Integrated EST framework (EST-Frame)

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EST-Frame deliverable 1.1 Frameworks for assessing societal impacts of emerging science and technologies

Ellen-Marie Forsberg, Oslo and Akershus University College

Erik Thorstensen, Oslo and Akershus University College

Erik de Bakker, LEI Wageningen UR

Philip Boucher, University of Nottingham

Nina Bryndum, The Danish Board of Technology

Kerstin Cuhls, Fraunhofer ISI

Davy van Doren, Fraunhofer ISI

Nils Heyen, Fraunhofer ISI

Kamilla Kjølberg, Oslo and Akerhus University College

Kate Millar, University of Nottingham

Rasmus Øjvind Nielsen, The Danish Board of Technology

Thomas Reiss, Fraunhofer ISI

Robert Smith, University of Nottingham

Sven Wydra, Fraunhofer ISI

EST-Frame

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SEVENTH FRAMEWORK PROGRAMME

Preface

This deliverable is produced as a component of the research work conducted within a European research project on integrated assessment of emerging science and technologies (EST-Frame). It builds on work across four case studies, specifically

i) nanotechnology in food,
ii) synthetic biology,
iii) biofuels, and
iv) cloud computing.

These case studies provide an overview of how technologies have been assessed nationally (respectively in the Netherlands, Germany, the UK and Denmark) and at an EU level. In addition, this work builds on studies of different assessment domains (viz. risk assessment, ethical assessment, foresight, technology assessment (TA), economic assessment and impact assessment).

Across all these studies, a number of individual assessments were reviewed using a standardised protocol. The results from these studies are published in four individual case study reports. This deliverable reports on the results from these case and domain studies. EST-Frame deliverable 1.2 aims to add analytic layer to these studies by exploring how policy trends influence on technology assessment and how an integrated framework might respond to these. Further details on the evolving EST-Frame integrated framework are outlined in a report (deliverable 1.3) which is also available on the project website (www.estframe.net).

An earlier version of this report was submitted to the European Commission June 28th 2013. The current version is slightly updated and edited after further work was carried out on the material for the publication of an article for a special issue of Science and Public Policy on results from the EST-Frame project: Forsberg, E-M., Thorstensen, E., Nielsen, R.Ø., de Bakker, E. 2014. Assessments of emerging science and technologies: mapping the landscape., Science and Public Policy, 41: 306-316.

If you have any comments on or questions regarding this report please contact the project coordinator:

Dr Ellen-Marie Forsberg (Ellenmarie.Forsberg@hioa.no)

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1 Executive summary

All assessment of emerging science and technology (EST) rests on the assumption that society ought to ensure responsible technology developments that in the short and long term provide societal benefits while minimising harms. In the EST-Frame project we have studied within four case studies how emerging science and technologies have been assessed;

i) nanotechnology in food,
ii) synthetic biology,
iii) biofuels, and
iv) cloud computing.

We have also studied six established advisory domains: risk analysis, impact assessment, economic assessment, foresight, technology assessment (TA) and ethical assessment. All in all 1506 assessment reports have been screened and 101 reports have been reviewed according to a protocol developed for our purposes. In these studies we have found that emerging science and technologies are assessed with a great width of methods and approaches. Several advisory domains are involved in producing such assessments and many assessments or reports are produced also outside the established advisory domains. Advisory domain assessments follow the conventions of their domains, and are imprinted with the cultures and traditions of their respective domains. Theses cultural assumptions influence the framing of the assessments, the choice of methods and how the assessments are reported.

The manifold of assessments has different intended purposes and functions. They frame their topics in different ways depending on their mandate, the traditions in the domains, the impact they want to have, the participants included, etc. This means that there is a wide range of assessments answering different questions. We have found that the advisory domains generally do not make use of systematic tools for situation analysis and method choice, though some such tools may exist. The domains also generally lack standards for transparent reporting of situation analysis, including framing assumptions, method choice and the unfolding of the assessment process.

We have found that all domains have a focus on methodological development, and try to tackle the complexities and uncertainties implied by emerging science and technologies. However, they do not often discuss such challenges with practitioners from other fields. There are sometimes collaborative assessment efforts across the domains, for instance between TA offices and ethics committees. However, most often the domains do not collaborate to solve methodological challenges. Even if there are many overlaps between the domains in terms of both topics and methods, there is a lack of communication between the domains. There seems especially to be a communication gap between ethicists and economists in the context of emerging science and technologies. From the project practitioner workshop we learned that such cross-domain learning was appreciated.

Assessments from outside the established advisory domains may be just as important for policy as those from inside. However, there is a risk that these have less institutionalised mechanisms for methodological reflection and learning. Legitimacy of the input, methods and output is important for assessments coming from both inside and outside the established advisory domains. In this study we found no institutionalised mechanisms for judging the quality and legitimacy of assessments that influence policy. Moreover, there was very limited transparency with regard to the impact of the different assessments on policy.

Several integrated methods exist, but from the 101 assessments reviewed in this project, very few could be characterised as integrated on several dimensions. Moreover, for those assessments that scored high on several dimensions relevant for integration, it was generally hard (though with some notable exceptions) to trace this back to systematic methodologies. From the project practitioner workshop and from literature studies we know that there is no established understanding of what the right approach to achieving integration is. However, integration happens when translating lessons from the assessments into practical EST policy. There is evidence from the project's case studies and discussions with end users that this translation process is not entirely transparent.

In the analytic work of the project we found that there is no comprehensive acknowledgement and transparency of the value-laden assumptions underlying EST assessments. In many cases of EST there is no 'innocent' starting point for assessment; a starting point that is not contested. This applies to risk assessment, to economic assessment, and to ethical assessment alike, as well as to all other assessments.

There are many EST assessments focusing on specific EST dimensions in a general way, such as health, safety and environmental concerns (HSE), security concerns, ethical concerns, economic projections, etc. These are important for an initial mapping of issues. We identified fewer assessments trying to tackle concrete EST related policy problems, such as specific applications in a specific geographical context. With increased practical problem orientation comes increased complexity in variables, as well as problems of delimiting the adequate scope of assessments. These are topics that need to be addressed in order to facilitate responsible technology governance in practice.

1.1 Recommendations for policy makers and assessment practitioners

1. Assessments should be transparent in their framing of the topic, situation analysis, method choice and practical process development. Only in this way is it possible to assess the quality and legitimacy of the assessments in their function as providing an evidence base for policy. Policy makers thus need to request such transparency. Transparency guidelines should be developed for advisory reports in general.
2. There should be increased interaction between the advisory domains in order to enhance learning and facilitate extended peer review. Such interaction should be facilitated by institutionalised instruments.
3. There should be increased focus on developing methods for tackling EST issues that have become practical policy issues. This inherently involves interdisciplinarity and broader involvement of stakeholders and/or the public. Policy makers should request such problem oriented assessment before the problems become acute.

4. In most cases, before a field of assesment reports can come to function as an evidence base for policy, some form of integration of the main lessons from these reports will be necessary. The legitimacy of this evidence base will increase when such integration is done in dialogical and problem-oriented interdisciplinary processes. Policy makers should work to institutionalise such forms of integrated assessment.

2 Introduction

'Emerging science and technologies' (EST) is a collective phrase currently used to describe a range of technological fields including (but not limited to) biotechnologies, nanotechnologies and certain information technologies. These technologies have been praised by some for their revolutionary potential for solving current global challenges and, not least, leading Europe out of the economic crises. These still early stage and novel technologies may allow us to manipulate our natural and social world in ways not previously imagined. As promising as they may seem, however, the same properties that provide new possibilities for innovation also present potential new risks. There are concerns and disagreements about the impact emerging technologies may have on human health and wellbeing, animals and the environment. There are ethical concerns about respect for human dignity, human enhancement, new monitoring potentials, the moral acceptability of creating life, social and intergenerational justice, etc. And in some cases there are good reasons to question the problem-solving capabilities as well as the true economic potential of such technologies.

These uncertainties and potential controversies give rise to what Kaiser et al. (2010) in the nanotechnology domain referred to as an 'assessment regime' in the interfaces between science and policy, where a host of actions have been taken to map public attitudes, engage the public in discussions, and provide evidence for policy making and regulation. National science societies, technology boards, ethics committees and research consortia organise actions and events including expert committees and the engagement of stakeholders and/or lay people in different participatory processes. Such activities are either self-initiated by the organisations or in most cases carried out based on requests from politicians or ministries, commissioned directly by different decision-makers, or conducted as part of open call research projects funded by the EC framework programmes or national research programs.

In addition to such events and assessment projects, emerging technologies are also subjected to the established regulations which require specific appraisals, such as risk assessments. Examples of these regulatory requirements are set out in REACH, the Directive on Deliberate Release of GMOs into the Environment, the Novel Foods Regulation, etc. There are also regulations at an EU and national level that require impact assessments of larger projects and programs. This diversity of assessment mechanisms – which again rely on a high level of research - implies that much evidence on facts and values are produced. However, there is still notable discussion as to what extent these assessments capture the scientific and societal complexity and controversy in these fields, and contribute to the development of robust, responsible and sustainable technology policy and governance.

The EST-Frame project has studied four technology cases (nanotechnologies in food production, synthetic biology, biofuels and cloud computing) in order to analyse the nature of the approaches that are currently being used to assess the technology development and how the different assessments can be compared. The work focussing on specifically the case study technologies are reported in separate case study deliverables (to be found on www.estframe.net). However, the analysis of the different kinds of assessment approaches as such is presented here.

2.1 About assessments and this assessment study

For an understanding of *assessment* we can start with a definition given by Van der Sluijs (2002), referring to Parson (1995), in his encyclopaedia contribution on integrated assessment:

> *Assessment* comprises the analysis and review of information derived from research for the purpose of helping someone in a position of responsibility to evaluate possible actions, or think about a problem. Assessment means assembling, summarizing, organizing, interpreting, and possibly reconciling pieces of existing knowledge, and communicating them so that they are relevant and helpful to an intelligent but inexpert decision-maker (Parson, 1995).

In discussing definitions of integrated assessment Tol and Vellinga (1998, 182) put it simply: 'In any of these definitions, "integrated" conveys a message of multi- or interdisciplinarity, and "assessment" a message of policy relevance'. We will see later in the report that 'integration' and 'integrated assessment' can have a number of meanings.

We have conceived of *advisory domains* as institutionalised assessment traditions, like Parliamentary Technology Assessment, Impact assessment, Foresights, Ethics assessments, etc. The domains studied were pre-selected on the basis of our common understanding of the general field of assessments in and around STI policy and is thus subject to both personal and professional biases. To counter this bias, we have paid special attention to the reactions of assessment professionals to our shortlist and modified it underway, ending up with a consolidated but in no way definitive selection of domains. Conceptually, we have abstained from attempts at building a strong epistemology for the concept of "domains". But when choosing to focus on "institutionalised" domains, we have depended on Greenwood et al. (2008) in which "institutions" are defined broadly as: 'more-or-less taken-for-granted repetitive social behaviour that is underpinned by normative systems and cognitive understandings that give meaning to social exchange and thus enable self-reproducing social order' (p. 5). The point has been to delimit our selection of domains from emerging or hybrid forms of assessment taking place as one-off experiments or transient phenomena and to focus instead on what may be said to be well-known interfaces between science, society and policy. With the idea of institutional domains come some degree of tradition, some common forms of practice and some degree of establishment within public decision-making systems.

As we will see in the report the domains are institutionalised to different degrees and institutionalisation is an ongoing project. Moreover, the borders of the domains are often blurred. Some domains often have designated advisory organisations, such as ethics and risk assessment. Others are defined more by their methods, such IA and foresights. The word 'domain' must therefore here not be understood as referring to a definite object, but to a set of more or less institutionalised practices. This report is structured by advisory domains, and includes reflections of the domain as such, their approaches and concrete assessments.

EST-Frame has studied different kinds of assessments of emerging science and technologies, using an analysis of current assessments as a means to reflecting on the status of EST assessments and on room for improvement. The content of this deliverable is based on these analyses, on interviews with assessment practitioners and policy makers, on input from a practitioner workshop organised in the project as well as on studies of practitioners' manuals and scientific literature from the domains. The full list of assessments analysed in the domain studies is provided in annex 3 to this document. The analysis documents, the EST-Frame 'raw data' (n = 101), are gathered in a separate compilation.

In order to make our analyses transparent and comparable each assessment was analysed with a a process characterisation table (table A in annex 1), as well as a purpose analysis table (table B in annex 1). Table A was constructed by the consortium as a way to gather information about the assessment process. Table B was developed in the European project *Technology Assessment: Methods and Impacts* (TAMI) for clarifying assessment purposes and roles (Decker and Ladikas 2004, 63). Both these tables were also used as a basis for an aggregated analysis at a case study level and at an advisory domain level.

In order to generate robust results this project is based on several sources of evidence, literature studies, reviews of assessments, interviews and workshops. However, the starting point for these studies was based on a pre-understanding shaped by our experiences as practitioners and researchers in our slightly different fields of EST appraisal. The consortium as a whole has experience from ethics, foresight, TA, economic assessment, risk assessment and impact assessment from different EST fields such as biotechnology, nanotechnology and ICT. Our experiences from our own fields were that integration was hard to carry out in practice, though our notions of integration were abstract and implicit. From our practical experience and research we therefore had assumptions about what were relevant dimensions when studying current assessments. We developed a process characterisation table that allowed us to analyse current assessments with regard to the following dimensions:

a) Impartiality
b) Transparency
c) Participation (of experts, stakeholders and lay people)
d) Scientific evidence base
e) Focus on uncertainties
f) Explicit values/ethics
g) Impacts considered
h) Retrospective/anticipatory
i) Considers narratives/worldviews/visions

These were selected based on a pre-understanding in the consortium that the main challenges in EST governance are related to scientific uncertainties and long term thinking about a broad range of impacts. Moreover, it was perceived that the main challenges in EST assessment were related to the fact that assessments are often contested due to their underlying values and framings, participation, perceived (im)partiality and (non-)transparency. The pre-understanding can be justified by reference to a large literature on EST governance and assessment, some of which is referred to below. The currently important notion of responsible research and innovation (RRI) is also a significant context for such dimensions (von Schomberg 2012, Owen et al. 2012, EC 2013). When assessing how the different case study technologies have been assessed these dimensions would seem prima facie to be relevant.

In addition we added cost as a relevant variable, as well as the assessments' self-reported success, and we believed it was important to study how policy trends affect EST assessment (see EST-Frame deliverable 1.2).

In this document the advisory domain level analyses will be reported. We will also reflect on relevant similarities and differences across the case studies. The assessments included in the analysis of each advisory domain were selected on the basis of their policy relevance with regard to the selected technology fields studied in the case studies, and on the basis of being exemplary for the methodological approaches in the different advisory domains. See annex 3 for an account of the reviewed assessments.

In chapter 3 we will briefly go through the advisory domains we have studied in the project. For each advisory domain we will go through the defining characteristics, as well as methodological resources and developments. We will end each description with a short summary of EST-Frame relevant points. In chapter 4 we compare and discuss the different advisory domains in a wider perspective.

A fundamental assumption in the project is that emerging science and technologies, with their potentially big – positive and negative – impacts on individuals, society, animals and the environment, must be developed in a socially robust and responsible way. This implies regarding these technologies with a comprehensive scope when developing policies, incentives and regulations. Based on an analysis of the current assessments the project has identified specific needs and principles for achieving integrated assessments, reported in deliverable 1.3. As the main practical output of EST-Frame is an approach to integrated assessments, the possibilities for integrated assessments is a recurrent theme also throughout this report. The concluding section draws learning points from our analysis and points forward to the model development part of the EST-Frame project.

3 Advisory domains

3.1 Risk analysis

Risk analysis as an approach has been a prominent form of identifying, evaluating and managing most forms of hazards. Initially this approach was developed to manage human health risks but the approach is now broadly applied to many aspects of potentially hazardous human behaviour ranging from financial services through to the nuclear industry. Before discussing the current application of risk assessment processes in emerging science and technology appraisals it is first important to (i) clarify aspects of the historical development of risk assessment, (ii) the role of risk assessment in different sectors, (iii) some definitions and application of terminology, (iv) the risk characterisation process and (v) aspects of the epistemological nature of techno-scientific risk assessment and the constructions of risk in wider society.

Early forms of risk calculations were recorded as approaches to understand the likelihood of losses when playing games of chance, e.g. in the 17th Century. More specific early forms of institutional risk assessments were seen in the 19th Century. It could be claimed that within Europe the application of the first formal approaches can be traced back to the early days of health inspections. For example in UK setting, the HM (His Majesty's) Factory Inspectorate's formulation of risk and responsibility under the provisions of the Factories Act 1833.

An institutional perspective of the historical use of risk assessment from one of the most prominent users of the method, the US Environment Protection Agency (EPA), provides an interesting insight to the method's origins.

> *1970s: EPA was involved with risk assessment practices since EPA's early days, although risk assessment per se was not a formally recognized process then. EPA completed its first risk assessment document in December 1975: Quantitative Risk Assessment for Community Exposure to Vinyl Chloride (Kuzmack and McGaughy, 1975). The next significant document appeared in 1976: Interim Procedures and Guidelines for Health Risk and Economic Impact Assessments of Suspected Carcinogens (Train, 1976). The preamble of this document, signed by the Administrator, signaled the Agency's intent that 'rigorous assessments of health risk and economic impact will be undertaken as part of the regulatory process.' A general framework described a process to be followed in analyzing cancer risks of pesticides, and the document recommended that the health data be analyzed independently of the economic impact analysis. (EPA 2012[1])*

This excerpt from the institution's own documents highlights the early use of risk assessment and management. The early forms of human health risk assessment and the development of specific risk assessment frameworks have lead to a diversity of uses today.

[1] EPA (2012) The History of Risk at EPA. Last updated: 31 July 2012. Accessed at http://www.epa.gov/risk_assessment/history.htm on 18 March 2013

Formulated in the techno-scientific form, determining risk is probabilistic and requires examining the likelihood of a harm occurring combined with a description of the nature of the harm. For many practitioners the assessment of risk – as it is operationalised in a risk assessment process – has a very practical purpose in supporting sound decision-making by the individual, professional institution or policy-maker. Noting this generic understanding of risk, it is important to clarify that the term risk analysis is used in a number of ways by different institutions and actors.

Different methods for risk assessment

Risk assessment has become one of the dominant forms of assessment in a number of fields. Risk assessment methodologies are used in a number of different ways and are embedded across distinct sectors, ranging from nuclear power and biotechnology to transport and the financial sector.

As a result of the use of risk assessment across these different sectors a number of more specialised methods of risk assessment have developed, such as:

- Human Health Risk Assessment
- Ecological Risk Assessment
- Environmental Risk Assessment (this includes human beings as a organism in the assessment; see Calow 1998)
- Economic Risk Assessment
- Actuarial Modelling
- Security Risk Assessment

Much has been written on the diversity of approaches, the sectors that use risk assessment and more specialised methods that have been developed (see e.g. Rosenthala et al, 2002).

It is interesting to note concepts of standard practice as set out in the context of an example sector. In the sector of animal health, the Swiss FVO set out a clear process for their risk assessment method:

> *Risk Assessment can be operationalised in this way: Current information is collected, documented and evaluated according to scientific criteria by means of literature research and expert elicitations. Existing knowledge gaps, limitations and uncertainties are transparently documented. Risk analysts assess the risk on the basis of this structured information. The risk consists of the probability that the undesired event might happen and the extent of the possible harm. For a qualitative risk analysis the result is described in words. If necessary and if there are sufficient data, the result may also be expressed as a numerical value on the basis of mathematical models (quantitative risk analysis).* (FVO, 2002, 4)

This procedure, with variations, is representative of HSE risk assessment in the area of emerging science and technologies.

A number of organisations have played a prominent role in the development of risk assessment approaches. In terms of new and emerging science and technology, these organisations often have direct advisory or regulatory functions. Some of the prominent organisations that will be considered later in the report are European Food Safety Authority (EFSA), EC Scientific Committee on Consumer Safety (SCCS), Scientific Committee on Emerging and Newly Identified Health Risk (SCENIHR) and Scientific Committee on Health and Environmental Risks (SCHER). Other national advisory committees, such as the UK Advisory Committee on Novel Foods and Processes (ACNFP) and the Netherlands Commission on Genetic Modification (COGEM), have contributed to the development of new approaches in the application and interpretation of risk assessment.

It is also valuable to note that some reports have emphasised the importance of certain framings or approaches to characterising risk. This is noted in the recent and significant publication by the Inter-Committee Coordination Group (SCCS, SCENIHR and SCHER 2013) who defined the two important areas of risk assessment as (i) Ecological Risk Assessment and (ii) Human Health Risk Assessment.

Risk Definitions and Terminology

Before discussing the specific steps of the risk analysis process, it is also valuable to point out the ways in which a number of terms are used when referring to risk assessment as there can be some differences across sectors and methods. For example, there can be a multiplicity of uses of the term risk assessment which represents different meanings and different elements of the risk analysis process.

In this report the terms *risk analysis* or risk appraisal are used to refer to the series of steps that identify, assess and manage risk. *Risk assessment* here refers to the methodological step in the process consisting of hazard identification and assessment. The risk analysis process in general involves five components:

(a) hazard identification;
(b) hazard assessment[2];
These two steps equate to *risk assessment*, which is then followed by:
(c) *risk management*; which often involves a form of cost-benefit analysis (CBA), followed by:
(d) *risk communication*;
(e) monitoring and evaluation

This can be simplified by some organisations to the three steps of risk assessment, risk management and risk communication[3]. Within a *risk assessment* process, the significance of a risk is also often further characterised in terms of: (i) severity; (ii) duration; (iii) reversibility; and (iv) compensatability (Mepham 2008, 330). Such a linear model is an idealisation. In reality the different steps are ongoing and iterative. It is also important to note that some individuals can also refer to risk assessment

[2] It should be noted that these two steps are commonly referred to as risk assessment, although some reports or articles refer to hazard identification separately from a notion of risk assessment.
[3] WHO refer to Food Risk Analysis as "a process consisting of three components: risk assessment, risk management and risk communication". (Accessed: 08/05/13)
http://www.who.int/foodsafety/publications/micro/riskanalysis_definitions/en/

when they mean the overall process of risk analysis which includes hazard identification through to monitoring and evaluation (i.e. a to e).

Within a *risk assessment* process, practitioners strive to characterise the nature of the hazard. The two step process described above can be broken down into a series of technical steps. For example, steps for chemical risk assessment in food have been set down by the Food Safety in Europe (FOSIE) initiative. These are (Clewell III et al, 2008):

- 'Hazard identification, by methods of animal-based toxicology, in vitro toxicology and epidemiology
- Dose–response assessment
- Exposure assessment
- Risk characterization'

Exposure assessment may also include vulnerability assessment. A further step can also be included, as acknowledged in the recent joint report from the SCHER, SCENIHR, and SCCS (2013, pp. 36-38). The stage 'Threshold of Toxicological Concern' is seen as the fifth step of risk assessment.

As well as a process, regulatory bodies have been created to manage, at the national level, aspects of risks and safety. Examples from the UK include Health and Safety Executive (HSE[4] – workplace and other occupational risks) and Food Standards Agency (FSA [5]– food related risks). Regulatory controls and guidelines, such as the UK Control of Substances Hazardous to Health regulations (COSHH) and wider EU processes such as Hazard Analysis and Critical Control Point System (HACCP), have been devised to assist with the identification, assessment and management of hazards (e.g. toxic chemicals). Such *risk management* involves practice and policies to minimise and manage the identified risks.

Product related risk assessments may end in allowing or rejecting market access. For other applications managers at this stage of the process apply a cost-benefit analysis (CBA). The outcome of this stage of the risk analysis process is often management strategies such as further information provision on the hazard, guidelines for use and regulations (including substance bans). For food-related risks, national organisation such as the UK Food Standards Agency (FSA) advise on issues of toxicity, etc., by a drawing on the (risk) management advice of a number of advisory committees (e.g. Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment – COT).

The nature of the response from such institutions will be affected by a number of factors such as whether the risks are voluntary or involuntary. Responses may include providing information to allow informed choices or regulating or banning use of substances. Regulators may conduct a cost-benefit analysis (CBA) and determine whether there is a need for regulation (consumer protection) against the drawbacks of over regulation (unnecessary costs and barriers to innovation).

[4] HSE http://www.hse.gov.uk/
Example GMO RA http://www.hse.gov.uk/biosafety/gmo/acgm/ecrisk.htm
[5] FSA http://www.food.gov.uk/. Example of transparent use of risk assessment in food:
http://www.food.gov.uk/science/sci-gov/decision-making

Organisations engaged in CBA often claim and aspire to deliver: 'consistency, transparency, targeting, proportionality, and accountability.' This is seen in the recent guidance in 2012 on transparency (as set out in the report by the Heads of National Food Agencies Working Group on Transparent Use of Risk Assessment in Decision Making, 2004) by the EU national Food Standards bodies.

