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Working Party on Biotechnology, Nanotechnology and Converging Technologies

Nine Technology Assessment Case Studies

Annex to the policy report "Technology assessment for emerging technology: Meeting new demands for strategic intelligence"

During 2021 and 2022, the Working Party on Biotechnology, Nanotechnology and Converging Technology (BNCT) animated and expert group composed of TA practitioners from dedicated TA agencies and from science and technology institutes where TA is practised, providing nine case studies as examples of TA in their respective countries.

This report provides these nine case studies as an annex to the policy report entitled "Technology assessment for emerging technology: Meeting new demands for strategic intelligence."

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Annex: Nine Technology Assessment Case Studies

Technology Assessment (TA) is an evidence-based, interactive process to bring to light the societal, economic, environmental, and legal aspects and consequences of new and emerging science technologies. In doing so, it informs public opinion, helps direct research and development, and acts as a source of strategic intelligence to shape policies that both promote and govern new and emerging technologies.

During 2021 and 2022, the BNCT animated an expert group, composed of TA practitioners from dedicated TA agencies and from science and technology institutes where TA is practised, provided a number of cases studies as examples of TA in their respective countries. Rather than seek a comparative case study approach, case selection focused on diversity and complementarity to illustrate the various facets of contemporary TA.

Supported by some case study guidelines (see Table 2 on the following page), nine case studies were explored—the resulting case study reports can be found in this annex and are listed, in order of appearance in Table 1 below. This is an annex to the full policy report *Technology assessment for emerging technology: Meeting new demands for strategic intelligence*.

Table 1. List of case studies

Case study title	Authors	Institute	Country
NANOTRUST	André Gazsó, Gloria Rose, Anna Pavlicek and Daniela Fuchs	Institute of Technology Assessment (ITA) / Austrian Academy of Science (ÖAW)	AT
STOA genome editing in crops	Lieve Van Woensel and Virginia Mahieu	Science and Technology Options Assessment (STOA) / European Parliament	BE
DNA dialogue	Jeroen Gouman	Rathenau Instituut	NL
Value-directed AI	Petra Verhoef, Linda Kool and Rinie van Est	Rathenau Instituut	NL
Industry & Manufacturing Agenda 2030	Luis Viseu Melo	Instituto Superior Técnico (IST)	PT
Biotechnology Assessment in Korea	Jiyoung Suh	Science and Technology Policy Institute (STEPI)	ROK
Novel and Exceptional Technology and Research Advisory Committee (NExTRAC)	Irene Gadani	National Institutes of Health (NIH)	US
GAO's Assessment of Vaccine Development Technologies	Sarah Harvey	Government Accountability Office (GAO)/Science, Technology Assessment, and Analytics (GAO-STAA)	US

The National Nanotechnology Initiative's Strategic Planning Process	Lisa Friedersdorf	National Nanotechnology Initiative (NNI) / National Nanotechnology Coordination Office (NNCO)	US

Table 2. Case study guidelines

Theme	Key questions	Examples
Section 1: TA topic, Purpose and Audience		
Technology area	Which technology? What level of maturity? What are the envisioned application areas? Is it an enabling technology or application specific?	Quantum computing (very early stage with a range of applications), 3D bioprinting (first demonstrations focused on health, cosmetic and pharma industries), Lab-on-a-chip (first products on market, a platform technology with many applications)
Technology Assessment agency or organizer	Who is the lead organizer and main responsible for the assessment?	Ministry, Public Research Organization, Parliament, Non-Governmental Organization, Intermediary Organizations, Technology Assessment Agency, etc.
Initiating factors	Why was the Technology Assessment initiated?	TA to *gauge public perceptions* of risks and ethical concerns on a particular technology. *Create shared research and innovation agendas* through anticipating desirable and undesirable developments of a particular technology domain. *To steer research and innovation activities towards a particular societal challenge or mission*.
Envisioned outcome	What are the main goals of the TA? Are the objectives clearly defined upfront or is the exercise explorative?	Identify potential ethics risks of emerging technology (e.g., 3D bioprinting), anticipating innovation challenges in upscaling (e.g., nano-enabled bioplastics), build trust and transparency in technology development (Responsible neurotechnology innovation)
Audience	Who is the target for the intelligence that is produced from the technology assessment?	Parliament, specific Ministries, Civil Society (for example to build trust), Firms (for example to stimulate responsible innovation), etc.
Section 2: TA Approach		
Assessment perspective	Which level of analysis does the activity take: 1. technology-centric (focusing on a particular technology) 2. innovation ecosystem centric (value chains and partnerships) 3. sectoral systems-level	1. Improving the functionality of the technology based on an improved understanding of user demands (e.g., neurotechnology for marketing, nanotechnology for health applications) 2. Understanding the transformation of value chains through the upscaling of the technology (what needs to be in place for a successful nano-enabled sustainable packaging value chain?) 3. Understanding the socio-technical system transformations due to the technology (agricultural system transformations due to zero-pesticide technological innovation)
Stakeholder Inclusion	Which stakeholders are included? What intelligence is provided through stakeholder involvement? In what way are stakeholders included?	Firms and industry associations, research communities, civil society organizations, citizens, user groups (e.g., patient associations), trade unions, financial actors, regulatory agencies etc.
Process	What are the different steps and activities? Which methods and tools are mobilized? Which capacities are needed to successful undertake the technology assessment approach?	Stakeholder engagement, horizon scanning, data mining, scenario development, constructive technology assessment, co-design, impact assessment.
Frequency	Is it a one-off activity? Or a repeated at regular intervals?	For example, the French *Cultiver et Protéger Autrement* program focusing on mission-oriented research for zero pesticide agriculture runs an anticipatory impact assessment activity which is repeated every year for the duration of the program (six years)
Section 3: Use of TA Outcomes		
How is the TA linked to decision making or agenda setting?	What is the relationship between the TA activity and decision-making?	For example, was the TA commissioned by a policy actor to inform decision-making? If Yes, how was the TA outcome mobilised to inform policy?
Section 4: National TA Context		
Embedding of TA	What is the current, and historical, embedding of TA in *local* settings and/or *national* governance systems of technology research and innovation?	For example, is there a long history and culture of TA in the national context of the case study? What forms of TA are common in this national context? Which forms of TA are less common or absent?

1 NANOTRUST and the Austrian Nano Risk Governance Network

Written by André Gazsó, Gloria Rose, Anna Pavlicek, Daniela Fuchs (Austrian Academy of Sciences, Institute of Technology Assessment, Austria) and Florian Part (University of Natural Resources and Life Sciences, Institute of Waste Management, Austria).

Introduction

The Austrian nanotechnology research programme Nano Initiative (NI) started in 2003 and an accompanying technology assessment (TA) was suggested from the Institute of Risk Research (IRR) of the University of Vienna to complete the three existing R&D-oriented research program lines. Despite the recommendation of the NI, it took more than three years to place the first safety-relevant projects. In 2006, the Institute of Technology Assessment (ITA) at the Austrian Academy of Sciences was assigned to produce a status report on the international environmental, health and safety (EHS) and ethical, legal and societal implications (ELSI) of research regarding nanotechnologies and nanomaterials by the Austrian Ministry of Traffic, Innovation and Technology (BMVIT). This may be interpreted as a strong indication for the fact that public debate on safety-relevant issues had become more relevant to authorities by this time. In 2007, the NanoTrust project at the Austrian Academy of Sciences, dedicated to nano-safety and governance, was funded by the BMVIT.

