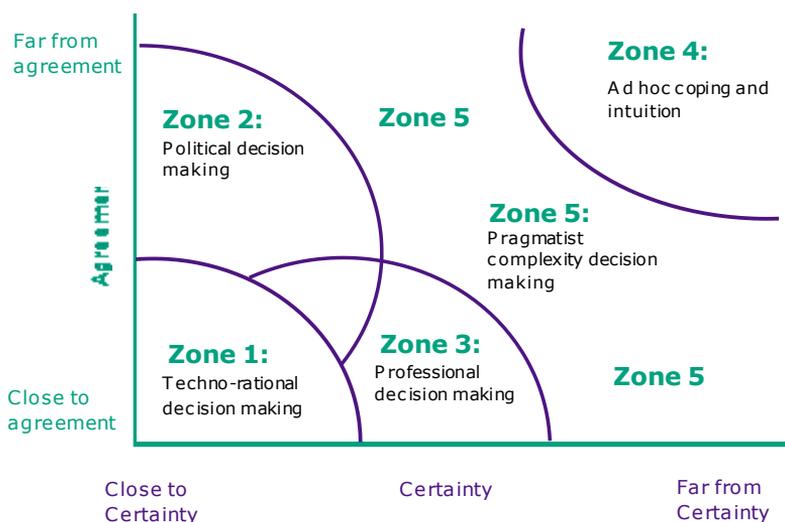
Zone 1 (e.g. efficacy of addiction treatments) – requires specialist scientific expertise and standard methods to assess efficacy and risks

Zone 2 (e.g. drug legality policies) – a value-laden political zone; scientific evidence and advice may inform it (e.g. with evidence on comparative health risks of drugs; likely health, economic and crime-related impacts of various options); however, scientific evidence is unlikely to be the primary factor influencing decisions;

Zone 3 (e.g. best strategies for reducing drug-related criminal activity) – expert dissent is common due to scientific uncertainties (e.g. complex and multiple cause-and-effect relations; evidence is largely based on experts weighing probabilities of different pathways;

Zone 4 – (e.g. helping drug addicts with a range of additional problems, e.g. health and poverty issues) – a chaos zone where ‘ad-hoc coping and intuition’ predominate; the role of scientific evidence is limited; some locally valid qualitative research may still be applicable;

Zone 5 – an area where complex science intersects with societal complexity: with a key role for scientific advisors as intermediaries, and for continual mutual learning with policymakers; recommended policy options may involve a preference for smaller pilot projects as learning exercises.



*Stacey diagram (Adapted from Ansell & Geyer, 2017; Geyer & Rihani, 2010)*

<sup>11</sup> The zone descriptions, including their applicability to science advice, have been adapted and expanded.

*Analysing a complex policy issue to define a question for scientific advice requires reflective deliberation – since typically a number of very different questions can be formulated, depending on the level of analysis (see e.g. OECD, 2015:9-10, Kovacic, 2017)<sup>12</sup>.*

*The deliberation needs to take a 'systems perspective', which helps policymakers and advisors 'think broadly about the whole picture rather than merely studying component parts in isolation' (Prewkitt et al., 2012:60).*

*The deliberation can be facilitated through the use of straightforward conceptual aids. An example (the 'Stacey diagram') is presented in Box 2.*

*A number of scientific methods can and are being used to analyse complex systems (e.g. in epidemiology, traffic management or climate change models; OECD, 2009:11-12). These methods include e.g. dynamic systems modelling, network analyses, sensitivity analysis or scenario modelling (ibid; OECD, 2017:22).*

Integrating foresight and horizon scanning into scientific advice is particularly important for 'wicked problems' (Rittel & Webber, 1973) that cross departments, cross disciplines and have timescales longer than the lifetimes of governments' (Beddington, 2013:22) see also (OECD, 2015:9-10).

Foresight and horizon scanning may also mitigate the risk of missing 'early warnings'. Stirling (2010:1029) provides historical examples: the belated recognition of the effect of seemingly benign and inert halogenated hydrocarbons on the ozone layer, and the slow recognition of the possibility of novel transmission mechanisms for spongiform encephalopathies (see also EEA, 2013) for more 'late lessons from early warnings'.

In the EC, the Joint Research Centre (JRC) has recently established the Competence Centre on Foresight – Megatrends Hub<sup>13</sup>, and has begun work on understanding potential implications of megatrends to specific policy issues in a systemic context.

Attention to 'foresight and other forward-looking tools' is given in the EC Better Regulation 'Toolbox'<sup>14</sup> which stresses that those tools 'complement quantitative modelling with a system thinking and long-term approach'. Among the roles of foresight in policy that are highlighted is 'inform[ing] policy by generating insights regarding the dynamics of change, future challenges and options that can be used as an input to policy conceptualisation and design'.

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<sup>12</sup> (Kovacic, 2017) provides an example of the issue of water scarcity and water management efficiency in Israel, which leads to different questions and different uncertainties depending on the 'scale of analysis' (e.g. the level of the agricultural sector, society as a whole, or the ecosystem as a whole).

<sup>13</sup> [https://ec.europa.eu/knowledge4policy/foresight\\_en](https://ec.europa.eu/knowledge4policy/foresight_en)

<sup>14</sup> Tool #2: 'Evidence-based Better Regulation'  
[http://ec.europa.eu/smart-regulation/guidelines/docs/br\\_toolbox\\_en.pdf](http://ec.europa.eu/smart-regulation/guidelines/docs/br_toolbox_en.pdf)

The European Parliament's team supporting the Panel for the Future of Science and Technology (STOA)<sup>15</sup> – the main scientific advisory body of the parliament - includes a foresight team.

*Greater integration of foresight and horizon scanning should be considered in the work of scientific advisory bodies in the EC - particularly those which offer proactive advice on complex policy issues involving significant future challenges.*

**When policy issues are contested, involve stakeholders - and other members of the public - as appropriate. Consider the use of the best available analytic-deliberative approaches.**

Complex policy issues addressed by scientific advice may be socially contested<sup>16</sup> – which means that there are widely different opinions in society about the desired goals and courses of action. Contestation is typically due to different values, beliefs and attitudes (SAPEA, 2019:35, Parkhurst, 2017:95).

In EU policy, examples of currently contested issues include migration and asylum, biotechnology (including e.g. gene editing), the use of pesticides in agriculture, climate change mitigation policies or the conservation of natural resources such as primeval forests<sup>17</sup>. Box 1 presents a case study of a contested national (UK) policy of badger culling, and Box 4 discusses an EU-wide case of measures taken to control the spread of a dangerous plant disease which have met with protests and contestation through courts.

An acute form of contestation is issue polarisation – where there are few middle-ground positions, and the issue is typically debated in binary terms (Parkhurst, 2017:77-8). International examples of polarising policy issues include abortion, same-sex marriage, the teaching of creationism at schools, or vaccination.

The scientific evidence which informs contested or polarising policy issues may be complex and uncertain – but in varying degrees, depending on the question or sub-question.

For example, in the area of climate change, there is overwhelming scientific consensus that climate change is real and caused by humans (cf. Benestad et al., 2016), and that taking no or little action will lead to catastrophic global

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<sup>15</sup> <http://www.europarl.europa.eu/stoa/en/home/highlights>

<sup>16</sup> This condition is also referred to as socio-political ambiguity (SAPEA 2019:35).

<sup>17</sup> See (Stokstad, 2017) and (Konarzewski et al, 2018) for the societal and scientific controversy around the logging of the Białowieża primeval forest in Poland, which led to a ruling by the European Court of Justice:  
<http://curia.europa.eu/juris/document/document.jsf?docid=201150>

consequences within a few decades. However, the exact effects of climate change on local weather patterns are subject to many uncertainties due to their complexity, as is the case also when deciding which specific mix of climate-change mitigation policies is likely to be the most effective environmentally and socially.

Whenever scientific advice is called upon to inform contested or polarising issues, members or representatives of the public should be involved from early stages (SAPEA, 2019:123; see also e.g. OECD, 2015:9-10; Konig et al., 2017:13).

In such cases, involving representative stakeholder organisations will often be sufficient and the most practical (National Research Council, 2008:15; see also GCSA UK, 2010). However, for highly contested issues, involving individual members of the public who are directly affected by possible policy outcomes or who have strong opinions about them should be considered, to help ensure that 'the process is not, or does not appear to be captured by organised interests that may not raise the full range of public concerns' (National Research Council, 2008:15).

*To be done well, public participation in scientific advice must have a clear purpose); it must follow clear principles and a rigorous method, and have clear commitment in terms of time and resources (National Research Council, 2008: 1-5).*

*All of the above success factors should be a part of the early joint reflection and analysis by scientific advisors and policymakers.*

Roles of scientific advisors participating in the analytic-deliberative process involving stakeholders and the public may include:

- together with policy makers, identifying any overlooked aspects of the problem which scientific advice might usefully address;
- clearly communicating the available evidence, including its uncertainties, the scientific criteria that have been applied to assess the evidence quality, the ways in which the evidence has been identified and used, and the measures taken to ensure impartiality in synthesising the evidence (see also 2.2.2. and 2.2.3.); this is a part of transparency identified as one of the features of good governance of evidence (Parkhurst, 2017:162);
- gathering new evidence relevant to the issue at stake (e.g. the experiential knowledge of practitioners affected by potential policy decisions);
- seeking consensus on a possible arbitration approach when scientific evidence is contested (e.g. due to the existence of dissenting evidence, or alleged bias in the evidence underpinning the advisory process);
- gauging the implications of the different policy options that scientific advisors are considering recommending, based on their analysis of the evidence;
- clearly communicating the reasoning that has led scientific advisors to formulate policy recommendations or options based on their analysis of the evidence.

A model that is held up as the most suitable for science advice to EU policy is an analytic-deliberative one, which combines a rigorous analysis of available scientific evidence with broader societal dialogue about its implications (SAPEA, 2019:125), such as the analytic-deliberative approach developed by the US National Research Council (2008). Box 3 summarises its most relevant elements.

### **Box 3. A model for integrating public participation in scientific advice**

*Adapted from US National Research Council (2008, 1996)*

#### **Possible purposes of public participation integrating scientific advice**

1. Improving policymaking quality (and relevance of scientific input), e.g. by clarifying the nature of the problem.
2. Improving legitimacy, e.g. by seeking consensus on: the problem to be addressed, the credibility of relevant evidence, the process for conducting an assessment or informing the policy decision.

#### **Key principles**

1. Ensuring transparency of decision-relevant information and analysis.
2. Paying explicit attention to both facts and values.
3. Promoting explicitness about assumptions and uncertainties.
4. Including independent review of official analysis and/or engaging in a process of collaborative inquiry with interested and affected parties.
5. Allowing for iteration to reconsider past conclusions on the basis of new information.

*The EC currently has extensive guidelines<sup>18</sup> and tools<sup>19</sup> on stakeholder consultation, which have been developed as part of the Better Regulation package. However, they do not explicitly consider how scientific advice and scientific evidence can be a part of the process. We recommend addressing this issue in future versions of that guidance.*

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<sup>18</sup> <https://ec.europa.eu/info/sites/info/files/better-regulation-guidelines-stakeholder-consultation.pdf>

<sup>19</sup> [https://ec.europa.eu/info/better-regulation-toolbox\\_en](https://ec.europa.eu/info/better-regulation-toolbox_en) (tools 53 to 56)

## 2.2. Ensure the quality of the scientific evidence

### 2.2.1. Use the full scope of good science

**Consider all good science – from all scientific disciplines and perspectives – that could contribute to the issue at hand. This includes natural sciences, engineering, medicine, social sciences and humanities.**

While methodologies such as randomised controlled trials (RCTs) and meta analyses are highly appropriate to many scientific questions (e.g. the efficacy and safety of medicines<sup>20</sup>), they are not suitable for many other questions of relevance to policy that science can address. Social sciences<sup>21</sup> rigorously address many questions of direct relevance to decision-making (e.g. about economic forecasting, public acceptability and perceptions, or demographic trends). They employ a variety of methodologies, some of which (e.g. RCTs) are very close to those employed in natural sciences. Qualitative research methods in social sciences are particularly helpful for understanding *why* and *how* certain social and human phenomena (e.g. political attitudes, or unhealthy behaviours such as poor nutrition) occur, rather than *how often* or with which probability (see INGSA, 2014b:10).

Humanities<sup>22</sup> are valuable particularly for placing long-term policy and societal issues, and science advice itself, in a broader cultural and socio-historical context, and providing general conceptual frameworks for thinking about them (Brom, 2019)<sup>23</sup>. Some of the methods used in the humanities (e.g. in the analysis of written records, and material artefacts) are akin to those in natural sciences; some others (e.g. in some branches of philosophy) rely mainly on logical reasoning and argumentation (SAPEA, 2019:39).

Research in any domain, and using any methodology (from RCTs through surveys to qualitative methods) can be done well or poorly. When done well, it has potential to offer valuable – and diverse - insights to policy. When done poorly, it may easily be misused by interest groups and 'merchants of doubt' (Oreskes & Conway, 2010) to undermine other solid evidence (see INGSA, 2014b:10).

Science has its own quality-control and self-correction mechanisms (such as testing to eliminate hypotheses), and is recently taking quality control further through increased attention to the reproducibility of results, where applicable. Good evidence synthesis for policy provides further quality mechanisms – e.g. by ensuring that the

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<sup>20</sup> See also the example of the use of randomised controlled trials in Box 2.

<sup>21</sup> E.g. economics, sociology, social psychology, political science, cognitive and behavioural sciences, sustainability science; public health studies; human, economic and social geography.

<sup>22</sup> E.g. philosophy, history, anthropology, ethics

<sup>23</sup> This corresponds to the uses of science in policy which are termed conceptual (Nutley, 2007:33-59) and which cover deliberative use (Gluckman, 2016), orientation (SAPEA, 2019:59) and enlightenment (SAPEA, 2019:58; Weiss, 1979; see also Parkhurst, 2017:24-5).

evidence considered is relevant and comprehensive, and reducing the arbitrariness of expert judgements (see 2.2.3.).

Developing scientific advice on complex policy issues (which often mean relying on scientific evidence that is equally complex) typically requires scientific expertise from different scientific perspectives - e.g. the perspectives of different scientific disciplines, but also different schools of thought within disciplines (SAPEA, 2019:124).