The use of CBA and the decision of a regulatory body to intervene is not based on scientific assessment / understanding alone. Since zero risk is seen as unachievable, the best 'known' evidence is used to manage the risks presented (as discussed above). In the UK, risk assessment is driven by a cost-benefit trade off. The ALARP principle (as low as reasonably practicable) is used to determine the process of 'weighing a risk against the trouble, time and money needed to control it' (HSE 2001, 88). Efforts to reduce risks are carried out only where they are either: i) intolerable or ii) reducing them further still is reasonable, given cost. Thus, ALARP describes the level to which society expects to see risks (e.g. food risks) controlled. The ALARA principle (as low as reasonably achievable) is a similar principle, common in radiation protection. Finally, the precautionary principle is an important risk management principle applicable in situations characterised by significant scientific uncertainties and potentially important consequences – which may be the case with emerging science and technologies. An EU communication on the precautionary principle outlines the principle in the following way:

> *The precautionary principle applies where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU (EU 2000)*

An important part of risk assessment is therefore to make a judgement on the level of scientific uncertainty in order determine whether the precautionary principle applies. If it applies, it has some consequences for risk management strategies, not least that a broader range of expertise is called for and monitoring schemes are developed (see pp. 38-41 of UNESCO 2005 for more details).

Risk communication is the process of providing information on specific risks to stakeholders and the wider public. An important component of this process is to ensure two-way communication channels (between the information provider and the information recipient) and that the process is transparent (presentation and data). Risk communication advice and guidelines are provided by various institutions, such as national health and safety agencies. However, this is often seen as difficult in practice because of differences in expert knowledge between the provider and recipients.

Risk assessment has now become the dominant approach in managing a wide range of risks associated with human behaviour, as such this approach has been embedded as a central method in a number of prominent science and policy-making institutions. The risk assessment approach has become embedded with a number of significant regulatory frameworks that are applied to emerging science and technology. Institutions have developed risk assessment approaches as either:

- Regulatory Tools for characterising specific risks, directly embedded with regulatory frameworks (e.g. assessing the human health effects of the inhalation of an organophosphate
- Risk Mapping Tools for understanding novel or complex risks (e.g. human consumption of GM crops)
- Risk Management Tools for assessing and weighing multiple risks (e.g. safety assessment of new transport vehicle)

One of the most prominent areas of risk assessment application is for the characterisation of specific risks for regulatory oversight. A number of have risk assessment units within their organisations such as:

- DG Environment; e.g. for the management of chemical use through REACH legislation;
- EFSA; e.g. as part of their food safety responsibilities;
- DG Sanco; e.g. for innovation governance
- EMEA; e.g. as part of their responsibilities to protection of patients

Challenges in risk analysis

Obvious challenges in risk assessment revolve around complexity and uncertainty (see for instance International Risk Governance Council (IRGC), 2005). IRGC describes complexity in the following way:

> *Complexity refers to the difficulty of identifying and quantifying causal links between a multitude of potential causal agents and specific observed effects. The nature of this difficulty may be traced back to interactive effects among these agents (synergism and antagonisms), long delay periods between cause and effect, inter-individual variation, intervening variables, and others. Risk assessors have to make judgements about the level of complexity that they are able to process and about how to treat intervening variables (such as lifestyle, other environmental factors, psychosomatic impacts, etc.). Complexity is particularly pertinent in the phase of estimation with respect to hazards as well as risks. Examples of highly complex risk include sophisticated chemical facilities, synergistic effects of potentially toxic substances, failure risk of large interconnected infrastructures and risks of critical loads to sensitive ecosystems. (IRGC, 2005, 29-30)*

Uncertainty ‘is different from complexity but often results from an incomplete or inadequate reduction of complexity in modelling cause-effect chains. […] It is essential to acknowledge in the context of risk assessment that human knowledge is always incomplete and selective and thus contingent on uncertain assumptions, assertions and predictions.’ (p. 30). The IRGC report outlines in detail challenges relating to uncertainty in risk assessment.

In addition the relation between the scientific dimension and the public continues to be a challenge.

The WHO has identified a number of challenges in their account of the development of risk analysis: ‘During the 1980s, scientific predictions were seen to be rational, objective and valid, while public perceptions were believed to be largely subjective, ill-informed and, therefore, less valid. This led to risk control policies that attempted to "correct" and "educate" the public in the more valid scientific notions of risk and risk management.' (2002, pp. 30-31). This is commonly known as the public deficit model, positioned in an approach called the 'public understanding of science' paradigm. Though this model is widely criticised[6] it still remains as a cultural assumption among many risk assessors and managers. The WHO notes that

> *this approach was increasingly challenged by public interest and pressure groups, which asked scientists to explain their methods and assumptions. These critical challenges often revealed the high levels of scientific uncertainty that were inherent in many calculations. [...] By the early 1990s, particularly in North America and Europe, it became apparent that relying mainly on the scientific approaches to risk assessment and management was not always achieving the expected results. It also became clear that risk had different meanings to different groups of people and that all risks had to be understood within the larger social, cultural and economic context. (World Health Organisation 2002, 30–31)*

Alongside the process oriented discussion it is thus also important to note the role of risk perception, as this can affect the development of new and integrated approaches (see Sandman, 1987, for a discussion of factors influencing the perception of risk). Scientists tend to use a technical vocabulary related to statistical probability that a particular set of circumstances will occur. However, risk and safety also relate to a feeling of confidence or wellbeing about one's situation, activities and outlook. Aspects of the socio-political process have a significant bearing on individual's perception and understanding of risk. Acceptability of risk, particularly imposed risk, depends on i) (in)voluntariness; ii) disinterestedness of the risk assessor; iii) distribution of potential costs and benefits; (iv) (un)familiarity; (v) (un)naturalness; (vi) level of compensation. (Health and Safety Executive, HSE 2001)

The embedded values within the whole risk analysis process is increasingly acknowledged (Wickson and Wynne 2012; Wandall 2004). The WHO highlights some of these assumptions:

> *Although risk assessment appears to follow a scientifically logical sequence, in practice there are considerable difficulties in making 'objective' decisions at each step in the calculations. Thus the risk modeller has to adopt a specific definition of risk and needs to introduce into the model a series of more subjective judgements and assumptions. Many of these include implicit and subjective values, such as the numerical expression for risk, weighting the value of life at different ages, the discount rates and choice of adverse health outcomes to be included. (WHO, 2002, 30-31)*

This reflects the changing relationship between the different elements of risk analysis and the way in which an increasing number of institutions now respond to risk with more awareness of insights from ethics, STS and the philosophy and theory of science.

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[6] In a report by the House of Lords, Science and Technology (*Third Report*) Sir Robert May called the approach "a rather backward looking vision" (section 3.9) and the British Council called it 'outmoded and potentially dangerous' ((HMSO, 2000, section 3.9).

Building on the techno-scientific form of risk assessment as described above and the increasing acknowledgement of societal and ethical dimensions of risk assessment and how they are embedded with certain knowledge systems, it is important to note the notion of risk society and recent sociological work related to risk that has implications for the role of risk analysis in integrated technology assessment.

Several factors have challenged the traditional risk assessment regime. These include:

- Increased acknowledgement of the significance of ecological risks (for instance in new legislation such as REACH)
- the challenge of novel technologies, where it is not clear whether 'old' methods apply to novel risks
- calls for greater public transparency and accountability
- drivers to increase trust
- greater recognition of the socio-political and ethical dimensions of risk assessment

Some examples of the new ethos are seen in recent activities of institutions and the responses of the risk assessment specialists:

- EFSA
- ICCG

Integrated risk assessment approaches are being developed and 'integration' here usually means integrating human and environmental risks. WHO notes that '[m]any international and national organizations have expressed a need for an integrated, holistic approach to risk assessment that addresses real life situations of multichemical, multimedia, multi-route, and multispecies exposures'[7]. The International Programme on Chemical Safety (IPEC) covened a group of international experts to respond to such a need, which resulted in a report to WHO/UNEP/ILO (2001), also reported in Damstra et al. (2003).

There are also current attempts at better integrating risk assessment and economic assessment. This is discussed in a report of the Inter-committee working group of the three DG SANCO risk assessment committees, *Making Risk Assessment More Relevant for Risk Management* (Scientific Committee on Health and Environmental Risks [SCHER] / Scientific Committee on Emerging and Newly Identified Health Risks [SCENIHR] / Scientific Committee on Consumer Safety [SCCS], 2013).

What is significant about much of this recent work on the strengths and limitations of risk assessment and the need for integrated approaches, is that there is a recognition that "risk assessments as currently carried out do not inform the risk management process as well as they should" (SCHER / SCENIHR / SCCS 2013, 7). This reduces the impact and value of technical risk assessment in policy-making and results in a potential gulf between the technical and social dimensions of technology governance. The report by the EC Risk Assessment Committees recognises the "important concerns about uncertainty", the need for much greater transparency in

[7] http://www.who.int/ipcs/methods/risk_assessment/en/index.html [Accessed 01.05.2013]

assumptions and processes and also recommends extending "dialogue to all stakeholders in both initial forums and final consultations as a way of clarifying issues and ensuring more ownership". These three aspects are important developments of the risk analysis and it could be argued leads to a need for cross domain integration. The current developments in the sector provide an excellent opportunity for a multi-stakeholder dialogue about cross domain integration.

Findings in the study

In the project fourteen risk analysis reports were selected for further analysis according to the project's protocol. Ten of these were drawn from the case studies, and an additional four were selected to give a broader picture of risk assessments with aspects that may otherwise have been missed from the case studies alone. Selection criteria were reports that were exemplars, policy relevance and relevance to EST. By their nature, emerging science and technologies are likely to be at relatively nascent stages of development. As such, in some cases products are yet to be developed and/or commercialised, and the applicability of risk assessment methodologies are still being debated. As a consequence of this most policy relevant risk analyses commonly focus on fundamental issues about methodology. This is less common in more established fields, such as biofuels and GMOs, where products are on or close to market, risk assessment guidelines already exist, and routine risk assessments are being carried out. The selection of assessments in this report includes some early stage demonstration type technologies and some more close to market technologies. The analysis therefore reflects this selection.

What is common for all the assessments is that they aim, not surprisingly, to raise knowledge on scientific and technological aspects. However, with the aim of informing policy/decision makers they also (but to a lesser degree) play a role or intend to facilitate the formation of attitudes on these aspects.

The selected risk analyses tend to score highly on traditional scientific aspects such as impartiality, transparency and participation of experts. Aside from the BfR report (2006) that explicitly sets out to include lay views, wider lay participation is excluded from the assessments. Similarly, stakeholder participation tends to be non-existent or limited. As risk assessments do tend to be of a technical or 'expert' nature this may not be surprising but the broader implication is that a small set of selected experts may be setting an agenda in the discussions around these ESTs.

Attention to uncertainties tends to vary quite significantly over the reviewed assessments, however this may not be a trend in the domain but more an observation from the selected risk assessments as some of the exemplar assessment have a very narrow focus. However, this could also be a result of the discipline-specific framing of issues; for example it is not a focus at all in the ICT related risk assessments whereas it is much more common for nanotechnologies. The impacts considered are not surprisingly influenced by the sector of the risk assessment. In ICTs economic risks are also included in the risk assessments, besides the security risks. Economic aspects are included in one of the biofuels reports. This may result from the framing of the scope of the assessment and the role it is intended to play in the risk management process. With the biofuels case, there is notable focus on environmental implications of novel developments so this results in a greater emphasis on ecological risk In general there is no mention of embedded values or ethical issues related to the topics investigated, and no positioning of the assessment in a normative context or in the context of underlying narratives of technologies. There is in general little contextualisation of the assessment or its conclusions, with the significant exception of the report of the International Risk Governance Council, which was one of the more comprehensive assessments. Yet it may be argued that reports, such as the example from the IRGC, represent not only risk assessment processes but also significant elements of risk management recommendations.

Within each of the case studies risk analysis plays different roles. In the case of nanotechnology, appropriate risk assessment seems to be perhaps the most important topic at this stage in the technology development. While there have been many public engagement activities and mapping of concerns, the discussion now seems to revolve around how to make sure applications are evaluated against appropriate risk assessment criteria and properly regulated. In synthetic biology the technology is still in its early phases, and though risk assessment discussions have begun, applications are still far from full development and are at a significant distance from the market and thus risk assessment applications are not yet on the top of the agenda, although there is discussion of appropriate risk assessment methodologies. Currently, one of the most important risk assessment discussions is whether synthetic biology can be treated under the current gene technology legislation, with its established risk assessment instruments. However, concerns about dual use indicate that specific security risk assessment measures need to be developed addressing concerns of biosecurity. Security risk assessment is the most important risk debate in emerging ICTs, and is being addressed comprehensively, but in a purely technical manner. In biofuels classical risk assessment approaches have not played a prominent role. Ecological risk has a role but has been somewhat superseded by LCA and other overarching sustainability oriented approaches. Social risks concerning land use are acknowledged as relevant, but are seldom included alongside the environmental and some commentators have expressed a need for more work in this area. So as a whole, assessments for biofuels tend not to focus around risk assessment, but have centred around characterising multiple levels of impacts using tools such as life cycle analysis.

The precautionary principle is evoked for several of the emerging technologies, but remains hard to operationalise. From the EST-Frame practitioner workshop and other dialogues with risk assessment practitioners the process of linking risk assessment through risk management to final communication is considered a constant challenge. This challenge is sometimes framed as a public deficit in knowledge and an inability to understand risk assessment and advice. There is also a perceived challenge to communicate outcomes from risk assessment to risk managers (i.e. the specifics about the risks), where risk managers would like clear cut and, preferably, quantifiable information on risk, that can then be used as input into risk-cost-benefit assessments (see for instance the report EC SCHER / SCENIHR / SCCS), 2013). Here possibilities for easier integration between risk and economic assessment are discussed. Again, the current developments in the sector provide an excellent opportunity for more inter- and cross domain work in this area.

Summary risk assessment

- Much methodological discussion is currently ongoing in the risk analysis domain, especially with regard to EST
- There are important discussions as to how risk assessment can be better integrated with other domains, in particular economic assessments
- There are perceived challenges in communicating risk assessment outcomes to many groups including specifically, wider publics and decision makers
- The analysis shows in general a low degree of reflection on assumptions in risk assessment and risk assessment continues to be seen as a purely technical (and non-normative) activity

3.2 Impact Assessment

Impact Assessment (IA) is a broad assessment domain covering various tools to predict the consequences of actions in order to integrate preventive measures in the planning of these actions. Impact assessment contains a range of different assessment methods, perspectives and tools often found in other advisory domains as well. However, the overall IA procedure is a relatively common ground for all types of Impact Assessments. The domain also contains various sub-groupings that integrate more or less successfully in various contexts.

The International Agency for Impact Assessment (IAIA) defines Impact Assessment as "a structured process for considering the implications, for people and their environment, of proposed actions while there is still an opportunity to modify (or even, if appropriate, abandon) the proposals. It is applied at all levels of decision-making, from policies to specific projects" (IAIA Wiki 2010). In the European political process, the EU Commission utilises impact assessments to prepare evidence for decision makers on advantages or disadvantages of proposed actions (EC 2012). Not limited to the European context however, impact assessments are employed in many different contexts and at many different levels of decision making.

Related to other broad assessment traditions such as technology assessment, risk assessment and life-cycle analysis, impact assessments seeks to provide multi-dimensional anticipatory decision support by highlighting "environmental" consequences in the broadest sense of the term including biophysical, social, economic, and institutional dimensions. Predicting consequences along so many different lines of inquiry is naturally a difficult process and, historically, they have received different levels of attention in different institutional settings. Since 2001, the European Union has promoted and made use of what is called Strategic Environmental Assessments (SEA), which is "generally understood as an impact assessment process that aims to mainstream environmental, social, economic and health issues and ensure the sustainability of strategic decisions" (IAIA Wiki 2010). Further, IA has played an important role in the European Commission's overall strategy on Better Regulation. The tendency in this connection has been to explicate methodology for balancing the triple bottom line of economic, social, and environmental sustainability. Furthermore, participatory assessment methods come to play an ever more important role as stakeholder and (sometimes) citizen involvement in the legislative process is seen as one tool among many to heighten the quality and sustainability of legislation.

While efforts are thus ongoing to secure in a systematic way the proper balance of multiple dimensions in impact assessments, describing the field and its history must necessarily begin with its initial internal divisions and thus take place in a few steps. We begin with the original configuration of environmental assessment, move on to the emergence of social impact assessment as an independent subfield, and finally move towards a description of the European Commission Impact Assessment (EU IA).

Environmental Impact Assessment (EIA)

EIA is described as the original form of impact assessment (Bond & Pope 2012, 2). More than 40 years ago the National Environmental Policy Act (NEPA) was written into US legislation. EIA primarily meant to be a means to assess the outcomes and unintended environmental consequences of proposed actions ranging from project proposals to policies. The aim was to include all aspects of the environment in the assessment, stretching from the potential impacts made on the social environmental level through to the biophysical environment (NEPA 1969, Morgan 2012, 5). Hence EIA was originally meant to be integrative, including social, health, economic and biophysical issues in the assessment of the relevant environmental impacts of actions and proposals (Morgan 2012, 5).

In reality a much narrower interpretation of EIA was carried out. The assessment was primarily addressing the environmental impacts made on the biophysical environment, and thus putting aside, even neglecting other important environmental impacts such as social and health impacts. Especially in the US there was a dissatisfaction with the way EIA was carried out, not taking the social, health and economic impacts into serious consideration in the assessment process (Morgan 2012, 7). As a consequence of this critique specific impact assessments developed under the umbrella of EIA. The early IAs that were developed were: Social impact assessment (SIA), Health impact assessment (HIA), and Strategic environmental assessment (SEA). Recent emerging impact assessments are: Sustainability assessment (SA), Regulatory impact assessment (RIA), Human Rights impact assessment (HRIA), Cultural impact assessment, Post-disaster impact assessment and Climate change impact assessment (Morgan 2012, 7).

The institutionalization of EIA is vast and firmly consolidated in many conventions. A search in the ECOLEX database, carried out in 2011, showed that out of the 193 member states of the United Nations, 191 had either signed some form of international convention on EIA or had EIA procedures incorporated to their national legislation (Morgan 2012, 6).

A short outline of a typical/conventional EIA process, as described by the International Institute for Environment and Development, involves: Screening alternatives, preliminary assessment, scoping, mitigation, a main EIA study and environmental impact statement, review and monitoring. All steps needs to be inclusive and provide information to decision-makers at every stage of the project planning cycle (IIED 2012, 2). Lawrence (2005: 78) describes a number of options on how to conduct a more refined, iterative and more complex EIA process. Here the process starts with preparing a proposal concept, undertake screening, scoping, baseline analysis, refine the proposal, adapt for different IA types, identify and predict key risks and impacts, conduct alternatives analysis, determine mitigation and management measures, determine impact significance, determine conclusions and recommendations, prepare draft report, prepare final report, decision making and implementation, and finally, undertake monitoring and management. All of these steps should be conducted with public and agency involvement at the major decision points during the process (Lawrence 2005, 78).

The actual methods used in these processes are manifold and adapted to each specific project proposal.

Less than ten years ago the EIA community commenced to build theory on the EIA processes. Planning theory produce the major bulk of theory, according to a review by Joe Weston (Weston 2010, 358). Theory on EIA can roughly be put into two strands: Rational procedural theories and substantive theories. Where the latter is concerned with placing EIA in a wider social learning process with sustainable development as a goal, the first strand is concerned with EIA´s role in projects and the decision making process (Weston 2010, 358).

In the early days of EIA the emphasis was basically on the procedural requirements connected with the direct impacts made by large capital projects on the physical and biological environment. Later, the definition has widened up to include concerns about social, cultural, human health and ecological effects. There is a greater sensitivity towards the cumulative effects and the indirect connections with other projects and activities. There is a growing awareness to include substantive environmental concerns such as biodiversity, environmental justice and sustainability. There is also an increased awareness on the adaption of the precautionary and pollution prevention principles, plus the request to include traditional knowledge from indigenous peoples (Lawrence 2005, 10). However, even if such considerations are acknowledged in the IA community they remain hard to include in publically commissioned IAs.

Social Impact Assessment

In the International Principles for Social Impact Assessment (SIA), Frank Vanclay says about SIA that it *"includes the process of analyzing, monitoring, and managing the intended and unintended social consequences, both positive and negative, of planned interventions (policies, programs, plans, projects) and any social change processes invoked by those interventions. Its primary purpose is to bring about a more sustainable and equitable biophysical and human environment"* (Vanclay, 2003: 5). As it could be difficult on the basis of this description to see the analytical difference between EIA and SIA, a bit of specific background for the development of this field is required.

SIA very much follows the historical development of EIA. SIA was written into the NEPA in 1970, it was originally part of the EIA process. Because of dissatisfaction with the way in which the social aspects of a traditional EIA was carried out, SIA developed in the direction of an independent assessment type in its own right. The picture of SIA now is that it, apart from being a traditional proponent led process, also is a process that can be initiated by communities (Vanclay 2011, 4).[8]

The traditional SIA process is characterised by being a pragmatic approach to predict impacts in a regulatory context, while newer versions to a greater extent emphasise the management of the social aspects of development (Vanclay 2011: 3). The traditional approach to SIA has come up with a number of limitations that have been taken into account. There is dissatisfaction among stakeholders about a limited access into the assessment and decision-making processes. SIA is not able to predict all impacts, and residual impacts and the eventual harm they can bring into communities are not considered carefully enough. It can become costly for the proponents if important issues are inadequately addressed in the SIA process. It can lead to lost business opportunities because of boycottes and blocades run by NGOs, as a consequence of overlooked issues that needed consideration in the SIA process. (Vanclay 2011, 5).

[8] We have seen from the discussion of sustainability assessments in EST-Frame deliverable 1.2 similar problems in including the social pillar of sustainability.

In many ways SIA has remained the poorer cousin of EIA (Lockie 2001, 277). SIA is not institutionalized on the same firm ground into world declarations and national legislations as EIA. However, a resent development very much aligned with the aims of SIA, is the concept of FPIC (meaning: Free, Prior Informed Consent, by the UN declaration on the Rights of Indigenous Peoples from 2007) which consists of general principles and steps on social responsibility that can be applied generally to all projects and plans (Vanclay, 2011, 6-7). Another development on an institutional level is the ratification of the International Standard ISO 26000 Guidance on Social Responsibility from 2010. The standard provides legitimacy to the SIA management process (Vanclay 20011: 99) but SIA as a specific and important type of impact assessment has not been mentioned explicitly in these two documents about social responsibility processes.

There has been a sharp divide between those SIA studies that were oriented towards the technical collection of primarily quantitative data, that could determine the nature of impacts in an “objective” way, and those that focused on a process-oriented approach, where the interests and ideas of the impacted communities could be represented in decision-making by facilitating community participation (Lockie 2001, 279). There has also been a lot of effort put into overcoming this dichotomy by trying to apply technical measurement tools within a more participatory framework (Ibid). The technocratic approach to IA is often the first choice and favored by those professionals with a background in the natural sciences (Ibid). Even if this approach is much contested from the more participatory strand in SIA, there are lots of evidence that this approach are continuing to be carried out in practice, partly because of devoting insufficient resources for SIA studies or of assigning the SIA process to underqualified people, often junior-staff within engineering consultancy firms that have been contracted to undertake an EIA (Lockie 2001: 285, note 1).

The EU Impact Assessment system

Impact assessment is not new to the European Union. Several impact assessment traditions are reinforced by directives such as The Environmental Impact Assessment Directive dating 1985 and the European Strategic Environmental Assessment (SEA) Directive from 2001. These where followed by a number of other topic-related or single sector assessments. However, single sector assessments did not cover impacts on policies (Bäcklund 2009, 1077). In 2011 the Impact Assessment Board found that the amount of EU IAs made have grown dramatically, which in itself shows that EU IA has become a consolidated way to approach complex policy areas within the EU (IAB 2011, 4).

The history of introducing Impact Assessment into EU decision-making begins with the wish to improve, simplify and make the regulatory environment in the EU more transparent. This need was already clearly expressed by the Edinburgh European Council twenty years ago (1992). The aim for revising regulation in the EU was followed by a number of reports, declarations and recommendations on how to undertake this endeavour. Still, not much happened during the following almost ten years, the main reason being a notable lack of political support (Meuwese 2008, 22-23).