Technology area

Which technology?

From the beginning, there was a great variety of research approaches and technologies which were all covered by the umbrella term “nanotechnologies” originally brought up by the U.S. National Science Foundation (NSF) in the late 1990s: technologies, processes, objects, structures, pores, materials and products. The description stayed rather vague and showed fuzzy borders to adjacent research areas during the next two decades up until now. Several existing definitions used in legal documents (e.g., the EU Cosmetics Directive) and the highly controversial EU proposition of 2011 did not really change this picture. One principal idea which had been discussed very early was the possibility to combine engineering and life science approaches on a very small scale, especially below 100 nm (which points to the concept of “converging technologies”). The second element of definition was the expectation to garner new functionalities at this size level, which is now part of the emerging debate on “Advanced Materials”.

Level of maturity

In principle, every level of maturity can be observed due to the great variety of possible applications and research areas. Most of the projects are more or less basic science but there are a lot of materials, compounds and products already in use and on the market—especially in the field of medical technologies, light weight complex plastics and construction materials.

Envisioned application areas are likewise diverse and barely comparable. We can find certain well-developed nanomaterials in the automotive & aerospace sector (light-weight materials and compounds), medicine (carriers for active ingredients, high throughput diagnostics, antibacterial effect in bandage materials and wound pads), textiles (e.g. so-called “smart” textiles), construction materials (new modified concretes to improve stability and brittleness), cosmetics, food production and food packaging materials (sensors for quality control) and agrochemicals (fertilizers, pesticides, herbicides, but also plant-nourishing products increasing bioavailability of different substances).

Is it an enabling technology or application-specific?

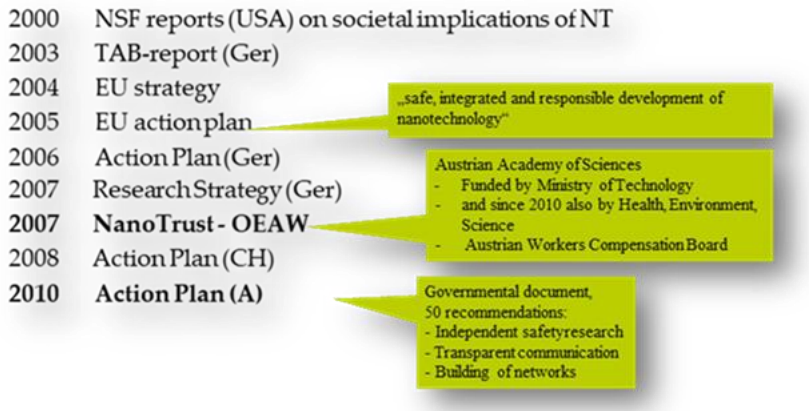
Because of their high variability and universal use, nanotechnologies are considered as one of the so-called key enabling technologies (KET), the others being advanced materials, advanced manufacturing and production technologies and biotechnology. KETs are technologies which are meant to retain the competitiveness of the European industries and capitalise on new markets worldwide. Originally part of a cluster called converging technologies (Nanotechnology, Biotechnology, Information technology and Cognitive science [NBIC]), nanotechnologies are now one important part in the field of advanced materials. The developing European research framework programme Horizon Europe will contain nanotechnologies mainly in the cluster “Digital, Industry and Space”, the areas of intervention being “manufacturing technologies”, “advanced materials” and “emerging enabling technologies”. But nanotechnologies and nanomaterials are modifiable in shape, structure and functionality for special purposes that one can expect nanotechnology research to be carried out also in other Horizon Europe clusters, such as “Health” (diagnostics and drug delivery), “Climate, Energy and Mobility” (e.g., water treatment and printable batteries) or “Food, bio-economy, natural resources, agriculture and environment” (indicators for food quality). It is obvious that nanotechnology is not “one” technology but is getting more and more important in a vast majority of technological sectors.

As already mentioned above nanotechnologies are an important group within the so-called “advanced materials” (materials which have new qualities or functionalities) and can be used in many sectors and application areas. Therefore, they are recently included by European research programmes into the list of “key enabling technologies” (KET). Certain materials and material combinations are designed and used for very specific purposes (e.g., nano silver in medical hygiene). Part of the definition of “advanced materials” is that these materials are designed for certain purposes and to solve well-defined problems.

Technology Assessment agency or organizer

Since the beginning of the nanotechnology debate (which finally evolved into mainly a nanomaterial safety debate), several actors have been involved in representing quite different agendas and motivations. Among these actors, three institutions play a critical role—the Austrian Academy of Sciences (Institute of Technology Assessment), the Austrian Ministry of Technology (Department for Innovation) and the Ministry of Environment (Department of Chemical Regulation). All of these actors were engaged in the early discussion around nanotechnology and their safe and sustainable development as demanded by the Nanotechnology Action Plan of the European Union. A timeline of the most influential publications regarding nanotechnology research in Europe is shown in Figure 1.

Figure 1. Early nanotechnology debate in Europe



The whole story therefore starts from three different origins around 2003—the establishment of the Austrian Nanotechnology Research Programme Nano Initiative (NI), the publication of the seminal nanotechnology report by the Technology Assessment Office of the German Parliament (TAB) and the publication of the Nanotechnology Action Plan and the Nanotechnology Research Strategy in 2004/2005. After that, we can observe a steady convergence of the different interested parties culminating in the formation of the rather informal (but influential) "Nanoplatform" of the Ministry of Environment on the one hand and founding of the Technology Assessment project "NanoTrust" at the Austrian Academy of Sciences—initiated and funded (solely for the first 6 years) by the Ministry of Technology. After 2010, the interest in the work and the activities of "NanoTrust" increased and other finding institutions came on board, namely the Ministry of Health, Ministry of Social Affairs and the Austrian Worker's Compensation Board (AUVA), responsible for workplace safety and the biggest worker insurance organisation in Austria (with more than 5.5 million insurance members). It has been one of the goals of NanoTrust to broaden the support to gain more stability and increase the credibility of its work.

Over the years, the project "NanoTrust"—originally planned as a research project with a strong focus on applications—evolved into a partner in the governance system to provide sound and structured information as a basis for qualified decisions. It has been a very tedious debate quite from the beginning to clarify the exact role of "NanoTrust", mainly by defining roles "NanoTrust" will not be able and willing to fulfil—namely, to carry out public outreach and taking or even participating in political decisions. Over the years "NanoTrust" has become a typical hybrid research scientific project (based at an institution mainly dedicated to basic research) conducting primary and secondary research, structuring and translating sound knowledge on risk and safety aspects of nanotechnologies and providing science-based policy advice if demanded. As a scientific institution, all information has to be publicly available to ensure the neutral position of the TA institution. This was—and still is—one of the main features to serve as a credible platform and a mediator for planning, designing and establishing the various instruments of the Austrian Nanotechnology Governance System.