Bringing in these different scientific perspectives on complex issues is particularly important in the early stages of problem identification (see above), when the questions for scientific advice are not yet well-defined. Hence, it may be far from certain what kinds of scientific expertise will be relevant – and a broad, plural approach at that stage can help determine what focus would be most appropriate.

Another stage when plural scientific perspectives are particularly important is developing policy options or recommendations. Next to policy practitioners, and relevant representatives of the public (see 2.1.2.), involvement of social sciences (e.g. economics, sociology, or behavioural and cognitive sciences) and humanities can be useful – since formulating science-informed policy options is connected with assessing the societal scenarios they may lead to, including any unintended consequences (see Cairney, 2016).

Developing scientific advice on a complex issue can lead to a number of highly specific scientific sub-questions. In our own practice, these have been in the natural sciences – e.g. toxicology, epidemiology or genetics. The sub-questions are likely adequately addressed within a single scientific discipline, which in practice means setting up panels of specialised experts from the same field. Formal methods of expert knowledge elicitation, which are used to quantify uncertainties, may go yet further by requiring experts to be recruited not only in a single discipline but also to have a fairly homogenous disciplinary profile (see 2.2.3.).

In current EC practice, the highest-level permanent scientific advisory bodies are **multidisciplinary**. The members of the Group of Chief Scientific Advisors, beyond representing diverse fields, are also required to have a broad vision which collectively allows **interdisciplinary** work<sup>24</sup>. The European Group on Ethics (EGE), which advises the EC College of Commissioners on ethical questions posed by scientific and technological innovation, also takes a multi- and inter-disciplinary perspective, with members ‘appointed for their expertise in the fields of law, natural and social sciences, philosophy and ethics’<sup>25</sup>. Other practitioners of scientific advice outside the EC stress the important effects of interdisciplinary deliberation within such bodies (see esp. Owens, 2015:148-9).

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<sup>24</sup> EC Decision 16.10.2015 on setting up the Group of Chief Scientific Advisors, [https://ec.europa.eu/research/sam/pdf/c\\_2018\\_1919\\_ec\\_decision\\_consolidated.pdf](https://ec.europa.eu/research/sam/pdf/c_2018_1919_ec_decision_consolidated.pdf)

<sup>25</sup> More on EGE at [https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/european-group-ethics-science-and-new-technologies-ege\\_en](https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/european-group-ethics-science-and-new-technologies-ege_en) ; see also Annex 5.

*Further improvements in multi- and inter-disciplinarity when advising the EC can be achieved through greater synergies between the Group of Chief Scientific Advisors and the European Group on Ethics.*

*For ad-hoc expert panels working on complex topics, which support permanent advisory bodies or are set up directly by policymakers in the EC, we recommend that multidisciplinary is thoroughly considered in the composition of the panels, and panel deliberations are structured in a way that favours interdisciplinary work.*

### 2.2.2. *Ensure rigorous evidence synthesis*

**Follow best practices in evidence synthesis and commission it only from bodies that apply rigorous standards.**

Good evidence for policy is defined as evidence that is appropriate (i.e. useful to the policy needs by addressing the right questions) and of high quality (Parkhurst, 2017:119). The aspect of appropriateness (i.e. defining the 'right' questions) is dealt with extensively in 2.1.2. This chapter deals with the quality of evidence, and in particular with the quality of evidence *synthesis* for policy.

Evidence synthesis for policy means bringing together the best available information and knowledge from different disciplines to inform policy making (The Royal Society & Academy of Medical Sciences, 2018). It can draw both on pre-existing documented sources and on new expert input (e.g. in the form of expert working groups or hearings). The section focuses on the former, as the latter is addressed in detail in 2.2.3.

Synthesis can be commissioned directly by policymakers (e.g. for the purpose of developing an evidence-based impact assessment of policy options) or by scientific advisory bodies which will then use it as a basis for developing their advice to policy.

A wide variety of approaches to, and methods of, evidence synthesis exist (see Annex 5). The choice between them often implies trade-offs (e.g. between speed and rigour) and is influenced by multiple factors, the most important of which include:

- *The purpose.* Evidence synthesis may be requested e.g. only to gain a preliminary understanding of the state of knowledge as part of the work on scoping the issue formulating questions (as in a scoping...review) or to systematically collate and *appraise* all the available and relevant evidence (as in the full systematic review).
- *The time available.* Evidence synthesis is used both in short-term emergencies (OECD, 2015) and to inform medium- or longer-term challenges policy.

Evidence may thus need to be synthesised in a matter of hours and days during a crisis (as in the case of the Fukushima disaster<sup>26</sup>), or over months or years - as in the case of the Intergovernmental Panel for Climate Change (IPCC), which oversees a comprehensive synthesis process with reports every five years (Craig, 2019).

- *Policy importance.* Scientific questions of high importance to policy decisions (e.g. on banning, or not, a very commonly used chemical agent) are more likely to require, and be granted, the use of more time-consuming methods which are less prone to biases. When evidence synthesis reveals a significant knowledge gap of high importance for long-term policies, this may in fact lead to requests for developing new primary evidence. Box 1 illustrates such a case where primary research was conducted for almost a decade to address the question of the effectiveness of badger culling as a means of controlling tuberculosis in cattle. Box 4 describes a request for a new EU risk-assessment study which informed the policy response to dangerous plant disease epidemic affecting several EU countries.
- *The breadth of the question.* Some of the most formalised synthesis methods (e.g. full systematic reviews) are not usually suitable for addressing broad and complex questions which are likely to require evidence from different disciplines and using a variety of scientific methodologies.

*The resources available* – including budget and staff.

Some synthesis methods offer more condensed versions – which are less time-consuming and resource-intensive but can be used for a similar purpose. For example a rapid evidence assessment is a condensed version of a full systematic review. (See Annex 5). Using condensed versions typically implies some compromises in terms of comprehensiveness and bias risks, but is always to be preferred over even less rigorous methods whenever possible (Collaboration for Environmental Evidence, 2018; Pullin, & Kaiser, 2014).

In the EC, evidence synthesis takes notably the following forms:

- synthesis offered by the Joint Research Centre in its role as the EC's science and knowledge service – esp. through Knowledge Centres in specific areas, which manage knowledge e.g. in the form of systemic reviews, meta-analysis and data visualisation, whereby the demand for knowledge is co-ordinated with EC policy departments (JRC, 2018). In addition, through its Competence Centres, the JRC works with EC policy clients to develop primary evidence e.g. through advanced methods such as modelling (which can be used e.g. to

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<sup>26</sup> The Fukushima disaster was a nuclear accident at the Fukushima Nuclear Power Plant in Japan. The accident was started by the tsunami following an earthquake on 11 March 2011 (Sato & Arimoto, 2016)

assess the environmental, economic, and social impacts of policies) and data-driven microeconomic evaluation;

- evidence review reports commissioned by scientific advisory bodies from public organisations (which is the current model used by the Group of Chief Scientific Advisors, with a network of academies of science designated as the evidence-synthesis body);
- evaluations and studies commissioned by EC policy departments from external contractors;
- synthesised outcomes of EU-funded research projects relevant to the policy area in question (Projects for Policy - P4P<sup>27</sup>).
- other available review reports (e.g. World Bank, OECD, European Parliament).

The general quality criteria of evidence synthesis include (Kowarsch et al., 2016):

- comprehensiveness – i.e. covering all relevant evidence in its various forms, from peer-reviewed scientific literature, through grey literature to opinion-based knowledge held by stakeholders (when appropriate), and allowing a clear picture of the gaps and uncertainties (what is unknown, partially known, or unknowable).
- interaction with clients and iteration: e.g. allowing a reframing of the question and the search approach based on the analysis of preliminary results;
- transparency of the synthesis methods - e.g. of the protocols used for searching, appraising and collating the evidence;
- aiming to minimise any biases to the extent possible for the method in question (Donnelly et al., 2018).

For some of the synthesis methods, particularly systematic reviews, rapid evidence assessments, ~~scoping...reviews~~ and ~~meta-analyses~~, detailed methodological and quality-assurance guidance exists (Collaboration for Environmental Evidence, 2018; Collins et al, 2014; Petticrew & Roberts, 2006; Woodcock, Pullin, & Kaiser, 2014).

The type of evidence included in evidence synthesis is largely determined by the question to be addressed, and typologies of evidence types are available to guide that choice (Petticrew & Roberts, 2003, 2006). For example, questions about the effectiveness of a policy intervention are likely to include primarily experimental studies (e.g. RCTs) and observational studies, whereas questions related to the motives of human behaviours and attitudes (e.g. resistance to some new technologies) will typically privilege qualitative studies combined with surveys.

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<sup>27</sup> [https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/p4p\\_en](https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/p4p_en)

The quality of specific pieces of evidence included in the evidence synthesis is another matter. Quality of underlying science is fundamental: even the most rigorous synthesis of unreliable studies will not lead to high-quality outcomes. The degree to which evidence quality can be appraised in the synthesis again depends on the choice of the method, and the volume of the evidence base. Full systematic reviews, which take the longest to complete, include the appraisal of the quality of each piece of evidence. More rapid methods may use proxy criteria of quality – e.g. the publication in peer-reviewed journals, combined with the scrutiny of the methodology statements provided by authors. Volume also matters: if the synthesis is composed of a small number of key studies, their quality can be appraised relatively quickly.

Appraising the quality of a specific piece of evidence requires recourse to the quality criteria applicable to the methodologies used in the study in question (RCTs, surveys, qualitative studies etc.; Parkhurst, 2017, Petticrew & Roberts, 2003, 2006; cf. Boyd, 2013). Naturally, they come in addition to the general quality criteria which are applicable to *all* science (such as honesty in acknowledging the limits of data and methods, integrity, scepticism, logical reasoning, the relevance and appropriateness of the data and methods used to the question under study, and openness to the claims that it generates being scrutinised, tested and refuted; SAPEA, 2019:38).

*Based on the evidence including practical experience, we recommend the following practices which together aim to ensure high quality of evidence synthesis in the EC:*

- *Commissioning evidence synthesis only from bodies which are demonstrably competent in recognised evidence-synthesis methods and demonstrably adhere to the quality standards relevant to those methods (Collins, et al, 2014; Parkhurst, 2017). For policymakers commissioning synthesis directly from contractors, a practical approach may be to stipulate such quality-assurance requirements in the terms of reference.*
- *Ensuring that evidence synthesis teams bring together synthesis methodology experts and topic experts.*
- *A reflective decision on the choice of the appropriate evidence synthesis approach - made in dialogue and interaction between providers and requesters (policymakers or scientific advisors) and guided by the key considerations such as purpose, policy importance, time and resource available and the breadth of the questions;*
- *Ensuring peer review of the evidence synthesis reports by experts who are not involved in the evidence synthesis or related scientific advisory process (Royal Society & Academy of Medical Sciences, 2018; SAPEA,2019; Karlsson & Takahashi, 2017)*
- *Encouraging the publication of synthesis reports in peer-reviewed scientific press, as further quality control layer which allows a broader scrutiny of the scientific community.*

### 2.2.3. Ensure rigour in expert consultation

#### **Ensure that expert consultations which are a part of evidence synthesis follow best practice to increase rigour, and reduce arbitrariness and bias.**

Next to pre-existing documented sources such as journal articles, evidence synthesis frequently includes expert consultation (e.g. in the form of expert working groups, hearings, or sounding boards).

Expert consultation is likely to be particularly helpful when:

- a) there are important gaps in the available evidence which could be addressed by eliciting expert judgement;
- b) scientific advice involves an interpretation of the evidence to formulate policy options or recommendations (if that is a part of the mandate – see 2.1.1.), as this requires judging the applicability of available knowledge to the specific policy context and making informed predictions (e.g. of a likely effectiveness of a course of action) on that basis.

In the above cases, expert consultation is often an essential part of evidence synthesis. However, expert judgement is prone to different kinds of bias, which must be managed and mitigated.

One category is bias driven by various kinds of interests (e.g. personal, financial, political, or ideological). It is dealt with extensively in 2.2.4.

In addition, there are cognitive biases and heuristics (SAPEA, 2019:61-70) which need to be reduced in the interest of a rigorous outcome (EFSA, 2018a:25; see also 2.2.4.).

The existing approaches to reducing cognitive bias in expert judgement range from very formalised and resource-intensive to fully informal and unstructured consultations, with the corresponding loss of precision and confidence in the outcome, and a corresponding growth of the risk of cognitive biases. The choice between them depends on a multitude of considerations including:

- a) the type of expert knowledge to be elicited (e.g. expressing a subjective probability of very well defined risk, or deliberation on a broad and complex topic of social policy);
- b) the complexity of the questions to be addressed (e.g. very precisely defined questions within a narrow area of expertise, or broad and interdisciplinary questions of policy strategy);
- c) the time and resources available, including for training the experts in formal elicitation methods.

At the most formalised and resource-intensive end of the spectrum is the formal expert knowledge elicitation (EKE; see Annex 5) which is used to obtain expert judgement in a specialised context of risk assessment, where statistical analysis of

data must be combined with expert judgements of probability (EFSA, 2018b:153-9; EFSA, 2014). If the time available is limited, EKE has a somewhat quicker and simpler semi-formal expert elicitation (see Annex 5) which is useful for the same purpose (EFSA, 2018b:147-151).

The above formal methods have applications only in specific contexts. On the other side of the spectrum is a fully unstructured approach to expert consultation, which consists in essence in gathering a set of experts – who may have been selected based on unclear criteria – to discuss evidence in a freestyle format, and are encouraged to give a consensus opinion (cf. Tyshenko et al., 2016).

An unstructured approach carries many risks of bias (Tyshenko et al., 2016; van Gelder, Vodicka & Armstrong, 2016). The principal ones include:

- the discussion may be excessively influenced by experts who are particularly vocal and persuasive;
- a confirmation bias and motivated reasoning, whereby experts may be looking for evidence supporting their views;
- a 'groupthink' bias - which overestimates agreement and consensus;
- bias resulting from questionable levels of representativeness and excellence;
- cumulatively, a risk of diminished trust in the results of expert judgement.

A number of measures can improve the rigour of informal expert consultations. Most of them are likely to imply only a marginal increase in resource-intensity (Tyshenko et al., 2016).