In 2000 the Lisbon Council decided to give the Commission mandate to propose a strategy for a more coordinated action on a regulatory reform. This mandate remained part of the Lisbon Strategy aimed at making EU the most competitive economy in the world by 2010[9]. This mandate resulted in the Communication on Better Lawmaking in 2002, which laid ground for the current strategy on Better Regulation[10]. A significant element of The Better Regulation strategy was to require Impact Assessments on Commission policy proposals. Three key objectives were endorsed in Better Regulation. Firstly it was to promote simplification and reduction of administrative burdens at the EU level. The second line of action was to work more closely together with the Member States to ensure that the better regulation principles was applied consistently throughout the EU by all regulators. Finally the third objective was to reinforce the constructive dialogue between stakeholders and all regulators at the EU and national levels (Better Regulation Website)[11]. These multiple objectives of the Better Regulation agenda are embedded in the EU IA system.

Another significant source of origin of the Commission IA was the increasing concern about sustainable development expressed by the Göteborg European Council in 2001, here the environmental dimension was added to the Lisbon strategy for employment, economic reform and social cohesion (Delanghe and Muldur 2007: 170). The Council conclusions stated that: *"The Union's Sustainable Development Strategy is based on the principle that the economic, social and environmental effects of all policies should be examined in a coordinated way and taken into account in decision-making." (Presidency Conclusions Göteborg European Council 2001in Delanghe and Muldur 2007, 170)*

The new comprehensive Commission Impact Assessment system was ratified with the Seville Council in 2002. Intrinsic to the new IA system was the possible discrepancy between the competitiveness and the sustainability goals expressed by the Commission in the Lisbon Strategy (Meuwese 2008, 26).

The result of the IA should enhance the quality of regulation by producing evidence based knowledge as the groundwork for decision-making, however IA also serves as a tool for better communication and coordination within the Commission services and to ensure better communication on the institutional level between the Commission, the Parliament and the Council. Furthermore the Commission aims at demonstrating openness to input from external stakeholders. This is followed up by the pursuit of providing transparency by explaining through the IA, why

[9] http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/ec/00100-r1.en0.htm [Accessed 01.05.2013]

[10] Easily presented in http://ec.europa.eu/governance/better_regulation/documents/brochure/br_brochure_en.pdf [Accessed 01.05.2013]

[11] The Better Regulation action lines draws on the Mandelkern Report, which was the result of a high level group set down by the ministers of public affairs under the French presidency in November 2000. The report focused on the EU Community institutions, specifically on the Commission. The OECD Better Regulation criteria had a crucial effect on the analysis in the report (Meuwese 2008, 34). The OECD criteria recommend systematic Impact Assessments on regulations: *"assess impacts and review regulations systematically to ensure that they meet their intended objectives efficiently and effectively in a changing and complex economic and social environment"* (OECD 2005, 4).

certain actions are necessary and thoroughly compared with alternative actions (Bäcklund 2009:1078).

Impact Assessments are carried out on the following type of legislative initiatives: '*(i) all legislative initiatives – those included in the Commission Legislative and Work Programme (CLWP) as well as those which are not – having clearly identifiable economic, social and environmental impacts and (ii) all non-legislative initiatives (such as White Papers, Action Plans, expenditure programmes, and negotiating guidelines for international agreements) which define future policies.'*[12]

The EU IA template is constructed by the Commission in order to provide an open tool which can contain any type of assessment that makes sense to put into use according to the policy problem to be analysed. In the guidelines outlined by the Commission it is encouraged to make use of for instance risk assessment and sensitivity analysis when developing a baseline scenario, which is one of the first key analytical steps recommended when doing an IA. But it is really up to the Directorate General in charge of the IA to decide which types of assessments are appropriate for doing a specific IA.

The first step in an IA is to do a "Roadmap". The Roadmap is a mini-IA where rough information on the key analytical steps in the IA is outlined. Next step is to decide whether a full IA is needed. If it is decided to carry out a full IA the same key steps are followed, but in a thorough manner. The key analytical steps are:

1) **Problem identification:** The first step demands describing the nature and extent of the problem, finding out who are the key players and affected populations, finding out about the underlying causes and drivers are, identifying if it is necessary for the EU to act by using the necessity and value added test and developing a clear baseline scenario that illustrates how the current situation would develop with no public intervention (European Commission 2009a, 24). If necessary include a sensitivity analysis and a risk assessment (European Commission 2009a, 5)

2) **Define the objectives:** The second step involves defining the key objectives on how to tackle the problem, and to make sure that they are in line with other EU policies and strategies, such as the Lisbon and Sustainable Development Strategies or the EU Chart of Fundamental Rights. Furthermore the objectives have to be SMART (Specific, Measurable, Achievable, Realistic, Time-dependent) (European Commission 2009a, 26).

3) Policy options to meet the objectives: This involves developing policy scenarios, including the "no policy change" scenario" and alternative approaches to legislative actions. A wide list of alternative policy options should be made, and these options should be tested against the proportionality principle. The set of options should include "no EU action (e.g. discontinuing existing EU action), if legislation already exist, improved implementation, self- and co-regulation, and international standards where these exist. The next step is to assess these options against other EU policy

[12] (see http://ec.europa.eu/governance/impact/commission_guidelines/docs/revised_ia_guidelines_memo_en.pdf, p. 1 [Accessed 01.05.2013])

objectives and effectiveness and efficiency criteria. The remaining policy option short- list should then be analysed in depth. (European Commission 2009a, 29)

4) **Impact Assessment:** This step involves identifying the economic, social and environmental impacts of the short-listed policy-options, followed by a qualitative assessment of the most important impacts. The last step is to finish with an in-depth qualitative and quantitative analysis of the most significant impacts (European Commission 2009a, 32) However, the operational aspects of the IA depends on the methods chosen by the Commission desk officer in charge of doing the IA (Raggamby 2008, 32). It is encouraged to provide as much quantification as possible (Guide European Commission 2009a, 32). It is suggested to use formal models and analytical tools when apt, such as macro-econometric models, computable general equilibrium models (CGE-models), sectoral models, simple causal models (problem trees) and impact matrices, environmental impact assessment models, microsimulation models, cost- benefit analysis, cost-effectiveness analysis, multi-criteria analysis, life-cycle analysis and risk analysis (European Commission 2009c, 45, 68, European Commission 2009a, 45-47)

5) **Compare the options:** The aim here is to look at how the different policy options in the short-list achieve the objectives. The options should ideally reach the objectives with a minimum of undesirable side effects such as compliance costs or administrative burdens. When comparing the options, all positive and negative impacts should be considered regardless of method is used in qualitative, quantitative or monetary terms. It is suggested to use cost-benefit analysis and cost-effectiveness analysis to assess budgetary cost-effectiveness and to use multi-criteria analysis when appropriate. The options should be ranked on how they score on the following three criteria: effectiveness (the extent to which options reach the objectives of the proposal), efficiency (how cost-efficient the option is) and coherence (are the options in line with the overall objectives in EU policy, do the options limit trade-offs across the economic, social or environmental areas). (European Commission 2009a, 45,-48)

6) **Outline policy monitoring and evaluation:** There should be made a *"broad outline of possible monitoring and evaluation arrangements"*. Evaluation should be timed in a way that it can be used for future retrospective impact assessments (European Commission 2009a, 49).

The Guidelines point out that IA is an iterative process, which means that many of the analytical steps carried out need to be revisited as a result of potential findings at a later stage of the process. They also suggest to use the consultative interface provided by the website "Your Voice in Europe"[13] and to think "out of the box" when carrying out an IA (European Commission 2009a).

Challenges in impact assessment

Interviews show that the DG employees often prefer in-house knowledge and hesitate to make use of external knowledge, because they find it time-consuming to communicate with scientists, and they lose control of what the external experts come up with. In-house knowledge, however, often cannot provide sufficient expert knowledge, and therefore the IA carried out is at risk at becoming overly simplifying and complexity reducing in its description of specific scientific points (Bäcklund 2009, 1081).

[13] http://ec.europa.eu/yourvoice/ [Accessed 01.05.2013]

The need for simplicity takes part of the Commissions quest for transparency. The more complex and advanced results that are displayed in the IA, the greater the risk of stakeholders becoming suspicious and critical towards the quality of the result, due to lack of ability to understand the advanced modelling tools behind the results (Bäcklund 2009, 1081). Indeed, some of the criticisms that the Impact Assessment Board (IAB) and the Auditors raises on the use of evidence based knowledge in the IA are quite opposed to how external studies consider this use. The IAB and Auditors claim that there are not enough use of in-house and member state expert knowledge in the IAs (IAB 2011, 28, EU Court of Auditors 2010, 40 § 70), whereas Bäcklund and Raggamby point to a rather weak knowledge base used in the EU IA, and a problematic preference in the DGs to make use of in-house knowledge, because of the difficulties experienced with the use of external scientific knowledge which might be expressed in a too complex manner (Raggamby 2008, 5). Complexity-seeking statements clash with the Commission's aim of expressing complex knowledge in simple and transparent terms in order to fulfil the transparency goal set for the IA tool (Bäcklund 2009, 1081).

Both evaluations solely focus on how EU IA is perceived within the EU institutions. There are no evaluations made by the Auditors or the IAB on how the EU IA is perceived among external stakeholders partaking in the EU IA processes, such as the experts, the scientists from industry and academia, business people, NGOs and the citizenry who are invited to partake in conferences, public consultations, expert groups, etc. Bearing in mind that one of the multiple objectives in introducing the EU IA was to provide the European policy-making process with transparency and democratic legitimacy by institutionalising a more participatory approach to public policy, it would be useful to know how the EU IA process is perceived by external participants as well.

The use of participatory processes in the EU IA as a policy instrument calls for a further investigation on whether or not these processes provide the policy process with more democratic legitimacy and transparency. A study shows that the type of participatory processes used in the EU can be used to mask power relations and thus does exactly the opposite of what they are claimed to do (Halpern 2008, 110). Halpern further suggests that this masking process is not always un-wanted in the political arena (Halpern 2008, 110, 114).

Findings in the study

Six impact assessments were reviewed in this study. If the coordinating function of the guidelines and the Impact Assessment Board are successful they should be quite similar and indeed we found that they are similar on several aspects. Impact assessments come out as more systematically reflective on the core contextual characteristics compared with other domains, assumedly because they are closer to policy. They also have a more stable set of purposes; all explore policy objectives, assess existing policies and introduce visions and scenarios. In addition, all of the six have also other functions, such as bridge building or introducing new action plans. With regard to the core process and substantial characteristics we find that all include experts and stakeholders. With one exception they also include lay people as well. However, even though participatory processes scores pretty high on the IA´s assessed here, it is due to the fact that they were explicitly carried out and used as a compulsory part of performing an IA. The scores do not tell us much about the quality of the processes or whether or not the participation added democratic legitimacy and transparency to the policy process. That said, the IA on "indirect-land use change" (assessment nr. 3, see annex 3) being an exception, with the use of repeated and diverse types of participatory processes put into use and referred to in the IA report.

The scientific evidence-base in the two IAs on research programs in Europe: The Horizon 2020 and the ERA, was to a great extent based on scientific publications produced within governmental systems. Only a minor part of the literature used, was derived from peer-reviewed publications. The four remaining IA´s appeared more balanced in this respect. It is widely recognised that, regulatory science produced within the policy-making system *"are fundamentally different from research driven by scientists collective curiosity"* (Jasanoff 2012, 171). One of the differences being, that quality control in scientific publications are qualified by peer review, whereas it is less clear what quality-control mechanisms regulatory scientific publications are submitted to.

With one exception, there was good transparency and discussion of the normative assumptions of the IAs. The Impact Assessment accompanying the Commission Proposal on amending the Directives on: Indirect Land-use change related to Biofuels and Bioliquids from 1998 and 2009 stands out as a best practice example with high scores on all dimensions.

Impact assessments are only relevant for EST once the technology is sufficiently mature to be subject for a public plan. For instance, as long as there is no comprehensive political or regulatory programme or plan for synthetic biology no impact assessments will be conducted. The same holds for nanotechnology in food and agriculture, although an impact assessment has been made on the part of nanotechnology (in general) in Horizon 2020 (European Commission 2011). Cloud computing and biofuels are technologies that already are broadly implemented and where public plans exist. The impact assessment mentioned above, on indirect land-use change, is relevant in biofuels policy. Although there are no impact assessments on cloud computing plans as such there are impact assessments on related topics, such as the Impact Assessment accompanying the Commission Proposal on amending the Regulation and the Directive on: General Data Protection from 1995.

Summary impact assessment

- IA/EIA was originally intended as an integrative assessment instrument. Over time, it has proven to be inadequate in practice; there has been dissatisfaction with how social factors and consequences have been dimmed in the assessment, in favour of a strong focus on the environmental impacts and the economic impacts and consequences. In response to this imbalance, in the traditional EIA process, many different IA traditions were invoked, and chose to separate themselves from EIA. The oldest and quite obvious is SIA and HIA (Health Impact Assessment) of a newer date is SEA (Strategic Environmental Assessment). EU Impact assessments intend to bridge these gaps again by an integrated approach.

3.3 Economic assessment

In Western liberal societies economic assessment is generally of high importance. Even if economic impact assessment is an important aspect of impact assessment in general we have in the project chosen to also study economic assessment as a separate domain in order to gain better insight in the methodological state-of-the-art and developments.

Economic evaluation of technologies is common in some technological fields (e.g. health technologies) but not in others (e.g. electronics). Economic evaluation – and most of the methodological discussions in literature – often refers to concrete research programmes or policy measures which may be linked to a certain technology, but not necessarily. Even if those government programmes are linked to certain technologies the economic evaluation of such programmes has a certain type of evaluation goals in mind: The main question is whether policy measures related to technologies have a positive economic impact in relation to the case of no policy measures[14]. Hence, the question is not whether the technological diffusion overall is associated with positive impacts. Moreover, only few policy analyses take into account technology developments in detail as a full analysis of the economic impacts of changes in technology and technology policy. This would require taking into account technological and social factors simultaneously which is often beyond the scope of the economic assessments.

For the analysis in advisory domains we focus on the economic effects of technologies. However, we take into account those policy assessments which have a clear link to technological change. In addition, we benefit from methodological discussions about economic evaluation. Please note that in this subsection the expression “economic impact” is used frequently which relates to changes in the economy due to technological developments. Some often-used examples are changes in net costs, changes in production, value added, employment, etc.

Several kinds of methods can be identified in existing literature. They are usually divided in two main groups, but inside these two groups they can be distinguished from each other by further criteria.

- **Top-down methods** based on econometric or other models (e.g. general equilibrium models, input-output, etc.) assess nation-wide or sector-wide impacts. The methods differ from each other and in theoretical paradigms, in the reflection of various impact mechanisms (prices, demand, etc.) and their reliance on (past) data.
- **Bottom-up methods based on case studies** of individual technologies/technology programmes. They differ from others in which dimensions of economic impact they include (e.g. costs, revenues, value added, social/health/environmental), to which extent economic reactions are considered.

[14] As such it can be seen as a limited impact assessment.

Please note that in some assessments a combination of different methods is popular, e.g. cases studies are integrated in a top-down input-output model to assess some economic-wide impacts. In addition, the studies with a prospective view are usually combined with scenario analysis.

A further disaggregation of these two main groups reveals the diversity of the methods. We distinguished 6-7 methodological approaches and selected one assessment from each approach. We characterise the methodological approaches shortly in the following:

Bottom-up methods:

- **Cost-benefit analysis (CBA):** Cost-benefit analysis is a systematic process for calculating and comparing benefits and costs of a technology (or project/investment/government policy). In many applications cost-benefit analysis, either explicitly or implicitly, has amounted to the assumption either that extra production in a market is measured by an outward shift of a vertical supply curve against a horizontal demand curve or that the value of inputs saved is measured by the downward shift of a horizontal supply curve against a vertical demand curve (Alston et al., 1995). Cost-benefit analysis is most widely used in areas where the benefit is not only in economic terms but in better health or less environmental burden.[15]
- **Techno-economic assessments (TEA):** TEAs usually use technical and engineering data for case studies to build an economic simulation model of production cost with and without the use of a specific innovation. Sometimes different process routes for a new product are compared. The TEAs may also include additional analysis for environmental effects etc. They are closely related to cost-benefit analysis but do not explicitly oppose these categories with each other and focus more on economic feasibility of new innovations and competing emerging products or production processes.
- **Economic value assessment:** Such approaches consist of the assessment of indicators (investment, employment, value added, needed skills, costs) for products or value chains by the use of the emerging technology versus existing production methods. It may enable to get a better idea of the economic value of a technology and may comprise various elements such as producer surplus (sales less costs) plus consumer surplus (consumer value less price) plus other externalities (net benefits to third parties). The main difference to the previous mentioned approaches lies in the kind of impacts which are assessed.

Top-down methods:

15 A similar method to cost-benefit analysis are the economic surplus methods. Based on some of the tools of welfare economics they look at how the interaction of supply and demand determines the value of market transactions. Applied to technology assessment, economic surplus methods show how research/technologies affects supply, demand, and their resulting market outcomes. By augmenting product qualities that increase demand, or by lowering costs of production that increase supply, research/technologies can expand markets and change the economic rewards for market participants. As economic surplus analysis is very closely related to cost-benefit analysis and only differs in the analysis of reacting on the market, it is unlikely that assessments differ considerably.

- **Indicator analysis:** The focus of the analysis is to assess (and often monitor over time) the development, diffusion, and economic impacts of a technology by using data from (usually) three indicator sets: input, output, and impact (or outcome) indicators. Input indicators describe capabilities and capacities in researching and developing a technology. Output indicators evaluate the extent of adoption and use of a technology, services and processes within each application field. Impact indicators assess the economic (such as company and market growth and job creation), social and environmental impacts of the technology.
- **Econometric analysis/CGE-models/Statistical analysis:** Econometric models such as multivariate regression estimate statistical relationships that include economic behaviour and technologies. The ability of econometric models or CGE to account for a variety of changes simultaneously makes them very useful for research assessment. Not only can they estimate a baseline or counterfactual scenario to model how variables would look without research/technology, but deviations from this estimate represent one way to assess the benefits of the technology. Econometric methods are applied on different aggregation levels: On a sectoral or macroeconomic level it enables to calculate the total impact of a technology on economic impact parameters such as growth, value-added, employment productivity and include indirect impacts (e.g. reduction of employment in non-innovating firms). On a micro-level causal effects between technology and economic changes can be analysed in-depth. Econometric methods have been mostly applied in the case for ICT, as the necessary data coverage is mostly fulfilled for this technology.
- **Input-output analysis:** The input-output model allows a disaggregated analysis of economic impact mechanisms of technologies and captures some of the indirect economic effects in other sectors, in particular jobs in supplier industries of the technology producers and users. E.g. in the case of both nanotechnology and the use of I/O-models in biotechnology research, these models can be used for forecasting and predicting potential future performance and economic output from a level of input.
- **Other models:** Beside I/O-models and econometrics other economic models can be used as well for such analysis. Probably most important are system dynamics and (in the future?) agent-based models. These models are in particular capable to include feedback effects between actors and to simulate dynamic developments.

Analysis of the selected assessments

The assessments analysed in this domain are presented in Annex 3. These are selected based on high policy relevance (in Germany or the EU) and relevance to the EST field, as well as representing a diversity of methods. It should be noted that perhaps due to the high policy relevance no ecological economics assessments or other 'alternative' economic assessments have been included.

The main role of the economic impact assessments is the raising of knowledge concerning scientific and technological aspects, more precisely, the economic consequences of technology. All of the reviewed studies extend the existing overview of the consequences of the respective technology. Most of the studies assess different technological options, but this seems to be less dependent on the method than on the scope of the individual study. Some of the studies have an impact on agenda setting. This is mainly the case where a technology is controversially debated and the assessment provides new insights.

Usually, economic assessments are highly complex because of the various impact mechanisms of emerging technologies (and resulting needs of data) as well as the different interdependencies and possible feedback effects in the economic system. Moreover, the underlying effects and kinds of economic impact differ highly between technologies. In consequence, even limited to the assessment of technological/scientific aspects, the economic assessment is highly challenging.

Consequently, policy aspects are covered only in some assessments, in particular in top-down models. The main challenge is that for a combination of policy analysis with technological change, both would have to be regarded simultaneously. Societal aspects are only covered in cases where the economic analysis is embedded in a study with wider aspects.

The mentioned challenges also lead to further limitations in the methodology: impartiality and transparency is highly difficult in complex modelling (but some studies are better than others). Internalisation of externalities such as ethical values is not included, and the assessments do not position themselves on in a normative context. Lay people are not included in any phase of the assessment; the framing, the valuation of included goods or in discussions of outcomes. Narratives/worldviews/visions are not thematised. PPPs, policy integration or further analysis of consumer acceptance is not included within the scope of these methods and are deemed to be of restricted value for these assessments. The main challenges and key questions for such assessments are which kind of economic impact channels should be regarded, which kind of indicators are of interest, and the interaction with the economic system. These are also the key issues in which the methods of economic assessment mainly differ.

Overall, there is no best kind of method of economic assessment. Top-down and bottom-up methods have specific advantages and disadvantages and the (often practiced) combination of both methods may provide the most insight. If we compare the various top-down methods (e.g. econometric vs. input-output) and bottom-up methods (e.g. cost-benefit with techno-economic assessment), those methods are preferable which take into account the complexity and the diversity of possible impacts of emerging technologies. This would argue for a comprehensive (bottom-up) cost-benefit analysis (like assessment 1) and complex top-down methods such as system dynamics (like assessment 7). But there is often a lack of reliable data available and/or it is too time-consuming to integrate it in complex models. That is why more simple methods (e.g. input-output-analysis) may be still adequate, depending on the specific aim and contexts of the study.

Level of systematic methodological reflection

Economic impact channels: Usually, a technology affects the economy by myriad impact mechanisms (e.g. changes in prices, production, efficiency, quality, demand via technological change) often across the economic system (different industry sectors, households, public sectors etc.). While many studies discuss and quantify different impact mechanism there is no standardised set of "widely recognized" effects to which the study refers. The studies differ in naming and considering the various effects.

Pros and cons of different methods: Systematic methodological reflections, which discuss the pros and cons or the suitability of methods in a specific context, do not exist (to our knowledge). Some articles provide short comparisons of the pros and cons of the different top-down models. As mentioned above, most methodological discussions in the literature are related to evaluating the economic impact of policy measures, and the methods used have a high overlap to those which evaluate the economic impacts of technologies. In consequence, some important issues are reflected and discussed in this context.

These shortages of systematic methodological reflections can be partly explained by the content of the studies and that the effects of technologies are highly context-specific. Nevertheless, the resulting methodological differences lead to varying results, and the reasons for these differences are hardly traceable and comprehensible for the public or even other experts. This constitutes a problem when such assessments influence policy, such as the economic assessment in the cloud computing study. Some improvements in setting or at least discussing standards are imaginable. One interesting initiative may be the OECD NESTI EEGPT (emerging, enabling and general-purpose technologies) Task Force which aims to build up a conceptual framework for statistical monitoring development, diffusion and impacts of technologies. However, the results have not been published yet.

Most common application contexts: The application context of the economic impact assessments differs widely. The assessments are sometimes conducted as a stand-alone study. But as the economic impact assessment is especially popular in (often highly regulated) research fields such as health, environment or energy they are combined with the analyses of other impacts, either directly as outcome parameters in the same model or in distinct analyses. Such approaches enable to get a better integrated governance perspective.

Strengths and weaknesses: As stated above, the economic evaluation can be in principle integrated in broader assessments either by directly combining it with other impacts (in particular social and environmental ones) in one assessment model or it can be at least contrasted to social, societal, and environmental assessments.

One weakness is that it is not an easy task to combine policy analysis with technological change, as both would have to be regarded simultaneously. Often the policy measures or its effect are transferred by rather rough assumptions in economic models. What is especially missing is a better integration of different policy mixes and impacts of policies.

Trends in the advisory domain: Some trends such as the usage of more complex models or efforts to integrate the potential impacts of policy measures on technological change can be observed for around the last two decades. Especially the trends to use models of higher complexity either to integrate additional outcome indicators, additional economic relationships or social factors and relationships may continue. One future trend might be an increased focus on agent-based models, as the traditional economic models fail to take the interaction of actors and related economic consequences into account. In our research we could not find an existing example for an economic assessment of technologies by agent-based modelling, but especially the integration/combination of agent-based models in or with other models may provide interesting possibilities for such assessments in the future.

Summary economic assessment

- The complexity of economic assessment of EST policies creates a significant methodological challenge in this domain
- There is often a lack of reliable data, or it is too time and resource consuming to collect these in a systematic way
- Still, methodological challenges are to a low extent explicated in the analysed assessments
- The resulting methodological differences lead to varying results, and the reasons for these differences are hardly traceable and comprehensible for the public or even other experts.

3.4 Ethical assessment

Emerging science and technologies raise difficult ethical questions, for instance about the meaning of life and death, autonomy, informed consent, justice and inherent value. Public ethical committees are established to advice on these matters, either by clarifying value conflicts, applying general ethical principles to new cases or coming up with substantive ethical advice on morally acceptable or unacceptable options, such as technology options.