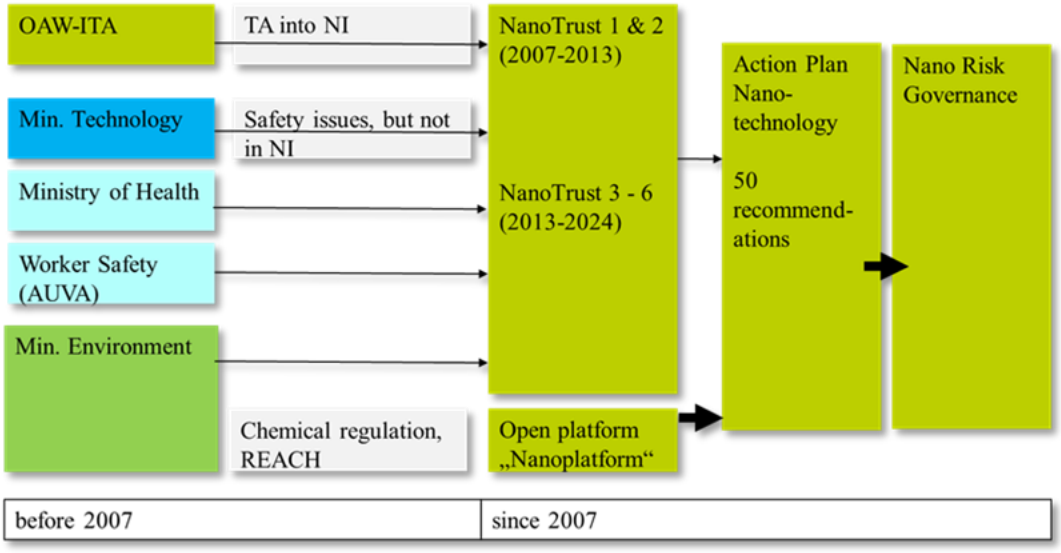
We can say that the principal motivation on the side of the Institute of Technology Assessment (ITA) has been the introduction of risk and safety issued into the Nanotechnology Initiative which was mainly focused on R&D.

Interestingly, the NI management has been rather open to this point as the ITA first made contact in spring 2003, just after the start of the NI. It would take another three and a half years to launch an appropriate technology assessment project like "NanoTrust". The Ministry of Technology as the main funding institution, on the other hand, decided to integrate technology assessment to complete its technology-

oriented activities and—perhaps—to prepare itself for adverse public communication. Its main motivation, however, originated in the increasing demand on structured knowledge about possible consequences of the application of nanomaterials as they were noticeably rolled out at the market. The Ministry of Environment has been interested in environmental effects of nanomaterials and nanoproducts mainly to fill in the space left by the then-new REACH Directive which did not specifically include nanomaterials at this time (it still does not but, since 2010, nanomaterials are part of an elaborate scientific debate in chemical regulation). At the same time, the Ministry of Environment took the chance to successfully include the nanomaterial debate into the compilation of the latest Governmental Programme which has been currently debated in 2007. This politically motivated move was the starting point for the later work on the Austrian Nanotechnology Action Plan (ÖNAP) which is more or less the basis for all ensuing political activities gathered around the Nano Governance System. The TA-project—which has meanwhile evolved into a process rather than a short-lived research project—has been active in all these efforts in different roles. This will be discussed below.

The development of this system and its pre-history from different points of origin but more or less the same inventory of knowledge (nanotechnologies were heavily debated at that time but surrounded mainly by uncertainties and not risks) into a convergent and increasingly co-operative governance process since 2007 is depicted in Figure 2.

Figure 2. Origins and Development of the Austrian Nano Governance System before and after 2007



Building the Austrian Nano Governance System

In 2009, Austria addressed the central issues of nanotechnology by drawing up the Austrian Nanotechnology Action Plan (ÖNAP), which was generated by the interdisciplinary cooperation of several federal ministries, agencies and institutions from science and economy, as a direct consequence of the ongoing discussion in the already existing nanotechnology network. The core of the Action Plan consists of about 50 recommendations for specific Austrian measures at national, European and international level and explicitly mentions the PP several times. The interdisciplinary working groups dealt with the topics 1) health and employee protection, 2) environment, 3) economy and 4) science, research and development. All interdisciplinary working groups invoke the PP. In all resumes it is implicitly mentioned.

Opportunities were seen primarily in the improvement of product properties. However, when considering nanomaterials in the work environment and worker protection, the focus is placed on the possible risks to human health—which have yet to be sufficiently clarified—and the resulting uncertainties rather than the opportunities. Nanotechnologies and products have the potential to make a significant contribution to resource and energy conservation as well as waste avoidance. When assessing the environmental impacts of nanotechnological processes and products, a life cycle-oriented approach is necessary. To date, these considerations are often missing or incomplete. The results of the latest national project from the NanoEHS fund (NanoAdd) showed that industry (according to its own statements) tends to avoid the use of nanomaterials because of the high potential of uncertainty.

The Austrian Nanotechnology Action Plan states that nanotechnological innovations should strengthen Austria as an economic region. Resource conservation is a possible contribution to a more sustainable development of new products using nanomaterials but this this has to be accompanied by in-depth risk research. Therefore, the national research funding program on environmental, health and safety of nanotechnologies (Nano-EHS) has been established in 2011 and is since then dedicated to foster research on safety aspects of nanomaterials. A primary goal was to involve the public in the creation and implementation of the ÖNAP. Therefore, both the draft (2009) and the implementation report (2012) were subject to public consultation on the internet. The comments received were published and considered.

The beneficial aspect of nanotechnology seems to play an important role in terms of public acceptance as well as the safety of nanotechnological applications. The further development of safety research and regulation therefore occupies a major place in Austria and is also being pursued to date in the national NANO Environment, Health and Safety research programme and by the NanoTrust accompanying research project, which became a part of the Austrian nano risk governance landscape itself.

During the years since 2007, a complex system of different and complementary instruments to assess and regulate the production and the use of nanomaterials has been established in Austria, engaging several dozen organizations and employing different formats and instruments such as a national communication strategy in nanotechnologies, a federal commission for nano safety and an independent nano safety research programme. The project “NanoTrust” has been involved in the conceptualization and practical implementation of these instruments from the very start in 2007. Figure 3 gives an overview over the main instruments of the Austrian Nano Governance system.

Figure 3. Austrian Nano Governance System

The basis for the development and the core for the nano risk activities is the Austrian Action Plan Nanotechnology (NAP) published in 2010 which has been described earlier. A very important element regarding many of the conceptual aspects were drawn from the work of the long-term research project NanoTrust at the Austrian Academy of Sciences (s. above) which has since its inception in 2007 become an element of the governance system itself. NanoTrust has also played an important role in implementing and at least partly operating many of the main elements, it is involved in shaping the nano-EHS-research programme (and therefore not liable to apply for its scientific calls as a project partner) and serves as regular provider of scientific content regarding nano risk and safety issues for the public information portal nanoinformation.at.