*To reduce cognitive bias and arbitrariness in expert consultation, the following measures are recommended for informal expert panels:*

#### Selection

- *Developing and weighing transparent scientific criteria for expert selection, such as excellence in the field, and the range of desired expertise profiles, a balance between early-career and established experts (plus any additional societal criteria such as geographical and gender balance);*
- *For assessing scientific excellence, adopting a comprehensive set of excellence criteria – rather than relying on traditional status-based markers of excellence (e.g. academic rank) or using only bibliometric criteria<sup>28</sup>.*
- *Documenting the extent to which the shortlisted and invited experts meet the selection criteria.*

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<sup>28</sup> A comprehensive set of excellence criteria used by the JRC for internal purposes in their 2030 Strategy provides one point of reference: [https://ec.europa.eu/jrc/sites/jrcsh/files/jrc-strategy-2030\\_en.pdf](https://ec.europa.eu/jrc/sites/jrcsh/files/jrc-strategy-2030_en.pdf)

- *Casting a wide net in the search for experts. Some of the existing expert search tools (which include both commercial and free-to-use publicly developed tools) may aid in this, e.g. in helping to identify centres of excellence and leading experts in a given field worldwide.*

#### Deliberation

- *Asking the the experts first to consider the questions individually in their own time and recording their judgments before a panel discussion, without consulting each other. Anonymous summaries of the independent judgements can then be distributed as input to panel discussion.*
- *Facilitating the discussion to mitigate the disproportionate influence of particularly vocal and persuasive experts.*
- *Expressly eliciting any dissenting judgements and opposing viewpoints.*
- *Encouraging the consideration of alternative scenarios and unintended outcomes.*
- *Considering the use of conceptual and visual aids (such as influence diagrams to consider systematically all the drivers affecting the issue at hand) and techniques (e.g. card-sorting exercises involving sorting influence factors).*
- *Particularly for expert deliberations involving qualitative assessment of different uncertainties: considering the use of suitable conceptual tools (such as the uncertainty matrixes) and methods aiming to increase the rigour of such assessments, such as the pedigree analysis (see 2.3.1.).*

#### Training

- *Raising the experts awareness of the main cognitive biases and heuristics that they are likely to be subject to in the course of deliberations; encouraging spotting and pointing out such biases in the course of deliberations.*

### 2.2.4. Refine the approach to conflicts of interest

#### **Refine the approach to managing conflicts of interest to ensure expert impartiality but also to reduce the risk of needlessly eliminating valuable expertise.**

Identifying and disclosing experts' interests, as well as assessing and managing their conflicts of interest is an important part of ensuring transparency and integrity in evidence synthesis and use (The Royal Society & Academy of Medical Sciences, 2018), and scientific advice (OECD, 2015:9-10; WRR, 2017; Leopoldina, 2014; GCSA UK, 2010; Gluckman, 2014; Konig et al., 2017).

In expert advice to policy, public scrutiny and controversy tend to focus on economic incentives which may adversely affect experts' impartiality (Moore et al., 2010; Rowe et al., 2013). However, 'interests' are not only financial – they may

include e.g. career advancement, professional recognition, ideological convictions or political engagement (Rowe et al., 2009, 2013; Young et al., 2009). The EC currently identifies several categories of interests which members of its expert groups need to declare: financial interests (such as employment, sponsorship, research grants, investments), influence on decision-making (such as membership of managing bodies), intellectual property rights, personal interests (e.g. interests of immediate family), public statements and positions, and 'other' (see Annex 1 for details).

'Interest' in a field of activity is not synonymous with a conflict of interest, and therefore must not automatically disqualify an expert. Experts have interests in their field practically by definition – e.g. by virtue of being employed by, or receiving research support from an organisation active in that field (OECD, 2015:9-10; Practitioner Consultation).

Hence, the 'avoidance' approach (Thagard, 2007) of automatically disqualifying experts with a certain type of interest may be both arbitrary and detrimental to the quality of the expertise (Rowe et al., 2013). Instead, conflicts of interest must be assessed and comprehensively managed (Rowe et al., 2013, Thagard, 2007). Five main strategies of COI management have been identified in scholarship (Thagard, 2007). They are summarised below, and the implications of each of them for the EC are discussed. The recommendations formulated below should apply to all experts consulted by the EC, whether appointed as members of formal expert groups, or consulted on an ad-hoc basis.

### **1. Clarity of the expert selection criteria and a transparent selection process**

*Managing conflicts of interest starts with clear and transparent criteria for selecting experts (Rowe et al., 2013), including clear and comprehensive criteria of scientific excellence and a description of the types of scientific expertise needed.*

*As described in 2.2.3., formal and semi-formal expert knowledge elicitation (EKE) methods must follow strict and extensive protocols. However, several measures discussed in 2.2.3. can and should be applied to informal expert consultations.*

### **2. Clarity of the exclusion criteria**

*For the purpose of selecting experts for a specific panel, committee or working group, it helps to have a clear list of the types of situations which definitely constitute a COI (Rowe et al., 2013).*

*Such 'hard' exclusion criteria can be complemented by a list of less clear-cut situations which may constitute a COI for a given expert panel, where the officials in charge of assessing COIs should decide on a case-by-case basis, including querying the applicants (ibid).*

*The reasons for the resulting decisions need to be transparently documented.*

The current general EC rules on COI<sup>29</sup> do not include such a list of exclusion criteria – and this may in fact not be practical, since these rules apply across the board to very diverse types of expert committees advising the EU. The 2016 Decision only invites EC officials to consider COI on a case-by-case basis.

However, some EU bodies - which regularly set up expert panels with similar disciplinary profiles and doing a similar type of work - have opted for such lists of exclusion criteria applicable to all their experts. Examples include the European Food Safety Authority (EFSA)<sup>30</sup> and EU research funding bodies such as the European Research Council (ERC)<sup>31</sup>. Both organisations also use a list of less clear-cut situations to be assessed on a case-by-case basis.

### **3. Public disclosure of interests**

A common strategy of dealing with COI is to disclose interests, so as to subject them to public scrutiny, to the degree that respects privacy rules (Thagard, 2007; Young, 2009, Rowe et al., 2013). However, using disclosure as the *only* strategy of managing COI is problematic, since disclosure has been found to lead to various perverse psychological effects (Cain et al., 2005; Thagard, 2007; Young et al., 2009). For example it may actually increase bias in experts who had disclosed their interest, as they may feel 'moral licence' to exaggerate their statements further (Cain et al., 2005); it may also negatively predispose the recipients of the advice or – conversely – lead them to be disproportionately influenced by the information that is likely to be biased.

In the EC today, members of expert groups<sup>32</sup> acting in personal capacity (i.e. expected to act 'independently and in the public interest') are required to declare interest. Their declarations of interest (DOIs) are subsequently disclosed publicly through the register of expert groups to the extent that is compatible with EU privacy rules<sup>33</sup>. Experts invited by the EC on an ad hoc basis are not required to submit written DOIs but must inform the EC before the meeting about any COI they have<sup>34</sup>.

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<sup>29</sup> Commission Decision of 30.5.2016 establishing horizontal rules on the creation and operation of Commission expert groups (henceforth, 'the 2016 Decision').  
[https://ec.europa.eu/transparency/regexpert/PDF/C\\_2016\\_3301\\_F1\\_COMMISSION\\_DECISION\\_PLUS\\_ANNEXES\\_EN.pdf](https://ec.europa.eu/transparency/regexpert/PDF/C_2016_3301_F1_COMMISSION_DECISION_PLUS_ANNEXES_EN.pdf)

<sup>30</sup> Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management  
[https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>31</sup> [https://ec.europa.eu/research/participants/data/ref/h2020/sql/erc/h2020-erc-se-rules-amended2\\_en.pdf](https://ec.europa.eu/research/participants/data/ref/h2020/sql/erc/h2020-erc-se-rules-amended2_en.pdf)

<sup>32</sup> Expert groups as defined by Commission Decision of 30.5.2016, i.e. either formal (established by a Commission decision) or informal, i.e. set up by an individual department that has obtained the agreement of the Commissioner and Vice-President responsible and of the Secretariat-General.

<sup>33</sup> <https://ec.europa.eu/transparency/regexpert/index.cfm>

<sup>34</sup> The 2016 Decision

*In the interest of further enhancements in transparency, and consistency, the EC should consider introducing the same requirements with respect to declaring and disclosing interests for all the experts consulted.*

Not all participants in the scientific advisory process are required to be impartial. Stakeholders representing specific interests (such as civil society, industry, business) can have a legitimate role in the scientific advisory process (see 2.1.2.), as long as their interests are clearly stated and disclosed. They openly participate in the process as issue advocates (or 'interest representatives' in EC terms). Their contributions may involve 'science-' or 'evidence-based advocacy' - which refers to the use and promotion of scientific evidence in order to influence policy in line with a particular agenda (Hutchings & Stenseth, 2016; Parkhurst, 2017:72), and for which the interpretation or selection of scientific evidence is therefore expected to be subject to bias.

*Interest representatives interacting with the EC are currently required to be registered in the EC Transparency Register<sup>35</sup>. The Register requires disclosing general goals and remit of an organisation as well listing the main EU initiatives, policies and legislative files followed by that organisation.*

*This approach could be further refined by requiring clear statements on the positions taken or public statements made by interest representatives on those specific initiatives, policies or files – by analogy to impartial experts, who are required to disclose such positions and statements.*

#### **4. Oversight**

Oversight as a COI management strategy refers to the actions of a supervisors or peers of an expert, who are tasked with identifying the COIs to which the expert in question may be oblivious (Thagard, 2007). A possible weakness in the oversight system that needs to be managed is that those tasked with oversight may be also be biased or act in arbitrary way (ibid).

In the EC, the oversight role is entrusted to EC officials responsible for setting up expert groups. It involves screening declarations of interest (DOIs)<sup>36</sup> prior to the expert's participation in an expert groups, and taking one of the measures defined in the 2016 Decision if a COI is found to exist. The main two measures are to

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<sup>35</sup> <https://ec.europa.eu/transparency/regexpert/index.cfm>

<sup>36</sup> In the case of experts invited on an ad-hoc basis, who currently do not need to submit DOIs but are required to inform the EC of any COI, the EC also needs to assess such information and decide on the measures to take.

exclude the expert, or to restrict their contribution (e.g. by exclusion from discussing specific items on the agenda)<sup>37</sup>.

*The two earlier recommendations on managing COI in the EC, i.e. the clarity of selection and exclusion criteria, are likely to reduce bias and arbitrariness in the decisions made by the COI assessors.*

## **5. Understanding bias**

The final strategy is improving the understanding the nature of bias, based on the best available scientific evidence (Mair et al., 2019), and considering that bias and conflict of interest are related but different concepts (Thagard, 2007, Moore et al., 2010).

In the EC, a conflict of interest (COI) is 'any situation where an individual has an interest that may compromise or be reasonably perceived to compromise the individual's capacity to act independently and in the public interest [...]'<sup>38</sup>. Thus a mere *risk*, or a *perception*, of bias of a certain kind is enough for a COI to exist: there is no need to prove that it *actually* occurred or that it did not occur.

Biases present in the creation, selection and interpretation of scientific evidence are not limited to those consciously driven by personal interest, such as financial or ideological motives (Parkhurst, 2017:155-8). Cognitive biases and heuristics are integral to human thinking (SAPEA, 2019:61-70; Parkhurst, 2017; Mair et al., 2019; see also 2.3.2. for example of cognitive bias in understanding uncertainty). They are not a matter of deliberate choice to act in personal interest at the expense of public interest (Young, 2009).

Awareness of cognitive biases does not usually mean that humans can avoid them (Kahneman, 2011), though spotting them in others is likely to be more successful (ibid). One example of cognitive bias is motivated reasoning, i.e. the 'tendency to arrive at conclusions about evidence that match people's pre-existing beliefs' (Mair et al., 2019:12). Motivated reasoning is not related to reasoning ability (ibid:12) and in fact more analytical reflection has been found to increase ideologically motivated reasoning (ibid:12).

*Cognitive biases are so integral to human thinking that they cannot be fully eliminated from expert consultation.*

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<sup>37</sup> The third option is to appoint the expert as an interest representative rather than an impartial expert, if that possibility exists for the group in question (see Annex 1 for details).

<sup>38</sup> The 2016 Decision.

However, a number of concrete strategies are available (see 2.2.3.), related to how expert panels deliberate, which can mitigate the adverse effects of cognitive biases on the outcomes.

### 2.2.5. Codify good scientific advice and consider oversight of its implementation

**Develop a single set of principles common to all scientific advice bodies in the European Commission, complemented with practical guidance, and consider entrusting a body or department with oversight of their implementation.**

Many valuable guidelines for and codified principles of scientific advice already exist at national and international level (see Annex 2). The Codes of practice for scientific advice are different in nature and purpose from other types of scientists' codes of practice, (e.g. those regarding research integrity (ALLEA, 2017), health research<sup>39</sup> or research and industry<sup>40</sup>), though they may share with them a common core, for example in matters of integrity (Sato & Arimoto, 2016).

There is currently no single EC code of practice for scientific advice. A number of principles of scientific advice and scientific expertise, as well some guidance for implementing them, can be gleaned from various existing documents. However, they are fragmented and sometimes dated. This is a systemic weakness observed already by the EC's first Chief Scientific Advisor (Glover, 2015).

The main currently existing documents include:

- the 2002 EC principles and guidelines on the collection and use of expertise by the Commission (see Annex 3). They date back 17 years at the time of writing and the extent to which they are followed in the EC is no longer clear (Glover, 2015);
- 2016 Commission Decision on the creation and operation of Commission expert groups (which concerns all experts consulted by the EC) – see Annex 1 and 2.2.4.;
- The Commission Decision on the setting up of the Group of Chief Scientific Advisors<sup>41</sup>, which lists a number of qualities which must be met by the Group members and its activities;
- DG JRC Statement on Scientific Integrity<sup>42</sup>;

<sup>39</sup> <https://code-of-conduct-for-health-research.eu/>

<sup>40</sup> [https://euraxess.ec.europa.eu/sites/default/files/am509774cee\\_en\\_e4.pdf](https://euraxess.ec.europa.eu/sites/default/files/am509774cee_en_e4.pdf)

<sup>41</sup> [https://ec.europa.eu/research/sam/pdf/c\\_2018\\_1919\\_ec\\_decision\\_consolidated.pdf#view=fi&pagemode=none](https://ec.europa.eu/research/sam/pdf/c_2018_1919_ec_decision_consolidated.pdf#view=fi&pagemode=none)

- Better Regulation toolbox<sup>43</sup> which includes guidance to policymakers at expert level on using scientific evidence and expertise.