The existence of a plethora of ethical committees, performing various kinds of ethical evaluations and giving advice on ethical issues, has become an ever more present feature of modern Western societies. These committees have different functions, for instance handling internal conflicts or dilemmas in organisations, applying and enforcing ethical codes or guidelines (e.g. medical research ethics committees) or advising authorities on sensitive issues that evoke public concerns (e.g. genetic engineering of food, stemcell research, etc.). Often they are asked to give advice when there is moral conflict between affected parties or between moral principles. The committees typically consist of experts from the professional groups that are relevant to the particular tasks, some stakeholders, and ethics experts. In some countries (like Norway) one or two lay representatives are often included.

In Europe there is a long tradition for ethics committees reviewing medical research. Since the 1990's national and international bioethics committees have also been common. The European Commission decided in 1991 to set up a Group of Advisers on the Ethical Implications of Biotechnology (GAEIB). The same year similar institutions were established in European countries, such as the Norwegian Biotechnology Advisory Board and the British Nuffield Council of Bioethics. The background for these new institutional arrangements was the advances in biotechnology, especially with regard to human applications. The human genome project was launched in 1990, and there was a general awareness of the sensitivity of such research, as well as of future new research trajectories within biotechnology. These predictions proved right, and issues like stem cell research and reproductive medicine have continued to trigger ethical concern. In addition, worries about non-human applications of biotechnology have also become pertinent, especially issues concerning genetic modification of plants and animals, and more recently, synthetic biology. Moreover, risk and uncertainties related to new technologies are increasingly seen as ethical issues. The EC GAEIB was in 1997 transformed into the European Group on Ethics in Science and New Technologies (EGE). While there is still a focus on biotechnology, the EGE has recently issued an opinion on a non-biotechnological topic such as emerging ICTs.

Biomedical ethics has a long tradition of theoretical and methodological work. In particular principle-based ethics and casuistry have been important models for accounting for practical deliberation and problem-solving of cases. In social policy ethics, and also in business ethics, the so-called stakeholder approach has been an important development. The original insight was that cooperation of stakeholders is important to the efficiency of a policy or a corporation.[16] However, as a stakeholder group is defined by having distinct interests in a matter, this is also a useful way of determining who the morally affected parties are. There are then ways of negotiating or balancing between the moral claims of these affected parties, for instance by going into actual negotiations or deliberations with the stakeholders. As the controversies of EST issues, for instance related to biotechnologies, are partly due to the conflicting interests of the different parties the stakeholder approach is also relevant here.

The ethics of emerging technologies has still not converged on a common methodology. Even if these technologies may be held to pose some radically new questions (for instance with respect to creating life), the ethics of emerging science and technologies will apply methodological resources from ethical fields like traditional bioethics, medical ethics, research ethics and business ethics.

In the area of biotechnology ethics the EU FP5 research project called Ethical Bio-TA Tools explicitly worked on refining tools for ethical assessment of biotechnology. One motivation for this work was the need for enhancing the quality of ethical assessments in order to achieve better transparency, accountability and justification. The guiding thought was that systematic ethical assessment would make it easier to identify shortcomings with regard to what facts and values are included in the assessments, as well as flaws and inadequacies in the argumentation on the facts and values: 'All ethical (bio)technology assessment tools developed in this project aim to improve the transparency of communicative processes about ethical values' (Beekman et al. 2006, 7).

Some of the different methods initially considered in the Ethical Bio-TA Tools project were principlism, the ethical matrix method, ethical delphi method, casuistry, stakeholder analysis, committee process, uncertainty management and ethical guidelines.[17] The list shows that there is a manifold of approaches one might take to ethical assessments, each with its own areas of application, as well as strengths and weaknesses. One tool might be better for evaluating more generic processes while other tools are more fitting for assessments of products and concrete applications. But for all tools and applications it is important that the tool can deal with all the relevant kinds of moral arguments.

Not all the methods listed above are equally common in the toolbox of EST ethics committees. Traditionally, the following four methods have been most common (see Forsberg 2003):

- The basic method of an ethics committee is committee judgement as a form of *discourse ethics* or pragmatic ethics stressing the testing of arguments in a discursive community of qualified individuals of different backgrounds and perspectives.
- Ethics committees also use an often implicit method of *casuistry*, where former judgements, the correctness of which the committee feels certain, are used as a guide for solving current

[16] The concept of 'stakeholder' appeared in 1963 at the Stanford Research Institute where it was defined as 'those groups without whose support the organization would cease to exist' (cf. Freeman 1984).
[17] For a full list see Beekman et al. 2006, 7.

cases. The discussions will then often revolve around what cases should be deemed paradigmatic for the current case.

- Ethics committees will often base their work on a defined normative basis, often a set of guidelines. For medical research ethics the Helsinki declaration of the World Medical Association, serves as normative basis. In EST ethics, there is no such similar established common normative background. There are, however, several sets of guidelines that committees use. The EGE refers to a whole set of normative documents at the start of their opinions. These include EC directives, the charter of human rights, etc. The EC *Code of conduct for responsible nanosciences and nanotechnologies research* is a normative basis for European ethical assessments in this field, and there are attempts at expanding this Code of conduct to all emerging science and technologies, notably in the form of the new European initiative on Responsible Research and Innovation (RRI).
- Commissioning ethics assessments from single or a small group of professionals, like philosophy or theology professors. In such cases the assessments will often involve applying different normative theories on the case at hand, most importantly utilitarianism, deontology, some perspectives on justice, virtue theory, etc. Such commissioned assessments may be used as input for discussion in an expert group.

Arguably, ethics committees have been thought to represent common morality and reasoned judgement (see for instance Beauchamp and Childress 2008). However, with the advent of controversial new technologies there has been an increasing awareness of the problem with assuming a common morality. When technology provides us with possibilities hitherto unthinkable, like creating new life, we simply do not have a common morality platform that can be applied. Or at least; the topics are likely to be so controversial in society that a small committee consisting of academic experts (often middle-aged, white men with higher than average education) cannot be expected to be accepted as moral authorities in society at large. This, and the general trends towards broadened participation in technology governance, has lead to ethics committees trying out new methods. Among the most important are:

- Roundtables: For their last two assessments (on ICTs and synthetic biology) EGE have organised roundtables as important input to the Group discussions.
- Value workshops: The Norwegian Committee for Research Ethics in Science and Technologies (NENT) organised in 1999 and 2000 two broad stakeholder workshops to discuss future fishery technologies.
- Hearings: The UK government's public debate and hearing initiative on GM crops, GM Nation?, from 2000 to 2004 consisted of several public debates together with opinion polls and online discussions (Gaskell 2004)

Challenges in the advisory domain

There are several controversies surrounding the methodologies of ethics committees, and objections come from different perspectives. First, there is the objection from outside ethics, namely from the Science and Technology Studies (STS) environment. In the report Taking European

Knowledge Societies Seriously (European Commission 2007), Ulrike Felt, Brian Wynne et al. dare the following bold claim:

> *Ethics has been used at times by EU institutions to neutralise political issues, to introduce norms outside the traditional process of law-making, to evoke society without involving it, to pay lip service to democratic concerns while only expert processes were taking place, to control citizens' behaviour and even to allow direct intervention into their bodies, and to exempt the market from ethical criticism and debate. In resorting to ethics as a supposedly participatory discourse, EU institutions have de facto engaged in unaccountable forms of biopolitics. Ethics is represented as if it is naturally a matter of expert judgment only, though this very framing has markedly shaped, and continues to shape, which ethics and whose values count in European politics. (p. 47)*

This is a call for a more participatory deliberation on moral values and their implications for technologies and policies, and it is a challenge of the legitimacy of the 'ethics experts'. Implicitly it holds that being educated in ethics does not make a person better qualified than others in making moral judgements, which, ultimately are related to personal convictions, upbringing, worldview, religion, etc. In a value pluralist Europe such pluralism cannot be adequately represented in a committee like the European Group on Ethics consisting of (then) 12 members (now 15). Felt, Wynne et al.'s criticism does not reflect the range of methodologies tried out, as well as applied more regularly, in ethics assessments. Still, from the analyses in this project we see that there is indeed room for broader participation in ethical assessments in general.

The opposite challenge has come from moral philosophers themselves against the more pragmatic approaches to ethics most often represented in ethics committees, and especially against involving the public in ethical assessments. From the perspective of moral epistemology there is a question whether moral knowledge should be conceived in a bottom-up or top-down fashion. Bottom-up ethicists believe that ethics is anchored in the moral intuitions of a population (e.g. Ross 1930). Top-down ethicists believe that ethical judgements must be anchored in general ethical principles that are justified a priori (typically a Kantian perspective) or by some sort of fundamental theory of value. There are also several versions in between, advocating an equilibrium between top-down and bottom-up justification (typically Rawls 1999). For top-down ethicists involving lay people or stakeholders in discussions of ethics may help establishing the facts of the matter, or be an important form of moral communication, but will not add to the validity of the ethical judgements made in the assessments.

The challenge from the side of the philosophers invites a serious response. In the Ethical Bio TA Tools project the term *soundness* was used to indicate such a concern for methodological quality of ethical tools (or 'frameworks', as they were called there). Kaiser et al. (2007, 68) gave the following definition: "an ethical framework is ethically sound, if and only if, its application produces understanding of ethically relevant considerations in such a way that within a given body of knowledge and on condition of its competent use no further considerations would decisively alter the normative conclusions drawn from the framework by the users". They also operationalised this definition to include:

1. Inclusion of values at stake;
2. Transparency;
3. Multiplicity of viewpoints;
4. Exposition of case relevant ethically relevant aspects;
5. Inclusion of ethically relevant arguments. (Kaiser et al. 2007, 68)

These points were again described in greater detail and used to assess different ethical tools.

The Bio TA Tools project also conducted a survey to ethical advisory bodies. The authors summarise the results in the following points:

1) 'Very few of the intended users reported having an explicit policy on the use of ethical tools. Indeed, for many correspondents the question arose for the first time through the survey inquiry;
2) Closer enquiry revealed that for some correspondents ethical guidelines occupied an important role in their advice on ethics; and that consequently they would place such guidelines among the potential tools for their work;
3) Few correspondents reported any experience of public consultation and/or participatory processes with stakeholders; and
4) Most correspondents expressed a positive interest in the development of such tools for practical ethical assessments, and a willingness to look further into the matter.' (Beekman et al. 2006, 19-20)

The currently important European notion of responsible research and innovation (RRI, see EC Expert group, 2013) holds that there should be equal focus on benefits as on risks/costs. However, in ethics the focus still seems to be on addressing risks (from a scientific point of view) and not benefits (including benefits from an economic point of view). As such, ethics seems to have an untapped potential for being a productive force bringing about innovations for the best of society, within for instance an 'ethics by design' approach.

Reviewed assessments

Ethical assessments are started at the request of a (supra)-governmental agency, at the request or initiative of one or several members of the committee or in response to public concerns. In this review, the EGE, the evaluations of the Norwegian Biotechnology Law, The US President's Commission on Bioethics, and the UNESCO are instances where a (supra)-governmental agency has requested opinions, while the Nuffield Council and the French and Italian bioethics committees have initiated such assessments themselves. None of the reports listed are the result of direct public concerns.

The French and Italian nanoethics reports share with EGE the methodology of roundtable discussions with selected invited experts. Inclusion of experts is omnipresent in all ethical assessments. In the cases of the US President's Commission on Bioethics and the Nuffield Council there is also included stakeholders and to some extent laypeople in different kinds of public meetings. The US President's Commission on Bioethics includes one stakeholder from a patients' organisation and the Norwegian Board of Biotechnology include several stakeholders, while the other committees did not include stakeholders. The only report to combine a quantitative survey of public perception of biotechnologies with an expert assessment was the Norwegian Directorate of Health. The UNESCO methods seem to be limited to literature reviews, without any specific validation methods.

Inclusion of laypeople or stakeholders could be seen as an obstacle to securing a solid scientific basis. The findings of this review do not support such a conclusion as there does not seem to be any relation between inclusion of laypeople or stakeholders, and scientific evidence.

In most cases the methodology for the assessment is made clear to the readers, but in several cases it is either taken for granted that the readers are aware of this methodology or the methodology is not addressed in the report.

The ethical assessments vary with respect to how they address policy trends. There does not seem to be a systematic reflection concerning factors as sustainability, internationalisation, privatisation, or other trends. Even though there are methodological difficulties in mapping the assumptions of such trends in the assessments, the disparities are so large that we should conclude that – as a rule – ethical assessments are concerned with values, but not the contextual larger trends for these values' realisation.

Seen in relation to the purpose analysis tables, we can see a multitude of roles that ethical assessments have in relation to the policy making processes. This can either be interpreted as a sign of the versatility of ethical assessments, as a sign of a lacking a proper political mandate, or as a sign of different traditions of ethical assessments. All ethical assessments that have been investigated intends to form attitudes on the scientific/ technological aspects, and most of them propose to engage public discussion about technological or societal aspects. It is quite surprising that there are so few that strive at raising knowledge about the societal aspects of technologies, while the policy aspects and the scientific aspects are the objects of most reports. None of the reports are actively engaged in creating actual policy.

Summary

- Ethical assessments are in general expert based, but some include stakeholders or lay people as part of the assessment process (in the form of hearings, or other)
- Most ethical committees consist of ethics experts, but many groups consist of members from the relevant profession and sometimes representatives of diverse societal groups and/or lay people.
- There has traditionally been varying degrees of methodological discussion in the assessment reports, and they are generally not high in transparency about their assumptions and the assessment process

- Ethical assessments seem generally to focus on the technological aspects, and not include reflection on socioeconomic consequences
- Emerging science and technologies may raise important new ethical concerns and ethical assessments are important to map these and clarify ethical dilemmas we as a society must face.

3.5 Foresights

According to one of the “classical” definitions, (technology) foresight is “the process involved in systematically attempting to look into the longer-term future of science, technology, the economy and society with the aim of identifying the areas of strategic research and the emerging generic technologies likely to yield the greatest economic and social benefits” (Martin 1995, 140).

To put it simply, one could say that *foresight is the structured debate about complex futures*:

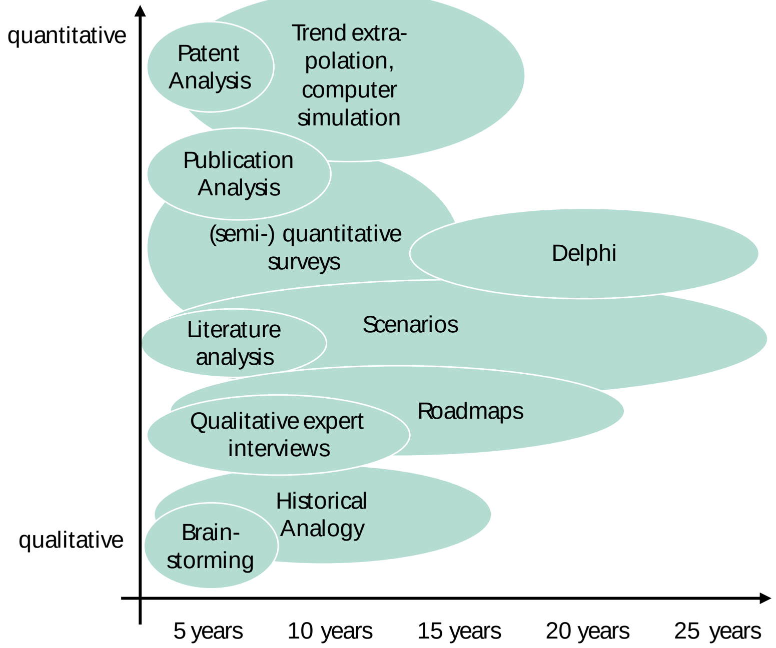
- “structured” because foresight is a systematic, science-based approach by applying theories and methods of futures research,
- “debate” because foresight is mainly based on the interaction of relevant actors,
- “complex” because foresight aims for a holistic view and strives to consider systemic interdependencies, and
- “futures” because foresight is about the active preparation for the future or different futures and is characterised by an open view on different paths into the future, by thinking in alternatives and by an orientation towards shaping the future.

In general, foresight focuses on a long- and medium-term view. Therefore, foresight is not planning but a step on the way to planning (strategic foresight). It should not be misunderstood as any form of prediction. The main *objectives* of foresight are:

- to think long-term,
- to enlarge the choice of opportunities, to set priorities and to assess impacts and chances,
- to get an overview about things to come,
- to prospect the impacts of current research and technology policy,
- to ascertain new needs, new demands and new possibilities as well as new ideas,
- to focus selectively on economic, technological, social and ecological areas as well as to start monitoring and detailed research in these fields,
- to define desirable and undesirable futures, and
- to start and stimulate continuous discussion processes.

Foresights work with a very broad range of *methods* depending on the specific aims of the project. Among them are *scenarios* (different approaches), *surveys* and *Delphi* surveys, *analyses* from surveys, simulations, extrapolations and other future studies, *monitoring*, structured *interviews*, *critical technology listings* according to a set of criteria (group work, panels, expert consultations, interviews etc.), consultation of single experts, *panel* sessions with discussions, *workshops* with different stakeholder groups, *votings* (online, offline, postal, fax), *creativity methods* such as brainstorming, *visioning*, *future conferences*, and *roadmaps*. The foresight methods which are often used in combination differ strongly from each other, for example in terms of (a) their quantitative or qualitative character and (b) their time horizon. Figure 1 shows a raw classification for selected methods according to these two dimensions.

Figure 1: Raw classification of selected foresight methods



Source: Fraunhofer ISI

Analysis of selected foresights

In nearly all the foresight processes chosen for the description here, scientific-technological aspects with cognitive/raising knowledge, normative/forming attitudes and pragmatic/initializing action targets are found. On the other hand, only in a few cases, societal aspects are tackled. The explanation is rather simple: As science and technology are man-made, it is regarded as easier to look into the longer-term future in S&T whereas the developments in society underlie even more and very different influences (e.g. rules, values, group dynamics, religious beliefs, cultural factors, economic situation etc.). Thus, foresight deals more often with issues from science and technology – with societal aspects as an impact.

Concerning policy impacts, it depends for whom the foresight processes are performed. Those in the ministerial contexts are concerned with policy aspects and here even with normative goal-setting or recommendations for pragmatic action. In all cases, it depends on the general objectives of the foresight process.

Analysis of the selected assessments show that most examples are well-balanced regarding participation in the assessments and most of them directly address impartiality or discuss why there is impartiality. In foresight, it is a big issue to involve actors of different kinds and make the procedure as transparent as possible. Therefore, most foresight processes chosen are transparent – and those with medium scores lost their transparency mainly because of the complexity of the processes and the many information inputs gained so that participants and sometimes even organisers who were only partly involved lost the overview (e.g. in Futur) and the relevant information was just communicated in a different way or informally.

In most of the examples, the participation of experts plays a large role. This is due to the fact that specific knowledge in science and technology is needed to judge on the topics and in the cases chosen, societal aspects are not in the forefront. Lay people are only involved in a few of the examples just because it did not fit, because the methodology was based on experts or because expert knowledge was necessary to judge on the matter.

In foresight, experts are often equivalent to the stakeholders and addressees which means that the persons involved and the target group are the same – in order to make them aware of new issues or to make them act on them.

The ‘evidence base’ in foresight is provided via methodological rigour and the involvement of experts, therefore most projects chosen here gained high scores. But this does not mean evidence in the sense of prediction or scientifically ‘proving’ futures (e.g. evaluating whether the prediction was right). Foresight rather has the task of summarising and formulating the future issues or assumptions, collecting pieces of evidence for the findings as well as organising an assessment of these findings. Often, tacit knowledge is used when working towards a clear and understandable formulation of things to come. How much the focus lies on uncertainties depends on the objectives of the foresight and the issues tackled.

For foresight, it is often more important to be open to any issue and topic and to provide possibilities for open thinking, sometimes even in alternatives (e.g. when scenarios are used) and to bring in new ideas not yet scientifically grounded so that the scientific base of foresight projects is different from e.g. classical TA projects. In most foresight processes, there is no underlying general value set found but rather open searches for opportunities.

Foresight is always about impacts but the weight on the impact dimension (social, economic etc.) depends on the objective of the foresight or the issue that is dealt with. Foresight is per se anticipatory; there are only a few that start with looking back. Some are performing backcasting, but this also in an anticipatory way.

In some foresight processes, visions and scenarios of all kind are worked out and dealt with. They also often contain narratives. Those projects based on (semi-) quantitative methods have none.

Concerning the self-reported success, there are mixed results, but most of them rate themselves (or are rated in external evaluations) as very or medium successful. For Futur and the BMBF Foresight Process Cycle I (please see annex), evaluations are available (but not publicly accessible). The costs of the selected projects are rather high, but this is due to the selection of the mainly large and government-related projects in this study.

Concerning the core contextual characteristics there are no strong findings for the selected foresights. The way they related to policy trends, such as liberalisation, is based on their different mandates. Most foresights assume internationalisation as a background development and a future development. In most processes, this is not mentioned as an issue, and only in a few cases it is an objective to foster internationalisation (none of the chosen examples). To foster private-public partnerships concerning specific issues is an often mentioned recommendation stemming from foresight processes as a result but is not an issue of the processes themselves. In 'overview' foresights, policy integration is regarded as necessary to foster or implement certain topics. In the other cases, it depends on the issue but it is generally not considered the task of foresight to tackle this question directly. Consumer acceptance is generally a topic in foresight, but as foresight is connected with long-term issues, it is rather difficult to assess if there will be consumer acceptance for products that do not exist, yet, or for research that is still unclear and difficult to understand. Therefore, this answer is case-specific.

Challenges and developments in the domain

There are pros and cons in the discussion about the institutional setting of the organisers of a foresight process: External organisers are often regarded as more neutral and objective than internal ones who do not want to 'advice themselves'. However, outsourcing the foresights makes it more difficult to implement the topics later on, because they are derived from external processes and 'not invented here'. Internal organisation of foresight is often performed in companies (not in the assessments reviewed in this study, though) with the aim of change management, organisational changes or bringing new topics into the portfolio of the company.

There is currently much methodological reflection, accompanied by frequent new developments in methods and method combinations. Method choice is generally carefully made in foresight and methods are chosen according to the assessment objectives (especially in the selected assessment examples). An important reason for this methodological awareness is probably that the whole field of foresight is still fragile and often regarded as 'unscientific'. There are several journals discussing foresight methodology and reporting methodological improvements (e.g. *Technological Forecasting and Social Change* or the *European Journal of Futures Research*). In Germany, for example, a national network has formed a working group on methodological issues in foresight (see *Netzwerk Zukunftsforschung* ("Network Futures Research")[18].

On the national level (or on the European level) foresight is applied for achieving an overview on upcoming issues or to put new issues on the agenda. It is mainly used for the identification of issues and often stops at the implementation point where different people, methods and applications take up the results, e.g. in departmental re-organisations, new research programmes or product development. On the regional level, foresight is generally applied to foster networking towards a common goal. On the communal and company level, more specific objectives are on the agenda (solving specific problems, starting innovations, re-organisations and so on).

Foresight is strong when it is used to open up minds and evoke awareness on things to come. The results are always important to be considered – especially if a good filter of what is 'noise' and what is 'real information' is followed. Foresight can (if performed well) be strong in fostering networking, bringing in different actors, also lay people, and therefore creating awareness in broader areas.

But even if important questions are raised, it is difficult to make the stakeholders move, implement something or take their measures. As the 'futures' are always rather far away, they seem to be weak

[18] http://www.netzwerk-zukunftsforschung.eu/) [Accessed 01.05.2013]

in initiating action, - perhaps because the users believe they will be dead, retired or not in their job anymore by the time the futures appear. The long time horizons may also be too long for policy-makers and their rather short-term election cycles.

There was a trend during the last three years towards the application of more quantitative approaches (modelling etc.), especially, but not only, on the European level. This may reduce the insights gained from the process. There are meanwhile new opportunities in new models. Since relying on quantitative approaches alone restricts our ability to accept uncertainty, to deal with it in a creative way and to integrate other types of knowledge, there is a need to better integrate qualitative and quantitative approaches. This should be attempted without setting the scene in favour of either of the two.

There is also the ongoing trend to look at "Grand Challenges", but it is still unclear how Grand Challenges are defined. It is also more and more neglected that there are also "Small Challenges" or disruptive innovations (social or technical) with huge impact. On the other hand, policy-makers appear to be ready to listen to the narratives of foresight in order to identify novel topics (new for themselves) or adapt others to new circumstances.

There is no theory on foresight or futures research. There are some approaches, but as the future is regarded as uncertain, the theories, epistemologies and methodologies are based on a weak fundament. The major basis for methodological choices is the individual objectives in the projects so that method combinations or even method mixes are often applied, which is sometimes criticised. Comprehensiveness is sought in some of the foresight projects, but not necessarily. In sectoral studies, single issues, themes or questions are addressed. The overview can never be completely comprehensive in a way that all areas that are lying ahead are addressed. As most foresight activities are performed rather pragmatically (see table B1) and exploratory to open up the space for new action or 'shaping the future', the expectations are and should be rather modest.