The roles of the TA process "NanoTrust" in the Nano Governance System

One of the concrete outputs of the NAP was the foundation of a Nano Information Platform (NIP) aiming to bring together experts from a wide variety of fields to establish transparent public communication on the safe use of nanomaterials. The NIP is a non-formalised, open (people participate on a voluntary basis and they are free to come and go whenever they want) yet stable (as in the sense of committed people who participate from the onset) group of around 10-12 stakeholder representatives (ministries, safety agencies, NGOs and research organisations), coordinated by the Ministry of Health. NanoTrust has taken part in this public communication network from its very beginning in 2010.

The result of these NIP expert discussions was the establishment of a nano-information portal (nanoinformation.at), hosted by the Austrian Ministry of Health yet being a common project of all the concerned ministries and other organisations such as the Austrian Academy of Sciences and Austrian Food Safety Agency. Since 2012, it has ensured transparent public communication on the safe use of nanomaterials through a continuous information flow between experts and the interested public. It gives people the option to interact with regulatory authorities and experts in case there are questions and concerns. Consumers' questions are collected through the portal and answered within a 2-week timeframe after establishing an intercommunication process among collaborating experts. Material for this public information platform is developed in different self-organized working groups.

A stable working group on worker safety was established in June 2011, under the responsibility of the Austrian Worker Compensation Board "AUVA", the biggest insurance company for workplaces in Austria. NanoTrust has initially suggested to install such a permanent working group and has since then been part of it and regularly takes part in their meetings until today. The nano-information portal establishes a two-way communication process by i) producing nano safety and risk relevant info addressing the interested public and ii) answering the consumers' questions. The NIP has been active since 2010, convening two or three times per year, being responsible up to date for the following tasks: operation and maintenance of the portal, public communication (consumers and the interested public), publication of risk and safety relevant documents produced by its members for use on the portal. An overview of the specific roles of "NanoTrust" is given in Figure 4.

Figure 4. The elements of the Austrian nano governance network and the roles of the project "NanoTrust"

year	Governance element	Responsible authority	task	Role of NanoTrust
2007	Nanoplatform NanoTrust	Ministry of Environment Austrian Academy of Sciences & Ministry of Technology	Network building, exploration Research, scientific counselling	Member Project holder
2010	Austrian Action Plan Nanotechnology (NAP)	Ministry of Environment, adopted by the Austrian Government	Political document, 50 recommendations (independent research, transparent communication, networks)	Member of all 4 expert groups (health, economy, environment, science)
2010	Nanoinformation Platform (NIP)	Ministry of Health		Founding member, contributor
2011	Permanent working group on worker safety	Austrian Worker Compensation Board	Evaluation of relevant publication and production of valid information	Founding member, contributor
2011	Nano-EHS research programme	Ministry of Technology & Ministry of Environment (now: Ministry of Climate Action) Programme organisation: Austrian Research Promotion Agency (FFG)	Guiding safety research	Scientific advice in preparing the annual research calls
2012	nanoinformation.at (web-based public communication portal)	Ministry of Health	Public communcation and consumer information	contributor
2013	Nano Information Commission	Ministry of Health	Providing an independent and stable platform	Chair and member

NanoTrust has been especially involved, from the onset, in the creation of the Nano Information Commission (NIK) of the Austrian Ministry of Health which represents the most formalised element of the Austrian nano risk governance landscape. The NIK was founded in 2013 as an advisory board to the Minister of Health. It consists of 23 members from ministries, agencies, universities as well as two NGOs.

The Nano Information Commission convenes two to three times a year having as main tasks i) to provide all members with information on the current research and developments in the field of nanotechnology safety, ii) to offer an opportunity to discuss and evaluate these findings and iii) to foster safety-relevant research concerning the use of nanomaterials in Austria. The NIK is concerned with the implementation of the Austrian Nano Action Plan and represents the diversity of opinions and the professionally sound state-of-knowledge of various scientific experts.

In contrast to the NIP, the NIK is not an open network: proposals for new members can be made by the plenum. ITA designates one full membership and a substitute to the NIK. The chair is hosted for five years and currently held by the Coordinator of the NanoTrust project. In 2019, the Nano Information Commission started its second period of operation and the Coordinator of the NanoTrust project has been re-elected as chair until 2023.

In 2011, the Austrian Nanosafety Research programme (Nano-EHS-programme) has been established which publishes annual calls for projects dealing with risk and safety relevant aspects of the use of nanomaterials. The Nano EHS programme is the instrument for targeted funding of environmental and health-related research to assess the risks of synthetic nanomaterials and advanced materials. Its establishment is in line with a recommendation of the Austrian Nanotechnology Action Plan, which was adopted by the Council of Ministers in March 2010. Originally, NanoTrust has been an initiator for establishing an independent Nanosafety research programme and has therefore been engaged in the Nano Action Plan's working group on science. After the start, Nanotrust took part as a project partner in several nanosafety projects (i.e., on waste management and nano additives) until 2015, thus establishing a tight co-operation with the University of Natural Resources (Department of Waste Management and Circularity). NanoTrust has been an important factor to place nanowaste management on the Austrian

research agenda and encouraging to build up an appropriate amount of research capacity in this field. After 2016, the role of NanoTrust changed fundamentally by taking on counselling tasks for the responsible steering committee of the Nano-EHS programme. Since 2016, NanoTrust is participating in the preparation of the annual calls and is therefore no longer available as a project partner. The specific role of supporting the steering committee's task of setting the specific research focus for the recent call (i.e., nanocarriers as research focus on the 9th call in 2021) is quite similar to the task fulfilled in the Nano Information Commission and the Standardisation Committee and consists of initiating the establishment of new and promising research areas and fostering nano safety research in Austria.

Another important approach to regulate the use of nanomaterials and nanotechnologies is standardisation. The Austrians standardisation committee 052.73 "Nanotechnology" consists of experts from research institutions, engineering and safety authorities. The committee is chaired by a member of the Institute of Technology Assessment (ITA) of the Austrian Academy since 2018 and therefore part of the regular work of the Nanotrust project. In 2019, a support project for AG 052.73 has been established at the ITA funded by the Austrian Ministry of Technology. The project was intended to generate additional knowledge on nano R&D, nano safety research and technology assessment and to increase the engagement of Austrian nano expertise in international standardisation projects, mainly the committees ISO/TC 229 "Nanotechnologies" and the CEN/TC 352 "Nanotechnologies". The role of NanoTrust is mainly to coordinate the regular committee meetings, to disseminate relevant knowledge created in the on-going standardisation activities to the Austrian nano-research community and to include Austrian expertise into international standardisation projects. Since its start in 2018, Austrian experts are now participating in 12 ISO and CEN working groups on nanotechnology topics.

Envisioned outcome

Are the objectives clearly defined upfront or is the exercise explorative?