*A single set of principles common to all EC scientific advice bodies should be developed, drawing on the recommendations set out in the present Opinion, and on existing guidance.*

*This could, for example, be in the form of an EC Code of Practice for Scientific Advice.*

*A set of principles should be complemented with further practical guidance designed for scientific advisors, experts and policymakers working together, e.g. in the form of a handbook or toolbox modelled on – or extending – the current Better Regulation toolbox.*

*The guidance should be a living toolbox that contains the implementation aspects including those addressed elsewhere in this Opinion, such as defining a clear mandate for scientific advice (2.1.1.), defining the questions (2.1.2.), involving stakeholders and the public (2.1.2), quality in evidence synthesis for policy (2.2.2.) and expert consultation (2.2.3.); ensuring impartiality (2.2.4.), and analysing and communicating uncertainties (2.3.).*

*Both the code of practice of and the guidance should be developed by all the main scientific advice practitioners in the EC in dialogue with policymakers at political and technical level, to ensure that it is workable and accepted by all.*

*In line with the principle of stewardship (Parkhurst, 2017), architects of the scientific advice system in the EC who have a public mandate (i.e. the EC President and College of Commissioners) should consider entrusting a body or department with the lead in developing the principles and guidance, and with oversight of their implementation across the EC.*

## **2.3. Analyse, assess and communicate uncertainties**

### *2.3.1. Use the most suitable uncertainty analysis approaches*

**Use best available approaches to identify, prioritise and assess uncertainties, and quantify them when possible.**

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<sup>42</sup> The full text of the statement - Annex 1 [https://ec.europa.eu/jrc/sites/jrcsh/files/jrc-strategy-2030\\_en.pdf](https://ec.europa.eu/jrc/sites/jrcsh/files/jrc-strategy-2030_en.pdf)

<sup>43</sup> Better regulation toolbox [https://ec.europa.eu/info/better-regulation-toolbox\\_en](https://ec.europa.eu/info/better-regulation-toolbox_en) (esp. Toolbox 4 and 21)

Uncertainty, at its most general, refers to all types of limitations in available knowledge (SAPEA, 2019:30; EFSA, 2018a:39). However, there are widely different types of uncertainty (SAPEA, 2019:30-35)<sup>44</sup>:

- *technical uncertainty* – which results from limitations in available data. It covers e.g. missing data, uncertainty about a single non-variable value of a parameter; uncertainty about the variability of data (multiple true values within a range)<sup>45</sup>, or randomness; uncertainty about measurement precision or about extrapolation validity;
- *methodological uncertainty* – which can be about how to assess a question; it can also be produced e.g. by limitations in the analytical strategies employed (e.g. uncertainty about excluded factors, about the reliability of expert judgement, or the appropriateness of search criteria to identify relevant literature);
- *epistemic uncertainty* – i.e. uncertainty about which kinds of knowledge are relevant to the question at hand, and about what is at stake; it may be produced by the high complexity and open-endedness of the system under study;
- *societal uncertainty* – which can be uncertainty about whether all relevant aspects of the policy problem at hand have been considered, about rival problem definitions, or about the value-laden assumptions or biases that may be present in the problem definition. The term may be extended also to 'scenario uncertainties' i.e. those concerning the possible outcomes of the different course of action including unintended consequences (cf. Petersen et al., 2013:30);

Assessing technical and methodological uncertainties belongs to the core activities of specialised risk assessment bodies such as the European Food Safety Authority (EFSA)<sup>46</sup>, or – at the national level – e.g. the German Federal Institute for Risk Assessment (BfR)<sup>47</sup>. These two types of uncertainty are addressed in extensive and recent EU guidance -developed for the field of food safety (EFSA 2018a,b), but are suitable to other fields due to the general nature of the approach.

EFSA guidance does not prescribe specific methods for uncertainty analysis but instead provides 'a harmonised and flexible framework within which different methods may be selected, according to the needs of each assessment' (EFSA 2018b:3; see Annex 6 for the main elements of the EFSA approach). The guidance

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<sup>44</sup> The four distinct categories are an idealisation since in reality the boundaries between e.g. epistemic and societal uncertainty, or between methodological and epistemic uncertainty, may be fuzzy

<sup>45</sup> EFSA (2018b:23) provides an illustration of uncertainty about a non-variable quantity ('the total number of animals infected with a specified disease entering the EU in a given year') and uncertainty about a variable quantity ('body weights in a population')

<sup>46</sup> <http://www.efsa.europa.eu/>

<sup>47</sup> <https://www.bfr.bund.de>

(EFSA 2018b) provides a detailed evaluation of the strengths and weaknesses of all the existing methods.

Under EFSA's model, uncertainties can be assessed through (a) statistical analysis of data or (b) expert judgement (see 2.2.3. and 2.2.4. for a discussion of how different biases in expert judgement are managed)<sup>48</sup>. Uncertainties for different parts of the assessment – relying on either of the approaches – can then be combined, using recognised calculation methods.

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<sup>48</sup> The most elementary judgements of this kind typically take the form of: (a) probability statements (on a scale of 0-100%), e.g. 'less than 5% likely'; (b) probability bounds, combining (a) with a specified range of a parameter – e.g. 'it is less than 10% likely that mean exposure exceeds 10 mg/kg bw per day' (EFSA 2018a:23).

#### Box 4. Case study: a response to a plant disease epidemic, and public contestation<sup>49</sup>

***Xylella fastidiosa*** is a bacterium endemic in parts of the Americas. It causes plant diseases. Many plants are asymptomatic carriers of the bacteria, which can contribute to its spread. The bacterium lives in the plant tissue and is normally spread by insects feeding on the affected plants.

In 2013, the bacterium was found infecting olive trees in the region of Apulia in **Italy**. The disease was causing a rapid decline in olive plantations and, by 2015, it was affecting the whole province of Lecce and other zones of Apulia. The bacterium had never previously been confirmed in Europe. In the EU territory, several cultivated plants of high economic value other than olives (e.g. plums and cherries) can be affected, as well as many widespread ornamental plant species.

Science advice in the form of a new risk assessment study requested from and provided by EFSA<sup>50</sup> confirmed that there is no biological or chemical control available that can eliminate the bacteria from a diseased plant in open field conditions. Other available scientific evidence indicated that certain insects which act as vectors for the disease can cover distances of ca. 100 meters in 12 days. Hence, the response of the EU and national authorities has been focusing on the insect vector. In 2015, the EC adopted a decision<sup>51</sup> which required removal not only of the infected plants, but also of all other plants susceptible to the disease – even in the absence of any symptoms of infection – situated within 100 metres of the infection.

Despite a majority scientific view that the response was appropriate for eradicating the disease, the measures met with public contestation in Italy. Farmers have protested against them as a threat to their livelihoods, and were supported by environmentalists who deplored the uprooting of ancient trees (including healthy ones). Individual national court rulings have found in the farmers' favour, stopping tree felling and the spraying of insecticide. A minority of dissenting scientists claimed that the trees could be healed through natural methods<sup>52</sup>. The European Court of Justice (ECJ), in a case brought by a group of individuals, confirmed the validity of the eradication measures under EU law. In September 2019, the ECJ – in a case brought against Italy by the EC, ruled that Italy was in breach of two of its obligations: to immediately remove at least all the infected plants in the containment area, and to conducting annual surveys<sup>53</sup>. Meanwhile, in Apulia, the disease has been spreading to the neighbouring zones. The demarcated area has been repeatedly changed and extended to address that. Due to the number of outbreaks, eradication of the disease in the buffer zone was no longer possible and in June 2018, the EC adopted a decision<sup>54</sup>, extending the demarcated area by 20 km.

The disease has also affected other EU countries. In **France**, there was the first outbreak in Corsica in 2015. Some 25 outbreaks occurred in mainland France, and some 350 in Corsica; the entire island was placed under containment in 2017. In **Germany**, an isolated finding in Saxony was reported in 2016. The plants were destroyed. Surveying in the buffer zone confirmed the absence of any other positive cases. In 2018, the disease the authorities declared the disease eradicated. In **Spain**, the first outbreak, in cherry trees, was reported in Mallorca in 2016. In 2017, the entire territory of the Balears was declared an area under containment. In 2017, the bacterium was also reported in the region of Valencia, and - in 2018- in one tree the Madrid region. The areas were demarcated and eradication measures taken. The EU territory - with the exception of the officially demarcated areas - is now considered free from *Xylella fastidiosa*. The

<sup>49</sup> The case study is based on EC and ECJ official data (except if indicated otherwise):

[https://ec.europa.eu/food/plant/plant\\_health\\_biosecurity/legislation/emergency\\_measures/xylella-fastidiosa\\_en](https://ec.europa.eu/food/plant/plant_health_biosecurity/legislation/emergency_measures/xylella-fastidiosa_en)

<sup>50</sup> <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5666>

<sup>51</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02015D0789-20180629&from=EN>

<sup>52</sup> <https://www.theguardian.com/world/2018/jul/22/italy-farmers-olive-trees-xylella-blight-cow-dung-puglia>

<sup>53</sup> <https://curia.europa.eu/jcms/upload/docs/application/pdf/2019-09/cp190106en.pdf>

<sup>54</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32018D0927>

EU has since supported two research projects with a total of ca. € 9m, with the aim to improve the knowledge of the bacterium and its vectors, and of possible prevention measures.

Overall, EFSA guidance is designed for dealing with well-defined (i.e. maximally unambiguous) questions<sup>55</sup>, and for expressing essentially all uncertainty assessments quantitatively, using probability (EFSA, 2018a:7; see also 2.2.3.). It also expressly excludes from its scope any uncertainties in the framing of the question for scientific assessment and those present in the decision making (EFSA, 2018b:12), as well as those which may involve the participation of stakeholders and the consideration of values (ibid:34-5).

By contrast, epistemic and societal uncertainties<sup>56</sup> are typically best expressed descriptively and not as probabilities (Petersen et al. 2013:30); they are intensely present in the framing of the question, and are concerned with societal and value-related aspects. This leaves them fully outside the scope of uncertainty analysis frameworks such as EFSA's.

Nevertheless, capturing the above uncertainties from the earliest stages of problem definition is crucial to help ensure that the questions to be addressed by scientific advice are the most relevant ones and that these questions are not prematurely reduced only to measurable risk (Nowotny, 2016; Stirling, 2010; see 2.1.2.).

Conversely, the chosen problem definition greatly affects later decisions on which types of uncertainties are considered to be the most important to deal with (van der Sluijs 2008). The case studies on badger culling in the UK (Box 1) and on a plant disease epidemic in Italy (Box 4) illustrate what may go wrong if epistemic and societal uncertainties are not considered from the outset next to technical and methodological ones.

An approach which can help capture diverse kinds of uncertainty from the earliest stages of problem definition is Knowledge Quality Assessment (KQA) (SAPEA, 2019:85-8). It has been adopted by several institutions and bodies (e.g. IPCC, EPA, Netherlands Environmental Assessment Agency - PBL) which deal with scientific assessments as part of an initial problem analysis (van Der Sluijs et al., 2008).

At their most general level, KQA tools are suitable for aiding deliberation between scientific advisors, scientific experts and policymakers (as well as stakeholders and members of the public as appropriate – see 2.1.2.), since they are designed for specialists and non-specialists alike (typically taking the form of straightforward checklists or questionnaires).

An example of a suitable tool currently in use at national level is provided in Box 5.

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<sup>55</sup> An example of a well-defined question for risk assessment is the one addressed by EFSA for the case of a plant disease described in Box 4: 'What is the effectiveness of *in planta* control measures against *Xylella fastidiosa*?' By contrast, an (unrelated) example of a broad and vaguely scoped question for initial deliberation is *How to create a sustainable and healthy food system for the EU?*

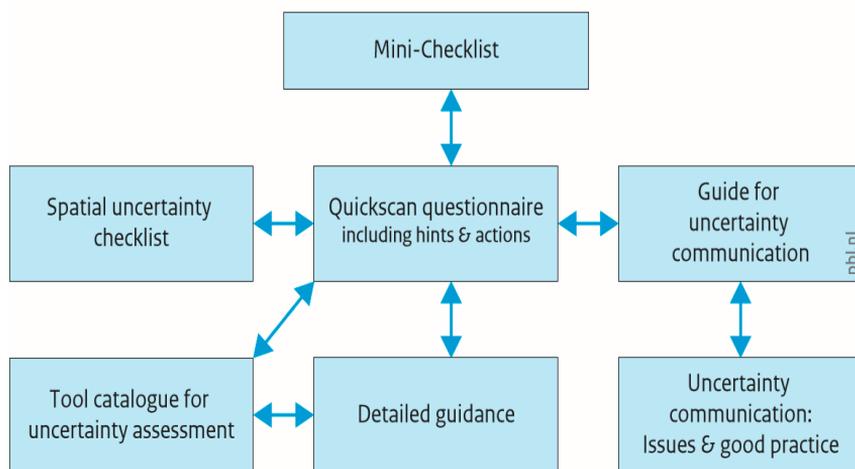
<sup>56</sup> Also referred to together as 'deep uncertainties': Stirling 2010; EFSA 2018b:34.

### Box 5. An example of a knowledge-assessment tool

*Guidance of the Netherlands Environmental Assessment Agency – PBL; revised 2nd edition (Petersen et al., 2013; see also SAPEA, 2019:87)*

The Guidance has been developed by the Agency in collaboration with Utrecht University. It has been in use since 2002, and is credited with ‘stimulating co-learning processes among scientific advisors and policymakers for a deeper understanding and awareness of uncertainty and its policy implications’ (SAPEA 2019:87).

The Guidance is built as a layered set of tools, with increasing level of detail and sophistication, whereby the recommended depth of analysis depends on the resources available and the importance of uncertainties for the issue at hand.



*Reproduced from Petersen et al. (2013)*

Van der Slujs et al. (2008) illustrate the application of the Guidance to a policy issue of regulating the health risks of particulate matter (PM).

The Mini-Checklist and the Quickscan Questionnaire are generally suitable as an aid in the deliberation with policymakers. They are built around the main questions listed below.