Summary

- We do not know the future and foresight is a concept to make policy-makers/decision-makers aware of their limits on the one hand, and what they know on the other. It is in most cases more important to identify what we know and what we do not know, and explore if others share the same expectations. Under these conditions, the future can be shaped (e.g. by forming alliances, allocating our resources etc.). Predictions and certainties cannot be expected – but to know the risks and especially the opportunities is already information worthwhile of conducting a foresight.
- Methodological discussions are significant in foresight and framing assumptions are explored in the foresight process, often involving discussing visions and narratives.
- Integration of complexity is an inherent part of foresight as foresight for instance often takes into view the innovation system in its entirety.
- It is hard to trace the impact of foresight on decision/policy making. Foresight has rather the effect of opening up deliberation to see new alternatives and action paths.

3.6 Technology Assessment

Technology assessment (TA) can - along with foresight studies - meaningfully be said to constitute the point of origination of specifically technology-oriented forms of assessment. Institutionally, TA is a tradition of attempts to organise capacities for forecasting and negotiating possible outcomes of technological options. The common aim of these attempts is to allow society in general and political decision-makers in particular to embark on new technological development paths only after careful consideration. The development of the TA tradition is linked to a number of national parliamentary institutions charged with the mission of carrying out a reflective societal function in practice. As such, TA has as a core concern the assessment of emerging sciences and technology. TA is therefore an important point of reference for any attempt at establishing collective responsibility in and around technological research and development.

Technology assessment (TA) emerged in the 1970s as an institutional solution to an institutional problem, namely the lack of a kind of knowledge *about* the science-technology-society (STS) relationship *active within* that relationship itself (Ganzevles and van Est 2012). Concretely, this problem was originally identified with a need for balanced policy advice for parliamentarians on the consequences of emerging science and technology. While the generic concept of "technology assessment" could meaningfully be applied to a variety of technology appraisal functions in private companies, consultancy firms, think tanks and universities (Vig and Paschen 2000), TA for the most part connotes a parliamentary connection even to the point where Parliamentary TA (PTA) is often conflated with the broader concept of TA.

A story often told in the TA literature is that of the line of succession reaching from the U.S. Congress' Office of Technology Assessment (OTA) established in 1972 to the establishment in the 1980's of similar institutions in a handful of European countries as well as at European level. It is also well known that while a republican Congress majority shut off funding to the OTA, the "TA movement" is still strong in Europe (Ganzevles and van EST 2012) and has played a significant role in the development of participatory methods for democratic deliberation on policies dealing with the future options and risks. In Europe, however, the cultural differences between Member States have led to a great diversity in institutionalisation. Some are organised as support functions within Parliament itself, while others have more remote ties with Parliament or government. These differences are also reflected in the different mandates of European PTA institutions. Some have mandates which specifically focus on the brokerage of state-of-the-art scientific knowledge as an informative basis for decision-makers' opinion formation while prohibiting the production of political recommendations. Others have more popular mandates to facilitate dialogue and decision-making across divisions between societal sectors, which has led to the adoption and development of participatory methods. Specific to the TA domain is the emphasis in some institutions of citizens' participation in processes of decision-making on issues of science and technology.

Approaches in (P)TA

Integration of expert and stakeholder viewpoints on emerging technology has always been at the core of TA assessments. Having been assigned the task of providing unbiased information to support decision-making in a highly political environment, TA from the very beginning has aspired to *neutrality* rather than the classical ideal of *objectivity*. Focus has been on the ability to balance different scientific perspectives on the same problem, to identify neutral positions in areas of contention between stakeholders, and to identify viable options for technological development and policy (Vig and Paschen, 2000). To this end, a range of group facilitation methods have been employed from cognitively integrative methods like expert advisory panels, Delphi panels and cross-disciplinary workgroups to methods based on cross-sectorial dialogue such as scenario workshops and café seminars. TA has never settled into a well-defined practice or settled on a universal framework for assessments, but has remained methodologically open, problem oriented and institutionally flexible (Grunwald 2009). This is precisely because part of TA's original purpose has been to act as what one might call a "meta-domain" for assessments of technology, and on a case-by-case basis to find a pragmatic middle between more or less extreme perspectives. Experience shows that methodological rigidity goes counter to such efforts.

In its earliest chapters, TA was first and foremost concerned with avoiding "unintended, indirect, or delayed" consequences of technology (Porter et. al. 1980). But in the 1980s, TAs early warning function was supplemented with the task of identifying positive potentials in emerging science and technology and to help pave the way for them. This led eventually to developments of direct-action forms of TA, where practitioners engage with technology development at its source (interacting with developers and producers) to achieve the necessary balance between the realisation of positive potentials and anticipation of negative consequences. These approaches became known as "constructive TA" (Schot and Rip 1997). One important contextual driver for this broadening of the TA mission may have been the long-term negative economic effects of the 1973 oil crisis, which led political decision-makers to turn to technology and innovation as a possible driver for new growth (Brunner, 1980), much the same as what we see happening today (OECD 2012).

TA institutions took up the task of mediating such conflicts through citizen participation because of the technology-centred conflicts in society in the late 1980's (concerning nuclear energy, pollution, computerisation and other issues). Often misunderstood as a soft addition to hard policy advice, early experiments in dialogue-based methods (such as consensus conferences, citizen hearings and future labs) left the impression that – beyond the inherent moral value of increased democratic legitimacy (Sclove 1995) – participatory methods could improve both the cognitive and strategic dimensions of such advice. As mentioned, this emphasis on including citizens in STI decision-making has been a defining trait of the TA domain in comparison to others. Cognitively, forward-looking exercises, which might also be found in other domains, benefit greatly from the inclusion of non-expert information on the day-to-day implications of new technologies. Strategically, the mutual learning aspect of participatory processes might help to secure the convergence of the interests and perspectives of different actors, perhaps leading to technological development more attuned to societal needs (Joss and Belluci 2002). Some observers claim that the "participatory turn" in TA has in fact helped establish TA as a provider of strategic intelligence within the decision-making system around science, technology and innovation (Smits et. al. 2010) aiming mainly at convergence among stakeholders' views rather than consensus in the habermasian sense. This interpretation at least seems to ring better with the self-understanding of TA practitioners.

The compounded tasks thus assigned to and taken up by PTA have made the field highly complex and difficult to delimit in any clear way. Adding to the confusion, the changes in TA's institutional environment brought about by globalisation and European integration has created a situation in which "'parliamentary TA' has become much broader than the label suggests" (Ganzevles and van Est 2012, 13). It no longer makes sense to take direct interaction with parliaments as the *a priori* determinant of a (P)TA organisation (ibid.). Instead, technology assessments have come to various degrees and in various ways to act as knowledge brokers and bridge builders between different spheres within society, ranging from parliament and government to developers and producers of science and technology as well as citizens and civil society organisations.

Examples of methods employed in TA, grouped according to paradigm

These examples are mainly taken from the TAMI final report (Decker and Ladikas 2004) with a few supplements from various TA organisations' websites. The list illustrates clearly the eclectic nature of TA methodology, which draws on a broad range of inspiration from diverse practices of research, participation and cross-sectoral communication.

Expert methods

- Delphi method, expert interviews
- Expert discussions, transdisciplinary working groups
- Modeling, simulation, systems analysis, risk analysis, material flow analysis
- Trend extrapolation, simulation, scenario technique
- Discourse analysis, value research, ethical analysis, value tree analysis

Interactive methods

- Consensus conference
- Expert hearing, parliamentary hearing, citizen hearing
- Focus groups
- Citizens jury, Planning cell
- Café seminars, Charette
- Future search conference
- Participative assessment
- Scenario workshops, perspective workshops
- World Wide Views

Communication methods

- Newsletter, focus magazine
- Policy briefs
- Science theatre
- Online communication (debate forums, questionnaires, info videos, etc.)
- Networking
- Dialogue conferences

With the evolution of PTA, described in the PACITA project[19], towards a broader role as facilitator of dialogue between societal sectors, the importance of effective communication to broader audiences (i.e. interested parties beyond participants and end-users of TA projects) becomes essential. But when trying to communicate TA results in the context of a 24-hour news cycle, the triple obligation of TA (to balance expert opinion, to mediate citizens' and stakeholders' views, and to communicate recommendations on this compound basis effectively) puts the original TA ideal of neutrality to the test. Demands for readability in popular communication forces TA organisations to adopt more "punchy" types of communication than usual, which entails the risk that the TA organisation may be perceived by as downplaying political and scientific complexity. The necessity for balancing these concerns in a pragmatic manner has led several TA organisations to strengthen and professionalise their communications departments considerably.

The significance of the communicative paradigm for TA, however, goes beyond the basic obligation to inform the general public of significant results. When governance processes become spread throughout networks involving public and private, local and global actors, communication is no longer incidental to the core project but rather essential to its completion. In practical terms: briefing members of parliament no longer ensures that those who need to be informed are in fact informed. Instead, significant results must be spread as much as possible throughout the system as a kind of irritant aimed at provoking unknown recipients into responding (e.g. Schirmer and Mölders 2008). Arguably, such a role was already described in the TAMI typology of roles (see column 2 of the typology table in Decker and Ladikas 2004, 9). Organisations must also seek to communicate and develop the very idea of TA as a societal function and enter into dialog with non-TA actors performing *de facto* TA functions in other parts of the governance system.

Over the years, a growing sensitivity to what "plays" in public debates and in policy circles has been developing in TA, and TA organisations have been honing the craft of funnelling broad and deep analysis into the 24-hour news stream in the form of concise and potentially controversial inputs. In a significant shift from its early beginnings, some TA organisations now produce as perhaps their most valued outcome specific policy recommendations timed to feed into specific decision-making processes. Still, the quality control of PTA organisations "must be from the academic perspective" even though the framing of messages must be made in accordance with a "feel for politics, which every member of PTA-staff is expected to have" (see the ongoing European project on TA, PACITA). TA communication thus balances on a thin line between over-academic, politically irrelevant information on the one side and over-simplified, politically laden messages on the other.

Analysis of the selected assessments

Nine assessments were selected for further analysis in the project, seven of these from established TA communities and two from expert groups performing assessments practically indistinguishable from expert TA assessments. The assessments stem from the nanotechnology, synthetic biology and ICT cases.

[19] http://www.pacitaproject.eu/ [Accessed 01.05.2013]

Generally, impartiality and transparency is high in this selection. In the selected assessments there is a very high variance in participation of experts and stakeholders. This can be explained by the very different functions these reports have, also shown in the aggregated purpose analysis table. Only one assessment included citizens' participation. This may be attributable to the subject matter of the cases, from which assessments were selected, which are all categorized as emerging science and technology. In these areas, expert TA perhaps still has a stronger role than participatory TA. Whether values, narratives or visions are being addressed in the reports also varies. TA is oriented toward policy relevance, but in the reports studied there is no systematic consideration of core contextual issues in the reviewed assessments. We know, however, from practitioner interviews that most TA institutions work internally with procedures for project preparation, which include situation analysis exercises such as policy analysis, context mapping as a basis for method choice, something which was also documented in the TAMI report. It would seem, therefore, that most TA institutions would be able relatively easily to provide the public a high degree of transparency about situation analysis and method choice in assessment reports.

In practice, it is very much up to the different assessment manager's/institution's professional judgment how the TA is carried out, and this explains the large variation between the different reports that are included as examples of TAs. As such assessments in this domain seem to be more up to the discretion of the project managers than for instance impact assessment, risk analysis and ethical assessment. In this regard, there may be higher requirements to methodological reflection and justification in each assessment. This, as well as the risks connected to being so close to policy, is perhaps why the domain has engaged in so much methodological work the last years.

From the case studies we see that TAs seem to have a place early in the technology development, but that perhaps citizens' participation is more difficult to establish in these phases due to the need for expert evaluation being perceived as more pressing. The TAs studied often have an anticipatory character and aim to address the most important societal or technical issues concerning the technology development, often in dialogue with stakeholders. They explicitly seek to address both benefits and risks from the technologies.

Summary

- TA is an assessment domain that is characterised by great diversity of functions and roles, which stems from the practice of drawing eclectically on methods and results from the more specialised mandates of risk assessors, economic assessors, ethics assessors, etc. TA can in this sense be viewed as a "meta"-domain for assessment of technology. There is a great diversity of institutions that perform TA in the senses described above. This has resulted in much methodological work at a European level to clarify TA functions and methodologies. This work has been of great value to established TA institutions and also serves today to provide conceptual and methodological resources to broad developments within the RRI movement.
- Established TA institutions often initiate assessment projects with wider participation, aiming at democratising science policy and to strike a neutral balance between diverse views. In this function they are distinguished from other assessment domains, the mandates

of which do not routinely prioritise the development of competencies for participatory methodology or allocate resources for them, but are more dependent on expert work. However, TA project managers may choose to apply other methods, such as desk top reviews and expert hearings. When such methods are used it is harder to identify differences to other domains, except that TA's generally are less specialised and more explicitly attuned to on-going political discussions.

4 Similarities and differences in the assessment domains

In this chapter we will reflect on the findings presented earlier in the report. In section 4.1 we will compare the domains. In section 4.2 we will mostly report from the project's practitioner workshop, organised at the Danish Board of Technology in April 2013 (see annex 2). We will then proceed to discussing legitimacy and assessments, before moving on to the question of integration and integrated assessment. After addressing some methodological limitations of the study we will conclude the chapter with a summary and recommendations to policy makers.

4.1 The relations between the domains

There are several overlaps between the advisory domains. For instance, it does not seem viable to uphold strict domain borders between technology assessment and closely related forms of anticipatory assessment such as foresight, impact assessment and risk analysis. At a methodological level, a similar range of methods and techniques can be found represented in all or several of these. TA typically includes policy analysis approaches such as foresight, economic analysis, systems analysis, strategic analysis, etc. Some institutions arguably play an even role in foresight and TA – choosing perspective according to the situation to be assessed. And at an organisational level, each of these domains in fact share(d) common institutional settings and networks (e.g. the International Association of Technology Assessment and Forecasting Institutions (IATAFI), the Forecasting and Assessment in Science and Technology (FAST) programmes, and even the International Association for Impact Assessment (IAIA) which at the time published a journal covering technology assessment as a topic (Vig and Paschen 2000)). It seems likely that the divisions between these domains are caused mainly by factors having to do with political dynamics and varying conjunctures of societal focus on e.g. risk, social concerns, innovation, competition, growth, etc., in addition to institutional factors having to with social dynamics and the competition for limited public funds between communities that otherwise share many common practices, institutional setups, roles and obligations.

Still, one could argue at least for some differing characteristics of foresight and TA, as shown in table 1.

	Foresight	Technology assessment
Time horizon	Long-, medium- and short-term; clear differentiation	Rather short- and medium-term; no clear differentiation necessary
Focus	Looking at alternatives, different (possible, realisable, desirable) futures	Looking at one specific technology (field), its potentials for development and its possible benefits and consequences
Objective	Working out the consequences of different futures and the measures to be taken now to shape the future in the desired direction	Working out the (desirable and non-desirable) consequences of the technology and its (possible) implementation and the measures to be taken now

Culture	Focus more on positive view of the future, on shaping the future, on chances of science and technology	Focus on negative and positive impacts, sometimes more on negative impacts (more critical), less on opportunities
Institutionalisation	Less institutionalised	More institutionalised

Table 1: Differing characteristics of foresight and TA. Source: Fraunhofer ISI

With regard to assessments that consider value issues, we see that this is not only done in ethical assessments, but also in TAs. In parallel with the development of advisory committees on the ethics of biotechnologies (and later more general science and technologies) there was also a development of technology assessment institutions. In several TAs ethical issues are given a prominent place (e.g. STOA 2010 and the TA-Swiss 2009 report also used by STOA). An example from the field of synthetic biology shows that there is not a big difference between the 2006 technology assessment made by the Rathenau Institute and the 2009 EGE ethical assessment. Perhaps most surprisingly the largest difference is that the EGE assessment was more participatory. While the TA was made by altogether three authors the EGE opinion rested on a roundtable discussion, in addition to the discussions in the Group. One may enquire about whether there is in fact a convergence of some forms of TA and some forms of ethics assessments. Paula (2008, 11) seems to confirm this in his book on ethics committees. That there is indeed a similarity in perspectives is implied in the fact that ethics institutions now and then directly cooperate with other technology assessment institutions of different kinds. Examples are:

- The project 'Synthetic Biology – Potentials of application, risk assessment and ethical aspects' co-organised by the Danish Board of Technology and the Danish Council of Ethics.
- Consensus conference on genetically modified foods were co-organised by the Norwegian National Committee for Research Ethics, the Biotechnology Advisory Board, and the Norwegian Board of Technology in 1996 and 2000.

Without having done a comprehensive review of technology assessments it can be assumed that those technology assessments that most explicitly focus on ethics are the ones related to biotechnology. The reason is that ethical controversy is a characteristic trait of many (if not most) biotechnologies. In the human domain this is related to embryonic stem cell research, reproductive biotechnologies and, increasingly important, synthetic biology. In the non-human domain it is related to 'playing God', 'inherent value' and 'tampering with nature' arguments, notably with regard to genetically modified crops and animals.

Even though there is quite a lot of overlap between some domains, there are still areas of little overlap. Scientists representing very clearly focused domains such as risk are often included in societal assessments, whereas scientists representing broader approaches such as social scientists or ethicists are more seldom included in the more narrowly focused scientific or economic assessments. This might be due to a lack of awareness of normative assumptions in seemingly purely technical assessments, or a conviction that the natural scientists or economists are able to handle such dimensions themselves. Or it may stem from a continued belief within the communities of the natural sciences and economics in the value of strong disciplinarity and clear divisions of labour between different branches of research.

This latter view seems to underpin attempts at integrating the risk and economic domains in risk-cost-benefit assessments. In their report on Making Risk Assessment More Relevant for Risk Management, a DG SANCO working group from the risk assessment committees states: ‘The Scientific Committees recommend that risk assessments and socio-economic analyses should be carried out along separate but parallel tracks, with dialogue between them being encouraged and facilitated by appropriate processes especially in the initial problem formulation.’ (SCHER (Scientific Committee on Health and Environmental Risks), SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), SCCS (Scientific Committee on Consumer Safety), 2013, p. 7).

From comparing the assessments across the advisory domains it appears that quite a few assessments addressing ethics (mostly ethical assessments and some TAs) address economic issues. However, the economic assessments and assessments considering economic projections or socio-economic scenarios hardly ever address ethical issues explicitly. This finding can be explained by reference to the differing mandates of such assessments. Nevertheless, this does not adequately acknowledge the fact that to a large extent economic projections and quantifications rest on judgements, which may include normative elements.

A way to shed light on the relation between the domains is to look at the overlap in the purposes of the reviewed assessments. When we aggregated these per domain we saw what roles the different domains most often intended to have. The findings that are based on our selection of assessments are presented in table 2:

Focus of the advisory domain assessments		**Role of assessment in policy making process**		
		Cognitive – raising knowledge	**Normative – forming attitudes**	**Pragmatic – initialising action**
Object	**Scientific/ technological aspects**	**Risk** **Economic** **Foresight** **TA**	**Risk** **IA** **Economic** **Ethical** **Foresight** **TA**	**IA** **Ethical**
	Societal aspects	**Risk** TA (50%)	IA (50%)	**Ethical**
	Policy aspects	**IA** **Economic** **Ethical** **TA** Foresight (55%)	**Foresight** **TA** IA (50%)	(Foresight 45%) (Ethical 36%)

Table 2

Bold indicates primary role (more than 60 % of the reviewed assessments indicated this role), not bold indicates secondary role (less than 60 % or less indicated this role). Obviously the selection of the assessments from the domains will impact on the picture in this table. Also the interpretation of the reviewers of the assessments will impact on the picture. Still, the figure illustrates an important point, namely the substantial overlap of the purposes of the different assessments. This shows a possible competition in forming the evidence base on scientific/technological aspects, as well as in forming attitudes on these. On the one hand, policy makers could pick among several assessments with the same function to inform their policies and these assessments are likely to differ with respect to the way the evidence base is portrayed. On the other, policy makers might want to integrate the lessons from all the assessments with the same function and appraise their different assessment approaches against each other. Though this obviously is a larger task choosing such a strategy is an important recommendation of the EST-Frame project.

Another way of comparing the domains is by relating them to a distinction between technology trajectories, science, technology and innovation (STI) policies, and specific applications. As we have seen the assessments addressing broad societal concerns (different sorts of TAs, ethical assessments and foresights, as well as a host of different variants with other names) may have varying – and mixed – purposes; informing politicians and the general public, putting issues on the societal agenda, generating new knowledge and increasing democratic participation in discussions of emerging science and technologies. These assessments play an important role in the justification of technology trajectories, as does economic assessments. Some of these assessments may be carried out early in the technology and policy life cycle; often aimed at initiating and justifying political and/or funding action in the emerging field.

STI policies are important for translating socio-technical pathways into technological strategies, such as regulatory measures, research and innovation programmes, etc. These are mainly assessed in impact assessments, foresights and economic assessments.

From the open discussions to the more application oriented assessments there is a political and policy making process where general concerns are translated into guidelines and premises for further regulation. This is a complex, ‘closing down’ (Stirling 2008) process involving many actors representing different professional stances, cultures and worldviews. From the nanotechnology case study we saw that the early assessments were focusing on deliberative explorations of values and concerns, while the later were focused on settling risk assessment and other regulatory issues. Here a number of premises are given and optimal policies and regulations are sought, realising the benefits of the technological options, while avoiding the costs. As such, these assessments have different functions than the broader ones and naturally they are carried out in different ways. In the EST-Frame analysis of risk and economic assessments we have seen that the broad spectrum of public concerns and values that are discussed in public discourse – and also embraced in high level official documents (the concepts of safety and sustainability are two examples) – are narrowed down and operationalised.

The table below may give an approximate picture of the relation between assessment domains and the different discourses, but it should be noted that the distinctions are not so clear in real life.

	Foresight (n = 10)	Technology assessment (n = 9)	Ethical assessment (n = 11)	Economic assessment (n = 11)	Impact assessment (n = 6)	Risk analysis (n = 14)

Technology trajectories	7	8	9	7		8
STI policies	10	3	4	5	6	
Specific applications				2		6

Table 3. The table portrays the function of the different domains related to stages in technology/policy development, based on the reviewed assessments. The numbers indicate how many of the reviewed assessments in the domains deal with technology trajectories, STI policies and specific applications. Many of the assessments address two or more of the categories, therefore the numbers add up to more than the total number of assessments.

In the case studies we have seen that this narrowing down continuously must be reopened. In the biofuels study we saw that the increased acknowledgement of the importance of indirect land use forced a reopening of broader discussions. In the practitioner workshop we heard about the assessment of a synthetic influenza virus only taking into account biosafety dimensions because biosecurity dimensions had not yet been put on the assessment agenda. This means that there is a need for a continuous communication across the advisory domains and with stakeholders and policy makers. The implications of, for instance, an economic assessment may lead to a need to do a new TA. A new public deliberation event may come up with new policy options to be considered in an IA. However, we see that such communication cannot be assumed to exist.

From the EST-Frame practitioner workshop and from interviews we have indications that the closer to policy an assessment is, the more influence the policy makers want to have on the assessment in order to avoid any big surprises that may be politically awkward. A selection of experts (with well-known profiles), even the use of internal staff, following pre-established guidelines, will reduce the perceived risks for the recipients of the assessments. Moreover; the closer to policy, the less transparency is often found. This is a barrier to communication. With generic or specific products, risk assessment is generally the only regulated assessment domain (although in some cases, other assessments may also be required by the law). Here again, specific guidelines for participation and methods are usually established. Too strong institutionalisation of the domains may also be a barrier to communication, as values become naturalised, implicit and cemented (see e.g. Forsberg et al. 2012 for a study of ethics and institutions).

With regard to assessments of technology trajectories in general – if and when there is no direct link to upcoming policy decisions - these seem to be more freedom in terms of method choices and participation. However, such freedom comes with higher requirements to justify framing assumptions, method choice and participation. This requires a proper conceptual apparatus to engage meaningfully with other domains.

Both with regard to technology trajectories, STI policies and technology applications there is in the case studies a tendency to focus on specific dimensions of these (such as HSE, ethics, economics, etc.) or treat issues at an abstract level (isolated from specific times and places). For instance, from the synthetic biology case study we have seen that although early assessments have been important for establishing an overview of the crucial issues, the fast changing and dynamic field of synthetic biology might require more practical approaches for assessments when applications start to arrive.