Some of the outcomes of the TA process are clearly defined and therefore regulated by the "NanoTrust" contract which is negotiated every three years with the funding bodies. The scope of activities has been modified over the years following current developments and adapted to the state of knowledge. The core tasks—serving as a neutral discussion platform and providing scientifically sound information—have stayed more or less the same being the appropriate function of a scientific institution. The ITA and its TA project "NanoTrust" keeps the role of an "honest broker" over all these years very stable because it seems to be part of the identity of its existence. Clearly defined are the tasks of producing publications on a regular basis (at least three NanoTrust-Dossiers, reviews on safety relevant topics), organising an annual conference, setting up and maintaining networks in the nano community and serving as a discussion platform. A rather new function (since 2016) is to support and advise the responsible governmental steering group regarding the scientific orientation of the Austrian nanosafety research programme "nano-EHS," which developed out of the regular work of screening the status of European nanosafety research. To avoid possible interest conflicts and to maintain credibility (and the possibility to serve as a trustworthy member of the Austrian nanoresearch community), "NanoTrust" does not longer participate as a research partner in the annual calls. Other tasks will remain explorative, for example, the regular screening of research and regulatory needs or the identification of strategic goals for nanomaterial and nanosafety research. These goals have not altered much over the last 15 years.

Audience

Who is the target for the intelligence that is produced from the technology assessment?

As mentioned above the alignment of “NanoTrust” has been rather scientific from the onset. Therefore, the activities and the publications of this TA-process is not addressed directly to the general public. However, “NanoTrust” takes part and has participated in public activities when invited, for example in information event on nanomaterials and food safety organised by the Ministry of Health. But the main audience of “NanoTrust” are persons with some kind of basic knowledge in safety and risk evaluation, regulatory aspects and communication needs regarding workplace safety, consumer protection and environmental safety. This will mainly encompass people like decision makers (ministries, agencies), fellow scientists and scientists from adjacent research areas, who want to get an overview over the most relevant topics, NGOs (consumer safety, environmental safety) who want to inform themselves about nanotechnologies, and scientific writers. In general, the activities are addressing persons with focused interest in nanotechnologies and nanomaterials or nanoproduct safety and some relevant expertise (chemistry, physics, medicine, biology / ecology etc.). Nevertheless, “NanoTrust” is supporting the work of the Nano Information Platform NIP which operates the public web portal “nanoinformation.at” for direct information exchange with the general public.

Juggling tensions in the nano risk governance system

In the following, we position NanoTrust within wider (normative) understandings of TA, in particular with regard to defending common fundamental rights and interests against partial interests (Torgersen 2019), as TA strives “to contribute to socially responsible technology policy” and hence, “is led by democratic values.” (Rose and Gazsó 2019, pp. 24). To do so, we have identified five tensions that NanoTrust faces: the tensions between (1) risk framing by experts and engaging the public; (2) aspects of stability and adaptability; (3) neutrality and partiality; (4) innovation and precaution; and (5) trust and flexibility.

Tension 1: Expert engagement vs. lay participation

NanoTrust’s original mandate were (and still are) monitoring activities (e.g., gathering knowledge, identifying and defining uncertainties, etc.) to structure (fragmented) information for evidence-based decision making, foremost directed at authorities. In this context, public perceptions of risk are mainly understood as drivers for resistance against the use of nanomaterials and should be taken seriously to avoid political contestation. However, societal engagement in the Austrian governance system addresses scientists, risk experts, stakeholders and authorities, but hardly includes engagement of a wider public (one exception may be the engagement of civil society organizations concerned with consumer-related agendas, e.g., Association for Consumer Information—VKI). Rather, the public is perceived as recipient of science-based and balanced information and thus, largely appears as an important but passive actor with information being provided accordingly (e.g., through the website nanoinformation.at). More active public engagement has been delegated to international projects, i.e., EU projects concerned with deliberation and co-creation under Responsible Research and Innovation (RRI) in FP7 and Horizon2020. While not core to the Austrian nano risk governance system, the input of such engagement activities is nevertheless appreciated for further consideration (e.g., in NIK meetings or at NanoTrust conferences). The main mandate of NanoTrust, however, is to efficiently inform a specific actor group (i.e., authorities) about findings and gaps on EHS topics on nanomaterials.

Tension 2: Stability vs. adaptability of the project

From its original main mandate, NanoTrust over time sought more active intervention in the Austrian nano risk governance system, e.g., by adopting a role as "issue advocate" (Pielke, 2012) within TA's agenda. For example, NanoTrust's actively pursued and strengthened hitherto marginalized EHS aspects through participating in projects of the nano-EHS program (from which it refrained soon to avoid double missions) to explore new issues and cooperation's. It engaged in an explorative research project (NanoMia) concerned with questions of waste management for nanomaterials, which led to a stronger integration of the project partners in the Austrian risk governance network and strengthened the issue of waste management on the (policy and research) agenda. Moreover, NanoTrust's engages in a working group for worker protection (based at the Austrian Workers' Compensation Board - AUVA), where it supports the prioritization and selection of issues to be addressed. In both cases, NanoTrust acts as "issue advocate" in terms of agenda setting, leading to a tension between adaptability and stability of the project. On one hand, such activities require a flexible project structure, which can provide start-up support for specific topics (and establishing respective contacts, i.e., BOKU, AUVA). On the other, these adaptations depend on NanoTrust's (original) monitoring function since a systematic overview on the field is required to be able to identify under researched aspects and to act as "issue advocate" altogether (Torgersen, 2019; Rose and Gazsó, 2019).

Tension 3: Neutrality vs. partiality

The question of remaining neutral is core for the NanoTrust project. Rose and Gazsó (2019) argue for an active understanding of neutrality characterized by: a fair behaviour and goodwill towards all participants; good scientific conduct and focus on a factual basis; interdisciplinarity and the presentation of the full scope of available knowledge and perspectives; pursuing common overarching goals; and maintaining independence (Rose and Gazsó 2019, pp. 25). In practice, this implies boundary work between the project and its scientific and political embedding, as illustrated by two examples. The first one was the definition of NanoTrust's role with regard to the Austrian nano-EHS funding program. As the original request to inform the decision-making of calls while competing for the program's resources compromised its "neutral" position, NanoTrust soon decided to refrain from competing. Ever since, it delivers an annual monitoring report of EHS-related projects and suggestions for research issues by the research community to the steering committee. By emphasizing its informing role and refraining from any decision-making activities, NanoTrust supports the interests of all participants (of the research community) equally, as long as their activities align with an EHS scope. Accordingly, this active neutrality can only be maintained as long as the project's characteristics align with the interests of all participants.

The second example is NanoTrust's role within the Austrian Nano Information Commission (NIK). NanoTrust's project lead was elected to chair the NIK until 2023; the chair's main functions are to invite new members and external experts (as guest speakers), and in principle, he has certain prerogatives when voting is required. To pursue the interests of all members equally, the convening character of the Commission is emphasized, by focusing on sharing information, openly discussing decisions about new members and topics and avoiding decisive voting. Thus, NanoTrust surrenders its privileges to ensure the functioning of the Commission as team effort. In terms of political independence, the Commission's mandate of sharing information has kept political interests at bay; moreover, the institutionalization of the chair (employee of a scientific (ÖAW) and TA (ITA) institution) accounts for an impartial stand within the governance system. Thus, active neutrality as pursued by NanoTrust is limited to a specific arena of participating actors and arguments.