1. *How is the problem framed; which contextual factors are included/excluded?*
2. *What are the main parties (stakeholders/ actors) involved; what are their views, roles, stakes and involvement with respect to the problem, and what would be the added value of involving certain stakeholders?*
3. *What are the main indicators/visualisations used and how do these relate to the problem definition?*
4. *How adequate is the knowledge base that is available?*
5. *What are the uncertainties relevant to this problem and what is their nature and location?*

NB. As needed, the responses to Question 5 can be developed in further detail with the aid of the Uncertainty Matrix, which is presented in Annex 7.

6. *How is uncertainty information communicated?*

Detailed Guidance and the Tool Catalogue are the most suitable for further expert analysis. They include an Uncertainty Matrix (see Annex 7), and the NUSAP methodology (see Annex 8).

The tool can also be used at deeper levels of analysis:

- the Uncertainty Matrix level (see Annex 7), as a somewhat more detailed extension of the quick checklist and questionnaire – which may still be suitable for deliberation with policymakers at more expert (technical) level. It is geared towards more detailed mapping of all the main uncertainties, including epistemic ones such ‘scenario uncertainties’, and societal uncertainties.
- The Numeral Unit Spread Assessment Pedigree (NUSAP) method (see Annex 8), suitable for scientific expert judgment but designed for systematic consideration and qualitative assessment of epistemic uncertainties (such as the strength of the empirical evidence) and allowing numerical expression of such uncertainties - as an ordinal scale (0-4) combined with verbal descriptions (SAPEA, 2019:89-90).

*To capture the disparate kinds of uncertainty in a coherent analytical framework which will be helpful in developing scientific evidence and advice in the EC for complex questions, we recommend a three-tiered approach:*

*1) Knowledge-quality assessment, including initial uncertainty mapping*

- *A broad analysis aided by straightforward heuristic tools, for use mainly to aid deliberation between scientific advisors, scientific experts and policymakers (as well as stakeholders and members of the public as appropriate) from the earliest stages of problem definition. Box 5 provides an example of a suitable tool.*

*2) Multi-criteria qualitative uncertainty assessment and prioritisation (if appropriate)*

- *An intermediate level, which continues to capture all relevant types of uncertainty and also includes more fine-tuned expert judgements on the reliability and strength of the available evidence to be used to assess specific uncertainties.*
- *This intermediate level of analysis is recommended particularly for very complex questions characterised by large and diverse uncertainties.*
- *This level of analysis is suitable for use by scientific advisors and/or main expert working groups supporting the advisors for specific topics.*
- *It can be applied e.g. to preliminary evidence analysis in between iterations with policymakers (and stakeholders as appropriate).*
- *It may also be suitable as an aid in the deliberation with specialist policymakers (e.g. policy units working on the details of policy initiatives – e.g. preparing impact assessments, stakeholder consultations or fitness checks).*
- *Currently available and suitable tools include the Uncertainty Matrix (see Annex 7), and, at scientific expert level, the NUSAP method (see Annex 8);*

both included in the more specialised part of the PLB Guidance summarised in Box 5.

### 3) Specialised risk assessment

- The most technical level, used to assess quantifiable uncertainties for very well-defined questions which have been identified as important to answer at more general levels of analysis.
- The assessment includes statistical analysis of data using recognised computational methods (whenever available), combined with expert judgement – the latter following strict protocols to reduce bias (from formal to semi-formal expert knowledge elicitation methods – see 2.2.3.).
- For use by specialised sub-panels of experts or entrusted to specialised risk-assessment bodies.
- EFSA (2018a,b) guidance provides a very comprehensive model for this level of assessment applicable beyond the area of food safety.

NB. The three-tiered approach assumes dialogue and feedback loops between the three levels, and multiple iterations particularly at level 1 and 2 (with scientific advisors – with their support staff- playing a key role as overseers and facilitators of the process).

### 2.3.2. Communicate uncertainties and diverging scientific views

**Where there are uncertainties in scientific evidence or advice, provide clarity about what is known, partially known, unknown, and unknowable.**

Expressing uncertainties in terms of probability can be ambiguous. Verbal expressions such as 'very likely' or 'unlikely' mean different things to different people (SAPEA, 2019:72). Box 6 shows an extreme example of the consequences of such ambiguity.

#### Box 6. Miscommunication due to ambiguous expression of uncertainty

An extreme example is provided by the L'Alquila case - a major and tragic earthquake in Italy in 2009. Scientific experts were imprisoned after being charged, among other things, with having contributed to the spread of reassuring messages that a large earthquake in the short term was 'unlikely', despite their consideration that earthquakes are not predictable in the deterministic sense. The use of the term 'unlikely' was ambiguous. (OECD, 2015).

To mitigate that ambiguity, the International Panel on Climate Change (IPCC) and EFSA recommend using harmonised approximate probability scales – which combine verbal and numerical expressions of probability (2018a:24; 2018b:61; Box 7

contains the EFSA scale). The ambiguity can be further reduced if the numerical expression is presented before the verbal expression – e.g. ‘70% certain (i.e. likely)’ - rather than vice versa (SAPEA 2019:71).

Communicating uncertainty is not without the limitations related to many universal cognitive effects in perceiving such information. As a result of which, complete unambiguity and neutrality of such communication is not achievable (Mair et al. 2019:46). Examples of cognitive biases and heuristics affecting risk perception are presented in Box 8 (see also SAPEA, 2019:61-4; EFSA, 2019:37-9).

For quantitative expressions of uncertainty (e.g. for approximate probability or probability distributions), EFSA has developed very comprehensive guidance (EFSA 2019) which is tailored to three broad audience categories (entry, informed, and technical level). The guidance also covers communicating inconclusive assessments, among others.

**Box 7. Approximate probability scale recommended for harmonised use in EFSA**

Probability term	Subjective probability range	Additional options	
Almost certain	99–100%	More likely than not: > 50%	Unable to give any probability: range is 0–100%
Extremely likely	95–99%		
Very likely	90–95%		Report as ‘inconclusive’, ‘cannot conclude’, or ‘unknown’
Likely	66–90%		
About as likely as not	33–66%		
Unlikely	10–33%		
Very unlikely	5–10%		
Extremely unlikely	1–5%		
Almost impossible	0–1%		

*Reproduced from EFSA 2019:24*

Other relevant uncertainties (including those which often result from the complexity of the issue – methodological, epistemic and societal – also need to be clearly outlined. As a general rule, though, this can be done only descriptively.

## Box 8. Examples of cognitive heuristics and biases in uncertainty communication

- Expressions of uncertainty are always directional (Teigen 2019). For example, they can be framed positively or negatively ('40% chance of success' vs. '60% risk of failure') which is known to influence how we interpret and react to the information (Kahneman, 2011; SAPEA 2019:65; Renn, 2008; EFSA 2019:38).
- People tend to be much more preoccupied by the seriousness of the hazard (e.g. radiation) rather than the risk of an adverse event (e.g. a radiation dose that is dangerous); (SAPEA 2019:63).
- People tend to be averse to ambiguity –i.e. they tend to prefer a risky but unambiguous option over an ambiguous one (e.g. '30% chance of win' vs. '20-40% chance of win'; EFSA 2019:13) and tend to see the latter type of information as a sign of incomplete science rather than a genuine distribution (SAPEA, 2019:64).
- People tend to fixate on lower, mid or higher values in a probability distribution depending on subtle changes in how a question about them is framed. For example, when presented with a projection of temperature rise 'by 2 to 5 degrees', people tend to pick the mid value as a scenario when asked what they think *will* happen, but pick the worst-case scenario when asked what *can* happen (Teigen, 2019).

Communicating uncertainties (as well as dissenting scientific opinions – see below) has the drawback of putting them in the spotlight of the public that may be sceptical about the evidence. This can come at the expense of communicating how much is already known and how broad consensus it may enjoy (van der Sluijs, 2012). Uncertainties that are communicated may also be strategically overplayed by issue advocates whose interests are adversely affected by the scientific advice being offered (see Oreskes and Conway, 2014; Parkhurst, 2017; see also 2.2.4.).

There is no known empirical evidence that communicating uncertainties increases trust among the broad public. Instead, there is limited experimental evidence that suggest that it does not increase it or even tends to lower it (Siegrist, 2019). This reaction of the public occurs because uncertainty tends to be seen as unhelpful in making decisions, and a sign of 'sloppy' or 'weak' science (ibid; see also EFSA 2019:47).

Despite these limitations, drawbacks and 'uncertainties about uncertainties' (Siegrist, 2019), open communication is an ethical imperative for scientific advice - since to do otherwise by knowingly exaggerating certainty and consensus would be fatal to the principle of the scientific advisor as an honest intermediary.

*As a general principle, uncertainties, gaps and limitations in available knowledge should always be clearly communicated in scientific advisory reports and in evidence synthesis reports in the least ambiguous way achievable, and in a way that is the most likely to be comprehensible to the respective target audiences (EFSA, 2019; INGSA, 2014b:8; OECD, 2015:9-10; The Royal Society & Academy of Medical Sciences, 2018; GCSA UK, 2010).*

**Expert panels and evidence reports should aim at consensus but not at the expense of deliberation rigour. Dissenting views should be documented and explained.**

Expert consensus is an ideal outcome but should not be pursued at all costs. First, excessive focus on consensus in expert panel deliberations may lead to various cognitive biases, such as overconfidence bias. Panel deliberation techniques are available and recommended in this Opinion to mitigate such adverse effects (see 2.2.3.). Seeking full consensus at the cost of overemphasising certainty and clarity can ultimately undermine the rigour of the evidence and the advice as well as trust in them (van der Sluijs, 2012:187).

Second, legitimate difference of views occurs even within single scientific disciplines. Legitimate dissent is defined as the occurrence of minority scientific positions which have been based on rigorous and recognised methods and meeting the relevant quality criteria, but arriving at different conclusions than most other scientists (van der Sluijs et al., 2010). It must be clearly distinguished from dissent driven by poor (or even fraudulent) science. The latter can be used by interest groups to undermine other solid evidence (see e.g. Benestad et al. for an example of climate change denialism); it needs to be weeded out within science itself and in the evidence synthesis (see 2.2.1 and 2.2.2.).

For a complex question, which is typically approached from different disciplinary perspectives, the probability of legitimate minority views is typically higher.

Scientific dissent can be of great value to policy – for example it may offer for example ‘early warnings’ that are relevant to policy both in terms of minority scientific views and warnings that the problem is more severe than it might appear at first (Stirling, 2010; van der Sluijs, 2012:187; see also 2.1.2.).

*When legitimate differences in scientific views cannot be resolved, they should be clearly identified and explained in evidence reports.*

### 2.3.3. Explain the path from evidence to the advice

**Explain the reasoning applied when analysing scientific evidence and developing policy options and recommendations.**

For any complex issue that is informed by scientific advice there tends to be a gap - to be bridged by scientific advisors - between (a) what is known (or partially known) about the different aspects of the problem and (b) the conclusions, informed by that knowledge, about the best courses of action for tackling the problem (INGSA, 2014b:9; Cairney, 2016:4) – if the scientific advice mandate includes the latter (see 2.1.1.).

For example, clear evidence of the health risks of excessive sugar consumption, and of the main drivers of that unhealthy behaviour, does not automatically lead to clarity about the optimal policy mix to address that problem in a particular (local, national or international) context - which could involve e.g. health warnings, consumer education, behavioural 'nudges' or financial disincentives (see Cairney, 2016:4; Nutley et al., 2007:39).

Bridging the gap between evidence analysis and formulation of the advice is likely to require support from somewhat different groups of experts for the two types of activity (Cairney, 2016:32; see also 2.2.1).

It also requires holistic and interdisciplinary reasoning by scientific advisors, who often analyse diverse sources of scientific evidence. They also need to be aware of the socio-political context relevant to the problem at hand. Their reasoning must be rigorous and include enhanced awareness among the advisors of the possible cognitive heuristics and biases that may affect them, in order to reduce their adverse impact on the outcome (see also 2.2.3.)<sup>57</sup>.

*The reasoning applied by scientific advisors when bridging the gap between evidence and their policy options or recommendations should include explaining the assumptions made and any normative positions taken (see 2.1.1.), as well as the limitations and uncertainties encountered.*

*The reasoning must be explained in a clear way that is accessible to non-specialists, in the public advisory reports and other communications.*

Scientific advice in the EC operates at multiple levels and takes various forms (see Annex 4).

At the top political level, it typically addresses highly complex issues - for which broad questions are formulated. An example from our own practice is the question we addressed in the opinion on food from the oceans:

*How can more food and biomass be obtained from the oceans in a way that does not deprive future generations of their benefits?*<sup>58</sup>

In such instances, scientific advisors typically formulate broad evidence-informed strategic options or recommendations for policy. Formulating them requires holistic and interdisciplinary deliberation (see above), underpinned by evidence spanning

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<sup>57</sup> One of frequent reasoning errors is that of over-generalisation - whereby internal validity (a policy has been proven to work somewhere) is taken as evidence of external validity (i.e. predicting that the policy will work everywhere, or in a very different context). This may lead to costly policy errors: Cartwright & Hardie, (2012) offer relevant case studies including one of a World Bank nutrition project (see also Parkhurst, 2017).

<sup>58</sup> [https://ec.europa.eu/research/sam/pdf/meetings/hlq\\_sam\\_052016\\_scoping\\_paper\\_oceanfood.pdf#view=fit&pagemode=none](https://ec.europa.eu/research/sam/pdf/meetings/hlq_sam_052016_scoping_paper_oceanfood.pdf#view=fit&pagemode=none)

various scientific disciplines and methodologies. The advice in such cases concerns policy action in highly complex systems (such as a food production and consumption system; see 2.1.2.) within which by definition is a multitude of cause-and-effect links some of which are uncertain.

Formulating options or recommendations at this level of complexity does not normally lend itself to quantitative expression as probabilities (Stirling, 2010; Peterson et al., 2013).

Instead, the options are usually more usefully assessed and expressed qualitatively in 'plural conditional' terms (ibid), i.e. as a range of possible scenarios (which can be construed in 'if-when' terms; cf. also WRR 2017b), with consideration of possible unintended outcomes.

Advice on policy action in highly complex systems with many uncertainties may also involve a preference for recommending pilot policy actions which allow for pragmatic learning (and a possible change of course), before large policy roll-outs. (see 2.1.2.).