4.2 Common challenges between the domains

From the EST-Frame practitioner workshop we learned that there were many shared challenges between the domains (please see annex 2 for the workshop program). In the workshop we had participants from all domains except economic assessment:[20] from ethics, TA, risk assessment, foresight and impact assessment (20 participants in addition to the EST-Frame researchers representing foresight, TA, ethics and economic assessment, see annex 2 for a participant list). These seemed to share many methodological perspectives, though here we must take into account selection bias and the framing of the workshop. The workshop was framed as a forum for cross-domain learning – with a special focus on integration in assessments – and in the invitation we mentioned that we would focus on three dimensions: situation analysis (or context sensitivity), method choice and dialogue (the justification of this focus is given in EST-Frame deliverable 1.3). The participants that wished to attend had therefore already both an interest in these issues and a framing for conceptualising them in the workshop. We can therefore not say that the results were representative of more general reflections in the domains. However, we did get a good picture of what was presented as challenges.

The need for good situation analysis or context sensitivity was stressed and mentioned by three of the participants as a main lesson to bring home. In the group discussions situation analysis and contextual sensitivity was linked to the question of what was assumed in the situation analysis of the assessments and how justified and transparent these assumptions were. One of the groups discussed whether one should always consider whether the scope of the assessment should be broadened. However, the framing and purpose of the assessment is not always determined by the assessors themselves, but by the commissioners of the assessments. Still, several groups stressed the need to uphold a certain flexibility concerning the framing of an assessment; that it should be responsive to reframing during the process. In fact, the possibility to reframe became a central topic during the workshop.

There seemed to be increasing common agreement on the need for transparency during the workshop. The importance of transparency was mentioned by three of the participants as a main lesson from the workshop. In the group work on challenges leading to weakly integrated assessments 3 out of 4 groups mentioned transparency as an important point. Transparency was related to framing assumptions, as well as method choice and the unfolding of the assessment process. It was noted that the more integrated the assessments are, the more difficult, and more important, transparency becomes.

[20] It has been difficult to engage economists in the project. There may have been several reasons for this. They might not relate to EST assessment as an identifying characteristic and might not engage much in these academic discussions. We did not identify many economics assessments in the case studies, so not so many potential participants were identified and invited. Those that were invited were not attracted by the topic, and turned down the invitation.

The workshop also discussed common challenges related to integration and integrated assessments. These discussions are briefly referred in the section 4.4 below.

4.3 Legitimacy and the role of the domains

In the case studies we saw that various kinds of assessments, with various profiles regarding transparency, participation, treatment of uncertainties and values, etc., were in a position to influence policy. Such potential impact on public policy making raises questions of legitimacy. Legitimacy is a status that the people confer on the government's officials, acts and institutions, through their belief that the government's actions are an appropriate use of power by a legally constituted governmental authority following correct decisions on making policies. Franck (1999, 1) defines legitimacy as ”the aspect of governance that validates institutional decisions as emanating from right process”. Van den Berghe (2006, 6) adds: ”In secularized, democratic societies, the primary source of legitimacy lies in the involvement of those impacted by a decision in the decision-making process leading to it.”'. Legitimacy can also be applied to technology advice in so far as it influences on policy making that affects broader societal issues. All contributions have a perfectly legitimate place in a democratic process, as long as they can be scrutinised in a broader dialogue. A legitimacy problem arises if such scrutiny is not possible or not done and the assessments still influence policy, perhaps because the assessment is seen as politically opportune by some political actors. There is therefore a significant need for knowledge assessment (Funtowicz 2006) of this evidence basis.

The quality of assessments can be evaluated by other experts simply by appraising the assessments' conclusions. In science this would take place in the usual peer review process. However, assessments may influence policy much faster than it would be possible to subject it to peer review, especially with the increasing tendency to disseminate in the form of short policy briefs. Still, by inviting experts to comment upon an assessment it is possible to judge whether the report seems prima facie to have adequate quality. In many cases, however, it is not possible to evaluate whether the assessment result is correct or of high quality simply by looking at the results. In such cases the transparency of the assumptions, methods and practical process is crucial in order to assess the participation, the design of the process, the framing assumptions, and the quality of the assessment dialogue (in the case more than one person was involved in the assessment). This has several implications.

First, it is a legitimacy problem when assessments relevant for democratic decision-making are done outside the public domain, for instance internally in ministries or supplied by private actors that do not provide the underlying data and methods for their conclusions. One may claim that there are less quality requirements for reports produced by stakeholders with the sole intention to put an issue on the public agenda, - and not assess the topic comprehensively. In other words, that the quality requirements are lower in some of the purposes outlined in the purpose analysis table. However, putting a topic on the public agenda may have significant effects, for instance to create public worries, and should therefore also be legitimate if it influences public policy.

The second important implication is that assessment domains are important in establishing legitimacy for their working procedures. Risk analysis, for instance, possesses a tool box that has gained legitimacy over the years. This does not mean that there are no methodological controversies about this toolbox, but that the domain practitioners themselves are involved in a methodological discussion that takes objections into account, develop their methods to new contexts, and have internal mechanisms for quality control through domain societies, conferences, journals, etc. We see from the domain studies that many domains have tools and guidelines for methodological choice (even if, in reality such choices seem mostly to be made on the basis of a professional intuitive judgement rather than in a formalised way). Moreover, in order to maintain legitimacy assessment domains – as institutions – need to adapt to expectations from their surroundings, on which they are dependent on resources or other support. This means that there is a societal responsiveness in the domains.

Some studies that are not institutionally anchored in any established advisory domain may use methods from the domain in their assessment, and may identify with the domain and be part of their learning practices (journals, conferences, etc.). Methodological choices made in any given assessment do not in themselves designate that assessment as belonging to one domain or the other, because, as we have seen, there is considerable methodological overlap between the domains. However, the methodological reflections accompanying the choices will relate to the methodological toolboxes of the domains that an assessment relates to, if it does relate to a domain (or potentially, several). Other assessments may have less of an identity. These assessments with no clear identity may be perfectly legitimate when they demonstrate appropriate transparency about their assumptions and methods. In the case they do not have such methodological discussion, it is harder to distinguish what quality criteria should be applied to evaluate its input and throughput legitimacy, and its position in policy should be further scrutinised. When there is an unclear description of what domain the assessment belongs to, this may in some cases reflect methodological unawareness and thus unjustified method choice.

We found 45 assessments out of a total of 65 assessments reviewed in the case studies that we could not easily characterise as belonging to any of the EST-Frame domains, but which nevertheless had a certain prominence in the case studies. Of these 45, some were carried out by research consortia (such as the Synbiosafe consortium), some by consultants (such as IDC), some by stakeholders (such as the ETC group), some by international organisations (such as OECD) and some were deliberative events specifically set up for the purpose. These were included in the case and domain studies because they appeared to have policy relevance. Many of these organisations are large and well-known, with institutional legitimacy (Suchman, 1993) and a reputation to protect. However, if the assessments are not anchored in domains with established quality criteria for the assessment work it is important that it is possible to evaluate the quality of these assessments properly. This requires at least appropriate transparency on the assumptions made in the assessments, the methods applied and the assessment process in general. With less of an institutional structure for ensuring such transparency and justified choices, assessments from non-institutionalised assessment domains must be carefully evaluated before taken as legitimate input to policy making.

4.4 Implications for the need for an integrated assessment framework

All the advisory domains described above relate to the notion of integration. Indeed most of them regard themselves as involved in integration; having tools of varying degrees of integration. From the above descriptions we know that:

- Foresight aims for a holistic view and strives to consider systemic interdependencies, starting from visions of possible futures.
- TA analyses may be called studies which 'comprehensively and systematically analyse and evaluate the prerequisites for and the positive and negative impact of introducing and (widely) applying technologies'[21]
- Ethical assessments are often conceived as application of prima facie ethical principles into all things considered judgements; i.e. a process of specifying and balancing principles in an integrated way (Beauchamp and Childress 2008).
- Economic analysis may be more or less integrated, and we have seen that there are several top-down and bottom up methods that can be used to integrate. Economic analysis may integrate social and environmental concerns by quantifying impacts, though quantifying a broad spectrum of impacts is highly demanding.
- Impact assessment seeks to provide multi-dimensional foresight and decision support by highlighting 'environmental' consequences in the broadest sense of the term including biophysical, social, economic, and institutional dimensions. Impact assessment in the EU is carried out in an 'integrated' fashion, referring to the three pillars of sustainable development.
- Risk analysis has tools for integration for instance of several kinds of risk (health and environmental), though such integrated assessments are seldom carried out.

There are also important lessons to be learned on integration in the domains. These can be analysed by explicating different concepts of integration. Building on Scrase and Sheate (2002), but expanding their approach, we identified a number of different understandings of integrated assessment (see deliverable 1.3 for a justification of this list). These can tentatively be listed in the following way:

Integration of assessment topics	a) Inclusion of all areas of topics into assessments b) Inclusion of values into assessments c) Inclusion of narratives into assessments d) Not isolating one topic at the expense of the whole e) Explicating assessment framing
Integration of assessment elements/methods	f) some specific elements (such as anticipation) are necessary in assessments g) targeted use of methods in assessment
Integration of assessment participants	h) Integration of broader experts/stakeholders/the public into assessments
Integration between assessments	i) Integration among assessments
Integration of assessment and governance	j) Integration of governance concerns into assessments k) Better integration of assessment into governance

[21] http://www.itas.fzk.de/eng/tadbe/wasist_e.htm [Accessed 01.05.2013]

Table 4

These dimensions are useful as a starting point for discussing different kinds of integration in the domains.

a) Inclusion of all areas of topics into assessments

This is a kind of integration where more and more factors are being included in the assessments. There are attempts of increasing the scope in all domains, taking more and more variables into account. These are important attempts; EST issues are complex and trying to tackle this complexity is important. However, there are two important problems with these attempts. First, comprehensive assessments that quantify all variables need to make a number of assumptions, about correct valuation and measurement. From the review of economic assessments above we can learn that quantification is a problematic feature of an integrated assessment, because the models may not be complex enough, the data may not be existing on all the variables and it is demanding in practice to reach agreement on all necessary assumptions (at least in an interdisciplinary team). Moreover, quantification in a single unit will assume that qualitatively different issues can be translated into the same unit, which is doubted by anti-reductionists. Second, even if quantification is not sought there is a problem with balancing qualitatively different concerns on the same scale. From impact assessment we learned that it started out as integrated, but became more fragmented due to balancing problems. Traditionally EIA was the main format for an IA. EIA was from the onset outlined as an integrated assessment tool, aiming at shedding light on all intended and unintended consequences linked to the introduction of new plans and projects. EIA quickly became a contested tool, because of the difficulties in finding a balanced way to assess all these different factors against one another. As a consequence, many specific impact assessments crystallised in their own right, such as Social Impact Assessment, Gender IA, Regulatory IA, Health IA, Strategic IA, Sustainability IA, and so forth. At the moment EU IA integrates in theory all these dimensions, but in practice this is harder.

b) Inclusion of values into assessments

Inclusion of values may mean two things. First, it may mean that ethical issues are considered alongside seemingly technical. In this sense, this point is similar to point a) above. Economists can for instance measure how important different ethical concerns are for people by using different costing methods. Second, it may also mean to include reflection on normative assumptions in the assessment. In the context of EST, where most emerging science and technologies involve both questions of facts and values, there is no value neutral grounds for assessments. Normative assumptions are made when topics for risk assessment or impact assessment are chosen, methods are applied and assessments are carried out. Integration may mean to explicate the values on which the assessment rests and place the assessment in a larger context of normative principles or theories. An example can be the decision whether synthetic biology is to be risk assessed like GMOs. This involves a decision on whether there is a morally relevant difference between ‘creating’ life and ‘changing’ life. Such a normative (even meta-ethical) judgement is relevant to make explicit in reports assessing risk management options in synthetic biology. With some exceptions, assessments outside ethics and TA did not address these dimensions.

c) Inclusion of narratives into assessments

Inclusion of narratives is a point similar to point b), but this refers less to ethics (ethical principles or ethical theories), and more to underlying stories that are told about nature, science, technology, etc. (see EST-Frame deliverable 1.3 for a more thorough account of narratives). Some call it 'lay ethics' (Dupuy 2010), normative stories told by people who do not frame their values in terms of ethical principles. All cultures have narratives. In institutionalised domains or assessment traditions, narratives may form an important part of the internal culture-building and identity-shaping. Making such stories explicit is hard. Few assessment reports will have a section on their underlying worldviews and narratives. But recipients of the reports may oppose them because they oppose the narrative they believe are underlying their approach. Indeed discussions about such assumptions have been important in the criticism against ethical assessment in 'Taking the European Knowledge Society Seriously', or the criticisms by Wickson and Wynne against risk assessment (as discussed above). Is the basic narrative that science and technology more or less working as it should, it only needs few moral corrections and technical regulation, - or more that we are on the way to destruction of the world as we know it and need fundamentally new normative frameworks and a new science (for instance post normal science, see Funtowicz and Ravetz 1993)? Self-reflection on narratives and worldviews in the assessment is a very ambitious form of integration. Moreover, one may also claim that such assumptions can only be teased out in dialogue with others, and not written as a form of a self-reporting that can be audited in an objective way. Such reflection was mostly found in foresights.

d) Not isolating one topic at the expense of the whole

This integration dimension is inherently related to anti-reductionism and the issue of problem-orientation. In the case studies we saw that there are many EST assessments focusing on general EST dimensions, such as health, safety and environmental concerns (HSE), security concerns, ethical concerns, economic projections, etc. These are important for an initial mapping of issues. We identified fewer assessments trying to tackle concrete EST related governance problems, such as specific applications in a specific geographic context. Where we did find such specific assessments, as in the case of cloud computing, we did not find a great richness in variables considered. On the contrary, we saw an unfortunate influence of the economic growth-paradigm on the degree of openness with which questions regarding broader societal desirability of the technology were posed (or rather not posed). In assessment situations closer to technological maturation, political stakes are raised and the breadth of values and voices considered tend to shrink. This may affect the possibility of responsible technology governance considering the real complexities of practical problems.

With increased practical problem-orientation comes increased complexity in variables, and problems arise of delimiting the adequate scope of assessments. A good example of this topic is the development of biofuels as an alternative to petroleum based fuels, without considering the effects in indirect land use (ILUC). After having presented biofuels as an environmental measure, it became apparent that a more complex set of environmental effects had not been considered, and that biofuels not necessarily was such an effective environmental solution. However, delimiting the right scope of the assessment is not easy, as became evident in a practical exercise on ethical assessment of genetically modified rape seed (see Forsberg 2007). GM rapeseed is a topic that can be said to involve industrial agricultural production as such, and trade restrictions on GM products may have effects on global trade. Should the assessment therefore include a comprehensive discussion of global agricultural trade? Where to draw the line in an assessment? Should only direct effects of a technology be assessed, or also secondary (or tertiary) effects? Another example, addressed in the practitioner workshop, was the case of risk assessment of Bisphenol A. Banning this substance because of its risks creates a situation where there is a risk that a different substance is taken into use instead, and this substance (though less controversial) may be more uncertain. Taking such alternatives into account is hard. Setting the right topic scope seems to be hard in all domains.

e) Explicating assessment framing

Framing in general is a difficult term, but it involves all the assumptions in an assessment, not only values, world views and topic definition (see e.g. Funtowicz 2006 and Stirling 2008, as well as EST-Frame deliverable 1.3). It may involve defining comparator technology, such as the decision whether synthetic biology should be compared with biotechnology, nanotechnology or information technology (see Torgersen and Schmidt, 2013). It may also involve decisions on appropriate experts to involve, for instance engineers or systems biologists, and decisions on what kind of scientific articles are relevant to include. Framing questions may also involve a decision on whether the topic is a topic for wider societal debate, or simply business-as-usual that can be handled in a casuist way of looking for earlier precedent cases, as well as determining what such precedent cases might be. We see that generally there is not much reflection on such framing choices in the assessment reports. Purely explorative reports may have less framing assumptions than reports trying to influence policy or reach a conclusion. Requirements on transparency in framing assumptions increase with increased (intended) policy impact.

f) Some specific elements (such as anticipation) are necessary in assessments

Some understand integration in very substantive ways. Responsible research and innovation (RRI) is a concept that gives instructions for technology assessment, and places anticipation and critical discussion of plausibility as central elements in integrated assessments (e.g. von Schomberg 2012). Anticipation is of course a crucial element in foresight, but not as an integrative element per se. Impact assessments and sustainability assessments have the triple pillars of sustainability as substantive integrative elements, but sustainability is perhaps just as much a prescription for balancing rather than a substantive principle with action guiding content (though there are sustainability approaches that pose substantive limits on acceptable solutions (see EST-Frame deliverable 1.2). However, these are not essential in IA or sustainability assessments in general. Other domains have integrative methods, such as the reflective equilibrium model in ethics, but no substantive requirement for an assessment to be integrated. One may be able to infer from different assumptions necessary elements such as anticipation, but one may also doubt whether any particular inference would be convincing to all domains. Substantive requirements for integration may instead be determined in dialogue on a case-by-case basis.

g) Targeted use of methods in assessments

A further understanding of integration comes from the TA domain, namely that an assessment can only be integrated if it is designed in a comprehensive approach that ensures that the choices of methods are not accidental, but rather a result of a comprehensive situation analysis and a systematic structure of method choice related to this situation analysis (see Decker and Ladikas 2004). Such tools are perhaps especially needed in the TA domain as this is a domain that potentially carries out assessments with all kinds of purposes and methods. There is thus a larger need for such tools than in domains, such as risk analysis, with a narrower scope, where methods and analytic variables are more limited by its very societal mandate. However, taking into account that EST may be seen to challenge established methods for risk and economic assessments, and possibly also ethical assessment, these domains may also need more systematic methodological choice and justification than for established technologies for which there is more precedence or where precedent choices are uncontroversial.

h) Integration of broader experts/stakeholders/the public into assessments

In an informal 'survey' at a workshop on integrated assessment carried out as a collaboration by EST-Frame and the EPINET project at the SNET 2012 conference we found that when asked what the audience considered the most important aspect of integration, integration of stakeholders and the public into assessment and governance was the integration dimension most frequently mentioned. This kind of wider participation is common in TA and IA, and takes place also in the other domains, but often in a more ad hoc manner. Stakeholders are generally more involved than the public. Integration as involving stakeholders and/or the public was also widely discussed in the project's practitioner workshop, where some argued that there should always be broader involvement, while others argued that this would have to depend upon the situation analysis.

i) Integration among assessments

This has been discussed above, in section 4.1, and we have seen that there are no systematic attempts at integration among assessments. Of course, politicians or policy makers may be supposed to perform this integrative function, but we have evidence that this is perhaps a too ambitious way to look at their function. From the practitioner workshop we heard that civil servants may choose to engage a familiar consultant to give such a meta-assessment of the total assessment status, and not attempt at such integration themselves. This is not surprising, as it is highly challenging to assess the different assessments, in terms of findings, methods, assumptions, participation, validity, etc. From the practitioner workshop we also saw that practitioners from different assessment domains where highly unaware of work in the other domains. We believe therefore that there is a big potential for strengthening the links between the assessments and appraising them as a body of knowledge relevant for solving complex EST governance issues.

In the practitioner workshop it was held that there is a de facto societal assessment of technologies, where individual assessment reports are part of this stream of critical, public discussion whether or not the assessments themselves are good or bad. Technology assessment should therefore been seen as a societal process, and not as something performed by separate assessment groups, ending up in reports or policy advice. We believe that such a distributed technology appraisal process (and co-creation of technology and policy) is important, but needs to be complemented by more systematic comparison and integration of assessments for policy. The workshop was an experiment in cross-domain dialogue about assessment. In this sense it could be seen as a test of the possibility of integration among assessments, through assessment dialogues. This seemed to be a successful experiment. In the final round of feedback in the workshop out of 12 out of 17 participants explicitly said that they would participate in regular cross-domain workshops for assessment reflection, and in the feedback form several participants noted that they had appreciated the occasion.

j) Integration of governance concerns into assessments

The cloud computing case study shows that assessments are integrated in terms of a “formative effect” of the cloud strategy production process. A policy strategy seems thus at an abstract level to be one of furthering conceptual integration of otherwise opposed assessment perspectives, i.e. the creation of a common ground for debate. We have found evidence that the development process leading up to the production of the European Commission's cloud computing strategy has had a formative effect on the field of assessments, that this formative effect is well known by assessment practitioners who may choose to actively position themselves (or not) according to this formation effect; that the formation effect thus acts indirectly as a mechanism for amplification (or not) of certain viewpoints and assessments perspectives in the policy making process; and that the final filter for inclusion (or not) of these viewpoints are the policy makers themselves along with the complex of staffers supporting them. A similar dynamic can be observed with regard to the land use/indirect land use issues in biofuels. For a discussion of how a wider range of governance concerns are included into assessments, please see EST-Frame deliverable 1.2 on policy trends.

k) Better integration of assessment into governance

This kind of integration is stronger in domains that have a specific governance (regulatory) function, such as risk assessment, impact assessment and, sometimes, ethical assessment. For other assessment domains impact on governance is harder to trace, as discussed above. But better integration of assessment into governance does not only mean more impact of assessments on governance. It can also mean that assessments are used in a better way in governance. This means that when potentially impacting on policy and decision making, the quality and proper place of assessments need to be appraised. As we argue in deliverable 1.3 this should be a systematic task and not done in an ad hoc way.

Based on an analysis of integration needs EST-Frame has developed a response to what we consider the most pertinent needs to address in the scope of the project. With the cross-domain starting point of this project we see our place in the interaction between the domains, and between the advisory level and the governance level, taking into account many of the dimensions above. Please see EST-Frame deliverable 1.3 for more information of the EST-Frame approach to such integrated assessment.

4.5 Methodological limitations of the study

As mentioned in section 2.1, a common methodology for the EST-Frame case and domain study execution was developed in order to make the case studies more comparable. In developing the methodology, there was a specific focus on the background of the assessments, the purpose of assessments and the processes applied in executing the assessment. In order to improve the comparability of reviews within and across the EST-Frame case studies, a ‘calibration group’ was established to align differences in understanding and scoring practices.

However, in spite of the calibration it should be clear that the reviews of the assessments are based on the assessor's judgements. Moreover, the selection of the assessments, though carefully made, will still necessarily impact on the general picture presented of the domains in this deliverable. Any selection and review of assessments has an irreducible subjective aspect, in spite of carefully developed research protocols. Because of these potential biases we have been careful to validate our findings with representatives from the field (interviews and case study workshops), and we also interpret our findings on the basis of published literature in the case study fields and in the field of technology assessment and governance in general. We believe that with this combination of evidence our reflections, conclusions, and recommendations are likely to be relevant and informative, even if they would not hold for any selection of assessments in the field.

We acknowledge that we touch upon numerous academic fields in EST-Frame, most significantly different fields within political and social sciences. There will be numerous articles, approaches and theories that are relevant perspectives to our studies in this project, and which we have not included here. This project has been practice oriented. We have not at the same time had the chance to investigate all these relevant topics also from different theoretical points of view. We encourage more studies, also of a more theoretical nature, of the topics discussed here in a practice oriented fashion. The main purpose of EST-Frame is to develop recommendations for the improvement of practice. Therefore, we will argue that the approach has been appropriate for the purpose.

The case studies were chosen to cover a wide range of assessment issues. Synthetic biology is a very early stage technology with hardly any applications to be commercialised in the short term (though synthetic biology approaches have already been used in applied research projects) and of which there is low public awareness. At the same time it is a technology with clear ethical implications, for instance with regard to 'creating life' and 'playing God'. Synthetic biology is also interesting due to the still ongoing negotiations about the identity of the technology and the relevant comparator technologies. Nanotechnology in food is a technology domain that easily evokes public concerns, due to the fact that food is loaded with both health worries and questions of identity. It also concerns important environmental issues. The same is the case of biofuels, though this is a technology (or a bundle of technologies) that are more established. Still, the technology debate is still developing, and especially the topic of sustainability and direct/indirect land use consequences makes this an interesting case study. Cloud computing, finally, is a case study of a technology that has been globally embraced with the average consumer having hardly any qualms or awareness of important security aspects, and critical scrutiny and debate being sequestered to a highly elite layer of discourse.

We believe that these four case studies together amounted to giving the project an interesting breadth of scope. However, we would encourage more case studies of assessments of also other emerging science and technologies in order to expand the knowledge base. These should include case studies also from eastern and southern Europe, and even from other continents.

Finally, as we briefly discussed above, the notion of an advisory domain is a difficult one. Moreover, one could argue for a different selection or description of these domains. For instance, are sustainability assessment or life cycle assessment parts of impact assessment, or should they be treated as separate domains? Should foresight or Future-Oriented Technology Analysis (FTA) be the overarching label for an anticipatory-explorative domain? We acknowledge that these and similar choices can be debated, but believe that we have in this study covered the most important topics related to assessment of emerging science and technologies.