Tension 4: Innovation vs. precaution

Looking at NanoTrust from a bird's eye's perspective, its overall function within the Austrian nano risk governance system becomes visible: it attempts to integrate considerations on EHS issues and risks early-on in mainstream nano innovation. Therefore, NanoTrust meets TA's agenda of "safeguarding" (nano-)technologies from the beginning and enable responsible and socially acceptable innovation. This is illustrated by the funding of the project: the scope of the agendas and protective goods of Ministries and authorities funding NanoTrust spans from innovation and technology (the main supporter of the project in the beginning) to health, environment, consumers or workers. Moreover, NanoTrust contributed to initiating and establishing the Austrian EHS community, as far as compatible with its position as research project. For example, when asked to act as reviewer in one of Austria's main funding agencies (FFG), the project declined, referencing to its status as research project; however, recurring to its integration in research networks, it was able to appoint appropriate reviewers for EHS issues.

Dimensions of good Technology Assessment practice in case of Nanotrust

In the case of Nanotrust, the eight main dimensions appeared to be appropriate to fulfil several necessary tasks to deal with the uncertainties connected to the development and the application of a then emerging class of materials (nanomaterials) and their products. The main purpose was to assess the existing scientific knowledge on risk and safety aspects regarding nanomaterials, to raise awareness of these topics among the research community and the regulatory bodies and to distribute appropriate knowledge for open discussion and informed decision-making. According to the ever-changing scientific knowledge level the specific issues covered vary, but the main goal (provision of sound and useable knowledge) does not. Thus, the main dimension of Nanotrust was and still is "Fit-for-purpose" whereby the specific purposes change and evolve over time.

The ongoing experience of Nanotrust reveals two other dimensions, which appeared to be most important for the success of Nanotrust. These two additional dimensions are stability (to ensure continuity over a long period) and the direct engagement of the process and its representatives in real-world process such as commissions, committees and official working parties. A detailed overview and explanation to these characteristics is given in Table 3.

Table 3. Characteristics of good Technology Assessment practice in case of Nanotrust

Dimensions	Description	NanoTrust and the Austrian Nano Risk Governance
Fit-for-purpose	TA process should be aligned with key goals, for example to: • deliberate and gauge opinions • inform key trends • build agendas • shape and steer governance	NanoTrust has originally funded as a three-year research project to concentrate on possible undesirable outcomes (on human health, the environment and the society) as an addition and a complement to the national R&I programme Nano-Initiative which did not encompass these topics. The purpose of the funding ministries was to build awareness to these issues within the Austrian nano-research community and to increase the risk preparedness of the responsible organisations. The main tasks of NanoTrust have not changed over the years and consist of knowledge production and dissemination, identification of research gaps and the provision of a neutral discussion platform for transdisciplinary uncertainty assessment, thus supporting qualified decision-making processes. NanoTrust has been placed at the Austrian Academy deliberately because a scientific organisation is able to guarantee a neutral and fair environment.
Legitimate and trustworthy	TA agent or institution must act as an "honest broker", maintain independence	The structure, tasks and outcomes of NanoTrust are publicly available as to the requirements of a public research project

	and be transparent about any normative stances they may take.	
Clear granularity and scope of TA focus	Which level of analysis does the activity take: • technology-centric (e.g. quantum computing) • value-chains focus (e.g., seafood chain from sea to fork) • socio-technical system perspective (e.g., mobility systems, energy distribution) • hybrid levels of analysis (e.g., novel technologies for different stages of clinical trial chain)	The TA-process NanoTrust is obviously technology-centric (focussing on nanomaterials and recently on advanced materials using nanoobjects). From an early stage on the discussion narrowed down to risk and safety relevant questions and branched out into questions related to regulatory significance, such as worker safety, consumer protection, environmental safety, chemical regulation and waste management.
Participation must be smart and inclusive	Which stakeholders are included and how they are included must be considered, based on a number of constraints: • resources available (staffing, funding) • scope (identifying relevant social groups based on topic and scope of TA) • time available (if short on time, may have to limit and focus inclusion)	NanoTrust was funded as an interdisciplinary research project and cooperates with non-scientific organisations - even though the representatives often have a scientific background but do not act as scientists. The whole governance system consisting of NanoTrust in its various roles and the governance instruments is clearly expert driven. Apart from this transdisciplinary mode of operation (e.g., within the commissions) NanoTrust also relies on regular meetings with a strategic advisory board. The general public is only included insofar as the information material produced by NanoTrust will be made available over the public information portal and by public events.
Interdisciplinary	The nature of emerging and converging technologies and their consequences requires an expanding range of insights and disciplinary knowledge.	To mobilise inter- and transdisciplinary knowledge is a main task of NanoTrust which is specified by contract. These contracts are re-negotiated during each prolongation to the process (every three years).
Explicit in terms of values, frames and biases	TA practitioners are challenged to unpack the values and framings of participants within TA exercises, as well as being aware of their own biases. Only then, can transparent, independent and useful strategic intelligence be produced.	This is part of building and maintaining trust as necessary prerequisite of a long-lasting transdisciplinary process such as Nanotrust. Every conflict of roles or interest were identified and openly discussed as soon it occurred. The strategic NanoTrust advisory board has played a crucial role to address these tensions and find feasible solutions. As a scientific project Nanotrust is provider of sound (albeit contradictory) knowledge but will not participate in the political decision process. But of course, the scientific advice will include all possible consequences and will not omit politically inconvenient details (which, by the way, was made clear before the start of the project and was decidedly desired by the ministries). Another example is the withdrawal of Nanotrust from the Nano-EHS research programme as soon it took over the role of the programme advisor.
Anticipatory and managing uncertainty well (at the right time)	TA for emerging technologies has to manage uncertainty over multiple timeframes: • near-term (5 years) • mid-term (10 years) • longer-term (15 years +) Thus, TA must be anticipatory, and clear about the timeframe of its assessment.	According to the regulatory emphasis of nano-safety issues the most important timeframe for Nanotrust and the Austrian Nano Governance System appeared to be near term (5 years and below). For research purposes a Mid-term time-frame is also relevant, specifically to identify trends in national and international research policy.
Producing useable intelligence	Key issues for utility of TA outputs for decision making include: • having a clear message • produce material that is easy to digest	The products of NanoTrust (Nanotrust dossiers, scientific articles, public events, commission and workshop reports etc.) are each clearly addressed to specific recipients

	• being timely so as to inform policy at the right time • having a clearly articulated connection to decision making process	- the NanoTrust dossiers for example are meant to inform the nano research community and are available both in German and English - workshop reports, e.g., protocols of the Nano-EHS-workshops, are addressed to the Nano-EHS-steering committee - specific report formats exist for the meetings of the Nano Information Commission and the standardisation committee - Informative events (e.g., on nano food safety) are directed to the interested public and therefore open for everybody Many of these documents pick up on problems that are topical and controversial at a given time which can easily followed by the history of the NanoTrust dossiers. The respective importance of these topics will be decided by both scientific interest and the regulatory demand. This might sometimes cause some tension but has always been solved by transdisciplinary discussion. The aim of Nanotrust is to provide meaningful knowledge for regulatory decision-making as early as possible.
Additional Dimensions		
Has to engage in real world activities	The TA agent or institution should be part of activities that are embedded and anchored in existing processes, such as standardisation committees, federal commissions or current topic related activities (such as working groups hosted by ministries or agencies). Thus, changing TA's role from a mere scientific observer to an actor and active contributor to the working group's outcome and making TA equally responsible both for the definition of the common goals and the specific results.	TA resp. its members become actors instead of mere observers and are therefore responsible for (1) defining the common goal(s) of the group, (2) identifying the necessary work items, and (3) producing the outcome of the work. Both are closely related to trust and the establishment of trusted environments. NanoTrust has been engaged in existing official processes from the onset and was in several cases involved to establish such working groups such as the Nano Information Commission which is the most formalised type of commission (Commission according to §8 Federal Ministry Act). The main goal is (quite appropriate for a scientific endeavour) to bring scientific knowledge as close to the regulatory process as possible.