Nevertheless, the likely impact of some types of policy options identified through this reasoning process may be amenable to being assessed through advanced modelling methods (see 2.1.2.), which should in such cases be comprised in the evidence base underlying the advice.

Scientific advisors may also be asked to answer very well-defined questions where the mandate for the advice expressly excludes formulating any policy options – thus asking the advisors to act as 'science arbiters' (see 2.1.1.). This is the core activity of risk assessment bodies. An example of a question comes from EFSA extended case study on melamine (EFSA 2018b):

*What are the risks to human health due to the possible presence of melamine in composite food products imported from China to the EU?*

Answering questions of the above kind involves quantification, which is typically achieved through a combination of statistical data analysis and expert judgement (see 2.3.1). Such scientific assessment may well be a part of the evidence used for scientific advice addressing issues at higher levels of complexity.

While quantification of the advice in terms of probabilities is not normally useful for the broad strategic scientific advice on complex issues, more structured and rigorous ways of expressing it qualitatively (rather than only through a narrative) could be considered.

*Scientific advisors operating at high levels of complexity could:*

- *consider expressing (through consensus – where achievable – or through a median score) qualitative aspects of the advice such as:*
  - *their degree of confidence that a policy option or recommendation will contribute to the stated policy objective;*
  - *their judgement of the importance of a policy option or recommendation in achieving the stated objective;*
  - *the overall strength of the evidence underlying the options or recommendations;*
  - *any other qualitative aspects of the advice considered important.*
- *consider expressing the above judgements numerically – e.g. through simple ordinal scales (e.g. 0-4) – in conjunction with narrative descriptions, in ways which are easy to communicate (including visually) to broad audiences including non-specialists; a method modelled on the ‘pedigree analysis’ (see 2.3.1. and Annex 8) can be considered.*
- *explicitly consider any unintended outcomes which the respective options and recommendations may lead to;*
- *whenever possible, consider in their advice the evidence on the possible impacts of policy options generated through advanced modelling methods.*

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# *Annexes*



## Annex 1 - EC rules on interest declaration and conflicts of interest<sup>59</sup>

Although the Commission has considerable in-house expertise, it needs specialist advice from external experts as a basis for policymaking. This may be provided by groups of experts or external consultants, or take the form of studies.

An expert group is a consultative body set up by the Commission or its departments to provide them with advice and expertise composed of public and/or private sector members which meets more than once.

Gathering expertise from various sources may include gathering the views of various stakeholders.

Expert groups may be composed of the following types of members [A-E]:

- A. Individuals appointed in their personal capacity who are to act independently and in the public interest
- B. Individuals appointed to represent a common interest shared by stakeholders in a particular policy area, who do not represent an individual stakeholder, but a policy orientation common to different stakeholder organisations. Where appropriate, those individuals may be appointed on the basis of proposals put forward by the stakeholders concerned
- C. Organisations in the broad sense of the word, including companies, associations, Non-Governmental Organisations, trade unions, universities, research institutes, law firms and consultancies
- D. Member States' authorities, at national, regional or local level
- E. Other public entities, such as third countries' authorities, including candidate countries' authorities, Union bodies, offices or agencies and international organisations

Type B and Type C members can only be appointed if they are registered in the Transparency Register<sup>60</sup>.

### Conflict of interest

Only individuals applying to be appointed as Type A members of expert groups or sub-groups are required to declare interest, i.e. to disclose 'any circumstances that could give rise to a conflict of interest. and are thus required to submit a declaration of interests ('DOI') form on the basis of the standard DOI form, together with an updated curriculum vitae ('CV'), as part of their application to become members of an expert group or sub-group.

The DOI form consists of a series of standard questions requesting individuals who wish to act as experts appointed in a personal capacity to disclose any interest relevant to the subject of the work to be performed. The questions are in the following categories of interest:

1. Employment, consultancy and legal representation (within the past 5 years)

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<sup>59</sup> Summary of key aspects based on Commission Decision of 30.5.2016 establishing horizontal rules on the creation and operation of Commission expert groups [http://ec.europa.eu/transparency/regexpert/PDF/C\\_2016\\_3301\\_F1\\_COMMISSION\\_DECISION\\_EN.pdf](http://ec.europa.eu/transparency/regexpert/PDF/C_2016_3301_F1_COMMISSION_DECISION_EN.pdf)

<sup>60</sup> <http://ec.europa.eu/transparencyregister/public/homePage.do>

2. Membership of managing bodies, scientific advisory bodies or similar (within the past 5 years)
3. Research support (e.g. grants, fellowships, sponsorship) – within the past 5 years
4. Financial interests (e.g. investments including stocks or shares)
5. Intellectual property (e.g. patents, trademarks, copyrights)
6. Public statements and positions within the past 5 years: (a) expert opinions and (b) representing an interest or defending an opinion in an official capacity

Each individual must assume full responsibility in relation to the content of the declaration submitted. Individuals who answer questions in the affirmative are asked in the DOI to supply further details. An affirmative answer in the DOI form does not automatically disqualify the individual concerned, but requires the competent Commission departments to have it screened in accordance with the Decision, in order to determine if a conflict of interest exists.

In principle, the conflict of interest assessment are to be performed by officials of the Unit responsible for the management of the group or sub-group in question. Officials operating in other departments may also be associated, as appropriate. For the purposes of the assessment, a number of factors are to be taken into account including the nature, type and magnitude of the individual's interest, as well as the degree to which the interest may be reasonably expected to influence the individual's advice. An interest is considered to be insignificant or minimal where it is unlikely to compromise or to be reasonably perceived as compromising the expert's capacity to act independently and in the public interest when advising the Commission.

Where the responsible officials consider partially or fully excluding an individual from the work of an expert group or sub-group, they may contact the individual in order to obtain any additional information that may be needed for the final assessment of any conflict of interest.

Where the competent Commission department concludes that no conflict of interest exists, the individuals in question may be appointed as members acting in a personal capacity, provided they possess the expertise required and the other conditions in these rules are fulfilled.

Where the competent Commission department concludes that the individuals' interests may compromise or be reasonably perceived as compromising their capacity to act independently and in the public interest when providing advice to the Commission, one of the following measures must be taken to deal with the conflict, depending on the specific circumstances:

(a) the individual's application shall not be retained; [...];

(b) the individual's appointment as member of the expert group or sub-group in a personal capacity shall be made subject to specific restrictions, e.g. exclusion from certain meeting and/or activities, (in particular from drafting opinions and recommendations), or requiring abstention from the discussion of, or vote on, specific items [...];

(c) the individual shall be appointed as member of the expert group or sub-group representing a common interest shared by a number of stakeholders (Type B member), after consultation of the stakeholders concerned. [...].'

The DOIs of Type A members of experts groups are made public through the register of expert groups.

Type B members and representatives of Type C members do not have to declare interest – because they are not required to act independently, but instead represent an interest that is openly declared. The Transparency Register, where they are required to register before they can be appointed, asks them to state the general goals of the organisation.

Representatives of Type D and E members do not have to declare interest, or be registered in the Transparency Register, since they are not required to act independently but express the views of public authorities which they represent.

The EC representative in an expert group may invite experts with specific expertise with respect to a subject matter on the agenda to take part in the work of the group or sub-group on an ad-hoc basis. Such invited experts do not have to submit DOIs. They are, however, required to inform the competent EC department before the meeting of any potential conflict of interest.

## Annex 2 – Codified principles and guidelines for science advice

### International Network for Government Science Advice (INGSA)

- A set of emerging guiding principles (INGSA, 2014b:8)
- Additional qualities for successful science advice (INGSA, 2014a:8)
- Crucial elements of a scientific advisory systems (INGSA 2018:10)

### Organisation for Economic Co-operation and Development (OECD)

- Policy recommendations: frameworks and mechanisms of science advice (OECD,2015:9-10)
- Guidelines and good practices for the advisory process (OECD, 2015:9-10)

### Denmark: Danish Council for Research and Innovation Policy (DFiR)

- Good use of research-based evidence in policymaking (Technopolis / DFIR 2015:ii)

### Germany: National Academy of Sciences, the Leopoldina

- Guidelines for advising policymakers and society<sup>61</sup>.

### Germany: The Union of the German Academies of Sciences and Humanities

- The cornerstones of political consultancy<sup>62</sup>

### Germany: Berlin-Brandenburg Academy of Sciences and Humanities (BBAW)

- Guidelines on good science advice to policy<sup>63</sup>,

### Germany: National Academy of Science and Engineering (acatech)

- Guidelines on science advice to policy and society<sup>64</sup>

### The Netherlands Scientific Council for Government Policy (WRR)

- Scientific and administrative integrity of the WRR<sup>65</sup>,
- The profile and working methods of the WRR (in Dutch)<sup>66</sup>,

### The Netherlands: the Royal Academy of Arts and Sciences (KNAW)

- A manual concerning academy advisory reports. Basic principles, procedure, and quality assurance<sup>67</sup>.

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<sup>61</sup>[https://www.leopoldina.org/uploads/tx\\_leopublication/2014\\_Leopoldina\\_Leitfaden\\_Politikberatung.pdf](https://www.leopoldina.org/uploads/tx_leopublication/2014_Leopoldina_Leitfaden_Politikberatung.pdf)

<sup>62</sup> <https://www.akademienunion.de/en/the-union/consultancy-for-politics-and-society/>

<sup>63</sup> [http://www.bbaw.de/service/publikationen-bestellen/manifeste-und-leitlinien/BBAW\\_PolitischeLeitlinien.pdf](http://www.bbaw.de/service/publikationen-bestellen/manifeste-und-leitlinien/BBAW_PolitischeLeitlinien.pdf)

<sup>64</sup> <https://www.acatech.de/Publikation/leitlinien-fuer-die-politikund-gesellschaftsberatung/>

<sup>65</sup> <https://www.wrr.nl/publicaties/publicaties/2017/01/02/wetenschappelijke-en-ambtelijke-integriteit-van-de-wrr>

<sup>66</sup> <https://www.wrr.nl/binaries/wrr/documenten/publicaties/2017/09/20/profiel-en-werkwijze-wetenschappelijke-raad-voor-het-regeringsbeleid/Werkwijze-profiel-WRR-2017.pdf>

### **UK: the Royal Society & Academy of Medical Sciences**

- Statement of Principles about evidence synthesis for policy<sup>68</sup>

### **UK: Government Chief Scientific Adviser / Government Office for Science (GO Science)**

- Principles of scientific advice<sup>69</sup>.
- Guidelines on the Use of Scientific and Engineering Advice in Policy Making<sup>70</sup>
- Code of Practice for Scientific Advisory Committees (CoPSAC)<sup>71</sup>

### **Australia**

- APS200 Project: the Place of Science in Policy Development in the Public Service<sup>72</sup>: *'Issues/challenges and opportunities in science advice to policy'* (contains core principles)

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<sup>67</sup><https://www.know.nl/shared/resources/adviezen/bestanden/ManualConcerningAcademyAdvisoryReports.pdf>

<sup>68</sup><https://royalsociety.org/~media/policy/projects/evidence-synthesis/evidence-synthesis-statement-principles.pdf>

<sup>69</sup> <https://www.gov.uk/government/publications/scientific-advice-to-government-principles/principles-of-scientific-advice-to-government>

<sup>70</sup>[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/293037/10-669-gcsa-guidelines-scientific-engineering-advice-policy-making.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/293037/10-669-gcsa-guidelines-scientific-engineering-advice-policy-making.pdf)

<sup>71</sup>[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/278498/11-1382-code-of-practice-scientific-advisory-committees.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/278498/11-1382-code-of-practice-scientific-advisory-committees.pdf)

<sup>72</sup> <https://archive.industry.gov.au/science/Documents/APS200ScienceinPolicyReport.pdf>

## Annex 3 – EC principles and guidelines on the use of expertise

The 2002 'Communication from the Commission on the collection and use of expertise by the Commission: Principles and Guidelines: improving the knowledge base for better policies'<sup>73</sup> has formulated three core principles:

1. Quality, divided into: excellence (of scientists, e.g. as endorsed by peer judgement); independence (to the extent possible; minimising the risk of vested interests, or making them explicit); pluralism (a diversity of viewpoints);
2. Openness: transparency, esp. about the issues are framed, experts selected, and results handled; (political) responsibility (instead of hiding behind the experts); (expert) accountability (e.g. by explaining the evidence and reasoning upon which it is based); care (whereby the level of openness should be in proportion to the task at hand).
3. Effectiveness: proportionality (of resources used), appropriateness of methods.

These principles have been subsequently translated into specific guidelines, which are paraphrased in an abbreviated form below:

1. Keep an adequate level of in-house expertise, in order to act as an 'intelligent customer'.
2. Identify policy issues requiring expert advice as early as possible; foresight exercises are recommended.
3. Urgency, complexity and sensitivity of the issue should determine the way of involving the experts.
4. Invite other interested departments to contribute.
5. First assess what the existing advice bodies can contribute (JRC, permanent committees).
6. Clearly set out the scope and objectives of expert involvement, and the questions they will address.
7. Scope the issue first to determine the profile of the expertise needed. Think pluralism and practical knowledge too.
8. Cast your nets as widely as possible – beyond the 'usual suspects'. Aim for at least 40% of each sex.
9. Consider both mainstream and divergent views (except widely discredited ideas).
10. Keep a record of the process.
11. Check whether you have sufficient expertise and evidence, and that the tasks are clearly understood.
12. Experts must declare any interest, and Commission must decide whether any conflict of interest would jeopardise the quality of the advice.
13. Release the key documents to the public promptly.
14. Consider members of the public as observers for some expert meetings, esp. on sensitive issues.
15. Experts must highlight the evidence used, as well as any uncertainty and divergent views.
16. Plan informed and structured debates between policymakers, experts and stakeholders.
17. For any policy initiative, describe the expert advice considered – including how it has, or has not, been taken into account.

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<sup>73</sup> [http://ec.europa.eu/governance/docs/comm\\_expertise\\_en.pdf](http://ec.europa.eu/governance/docs/comm_expertise_en.pdf)

## Annex 4 - Science for policy landscape in the EC

The European Commission (EC) has relied on science for its policies practically since their inception. The predecessors to the Joint Research Centre (JRC) date back to the late 1950s, and a plethora of sources of evidence and advice has grown since then (in the form of standing scientific committees, *ad-hoc* expert groups, studies conducted by consultants, and more).