5 Conclusion and recommendations

All assessment of emerging science and technology (EST) rests on the assumption that society can and ought to ensure responsible technology developments that provide societal benefits and avoid harms – in the short and long term. In the EST-Frame project we have studied within four case studies how emerging science and technologies have been assessed;

v) nanotechnology in food,
vi) synthetic biology,
vii) biofuels, and
viii) cloud computing.

We have also studied six established advisory domains: risk analysis, impact assessment, economic assessment, foresight, technology assessment (TA) and ethical assessment. All in all 1506 assessment reports have been screened and 101 reports have been reviewed according to a protocol developed for our purposes. In these studies we have found that emerging science and technologies are assessed with a great width of methods and approaches. Several advisory domains are involved in producing such assessments and many assessments or reports are produced also outside the established advisory domains. Advisory domain assessments follow the conventions of their domains, and are imprinted with the cultures and traditions of their respective domains. Theses cultural assumptions influence the framing of the assessments, the choice of methods and how the assessments are reported.

The manifold of assessments has different intended purposes and functions. They frame their topics in different ways depending on their mandate, the traditions in the domains, the impact they want to have, the participants included, etc. This means that there is a wide range of assessments answering different questions. We have found that the advisory domains generally do not make use of systematic tools for situation analysis and method choice, though some such tools may exist. The domains also generally lack standards for transparent reporting of situation analysis, including framing assumptions, method choice and the unfolding of the assessment process.

We have found that all domains have a focus on methodological development, and try to tackle the complexities and uncertainties implied by emerging science and technologies. However, they do not often discuss such challenges with practitioners from other fields. There are sometimes collaborative assessment efforts across the domains, for instance between TA offices and ethics committees. However, most often the domains do not collaborate to solve methodological challenges. Even if there are many overlaps between the domains in terms of both topics and methods, there is a lack of communication between the domains. There seems especially to be a communication gap between ethicists and economists in the context of emerging science and technologies. From the project practitioner workshop we learned that such cross-domain learning was appreciated.

Assessments from outside the established advisory domains may be just as important for policy as those from inside. However, there is a risk that these have less institutionalised mechanisms for methodological reflection and learning. Legitimacy of the input, methods and output is important for assessments coming from both inside and outside the established advisory domains. In this study we found no institutionalised mechanisms for judging the quality and legitimacy of assessments that influence policy. Moreover, there was very limited transparency with regard to the impact of the different assessments on policy.

Several integrated methods exist, but from the 101 assessments reviewed in this project, very few could be characterised as integrated on several dimensions. Moreover, for those assessments that scored high on several dimensions relevant for integration, it was generally hard (though with some notable exceptions) to trace this back to systematic methodologies. From the project practitioner workshop and from literature studies we know that there is no established understanding of what the right approach to achieving integration is. However, integration happens when translating lessons from the assessments into practical EST policy. There is evidence from the project's case studies and discussions with end users that this translation process is not entirely transparent.

In the analytic work of the project we found that there is no comprehensive acknowledgement and transparency of the value-laden assumptions underlying EST assessments. In many cases of EST there is no 'innocent' starting point for assessment; a starting point that is not contested. This applies to risk assessment, to economic assessment, and to ethical assessment alike, as well as to all other assessments.

There are many EST assessments focusing on specific EST dimensions in a general way, such as health, safety and environmental concerns (HSE), security concerns, ethical concerns, economic projections, etc. These are important for an initial mapping of issues. We identified fewer assessments trying to tackle concrete EST related policy problems, such as specific applications in a specific geographical context. With increased practical problem orientation come increased complexity in variables, as well as problems of delimiting the adequate scope of assessments. These are topics that need to be addressed in order to facilitate responsible technology governance in practice.

5.1 Recommendations for policy makers and assessment practitioners

1 Assessments should be transparent in their framing of the topic, situation analysis, method choice and practical process development. Only in this way is it possible to assess the quality and legitimacy of the assessments in their function as providing an evidence base for policy. Policy makers thus need to request such transparency. Transparency guidelines should be developed for advisory reports in general.

2 There should be increased interaction between the advisory domains in order to enhance learning and facilitate extended peer review. Such interaction should be facilitated by institutionalised instruments.

3 There should be increased focus on developing methods for tackling EST issues that have become practical policy issues. This inherently involves interdisciplinarity and broader involvement of stakeholders and/or the public. Policy makers should request such problem oriented assessment before the problems become acute.

4 In most cases, before a field of assesment reports can come to function as an evidence base for policy, some form of integration of the main lessons from these reports will be necessary. The legitimacy of this evidence base will increase when such integration is done in dialogical and problem-oriented interdisciplinary processes. Policy makers should work to institutionalise such forms of integrated assessment.

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Annex 1 Analytic tables

Table A. Process characterisation table:

Assessment [name]	Description in words	Coding
Core process characteristics		
A. Impartiality	Does the report appear well balanced? Is there well-balanced participation in the assessment? Do they explicitly address the topic of impartiality?	5: Priority in assessment 4: Efforts made to achieve 3: Dealt with sufficiently 2: Not an aim 1: Not mentioned
B. Transparency	How transparent is the process? How well characterised is the participation and procedures?	
C. Participation, experts	What role have experts had?	5: Interactive participation – used in conclusion 4: Interactive participation – not used in conclusion 3: One-directional participation – used in conclusion 2: One-directional participation – not used in conclusion 1: No participation
D. Participation, lay people	What role have lay people had?	
E. Participation, stakeholders	What role have stakeholders had?	
Core substantial characteristics		
F. Scientific evidence basis	How important is the scientific status in the assessment? To what extent is the assessment scientifically informed? Scientific here means technological/natural science knowledge.	5: Complete coverage of references; majority of references are from peer-reviewed literature 4: Majority of facts and assumptions are backed by references, generally from non-reviewed sources 3: Limited references are given; majority of references are from peer-reviewed sources 2: Limited references are given; majority of references are of from non-reviewed sources 1: No references are given related to given facts or used assumptions
G. Focus on uncertainties	To what extent are scientific uncertainties related to the technological and natural science status addressed?	
H. Explicit values/ethics	To what extent are ethical values addressed and discussed? To what extent does the assessment have an explicit value basis?	
I. Impacts considered	Are environmental (Env), social (Soc), security (Sec) and/or economic impacts (Econ) considered?	Env/Soc/ Sec/Econ
J. Retrospective/anticipatory	Is it considering the current status or considering future developments and options?	**Retrospective**: R1 (0 -5 years), R2 (0 – - 15 years), R3 (0 – > - 15 years), R – unspecified retrospective **Anticipatory**: A1 (0 - 5 years), A2 (0 – 15 years), A3 (0 – >15 years), A = unspecified anticipatory
K. Considers narratives/worldviews/visions	Does the assessment address these?	Narratives: Na / Worldviews: W / Visions: V / Scenarios: Sc
Core practical characteristics		
L. Self-reported success/efficiency	How does the report/respondent characterise the success of the assessment? High / Medium / Low	H/M/L
M. Cost	Cost: High (>€ 60 000), Medium (€25 000 – 60 000), Low (<€ 25 000)	H/M/L
Core contextual characteristics		
N. Assumes liberalisation	**RY**: Trend is explicitly discussed and the authors conclude that the trend is in play in the case **RN**: Trend is explicitly discussed and the authors conclude that the trend is not in play in the case **R?**: Trend is explicitly discussed and the authors do not know whether or not the trend is evident in the case **UY**: Trend is not explicitly discussed, but there is evidence that the authors think that the trend is in play in the case **UN**: Trend is not explicitly discussed, but there is evidence that the authors think that the trend is not in play in the case **U?**: Trend is not explicitly discussed and no indication as to its role in the case is given	RY/RN/UY/UN*
O. Assumes internationalisation		RY/RN/UY/UN*
P. Takes public/private partnerships (PPP) into account		RY/RN/UY/UN*
Q. Assumes policy integration		RY/RN/UY/UN*
R. Assumes consumer acceptance		RY/RN/UY/UN*
S. Addresses sustainability		**RY/RN/UY/UN**

Table B. Purpose analysis table:

Focus of the assessments		Role of assessment in policy making process		
		Cognitive – raising knowledge	**Normative – forming attitudes**	**Pragmatic – initialising action**
Object	**Scientific/ technological aspects**	**Scientific Assessment** a) Technical Options Assessed and Made Visible b) Comprehensive overview on consequences given	**Agenda Setting** f) Setting the agenda in the political debate g) Stimulating public debate h) Introducing visions or scenarios	**Deframing of Debate** o) New action plan or initiative to further scrutinise the problem at stake p) New orientation in policies established
	Societal aspects	**Social Mapping** c) Structure of conflicts made transparent	**Mediation** i) Self-reflection among actors j) Blockade-running k) Bridge building	**New Decision-making** q) New ways of governance introduced r) Initiative to intensify public debate taken
	Policy aspects	**Policy Analysis** d) Existing policies assessed e) Setting the agenda in the political debate	**Re-Structuring the Policy Debate** l) Comprehensiveness in policies increased m) Policies evaluated through debate n) Democratic legitimisation perceived	**Decision Taken** s) Policy alternatives filtered t) Innovations implemented u) New legislation passed

Annex 2 Agenda and participants practitioner workshop

Workshop: Assessing emerging science and technologies: learning from experience

Copenhagen, April 16 – 17 2013, Host: The Danish Board of Technology, under the auspices of the EST-Frame project, Toldbodgaden 12.

AGENDA

April 16th - Experiences

12.00 – 13.00: Lunch

13.00 – 14.00: Welcome and round around the table.

14.00 – 15.00: Introduction to EST-Frame, the findings in the project, our concepts of integration and dimensions for integrated assessment

15.00 – 15.30: Coffee

15.30 – 16.30: First group session (heterogeneous groups): All group members identify 1-2 cases they believe are examples of weakly integrated assessments:

a) For assessment practitioners: from their own assessment practice
b) For those not directly involved in assessment: problematic assessments they are aware of
NB! We are in particular interested in challenges related to achieving integration of concerns, including challenges related to communication between disciplines and between advisory or assessment domains

Each group chooses 1-2 cases and analyse the challenges on the following dimensions: communication, contextual sensitivity and method choice.

16.30 – 17.30: Second group session (new group compositions, still heterogeneous): All in the groups identify 1-2 examples of good assessments, and analyse what makes these assessments successful based on the three dimensions from the first session.

17.30 – 18.30: Plenary presentation from the groups

19.00: Dinner

April 17th - Learning

09.00 – 10.30: Third group session (back to the groups from the first group session): Applying the lessons from the good examples to the cases identified in the first group session: How could similar assessments be improved in the future?

10.30 – 11.00: Coffee and tea, refreshments

11.00 – 12.00: Presentation from the third group session

12.00 – 12.45: Final session: *Find a partner and discuss, and then individually report on your experiences from the workshop related to the following questions:*

a) *How will you use the discussions from the workshop in your practice when you go home?*
b) *What would be useful outputs from the EST-Frame project for you in your daily job?*
c) *Would you participate in regular cross-domain workshops for assessment reflection?*

12.45 – 13.00: Evaluation and closure of the workshop

13.00 – 14.00: Lunch

PARTICIPANTS

Astrid	Epp	Bundesinstitut für Risikobewertung	Germany	Risk assessment
Audrun	Utskarpen	Norwegian Biotech Advisory Board	Norway	
Davy	Van Doren	Fraunhofer ISI	Germany	EST-Frame
Ellen-Marie	Forsberg	Oslo and Akershus University College, Group for Responsible Innovation	Norway	EST-Frame
Erik	Thorstensen	Oslo and Akershus University College, Group for Responsible Innovation	Norway	EST-Frame
Gert	Johansen	Danish Nature Agency	Denmark	Impact assessment
Helge	Torgersen	Institut für Technikfolgen Abschätzung	Austria	TA
Jakob	Elster	Norwegian Research Ethics Committees	Norway	Ethics
Jean-Christophe	Pages	Haut Conseil des Biotechnologies	France	
Jessica	Thio	The Dutch Ministry of Economic Affairs	The Netherlands	Risk assessment
Karel-Herman	Haegeman	JRC - Institute for Prospective Technological Studies	European Commission	FTA
Kate	Millar	University of Nottingham, Center for Applied Bioethics	UK	EST-Frame
Kristin	Misund	Borregaard industries	Norway	Industry
Kristrun	Gunnarsdottir	Lancaster University	UK	EPINET project
Lars	Klüver	Danish Board of Technology	Denmark	EST-Frame
Marc-Jeroen	Bogaardt	LEI	The Netherlands	EST-Frame
Marian	Deblonde	VITO, Sustainable materials	Belgium	TA/ethics
Michael	Humphries	UK Department for transport	UK	
Michael	Søgaard	Aalborg Universitet	Denmark	TA
Morten	Andreasen	Danish Ethical Council	Denmark	Ethics
Nils	Heyen	Fraunhofer ISI	Germany	EST-Frame
Nina	Bryndum	Danish Board of Technology	Denmark	EST-Frame
Payam	Moula	Kungliga Tekniska Høgskolan	Sweden	
Peter	Mills	Nuffield Council for Bioethics	UK	Ethics
Philine	Warnke	Austrian Institute of Technology	Austria	Foresight
Philip	Boucher	University of Nottingham, Center for Applied Bioethics	UK	EST-Frame
Rasmus Øjvind	Nielsen	Danish Board of Technology	Denmark	EST-Frame

Ruth	Mampuys	COGEM	The Netherlands	
Stephan	Lingner	Europäische Akademie	Germany	TA
Thomas	Reiss	Fraunhofer ISI	Germany	EST-Frame
Vibeke	Dalen	Norwegian Directorate of Health	Norway	Ethics
Volkert	Beekman	LEI Wageningen	The Netherlands	EST-Frame

Annex 3 Results from assessment domains studies

Risk analysis

The assessments have been selected because they either represent a prominent assessment that has been applied to one of the case studies or they represent an important type of the method for this assessment domain, i.e. risk assessment. In terms of selection criteria, the following could be applied and one or more are applicable for each assessment selected:

- Classical application of a type of method with this domain
- High policy relevance
- High assessment relevance for specific case studies
- European/international and / or national and / or regional
- Diversity in embedded contextual characteristics

Risk analysis: Selected assessments

No	Title and details of the risk analysis assessed
1	EFSA (2011): *Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain* <http://www.efsa.europa.eu/en/efsajournal/doc/2140.pdf>
2	ENISA (2009). *Cloud computing. Benefits, risks and recommendations for information security. (including SME survey Information assurance framework)* http://www.enisa.europa.eu/activities/risk-management/files/deliverables/cloud-computing-risk-assessment
3	ENISA (2011). *Security and resilience in governmental clouds* http://www.enisa.europa.eu/activities/risk-management/emerging-and-future-risk/deliverables/security-and-resilience-in-governmental-clouds
4	International Risk Governance Council (IRGC) (2008). *Report: Risk Governance of Nanotechnology Applications in Food and cosmetics* http://www.irgc.org/IMG/pdf/IRGC_Report_FINAL_For_Web.pdf
5	International Risk Governance Council (IRGC) (2009). *Risk governance of synthetic biology* http://irgc.org/wp-content/uploads/2012/04/IRGC_Concept_Note_Synthetic_Biology_191009_FINAL.pdf

6	FAO/WHO(2010). *Expert meeting on the application of nanotechnologies in the food and agriculture sectors: potential food safety implications* http://whqlibdoc.who.int/publications/2010/9789241563932_eng.pdf
7	ADAS (2010) *Environmental risk assessment of GM crops in Scotland Prepared for: Scottish Government. Prepared for Scottish Government*. http://www.scotland.gov.uk/Resource/Doc/278281/0114282.pdf
8	California Environmental Protection Agency (2000) *Risk Assessment of Polychlorinated Biphenyls (PCBs) in Indoor Air (Report produced for the Department of Toxic Substances, US EPA)* http://www.dtsc.ca.gov/assessingrisk/upload/risk-assess-PCB.pdf
9	Hammond, G.P., Howard, H.R. and Tuck, A., (2012). 'Risk assessment of UK biofuel developments within the rapidly evolving energy and transport sectors', *Proc. Instn Mech. Engrs Part O: Journal of Risk Reliability* doi: 10.1177/1748006X12448147
10	EFSA Scientific and Technical Report (2012) *Defining Environmental Risk Assessment Criteria for Genetically Modified Insects to be placed on the EU Market* (Prepared by Mark Benedict, Michael Eckerstorfer, Gerald Franz, Helmut Gaugitsch, Anita Greiter, Andreas Heissenberger, Bart Knols, Sabrina Kumschick, Wolfgang Nentwig and Wolfgang Rabitsch) http://www.efsa.europa.eu/en/search/doc/107e.pdf
11	BFR (2006) *BfR Consumer Conference on Nanotechnology in Foods, Cosmetics and Textiles and Delphi to Experts* http://www.bfr.bund.de/cm/349/bfr_consumer_conference_on_nanotechnology_in_foods_cosmetics_and_textiles.pdf
12	SCENIHR (2009) *Risk Assessment of Products of Nanotechnology* http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf
13	RIVM (2008) *Nanotechnology in Perspective: Risks to Man and the Environment* http://www.rivm.nl/bibliotheek/rapporten/601785003.pdf
14	RIKIILT & RIVM (2008 / 2009) *Health Impact Nanotechnologies in Food Production* http://www.rivm.nl/bibliotheek/digitaaldepot/healthimpactnanotechnologies.pdf

Risk analysis: Process characterisation table

Details	Code	1: Risk	2: Risk	3: Risk	4: Risk	5: Risk	6: Risk	7: Risk	8: Risk	9: Risk	10: Risk	11: Risk	12: Risk	13: Risk	14: Risk
	Lead Author	EFSA	ENISA	ENISA	IRGC - nano	IRGC - synthbio	FAO/WHO	ADAS	Davis et al	Hammond, Howard & Tuck	UBA/ EFSA	BFR	SCENIHR	RIVM	RIKILT / RIVM
	Year	2011	2009	2011	2008	2009	2010	2010	2002	2012	2012	2006	2009	2008	2008/09
	Assessed by	HB	HB		KK			RDJS	RDJS	RDJS	RDJS				
PROCESS CHARACTERISATION															
Core process characteristics	A. Impartiality	6	6	3	4	6	6	4	4	6	6	6	4	4	4
	B. Transparency	5	3	3	4	3	5	5	4	5	5	4	4	4	4
	C. Participation, experts	6	6	6	6	6	6	5	4	6	6	6	6	4	4
	D. Participation, lay people	1	1	1	1	1	1	1	1	1	1	6	1	1	1
	E. Participation, stakeholders	1	2	2	1	1	1	1	1	3	1	5	1	1	1
Core substantial characteristics	F. Scientific evidence basis	6	6	4	6	6	6	4	3	6	6	6	6	6	6
	G. Focus on uncertainties	5	1	5	5	5	2	4	1	4	3	2	4	5	5
	H. Explicit values/ethics	1	1	1	3	5	1	1	1	3	1	1	1	1	1
	I. Impacts considered	Health	Soc, Econ	Econ, Soc	Env, Soc, Soc	Env, Soc, Soc	Health	Env	Health	Env, Econ,Soc	Env, Health	Ec, Health	En	En, So, Health	So, Health
	J. Retrospective/ anticipatory	A1	R1, A1	A1	A2	A3	A1	A2		A	A2		A	A	A
	K. Considers narratives/ worldviews/visions			Vi											
Core practical characteristics	L. Self reported success/efficiency														
	M. Cost		M			Vi									
Core contextual characteristics	N. Assumes liberalisation		RY	RY	RY	R?	UN	U?	U?	U?	U?	U?	U?	UY	RY
	O. Assumes internationalisation	UY	RY	UY	RY	R?	RY	R?	U?	R?	U?	U?	U?	UY	RY
	P. Takes public/ private partnerships into account		UN	UN	RY	U?	U?	U?	U?	U?	U?	U?	U?	U?	U?
	Q. Assumes policy integration	UN	UN	UN	?	RY	U?	RY	U?	RY	U?	U?	U?	UY	RY
	R. Assumes consumer acceptance		UN	UY	RN	U?	RN	U?	U?	R?	U?	RY	U?	UY	UY
	S. Considers sustainability	UY	UN	UN	RY	RY	U?	U?	U?	RY	U?	UN	UY	U?	U?

Risk analysis: Purpose analysis table

<table>
<tr><td colspan="2" rowspan="2">Focus of the advisory domain assessments (Risk analysis)</td><td colspan="3">Role of assessment in policy making process</td></tr>
<tr><td>Cognitive – raising knowledge</td><td>Normative – forming attitudes</td><td>Pragmatic – initialising action</td></tr>
<tr><td rowspan="3">Object</td><td>Scientific/ technological aspects</td><td>a): 2,3,7,11,13,14
b): 2,3,6,7,8,9,10,11,12,13,14
TOTAL: 11</td><td>f): 7,8,9,13,14
g): 6,11
h):1,2,3,5
TOTAL: 11</td><td>o): 1,2,13
p):
TOTAL: 3</td></tr>
<tr><td>Societal aspects</td><td>c):10
TOTAL: 10</td><td>i):
j):9
k):
TOTAL: 1</td><td>q): 3,4,5,13
r):6
TOTAL: 5</td></tr>
<tr><td>Policy aspects</td><td>d):13,14
e): 2,4,5,14
TOTAL: 5</td><td>l): 13
m):
n):
TOTAL: 1</td><td>s):
t):
u):
TOTAL: 0</td></tr>
</table>

Impact assessment

Six relevant Impact Assessments done recently related to different policy instruments used by the European Commission were selected for analysis. The EU Impact Assessments picked out for analysis in the Purpose and Process tables were chosen by one of the following two criteria:

1) The impact assessment should assess an emerging technology as closely related to the technologies chosen for the case studies in the EST-Frame Project.

2) It should assess the political agendas and strategies for supporting emerging science and technology as expressed by the different policies on science, research and technology in the EU

Impact assessment: Selected assessments

The chosen impact assessments

No	Title and details of the impact assessements assessed
1	European Commission (2011). *Impact Assessment accompanying the Commission Proposal on a Regulation on: Horizon 2020 – The Framework Program for Research and Innovation* http://ec.europa.eu/research/horizon2020/pdf/proposals/horizon_2020_impact_assessment_report.pdf
2	European Commission (2012 a). *Impact Assessment accompanying the Commission Communication on: Reinforced European Research Area Partnership for Excellence and Growth* http://ec.europa.eu/research/era/pdf/era-communication/era-impact-assessment_en.pdf
3	European Commission (2012b). *Impact Assessment accompanying the Commission Proposal on amending the Directives on: Indirect Land-use change related to Biofuels and Bioliquids from 1998 and 2009*
4	European Commission (2012c). *Impact Assessment accompanying the Commission Communication on: Renewable energy: a major player in the European energy market* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0149:FIN:EN:PDF
5	European Commission (2012d). *Impact Assessment accompanying the Commission Proposal on amending the Regulation and the Directive on: General Data Protection from 1995* http://ec.europa.eu/justice/data-protection/document/review2012/sec_2012_72_en.pdf
6	European Commission (2012e). *Impact Assessment accompanying the Commission Proposal for a Regulation on: Electronic identification and trust services for electronic transactions in the internal market* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0135:FIN:EN:PDF

Impact assessment: Process characterisation table

Details	Code	1	2	3	4	5	6
	Lead Author	European Commission: DG RTD	European Commission:DG RTD	EC: DG ENER & DG CLIMA	EC: DG ENER	EC: DG JUST	EC:DG INFSO
	Year	2011	2012	2012	2012	2012	2012
	Assessed by	NB	NB	NB	NB	NB	NB
PROCESS CHARACTERISATION							
Core process characteristics	A. Impartiality	3	4	5	4	5	3
	B. Transparency	4	4	5	4	4	2
	C. Participation, experts	4	5	5	5	4	4
	D. Participation, lay people	2	5	2	5	4	4
	E. Participation, stakeholders	4	5	5	5	4	4
Core substantial characteristics	F. Scientific evidence basis	4	4	5	4	3	4
	G. Focus on uncertainties	4	3	5	5	4	4
	H. Explicit values/ethics	5	3	5	4	4	1
	I. Impacts considered	Env, Econ, Soc, Sec	Env, Econ, Soc	Env, Econ, Soc	Env, Econ, Soc	Econ, Soc	Env, Econ, Soc
	J. Retrospective/ anticipatory	R2, A2	R2, A2	R2, A3	R1, A3	R2, A3	R2, A3
	K. Considers narratives/ worldviews/visions/Scenario			SC	SC	SC	SC
Core practical characteristics	L. Self reported success/efficiency						
	M. Cost		RN	RN		RY	RY
Core contextual characteristics	N. Assumes liberalisation	RY	RY	RY	RY	RY	RY
	O. Assumes internationalisation	RY	RY	RY	RY	RY	RY
	P. Takes public/ private partnerships into account	RY	RY	R?	U?	U?	U?
	Q. Assumes policy integration	RY	RY	RY	RY	RY	RY
	R. Assumes consumer acceptance			RY	RY	RY	RY
	S. Considers sustainability	RY	RY	RY	RY	U?	U?