2 STOA's exploration of the societal concerns surrounding genome editing in crops

Written by Lieve Van Woensel and Virginia Mahieu; Scientific Foresight Unit, within the Directorate-General for Parliamentary Research Services (EPRS) of the Secretariat of the European Parliament.[1]

Introduction

STOA recently conducted an online stakeholder engagement exercise elucidating the societal concerns surrounding a highly topical and controversial issue—genome editing in crops—in order to support decision-making by the Members of the European Parliament (MEPs). The project was organised and run in partnership with the Danish Board of Technology (DBT) Foundation, and its purpose was to inform MEPs about the challenges of genome editing in the 21st century (with a focus on crops) and the societal hopes and concerns surrounding the possible implementation of this new and emerging technology to support European food production.

We chose this project for this OECD anticipatory technology assessment case study for several reasons. First, due to its particularly controversial and sensitive nature, it necessitated a high level of neutrality and precision in its execution. Second, out of necessity from COVID-19, STOA needed to develop the efficiency of its online stakeholder engagement methods, making the project entirely online by design as opposed to adapting events that were originally intended to take place in person. This project was a perfect opportunity to test a new(-to-STOA) approach to scientific foresight with a highly participatory component, and the online aspect revealed its own advantages over in person.

Finally, the project was a collaboration with other BNCT members: we utilised an already-available report by the Rathenau Instituut on 'Genome editing in plants and crops' as a starting point for developing the engagement content and collaborated with the DBT Foundation who have a wealth of experience in online citizens' engagement. Furthermore, the DBT Foundation have previously worked on the topic of genetically modified organisms (GMO), giving them the experience necessary to tackle this project. Cooperation with these peers minimised duplication of efforts by sharing best practices, rendering the process more efficient whilst strengthening the international foresight network.

The project: background

The main mission of STOA is to provide Members of the European Parliament (MEPs), their Committees and other parliamentary bodies with high-quality, impartial and evidence-based information regarding developments in science and technology. The resources STOA provides to support policy-making include briefings and reports, as well as the opportunity for MEPs to directly exchange with scientists and other

experts through online events, workshops and roundtables. In the case of genome editing, the idea was to produce a series of resources that could inform the committees of the European Parliament and its MEPs about the role of genome editing in mitigating the challenges of the 21st century and the debate taking place around a potential revision of the GMO directive. The first was an online event, which took place on 15 March 2021 on "The challenges of genome editing in plants, with a focus on crops." Prominent speakers including researchers, policy-makers, and representatives from NGOs were invited to present and discuss the possible benefits and societal concerns expected from genome editing. Finally, STOA performed a foresight study[2] with a stakeholder engagement component to produce a document that concisely and accessibly summarises the societal concerns surrounding genome editing. This final project is the one that we will describe here.

This exercise included an online survey and a workshop in order to gain an overview of the concerns (hopes and fears) present in a representative group of stakeholders that work with or are impacted by genome editing. The online survey used hypothetical policy options, borrowed from the 2019 report by the Rathenau Instituut on 'Genome editing in plants and crops,' to guide stakeholders to identify arguments for and against several potential regulation scenarios, ranging from full regulation as for current GMOs to a levelled approach based on the societal and ethical assessment of the value of the application. The concerns and arguments were then refined with the help of the stakeholders themselves during the subsequent workshop.

The technology: genome editing in crops

New genetic technologies (NGTs)[3]—mainly CRISPR-cas9—have come to the forefront of discussions for their potential to contribute to agricultural sustainability, particularly in relation to the European Green Deal objectives. Crops can be improved through traditional breeding methods, but NGTs can make the process faster and easier. Genetic modification techniques are strictly regulated in the EU under the genetically modified organism (GMO) directive. The directive defines a GMO as "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination." However, whether changes made with NGTs could also occur naturally is a contentious issue. The question is whether NGTs should be treated differently or even exempt from this directive. The European Court of Justice (ECJ) ruled[4] in 2018 that NGTs would be subject to the same requirements as older techniques (and therefore come under the GMO directive). While the Court's stance on this issue is clear, amendments to the GMO directive by the European Commission are not impossible.

In fact, some are calling for a revision of the directive, noting that given the rapid advances in the development of the technology, it is no longer fit for purpose. Other regions of the world have begun to differentially regulate or even deregulate NGT products. However, NGTs are the subject of controversy as while some believe they can bring improvements to European crop production, others are concerned about many practical problems associated with their use. For example, there is doubt as to whether these technologies can actually deliver on their promises. Another example is that the precise and subtle nature of the changes made possible through NGTs make them difficult to detect, and therefore difficult to trace through the production chain. Thus, the debate continues.

The European Group on Ethics in Science and New Technologies (EGE) published in March 2021 its opinion the Ethics of Genome Editing,[5] which underlines overarching issues including the definitions of naturalness and biodiversity. Indeed, while there are many complicated practical challenges to the implementation of genome editing that necessitate careful consideration, at the core of the fierce division of opinions is a question of how ethical or even necessary it is to influence natural biodiversity for the sake of human profit. Shortly thereafter, in April 2021, at the request of the Council the Commission published a study[6] regarding NGTs, with the key findings that they have the potential to contribute to sustainable

food systems, and that the current GMO legislation is no longer fit for purpose as the original directive was put in place in the early times of genetic editing techniques. With this, the Commission announced a new open consultation process[7] to re-examine this topic and discuss a new legal framework for NGTs.

The European Parliament has a history of taking a strong stance on genome editing, having objected to every proposed authorisation of genetically modified food and feed in the 2014-2019 term. Still, the technology continues to evolve and has become a pressing matter for the EU. The Parliament must therefore consider the Commission's work and prepare to review the current evidence.

The method: online stakeholder engagement

The stakeholder engagement project consisted of four key stages. The first stage was to identify background information and hypothetical scenarios to guide foresight analysis and to prepare a survey based on these scenarios. These scenarios help to broaden the mind and guide exploration of the consequences and concerns surrounding each regulatory scenario. STOA uses the STEEPED approach to support its foresight work, which is a systematic way of conducting an initial overview of existing and emerging opinions (hopes and fears) concerning the topic under discussion, as well as an assessment of their associated impacts. This method allows a 360° exploration across seven perspectives: societal, technological, economic, environmental, political/legal, ethical and demographic. The STEEPED approach can be applied at several points in the foresight process, including horizon scanning, scenario building and stakeholder selection. In the case of genome editing, hypothetical policy scenarios were already well defined by the Rathenau Instituut, rendering the process easier.