The system of scientific committees in the areas of food safety and consumer protection in 1997<sup>74</sup>. Following a series of food crises in the late 1990s, the **European Food Safety Authority (EFSA)**<sup>75</sup> was established in 2002 to be a source of scientific advice and communication on risks associated with the food chain. A decade later, the office of the Chief Scientific Advisor (CSA) was established by President Barroso in 2012.

The next step came in 2015 under President Juncker, when the CSA was replaced with a mechanism, the **Scientific Advice Mechanism (SAM)**<sup>76</sup>, whose core is a collective body, the High-Level Group of Scientific Advisors (hence renamed the Group of Chief Scientific Advisors). As part of the mechanism, the Group currently relies for evidence synthesis mainly on a consortium bringing together networks of European academies of science - Science Advice for Policy by European Academies (SAPEA)<sup>77</sup>.

The European Commission has an in-house science and knowledge management service, **Joint Research Centre (JRC)**, which employs over 2000 scientists, and can both manage and generate evidence informing policies.

The **European Group on Ethics (EGE)**<sup>78</sup> also advice to the highest level of policymaking – related to the ethical aspects of scientific developments and new technologies.

Many other formal and permanent advisory bodies, continue to exist. There are 747 active **Expert Groups** (as of May 2019) that advise the European Commission. These include groups of experts nominated by member states or competent authorities, representatives of private and third sector stakeholders, academics, professional, and other experts. Many Directorates General (DGs) have **Advisory Committees** focused on providing scientific advice. For example, in DG Health and Food Safety, the Commission can draw on three scientific committees: the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHEER) and the Inter-Committee Coordination Group (ICCG).

**Comitology committees**, with experts designated by EU Member States and Member States representatives, are covered in a separate registry<sup>79</sup>.

The European Parliament and the Council of the European Union (EU) have set up a number of decentralised Agencies - **EU Agencies** - to carry out specific legal, technical or scientific tasks within the European Union with a strong science component to provide scientific and technical advice to EU institutions, Member States and other relevant EU policymakers.

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<sup>74</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32000D0443&from=EN>

<sup>75</sup> <http://www.efsa.europa.eu/>

<sup>76</sup> <https://ec.europa.eu/research/sam/index.cfm>

<sup>77</sup> <https://www.sapea.info/>

<sup>78</sup> [https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/european-group-ethics-science-and-new-technologies-ege\\_en](https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/european-group-ethics-science-and-new-technologies-ege_en)

<sup>79</sup> [https://ec.europa.eu/info/about-european-commission/service-standards-and-principles/transparency/comitology-register\\_en](https://ec.europa.eu/info/about-european-commission/service-standards-and-principles/transparency/comitology-register_en)

## Annex 5 - Examples of evidence synthesis methods

A non-exhaustive list of evidence synthesis methodologies and is based on (Collins et al., 2015; Haddaway & Bilotta, 2016; Pullin et al., 2016; The Royal Society & Academy of Medical Sciences, 2018; Petticrew and Roberts 2013; EFSA 2018ab)

Method	Summary	Strengths	Weaknesses
<b>Full systematic Review</b>	Structured, methodology following an a priori protocol to comprehensively collate, critically appraise and synthesise existing evidence.	Full documentation  Methods are documented transparently.  Low risk of Bias	High time and resources requirement  Not suitable for broad topic issues
<b>Scoping Review</b>	Structured, methodology, preferably following an a priori protocol to collate and describe existing research evidence in a broad topic area, following a systematic map methodology	Potentially upgradable into a full systematic review/systematic map without complete repetition. Suitable for broad topics.	Not as reliable as a full systematic. Does not usually provide detailed analysis of the content/findings of evidence. Often just shows what evidence exists.
<b>Meta-analysis</b>	A statistical tool to reanalyse existing data from multiple studies.	Powerful statistical tool for summarizing multiple, possibly contradictory research studies. Publication bias can be assessed statistically.	Not a standalone review method, relies upon one of the other synthesis methods to provide data; requires considerable technical skills. Not suitable for broad topic areas: requires very specific question.
<b>Rapid evidence Assessments</b>	Follows systematic review methodology but with components of the process simplified or omitted to produce information in a short period of time	Typically quicker Follows methodological principles of systematic review Methods are documented transparently	Not fully comprehensive Not as reliable as a full systematic review protocol Not usually suitable for very broad topics
<b>Systematic map</b>	Structured, step-wise methodology following an a priori protocol to comprehensively collate and describe existing research evidence. Reporting requirements include: protocol of methods, fates of all articles screened at full text, transparent documenting of all methods used.	Any type of documented information can be included.  Very comprehensive - likelihood of missing information is low. Fully systematic, transparent method with full documentation allowing verification and repeatability Low risk of bias	High time/resources  Systematic maps with large evidence bases may become out-of-date relatively quickly
<b>Unstructured expert consultation</b>	The consultation of a set of experts, either individually or in a group, encouraged to produce a consensus judgement,	Rapid access to knowledge Can incorporate all types of knowledge Low cost	Not systematic or comprehensive No documentation of the evidence or studies used  Highly subject to bias
<b>(Formal) expert knowledge elicitation (EKE)</b>	The consultation of a set of experts with the purpose of eliciting probability judgements, which follows strict protocols for expert recruitment (to ensure well defined and homogenous expertise profiles) as well as strictly defined techniques for eliciting individual judgements and for aggregating them	Very high strength, transparency and reproducibility of expert judgement	Assessment typically takes a few months to complete and requires substantial experience or training of the experts
<b>Semi-formal expert elicitation</b>	A simplified and quicker version of EKE. It follows reduced requirements (which include e.g. a predefined number and profile of the experts, ensuring that they receive at least basic training in probability judgements, the use of a recognised elicitation and aggregation method, and documented procedure and results)	Useful in risk assessments when empirical basis is limited or cannot be fully synthesised due to time and resource limits Much less time needed than for EKE: assessment typically takes only a few days	Some shortcuts are accepted compared to EKE (e.g. the time used in EKE for iterative question reframing is eliminated), with some loss of strength of evidence

## Annex 6 – Main elements of EFSA uncertainty assessment guidance

### Identifying uncertainties affecting the assessment

In assessments that follow standardised procedures, only non-standard uncertainties need to be identified.

### Prioritising uncertainties within the assessment

To be done by expert judgement during the planning process, but in more complex assessments it may be done explicitly using influence analysis or sensitivity analysis. The relative influence of different uncertainties, and the strength of the knowledge based for assessing them can be judged in approximate ways using the NUSAP method (see below).

### Dividing the uncertainty analysis into parts (as appropriate)

Depending on time and resources available, it may be sufficient to characterise overall uncertainty for the whole assessment directly, by expert judgement. In other cases, it may be preferable to evaluate uncertainty for some or all parts of the assessment separately and then combine them, either by calculation or expert judgement (see the figure below).

### Ensuring that the questions or quantities of interest are well-defined

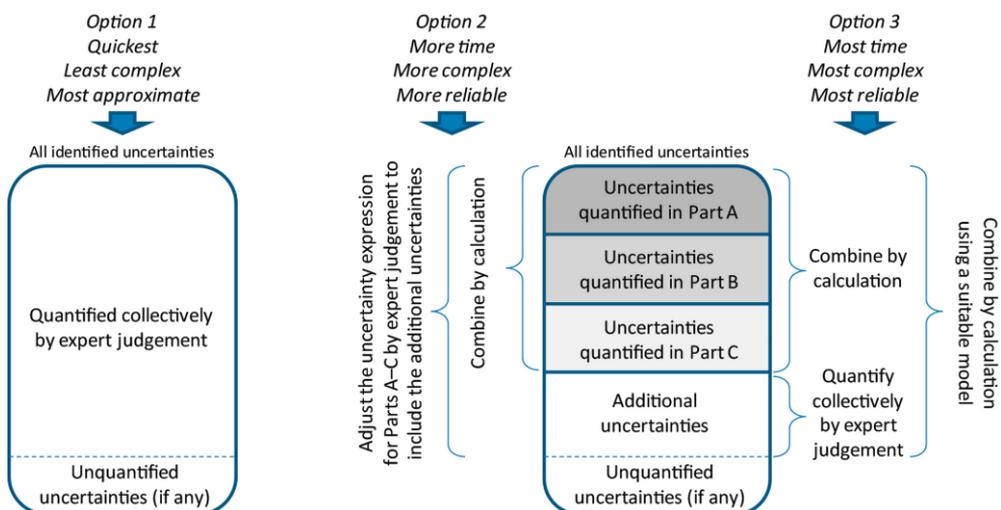
This is necessary to allow expressing uncertainty about the true answer or value clearly and unambiguously. For standardised assessment, the questions or quantities of interest should be predefined.

### Characterising uncertainty for parts of the uncertainty analysis (if applicable)

Uncertainties can be assessed and quantified using statistical analysis of data (recommended whenever available) or expert judgement.

### Combining uncertainties from different parts of the analysis (if applicable)

**Characterising overall uncertainty** (see the figure below for options – reproduced from EFSA, 2018:29)



### Prioritising uncertainties for future investigation

**Reporting uncertainty analysis in scientific reports for decision makers** (see also 2.3.3.)

## Annex 7 – An uncertainty matrix

Guidance of the Netherlands Environmental Assessment Agency – PBL; revised 2<sup>nd</sup> edition (Petersen et al. 2013) – part of the 'Detailed Guidance'; see Box 5 for an overview of the entire approach

UNCERTAINTY MATRIX		Level of uncertainty (from 'knowing for certain' (deterministic knowledge) to 'not even knowing what you do not know' (total ignorance))		Nature of uncertainty		Qualification of knowledge base (backing)			Value-ladenness of choices			
		Statistical uncertainty (range+ chance)	Scenario uncertainty (range indicated as 'what-if' option)	Recognised ignorance	Knowledge- related uncertainty	Variability- related uncertainty	Weak -	Fair 0	Strong +	Small -	Medium 0	Large +
<b>Context</b>	Location ↓	Assumptions on system boundaries and ecological, technological, economic, social and political context										
	<b>Expert judgement</b>	Narrative; storyline; advice										
<b>M o d e l</b>	<b>Model structure</b>	Relations										
	<b>Technical model</b>	Software and hardware implementation										
	<b>Model parameters</b>	Input data; driving forces; input scenarios										
<b>Data</b> (in a general sense)	<b>Model inputs</b>	Input data; driving forces; input scenarios										
	Measurements; monitoring; surveys	Measurements; monitoring; surveys										
<b>Outputs</b>	Indicators; statements	Indicators; statements										

## Annex 8 – NUSAP method of uncertainty assessment

*Adapted from: SAPEA (2019:89); van der Sluijs (2008, 2017), EFSA (2018b:125-130)*

NUSAP is an acronym standing for the five elements of the method: numeral, unit, spread, assessment and pedigree. The first three elements together refer to common quantitative expressions of technical uncertainty, such as the variability range (e.g. 5-10 mg/kg bw per day)

The latter two elements are qualitative and fully based on expert judgement, the outcomes of which are meant to be combined with the quantitative aspects:

- 'assessment' refers to expert judgement of reliability;
- pedigree is a multi-criteria analysis of the scientific strength of the evidence. It allows numerical expression of 'scientific strength' including aspects such as the strength of the empirical basis of the available evidence, or the influence of a given uncertain parameter on the overall assessment results. It uses simple ordinal scales (0-4), combined with verbal descriptions for each grade.

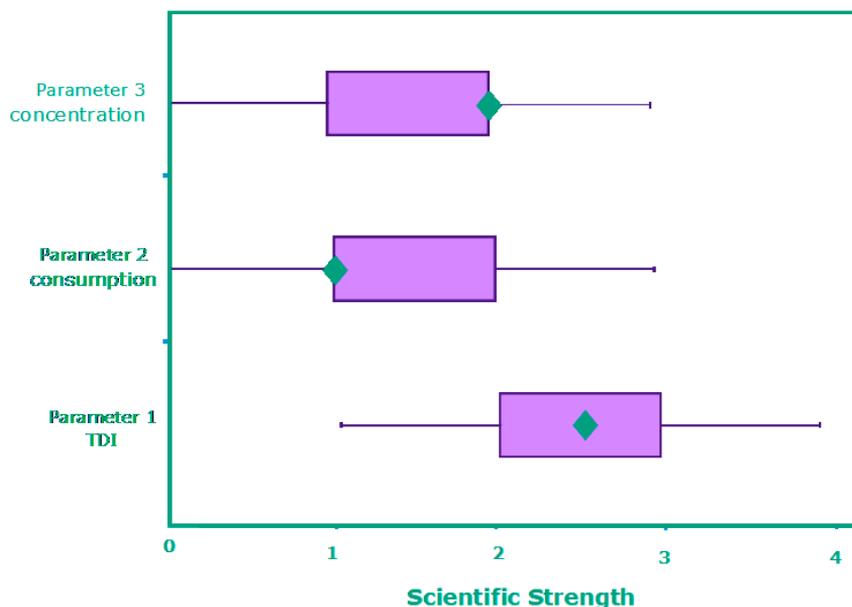
An example of a pedigree matrix is shown below:

Score	Strength				Effect
	Proxy	Empirical basis	Methodological rigor	Validation	Influence on results
4	Exact measure of the desired quantity (e.g. from the same geographical area)	Large sample, <u>direct measurements</u> (recent data, controlled experiments)	Best available <u>practice</u> (accredited method for sampling/diagnostic test)	Compared with <u>independent measurements of the same variable</u> (long domain, rigorous correction of errors)	
3	Good fit or measure (e.g. from another but representative area)	Small sample, <u>direct measurements</u> (less recent data, uncontrolled experiments, low non-response)	Reliable method (common within established discipline)	Compared with <u>independent measurements of closely related variable</u> (shorter time periods)	No or negligible impact on the results
2	<u>Well correlated</u> (e.g. large geographical differences, less representative)	Very small sample, <u>modelled/derived data</u> (indirect measurements, structured expert opinion)	Acceptable method (limited consensus on reliability)	Compared with <u>measurements of non-independent variable</u> (proxy variable, limited domain)	Little impact on the results
1	Weak correlation (e.g. very large geographical differences, low representativity)	One expert <u>opinion, rule of thumb</u>	Preliminary method (unknown reliability)	Weak, indirect <u>validation</u>	Moderate impact on the end result
0	<u>Not clearly correlated</u>	<u>Crude speculation</u>	<u>No discernible rigor</u>	<u>No validation</u>	<u>Important impact on the end result</u>

*adapted from EFSA 2018b:125*

Median scores obtained through qualitative pedigree analysis (i.e. expert judgement) can then be plotted against quantitative parameters (e.g. expressed as variability ranges).