Impact assessment: Purpose analysis table

<table>
<tr><td colspan="2" rowspan="2">Focus of the advisory domain assessments (Impact assessment)</td><td colspan="3">Role of assessment in policy making process</td></tr>
<tr><td>Cognitive – raising knowledge</td><td>Normative – forming attitudes</td><td>Pragmatic – initialising action</td></tr>
<tr><td rowspan="3">Object</td><td>Scientific/ technological aspects</td><td>a): 3,4
b):3
TOTAL: 2</td><td>f):
g):
h): 1,2,3,4,5,6
TOTAL: 6</td><td>o): 1,3,5,6
p):
TOTAL: 4</td></tr>
<tr><td>Societal aspects</td><td>c):
TOTAL: 0</td><td>i):
j):
k): 1,2,4
TOTAL: 3</td><td>q): 1
r):
TOTAL: 1</td></tr>
<tr><td>Policy aspects</td><td>d): 1,2,3,4,5,6
e): 1,2,3,4,5,6
TOTAL: 6</td><td>l):
m): 2,3,5
n):
TOTAL: 3</td><td>s):3
t):
u):
TOTAL: 1</td></tr>
</table>

Economic assessment

Economic assessment: Selected assessments

- Diversity, assessments from different methods are chosen
- High policy relevance
- Germany AND EU

No	Title and details of the economic assessments assessed
1	*Cost-Benefit Analysis*: Bundesministeriums für Umwelt (2010). Naturschutz und Reaktorsicherheit *Einzel- und gesamtwirtschaftliche Analyse von Kosten- und Nutzenwirkungen des Ausbaus Erneuerbarer Energien im deutschen Strom- und Wärmemarkt* (Economic evaluation of costs and benefit effects of RE expansion in the German electricity and heat sector) http://www.bmu.de/fileadmin/bmu-import/files/pdfs/allgemein/application/pdf/endbericht_ausbau_ee_2009.pdf
2	*Techno-economic assessments:* The BREW Project (2006). *Medium and Longterm Opportunities and Risks of the Bio-technological Production of Bulk Chemicals from Renewable Resources – The Potential of White Biotechnology* http://www.bio-economy.net/applications/files/Brew_project_report.pdf
3	*Economic Value Assessment*: Oakdene Hollins (2010) *A comparative methodology for estimating the economic value of innovation in nanotechnologies* http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&Completed=0&ProjectID=17332
4	*Indicator Analysis:* ETEPS (European Techno-Economic Policy Support Network) (2006). *Consequences, Opportunities and Challenges of Modern Biotechnology for Europe (BIO4EU)* http://www.isi.fraunhofer.de/isi-media/docs/t/de/publikationen/Bio4EU-modern-biotechnology-for-europe.pdf
5	*Econometric analysis/CGE-models/Statistical analysis*: Centre for Economic Performance (2010). *The Economic Impact of ICT* https://ec.europa.eu/digital-agenda/en/news/economic-impact-ict-smart-20070020

6	*Input-Output model*: Nusser M.; Sheridan, P.; Walz, R.; Wydra, R. & Seydel, P. (2007) *Makroökonomische Effekte Nachwachsender Rohstoffe* (Macroeconomic Effects of Renewables) http://ageconsearch.umn.edu/bitstream/96748/2/3_Nusser.pdf
7	*Other models*: Study for the Committee on Employment and Social Affairs of the European Parliament (2002). *Impact of Structural Change and Technology on Employment* http://www.mcrit.com/espon_scenarios/files/DOCUMENTS/eur20258en.pdf
8	*Other models*: Etro, F. (2011). The economics of cloud computing. Retrieved from http://www.intertic.org/Policy%20Papers/Report.pdf

Economic assessment: Process characterisation table

Details	Code	1	2	3	4	5	6	7	8
	Lead Author	BfU	BREW	Oakdene Hollins	ETEPS	CEP/LSE	Nusser et al	IPTS – ESTO	Intertic, Etro
	Year	2010	2006	2010	2006	2010	2007	2002	2009/201
	Assessed by	ISI	ISI	ISI	ISI	ISI	ISI	ISI	DBT / RN
PROCESS CHARACTERISATION									
Core process characteristics	A. Impartiality	3	3	2	3	4	3	2	2
	B. Transparency	4	4	5	4	4	3	3	3
	C. Participation, experts	3	5	5	5	1	3	4	1
	D. Participation, lay people	1	1	1	1	1	1	1	1
	E. Participation, stakeholders	1	4	4	3	1	1	1	1
Core substantial characteristics	F. Scientific evidence basis	4	5	3	4	2	3	3	3
	G. Focus on uncertainties	3	4	1	3	1	2	2	2
	H. Explicit values/ethics	1	4	1	3	1	1	1	1
	I. Impacts considered	En, Ec, So, Se	En, Ec, So	Ec	En, Ec, So	Ec, So	En, Ec	Ec	Econ
	J. Retrospective/ anticipatory	R (A)	A	A	R,A	R	R,A	A	A1
	K. Considers narratives/ worldviews/visions		Vi, (Wo)				Vi	Vi	
Core practical characteristics	L. Self reported success/efficiency	H	H	H	H	H	H	H	
	M. Cost	H	H	H	H	H	H	H	
Core contextual characteristics	N. Assumes liberalisation	RN	UY	UY	RN	RN	RN	RN	UY
	O. Assumes internationalisation	RN	RY	RY	RY	RY	RY	RY	UY
	P. Takes public/ private partnerships into account	N/A	N/A	N/A	N/A	N/A	N/A	N/A	UN
	Q. Assumes policy integration	(RY)	N/A	N/A	N/A	N/A	N/A	N/A	UN
	R. Assumes consumer acceptance	UY	UY	UY	RY	UY	UY	UY	UY
	S. Considers sustainability								UN

Economic assessment: Purpose analysis table

Focus of the advisory domain assessments (Economic Assessments)		Role of assessment in policy making process		
		Cognitive – raising knowledge	Normative – forming attitudes	Pragmatic – initialising action
Object	Scientific/ technological aspects	a):2,3,(4),6,7 b):1,2,3,4,5,6,7 **TOTAL: 7**	f):1,(2),(3),4,8 g):1,4,(5),(7) h):2,6,7 **TOTAL: 6 (8)**	o): p):1,(2),(3),(5),(6),(7) ,8 **TOTAL: 2 (7)**
	Societal aspects	c):1 **TOTAL: 1**	i): (1) j): k): (1) **TOTAL: (1)**	q): r):4 **TOTAL: 1**
	Policy aspects	d):1,(2),5,7 e): (2),(4),5,6,7 **TOTAL: 4 (6)**	l): 5,7 m): n): **TOTAL: 2**	s): (7) t): (3) u): **TOTAL: (2)**

Ethical assessment

Ethical assessment: Selected assessments

No	Title and details of the ethical assessments assessed
1	The Norwegian Directorate of Health (2011). *Evaluation of the Norwegian Law on Human Biotechnology,* http://www.helsedirektoratet.no/publikasjoner/evaluering-av-bioteknologiloven-status-og-utvikling-pa-fagomradene-som-reguleres-av-loven/Publikasjoner/evaluering-av-bioteknologiloven-status-og-utvikling-p%C3%A5-fagomr%C3%A5dene-som-reguleres-av-loven.pdf
2	The Norwegian Biotechnology Advisory Board (2011) *Comments on the Evaluation of the Law on Biotechnology* http://www.bion.no/filarkiv/2011/12/bioteknologiloven_evaluering_Bioteknologinemnda.pdf
3	European Group on Ethics in Science and New Technologies to the European Commission (EGE) (2012). *Ethics of information and communication technologies, Opinion no. 26, 2012* http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion_27_iea__2013.pdf
4	European Group on Ethics in Science and New Technologies to the European Commission (EGE) (2009). *Ethics of synthetic biology, Opinion no. 25, 2009* http://ec.europa.eu/bepa/european-group-ethics/docs/opinion25_en.pdf
5	Nuffield Council on Bioethics (2012). *Emerging biotechnologies: technology, choice and the public good,* http://www.nuffieldbioethics.org/sites/default/files/Emerging_biotechnologies_full_report_web_0.pdf
6	Presidential Commission for the Study of Bioethical Issues (2010). *The Ethics of Synthetic Biology and Emerging Technologies* http://www.bioethics.gov/documents/synthetic-biology/PCSBI-Synthetic-Biology-Report-12.16.10.pdf
7	Nuffield Council on Bioethics (2011). *Biofuels: ethical issues* http://www.nuffieldbioethics.org/sites/default/files/Biofuels_ethical_issues_FULL%20REPORT_0.pdf
8	UNESCO (2006). *The Ethics and Politics of Nanotechnology* http://unesdoc.unesco.org/images/0014/001459/145951e.pdf

9	Comité Consultatif National d'Ethique pour les Sciences de la Vie et de la Santé (CCNE) (2007). *Questions éthiques posées par les nanosciences, les nanotechnologies et la santé*, http://www.ccne-ethique.fr/docs/fr/avis096.pdf
10	UNESCO (2007). *Ethical Implications of Emerging Technologies: A Survey* http://unesdoc.unesco.org/images/0014/001499/149992e.pdf
11	Comitato Nazionale per la Bioetica (2006). *Nanoscienze e Nanotecnologie* , http://www.governo.it/bioetica/testi/nanoscienze_nanotecnologie.pdf

Ethical assessment: Process characterisation table

Details	Code	1	2	3	4	5	6	7	8	9	10	11
	Lead Author	Directorate of Health	Biotechnology Advisory Board	EGE ICT	EGE Synthetic biology	Nuffield Council on Bioethics	US Bioethics	Nuffield Council on Bioethics	UNESCO	CCNE	UNESCO	Bioetica
	Year	2011	2011	2012		2012	2010	2011	2006	2007	2007	2006
	Assessed by	Erik Th	Erik Th	Tekno.dk	ISI	Erik Th	Erik TH	PB - Unott	Erik Th	Erik Th	Erik Th	Erik Th
PROCESS CHARACTERISATION												
Core process characteristics	A. Impartiality	4	4	4	4	5	5	4	3	4	5	4
	B. Transparency	3	2	3	3	5	4	4	2	3	3	3
	C. Participation, experts	5	5	5	5	5	5	5	2	5	3	5
	D. Participation, lay people	2	2	1	1	2	2	4	1	1	1	1
	E. Participation, stakeholders	2	2	3	3	5	3	5	1	1	1	1
Core substantial/ characteristics	F. Scientific evidence basis	5	4	3	3	5	5	5	2	4	3	5
	G. Focus on uncertainties	3	3	5	5	5	3	4	2	3	1	5
	H. Explicit values/ethics	4	5	5	5	5	5	5	4	5	4	5
	I. Impacts considered	Soc, Econ	Soc, HS	Econ, Soc, Env, Sec	Env, Soc, Sec	Econ, Soc, Env, Sec	Econ, Soc, Env, Sec	Soc, Env, Econ, Sec	Econ, Soc	Env, Soc, Sec	Soc, Sec	Econ, Soc, Env, Sec
	J. Retrospective/ anticipatory	R2	R2, A1	R, A	R, A	R3, A3	R2, A1	R1, A1	R1	A1	R1, A1	R1, A1
	K. Considers narratives/ worldviews/visions				Wo	Na, Vi		/	Vi	Na		
Core practical characteristics	L. Self reported success/efficiency							/				
	M. Cost			M, H	M, H	M, H	M, H	/	L	L	L	L
Core contextual characteristics	N. Assumes liberalisation	UY	RY	RY	RY	RY	R?	UN	UY	UY	Ry	RY
	O. Assumes internationalisation	RY	RY	RY	RY	RY	R?	UY	RY	UY	Ry	UY
	P. Takes public/ private partnerships into account	U?	UY	UN	UN	RN	UY	U?	UN	UN	U?	U?
	Q. Assumes policy integration	RY	RY	UN	UY	RY	RY	RY	RY	UN	RY	UN
	R. Assumes consumer acceptance	RY	RY	UY	RN	RY	RN	U?	U?	UY	UY	UN
	S. Considers sustainability	U?	U?			RY	UN	RY	UN	RY	UN	RY

Ethical assessment: Purpose analysis table

Focus of the advisory domain assessments (Ethical assessment)		Role of assessment in policy making process		
		Cognitive – raising knowledge	Normative – forming attitudes	Pragmatic – initialising action
Object	Scientific/ technological aspects	a): 3,7 b): 2,3,6,7 **TOTAL: 4**	f):1,2,3,4,5,6,7,8,9,10,11 g):2,3,4,5,6,9,11 h): 7,8,11 **TOTAL: 11**	o): 2,3,4,5,6,7,9,10 p): 1,2,5,7 **TOTAL: 9**
	Societal aspects	c):8 **TOTAL: 1**	i): 1,5,6 j): 5,9,11 k): 5,6,9 **TOTAL: 4**	q): 3,4,5,7,10 r): 1,3,4,5,6,9,10,11 **TOTAL: 9**
	Policy aspects	d): 3,4,5,7 e): 1,2,3,4,5,6,7 **TOTAL: 7**	l): 1,2,5,6,7 m):5 n): 5 **TOTAL: 5**	s): 2,5,7,9 t): u): **TOTAL: 4**

Foresight

- High policy relevance
- European/international AND national AND regional
- Diversity: quantitative AND qualitative
- Diversity: participatory/discursive AND non-participatory/non-discursive

Foresight: Selected assessments

No	Title and details of the foresights assessed
1	Fraunhofer Institute for System and Innovation Research (2005). *Manufacturing Visions – Integrating Diverse Perspectives into Pan-European Foresight (ManVis)* http://foresight.jrc.ec.europa.eu/documents/Final_Report_final.pdf
2	EU DG Research (EUROPEAN COMMISSION Directorate-General for Research and Innovation) (2012). *Global Europe 2050 – Foresight Report* http://ec.europa.eu/research/social-sciences/pdf/global-europe-2050-report_en.pdf
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7	Fraunhofer Institute for System and Innovation Research (2012). *GHG-TransPoRD – Reducing Greenhouse-Gas Emissions of Transport beyond 2020: Linking R&D, Transport Policies and Reduction Targets* http://www.ghg-transpord.eu
8	NFR (The Research Council of Norway) (2007). *Foresight biofuels and bioenergy* http://www.forskningsradet.no/prognett-renergi/Foresight/1253962202919

9	UNCTAD (United Nations Conference on Trade and Development) (2009). *The Biofuels Market: Current Situation and Alternative Scenarios* http://unctad.org/en/Docs/ditcbcc20091_en.pdf
10	Scarlat, N., Dallemand, J.-F., & Banja, M. (2013). Possible impact of 2020 bioenergy targets on European Union land use. A scenario-based assessment from national renewable energy action plans proposals. *Renewable and Sustainable Energy Reviews*, 18, 595–606. doi:10.1016/j.rser.2012.10.040
11	World Economic Forum (WEF) & Accenture (2010). *Exploring the future of cloud computing: Riding the next wave of technology-driven transformation* http://www3.weforum.org/docs/WEF_ITTC_FutureCloudComputing_Report_2010.pdf

Foresight: Process characterisation table

Details	Code	1	2	3	4	5	6	7	8	9	10	11
	Lead Author	Frauenhofer ISI	EU DG Research	Frauenhofer ISI	BfBF	Frauenhofer ISI	Fazit Forschung	Frauenhofer ISI	NFR	UNCTAD	Scarlat / Dallemand / Banja	WEF & Accenture
	Year	2005	2012	1998	2003	2009	2005-2010	2012	2007	2009	2013	2010
	Assessed by	ISI	ISI	ISI	ISI	ISI	ISI	ISI	OAUC	UNOTT	UNOTT	DBT
PROCESS CHARACTERISATION												
Core process characteristics	A. Impartiality	5	4	5	3	5	4	5	2	5	4	4
	B. Transparency	5	4	4	3	3	5	5	2	5	5	3
	C. Participation, experts	5	5	5	2	4	4	5	5	2	2	5
	D. Participation, lay people	1	1	2	4	1	3	1	1	1	1	2
	E. Participation, stakeholders	3	3	5	3	4	5	5	5	1	1	4
Core substantial/ characteristics	F. Scientific evidence basis	4	5	4	1	4	5	4	2	4	5	4
	G. Focus on uncertainties	5	5	1	1	1	5	5	1	2	2	5
	H. Explicit values/ethics	3	3	2	1	3	3	3	1	2	1	1
	I. Impacts considered	En/So/Ec	En/So/Se/ Ec	En/So/Se/ Ec	En/So/Se/ Ec	En/So/Se/ Ec	En/So/(Se)/ Ec	En/So/Ec	Ec. En, So	Env, Econ	Env, Econ	En, So, Se, Ec
	J. Retrospective/ anticipatory	A	A	A	A	A	A	A	A	A3	R1, A3	A
	K. Considers narratives/ worldviews/visions	Na/Vi	Na/ Wo/ Vi	(Na)/Vi	Na/Vi	Na	N/A	Vi	Vi	/	/	
Core practical characteristics	L. Self reported success/efficiency	M	M	H	L	H	H	H	?	/	/	
	M. Cost	H	L	H	H	H	H	H	M	/	/	H/M
Core contextual characteristics	N. Assumes liberalisation	RY/ RN	RY/ RN	UY	N/A	N/A	N/A	RN	?	RY	RN	RY
	O. Assumes internationalisation	RY/ RN	RY/ RN	RY	N/A	N/A	RY	RY	RY	RN	RN	RY
	P. Takes public/ private partnerships into account	N/A	RY	UN	UY	UY	N/A	N/A	UY	U?	U?	RY
	Q. Assumes policy integration	RY/ RN	RY/ RN	UY	N/A	RY	UY	RY	UN	U?	U?	RY
	R. Assumes consumer acceptance	RY/ RN	RY/ RN	RY	RY	UY	RY	RY	RY	U?	U?	RY
	S. Considers sustainability											RY

Foresight: Purpose analysis table

Focus of the advisory domain assessments (Foresights)		Role of assessment in policy making process		
		Cognitive – raising knowledge	Normative – forming attitudes	Pragmatic – initialising action
Object	Scientific/ technological aspects	a): 1, 3, 4, 5, 6, 10, 11 b): 3, 4, 5, 6, 7, 10, 11 **TOTAL: 8**	f): 1, 3, 4, 5, 11 g): 1, 2, 3, 4, 7 h): 1, 2, 3, 4, 6, 7, 8, 10 **TOTAL: 10**	o): 1, 3, 4, 11 p): 1, 4, 5 **TOTAL: 5**
	Societal aspects	c): 4, 5, 6, 7, 11 **TOTAL: 5**	i): j): k): 4, 5 **TOTAL: 2**	q): r): 4 **TOTAL: 1**
	Policy aspects	d): 2, 5, 6, 9, 10 e): 2, (3), 7, 9 **TOTAL: 6 (7)**	l): 2, 4, 5, 7, 9, 11 m): 3 n): 3, 4 **TOTAL:7**	s): 2, 3, 4, 5 t): 7 u): **TOTAL: 5**

Technology assessment

Technology assessment: Selected assessments

No	Title and details of the technology assessment assessed
1	TA-Swiss (2009) *Nanotechnology in the Food Sector* http://www.europarl.europa.eu/RegData/etudes/etudes/join/2009/424755/IPOL-JOIN_ET%282009%29424755_EN.pdf
2	Rathenau (R. van Est, H. de Vriend and B. Walhout) (2007), *Constructing life: the world of synthetic biology*, http://www.synbiosafe.eu/uploads///pdf/BAP_Synthetic_biology_nov2007%5B1%5D.pdf
3	Rathenau (Est, R. van, B. Walhout) (2007). *Verslaglegging workshop nanovoedselveiligheid* (Reporting workshop nano foodsafety; in Dutch), http://www.rathenau.nl/uploads/tx_tferathenau/Verslaglegging_workshop_Nanovoedselveiligheid_13_juni_2007.pdf.
4	Schubert, L. (2011), *The Future of Cloud Computing – Opportunities for European Cloud Computing Beyond 2010*, European Commission, Expert Group Study. http://cordis.europa.eu/fp7/ict/ssai/docs/cloud-report-final.pdf
5	Friedwald et. al. (2010), Ubiquitäres Computing. Das ”Internet der Dinge”- Grundlagen, Anwendeungen, Folgen. Studien des Büros für Technikfolgen-Abschätzung beim Deutschen Bundestag – 31. Edition Sigma, Berlin. http://www.tab-beim-bundestag.de/de/pdf/publikationen/buecher/UbiComp-Bd31.pdf
6	Robinson et. al. 2011, *The Cloud: Understanding the Security, Privacy and Trust Challenges,* RAND Corporation, http://cordis.europa.eu/fp7/ict/security/docs/the-cloud-understanding-security-privacy-trust-challenges-2010_en.pdf
7	The Danish Board of Technology (2011): Workshop: Tingenes Internet (the Internet of Things) http://www.tekno.dk/subpage.php3?page=podcast/2011_10_06.php&toppic=oplysning#top
8	UK POST (2011), Cyber Security in the UK. POSTNOTE 389. Houses of Parliament, Parliamentary Office of Science and Technology http://www.parliament.uk/business/publications/research/briefing-papers/POST-PN-389
9	ETAG (201X). Potential and impacts of Cloud Computing Services and Social Network Sites (under study)

Technology assessment: Process characterisation table

Details	Code	1	2	3	4	5	6	7	8	9
	Lead Author	TA-Swiss	Rathenau	Rathenau	Schubert, EC Expert Group	TAB / Friedwald	RAND, Robinson	Danish Board of Technology	UK POST	ETAG
	Year	2009	2007	2007	2010	2010	2011	2011	2011	201-
	Assessed by	DBT	DBT	DBT	DBT	DBT	DBT	DBT	DBT	DBT
PROCESS CHARACTERISATION										
Core process characteristics	A. Impartiality	5	4	3	4	5	5	4	5	5
	B. Transparency	5	4	4	2	3	5	4	2	4
	C. Participation, experts	5	1	4	5	1	1	4	1	3
	D. Participation, lay people	1	1	1	1	1	1	4	1	1
	E. Participation, stakeholders	5	1	4	1	1	4	4	1	2
Core substantial characteristics	F. Scientific evidence basis	4	5	3	5	5	5	3	4	5
	G. Focus on uncertainties	5	5	4	5	3	5	5	2	5
	H. Explicit values/ethics	5	5	2	1	1	5	3	1	1
	I. Impacts considered	Env, Econ, Soc, Sec	Env, Soc, Sec, Hs	Env, Soc, Hs	Econ, Sec, Env	Sec, Econ	Sec, Econ	Econ, Sec, Soc	Sec	Econ, Sec, Soc
	J. Retrospective/ anticipatory	A	A	?	A3	R2, A1, A3	A2	A1, A2	A1, A2	R1, A1, A2
	K. Considers narratives/ worldviews/visions	Vi	-	Vi		Vi	Na	Hy		Na
Core practical characteristics	L. Self reported success/efficiency	H	M	H		?		M	?	?
	M. Cost	?	M	L	H	M		L	?	H
Core contextual characteristics	N. Assumes liberalisation	RY	RY	RY	RY	RY	UY	UY	?	RY
	O. Assumes internationalisation	RY	RY	UY	RY	RY	UY	RY	UY	RY
	P. Takes public/ private partnerships into account	RY	UN	?	UN	UN	UY	UN	UN	RY
	Q. Assumes policy integration	UN	UN	UY	RY	RY	RN	UY	UY	RY
	R. Assumes consumer acceptance	RN	UN	RY	UY	RN	RN	RN	?	RN
	S. Considers sustainability	?	UN	RN	RY	UN	UN	RY	UN	RY

Technology assessment: Purpose analysis table

Focus of the advisory domain assessments (Technology assessment)		Role of assessment in policy making process		
		Cognitive – raising knowledge	Normative – forming attitudes	Pragmatic – initialising action
Object	Scientific/ technological aspects	a): 1,2,4,5,6,7,8,9 b): 4,5,8,9 **TOTAL: 8**	f): 1,2,3,4 g): 2,7 h): **TOTAL: 5**	o): 2,4 p): 6 **TOTAL: 3**
	Societal aspects	c): 1,2,3,6 **TOTAL: 4**	i):7 j): k): 3 **TOTAL: 2**	q):2 r): 2 **TOTAL: 1**
	Policy aspects	d): 2,3,8,9 e): 5,6 **TOTAL: 6**	l): 1,2,3,5,6 m): n): **TOTAL:5**	s): 2,4 t): u): **TOTAL: 2**