An example below uses EFSA case study of melamine risk assessment. It shows (a) three quantitative parameters (health-based guidance value for melamine; consumption of melamine containing chocolate and melamine concentration in milk powder) with their technical uncertainty (variability ranges) shown as purple boxes, and (b) the median of scores of 7 experts on all four dimensions of the 'pedigree analysis' (green diamonds), with the error bars showing the range of all scores.



Van der Sluijs (2008) illustrates its application of NUSAP to expert judgement concerning monitoring the emissions of three air pollutants ( $\text{NH}_3$ , VOC,  $\text{PM}_{10}$ ).

The reported strengths of the method include the fact that it adds rigour to qualitative judgements by encouraging systematic and consistent analysis of various uncertainties, is easy to use (including for quick informal analyses – SAPEA 2019:90), and the result are easy to understand for non-experts.

The reported weaknesses of the method include the fact that it still results in fairly approximative judgement, and – as for other structured methodologies – the need to train experts in the method (EFSA 2018b:128-130).

## Annex 9 – Experts consulted

<b>Surname</b>	<b>Name</b>	<b>Affiliation</b>
<b>Baghramian</b>	Maria	University College Dublin, IE
<b>Bertolini</b>	Roberto	World Health Organization Representation to the EU, member of the EC's Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), IT
<b>Bestmann</b>	Sven	University College, UK
<b>Brom</b>	Frans	The Netherlands Scientific Council for Government Policy (WRR) and Tilburg University, NL
<b>Cairney</b>	Paul	University of Stirling, UK
<b>Capaccioli</b>	Massimo	University of Naples Federico II, IT
<b>Cemma</b>	Masha	Office of the Chief Science Advisor of Canada, CDN
<b>Collins</b>	Alexandra	Centre for Environmental Policy, Imperial College London
<b>de Rijcke</b>	Sarah	Centre for Science and Technology Studies, Leiden University, NL
<b>Dietrich</b>	Daniel	University of Konstanz, DE
<b>Drotner</b>	Kirsten	University of Southern Denmark, DK
<b>Dubertret</b>	Louis	National Academy of Technologies of France, FR
<b>Ferguson</b>	Mark	Chief Science Advisor of Ireland, IE
<b>Fischhoff</b>	Baruch	Carnegie-Mellon University, US
<b>Funtowicz</b>	Silvio	University of Bergen, NO
<b>Geyer</b>	Robert	Lancaster University, UK
<b>Giampietro</b>	Mario	Universitat Autònoma de Barcelona, ES
<b>Gropas</b>	Ruby	European Political Strategy Centre (EPSC), BE
<b>Hacker</b>	Jörg Hinrich	German National Academy of Sciences Leopoldina, DE
<b>Halligan</b>	Peter	Chief Scientific Adviser for Wales, UK
<b>Hart</b>	Andrew	Non-affiliated-expert
<b>Holst</b>	Cathrine	University of Oslo, NO
<b>Hugas</b>	Marta	European Food Safety Authority (EFSA), IT
<b>Irwin</b>	Alan	Copenhagen Business School (CBS), DK
<b>Kaiser</b>	Matthias	University of Bergen, NO
<b>Keizer</b>	Anne Greet	European Science Advice Forum (ESAF), NL
<b>Kovacic</b>	Zora	Universitat Autònoma de Barcelona, ES
<b>Kreyza</b>	Joachim	Joint Research Centre, European Commission, BE
<b>Kuhlmann</b>	Stefan	University of Twente, NL
<b>Lentsch</b>	Justus	IASS Potsdam - Institute for Advanced Sustainability Studies, DE
<b>Luty</b>	Tadeusz	Wrocław University of Science and Technology, PL
<b>Makarow</b>	Marja	Biocenter Finland, FI
<b>Moberg</b>	Christina	Royal Institute of Technology, Stockholm, SE
<b>Montuschi</b>	Eleonora	London School of Economics, UK and and University of Venice Ca' Foscari, IT
<b>Morega</b>	Alexandru	University Politehnica of Bucharest, RO
<b>Nowotny</b>	Helga	Social Studies of Science, ETH Zurich, CH
<b>Owens</b>	Susan	University of Cambridge, UK
<b>Parkhurst</b>	Justin	London School of Economics and Political Science (LSE), UK
<b>Petersen</b>	Arthur	University College London, UK
<b>Prainsack</b>	Barbara	University of Vienna and King's College London, AT and UK
<b>Reisch</b>	Lucia	Copenhagen Business School, DK
<b>Renn</b>	Ortwin	International Institute for Advanced Sustainability Studies (IASS), DE
<b>Sahlin</b>	Nils-Eric	Lund University, SE
<b>Stirling</b>	Andy	Sussex University, UK
<b>Van der Sluijs</b>	Jeroen	University of Bergen, NO
<b>Vargas</b>	Rosalia	Ciência Viva, PT
<b>Vermeier</b>	Koen	Global Young Academy GYA and CNRS, FR
<b>Vretenar</b>	Dario	University of Zagreb, HR
<b>Wilsdon</b>	James	University of Sheffield, UK
<b>Zerbi</b>	Filippo	National Institute of Astrophysics, IT

## Annex 10 – List of Abbreviations

<b>COI</b>	Conflict of interest
<b>DOI</b>	Declaration of interest
<b>EFSA</b>	European Food Safety Authority
<b>EKE</b>	Expert knowledge elicitation
<b>EU</b>	European Union
<b>KQA</b>	Knowledge-Quality Assessment
<b>NGO</b>	Non-governmental organisation
<b>NUSAP</b>	Numeral Unit Spread Assessment Pedigree (an uncertainty assessment method)
<b>SAPEA</b>	Science Advice for Policy by European Academies

## Annex 11 – Glossary

<b>Term</b>	<b>Definition</b>
Ambiguity	In this Opinion, variability of interpretations based on identical observations or data assessment.
Analytic-deliberative model	A model of public participation in scientific advice which combines a rigorous analysis of available scientific evidence with broader societal dialogue about its implications.
Approximate probability scale	A scale which combines verbal and numerical expressions of probability.
Cognitive bias	An involuntary pattern of thinking that leads to distorted perceptions and judgements that can result in errors in reasoning, logic and evaluation.
Complexity	A characteristic of a (natural or social) system where there are strong interactions among its elements, and where the cause-effect links between a multitude of interdependent variables are not fully understood or predictable
Conceptual use (of science in policy)	Complex and often indirect ways in which science can have an impact on the knowledge, understanding and attitudes of policy makers and practitioners
Deliberative use (of science in policy)	Scientists and policymakers engage in a dialogue with the purpose of defining the questions to be answered through a reflective, nuanced and rigorous deliberation.
Emergence	Behaviour resulting from interactions at local level which restricts the behaviour of the whole system, thus making predictions of policy impact difficult. For complex policy issues, this implies that it can be useful to employ pilot schemes before big central policy roll-outs
Enlightenment (as a use of science in policy)	Being informed about the state-of-the-art of factual issues and causal/functional relationships that form reliable knowledge
Epistemic uncertainty	Uncertainty about which kinds of knowledge are relevant to the question at hand, and about what is at stake
Evidence-based advocacy	The deliberate process, based on demonstrated

	evidence, to directly and indirectly influence decision makers, stakeholders and relevant audiences to support and implement actions that contribute to issues of common interest.
Expert knowledge elicitation (EKE)	A systematic, documented and reviewable process to retrieve expert judgements from a group of experts, often in the form of a probability distribution
External validity	The extent to which the findings of a study can be generalised or extrapolated to the assessment question at hand.
Foresight	Informing policy by generating insights regarding the dynamics of change, future challenges and options that can be used as an input to policy conceptualisation and design.
Full systematic review	A type of literature review that uses systematic methods to collect secondary data, critically appraise research studies, and synthesize findings qualitatively or quantitatively.
Hazard	The intrinsic potential of an event, substance etc. to cause harm
Horizon scanning	The systematic examination of potential (future) problems, threats, opportunities and likely future developments.
Heuristics	Any approach to problem solving or self-discovery that employs a practical method, not guaranteed to be optimal, perfect, or rational, but instead sufficient for reaching an immediate goal
Interdisciplinarity	Building links between disciplines.
Internal validity	Internal validity refers to the degree of confidence that the causal relationship being tested is trustworthy and not influenced by other factors.
Issue advocate	In science advice, an agent representing and advocating specific interests – e.g. the stakeholders consulted when developing the advice
Issue bias	A way of evidence creation, selection and interpretation which is biased in favour of particular social or political concerns, or privileges particular scientific methods, in non-transparent ways.

Issue polarisation	An acute form of contestation where there are few middle-ground positions, and the issue is typically debated in binary terms.
Knowledge-quality assessment	A method comprising systematic analysis of, and critical reflection on, uncertainty, assumptions and dissent in scientific assessments in their societal and institutional contexts.
Meta-analysis	A set of methods that can combine quantitatively the evidence from different studies in a mathematically appropriate way.
Methodological uncertainty	Uncertainty about how to assess a question; it can also be produced by limitations in the analytical strategies employed (e.g. uncertainty about excluded factors, about the reliability of expert judgement, or the appropriateness of search criteria to identify relevant literature).
Multidisciplinarity	The coordinated application of several academic disciplines or subjects without attempting to develop a common understanding of the phenomenon to be studied.
Nudge	Any aspect of the choice architecture that alters people's behaviour in a predictable way without forbidding any options or significantly changing their incentives.
NUSAP	An acronym of a method of assessing uncertainty, standing for the five elements of the method: Numeral, Unit, Spread, Assessment and Pedigree.
Orientation (as a use of science in policy)	Familiarisation with and gaining a more in-depth understanding of a challenge or a problematic situation, including visions and plans for future actions.
Path dependence	Dependence on the initial decisions and conditions (e.g. resources historically committed to a policy). In policy and scientific advice this often means that starting policies from scratch is very rarely an option.
Peer review	A procedure where scholarly work is evaluated by experts of the same discipline against a set of criteria to ensure that it meets the quality standards necessary for publication.

Pedigree analysis	A part of the NUSAP method of uncertainty assessment which allows an assessment of qualitative aspects of uncertainty through the use of simple ordinal scales (0-4) combined with verbal descriptions.
Probability	Defined depending on philosophical perspective: (1) the frequency with which sampled values arise within a specified range or for a specified category; (2) quantification of judgement regarding the likelihood of a particular range or category
Probability bound	A probability or approximate probability for a specified range of values
Probability distribution	A description of the possible values of a random variable, and of the probabilities of occurrence of these values.
Qualitative research methods	Methods focused on meaning associated with observed behaviour, rather than with numerical measurement. The emphasis is on subjective understanding, communication, and empathy, rather than prediction and statistically valid explanations.
Rapid evidence assessment	A structured, step-wise methodology, usually following an a priori protocol to comprehensively collate, critically appraise and synthesise existing research evidence (traditional academic and grey literature), following systematic review methodology but with components of the process simplified or omitted to produce information in a short period of time.
Reproducibility	The closeness between the results of different assessments/measurements carried out with same methodology on the same object.
Risk	The chance or probability that harm or the experience of an adverse effect will occur if exposed to a hazard.
Scientific dissent	The occurrence of minority scientific positions which have been based on rigorous and recognised methods and meeting the relevant quality criteria, but arriving at different conclusions than most other scientists
Scoping review	Structured methodology, preferably following an a priori protocol, to collate and describe existing

	research evidence in a broad topic area, following a systematic map methodology.
Scoping workshop	In scientific advice, a workshop the objective of which is to define the scope of future science advice.
Semi-formal expert elicitation	A structured and documented procedure for eliciting expert judgements that is intermediate between fully formal elicitation and informal expert judgements
Societal uncertainty	Uncertainty about whether all relevant aspects of the policy problem at hand have been considered, about rival problem definitions, or about the value-laden assumptions or biases that may be present in the problem definition.
Subjective probability	A type of probability derived from an individual's personal judgment or own experience about whether a specific outcome is likely to occur. It contains no formal calculations and only reflects the subject's opinions and past experience.
Systems perspective	Thinking broadly about the whole picture rather than merely studying component parts of the problem in isolation.
Technical bias	Evidence utilisation that does not follow principles of scientific best practice – e.g. invalid use of pieces of evidence or failing to systematically include all evidence.
Technical uncertainty	Uncertainty which results from limitations in available data. It covers e.g. missing data, uncertainty about a single non-variable value of a parameter; uncertainty about the variability of data, or randomness; uncertainty about measurement precision or about extrapolation validity.
Uncertainty	All types of limitations in available knowledge.
Uncertainty assessment	Specific methods used by experts to assess the level of uncertainty: the 'assessment' refers to expert judgement of reliability of the evidence often though measurement.
Uncertainty analysis	The process of identifying and characterising the uncertainties relevant to the question at hand.

Wicked problems	A problem that is difficult or impossible to solve because of incomplete, contradictory, and changing requirements that are often difficult to recognise.
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We live in a complex and ambiguous world, where trust in both science and politics can be put into question – where scientific evidence is dismissed and policy decisions contested on the assumption of partiality and private interests. Nevertheless, at present the role of science is crucial to inform policy-making in order to provide clarity and assess the consequences of policy options in a systematic way. In order to ensure that trust in science is maintained, science advice needs to be provided in an impartial, reliable, relevant and transparent way, following a set of principles and building on existing best practices.

This scientific opinion, informed by a scientific evidence review report by the Scientific Advice for Policy by European Academies (SAPEA) consortium, makes the following recommendations to ensure the quality and relevance of scientific advice:

- Engage early and regularly with policy-makers and define together the boundaries of the advice, the question and its scope, as well as the best way to address it. Involvement of stakeholders or the public in the process can also be envisaged
- Improve the quality of scientific advice by rigorous synthesis of existing evidence and transparent debate
- Analyse and communicate uncertainty and diverging views related to the scientific evidence and the policy options recommended

### *Studies and reports*