The survey therefore took the form of a questionnaire prompting reactions to four hypothetical policy options based on those proposed by the Rathenau Instituut: 1) no revision of the GMO directive, 2) deregulation of NGT products that contain no foreign DNA, 3) a risk assessment approach based on the level of genetic change, and 4) a level-based approach where evaluation would be based on societal and ethical values. Participants were prompted to give their arguments for and against each policy option, as well as any other important information they wished to include.

The second stage was to do a stakeholders' analysis, and to invite relevant stakeholders to respond to the survey. We used the STEEPED approach in the stakeholder selection part of this project to ensure coverage of a broad spectrum of opinions from representatives of all stakeholder groups concerned by the issue under investigation. Furthermore, fitting well within the theme of this project, another new method for stakeholder selection was tested: a 'snowball' selection method. An original 'core group' of stakeholders was identified and invited to participate in the study, and they were each asked to nominate three of their peers—the 'snowball group'—that they believed were also closely implicated in the field. This drastically broadened the input of relevant stakeholders and made it possible to identify any that had initially been missed. In some cases, members of the 'core group' nominated each other or the same peers. Analysis of the variety and overlap of stakeholder nominations helped to avoid gaps and reduce bias in the selection process. In total, STOA sent out 52 invitations to this stakeholder engagement exercise. Of these, 40 responded, corresponding to a 'core group' of 15 participants and a 'snowball group' of 25 participants. These participants came from a well-balanced range of backgrounds such as agrarian industry and research, famers and environmental NGOs, administration and policy, consumers and lobby watch organisations and more.

In the third stage, the individual concerns and arguments expressed by all participants were synthesised and consolidated into four documents, one for each policy option. The 'core group' of stakeholders was then invited to a live online workshop, with the aim to collectively fine-tune these documents to ensure accuracy and clarity. Crucially, the purpose was not for the participants to convince each other of their opinions, but rather to agree on the correct formulation of the arguments presented. The participants were

divided into four mixed groups, each including as broad a variety of positions as possible. All groups worked on one initial document, adding their comments to the phrasing of the arguments in the initial version proposed by STOA and introducing any original arguments and opinions they felt were missed or not represented. The four groups then rotated three times for a total of four different sessions, so that each group analysed each of the four policy options.

The fourth and final stage was to produce a report based on the documents successively revised by the workshop participants. This final report includes a broad range of opinions reflecting all possible wishes and concerns, lightly edited for clarity. It presents the identified arguments and concerns in multiple grouped formats to facilitate reading: condensed according to topic, organised according to the relevant parliamentary committee, and concisely summarised. The original format (grouped per policy option) obtained as a result of the workshop is also presented in the appendix.

The results: lesson learned

Overall, in our view, the project has been successful. Though it was very recent, and its products have not yet come to fruition, it has resulted in a comprehensive publication that will inform MEPs on the considerations to be taken into account in the inevitably upcoming debates on genome editing. The key areas of concerns expressed included general concerns about the EU policy-making process, the practical implementation of new legislation and societal safeguards, uncertainty and unknowns surrounding the new technology, and the implications of potential legislative changes for innovation and competition within and outside the EU. Some further examples included concerns over the social acceptability and consumers' freedom of choice, traceability, the justification and application of the precautionary principle and potential health and environmental risks and associated liability issues.

Valuable lessons were learned during this project that may prove useful for future similar cases. Generally speaking, the results of this project indicated that, as for many controversial topics, it is difficult to deduce arguments for and against genome editing as a whole. The approach of looking at the topic through the lens of various hypothetical regulatory scenarios helped to tease apart intricate and situation-specific concerns. Furthermore, the 'snowball' method proved a very simple yet effective way of multiplying participants in the engagement process. And lastly, having the initial survey online meant that participants could work in their own time and therefore thoroughly prepare and research their responses, though care should be taken in describing the expectations and constraints for the responses as some participants included extensive references to scientific literature to justify their arguments that were difficult to summarise for the purposes of the workshop.

This case reflects most of the dimensions of technical assistance mentioned in this report. It reflects inclusive stakeholder participation, in a participatory approach. Moreover, it was conducted in an interdisciplinary manner. And, not least, this STOA case which was conducted for the European Parliament addressed a broad range of values and uncertainties about new genetic technologies.

It is one of the fundamental pillars of the EU to ensure that through democracy, citizens can freely express their views and have a say on their future. When making evidence-based policy choices about new and influential technologies it is essential to factor in not only the scientific evidence, but also the societal context in which the technology would be applied. With something as important and fundamental to European life as food safety and security, it is especially important to give consideration and a voice to all sides of the controversial issue that is genome editing. This project has also highlighted the importance of collaboration at every stage. Collaboration and sharing of practices between STOA and the DBT Foundation were essential to both developing and implementing this project. Collaboration between stakeholders (that did not necessarily agree) to help refine each other's views ensured true participation in the engagement process. And finally, collaboration with technology assessment networks such as the

BNCT, and the wider dissemination of the methods and results of subject-specific projects such as genome editing and its role in 21st century food production, are essential for promoting evidence-based, democratic and future-proof policy-making.

3 The DNA-dialogue: a broad societal dialogue on human germline genome editing in the Netherlands

Written by Jeroen Gouman and Petra Verhoef, Rathenau Instituut, the Netherlands

TA topic, purpose and audience

Political background of the DNA-dialogue

A multidisciplinary consortium was initiated in the Netherlands at the end of 2018 by eleven organizations with the shared goal of initiating a broad societal dialogue on the clinical application of Human Germline Genome Editing (HGGE),[8] a technique in which genetically altered embryos are potentially inserted in the uterus of the would-be mother to develop and be born. This initiative resulted in the two-year project titled 'The DNA-dialogue: a public dialogue on human germline genome editing' (from here: The DNA-dialogue).

Whilst this project was in a sense a bottom-up initiative by Dutch organizations with a shared vision that broad societal reflection on HGGE was urgently needed, the political context at the time meant that it was likely such an initiative would be welcomed, and financially supported by the government. The Dutch Cabinet that took office in 2017, did explicitly state in their coalition agreement that legislation on handling of embryos for research or reproduction (captured in the Dutch Embryo law) would only be altered after societal dialogue has taken place. For an important part because two of the four coalition parties (the liberal party D66 and the Christian party CU) had very different views on medical ethical topics such as abortion, research with human embryos and end of life decisions). Furthermore, it specifically named HGGE as one of the topics that requires further inquiry and dialogue. The project proposal for the DNA-dialogue was thus welcomed and financially supported by the Dutch Ministry of Health, Wellbeing and Sports.

Scientific background of the DNA-dialogue

Gene editing techniques have existed for almost half a century and their potential use to alter the genome of future children has been envisioned for many decennia in ethical discussions and the public imagination (Carroll 2017). A recent study found that most countries, including the Netherlands, have laws that explicitly ban reproductive HGGE, many others have regulation that prohibit it and no countries currently have laws that explicitly approve it (Baylis et al. 2020). Furthermore, reproductive HGGE is prohibited under several human rights treaties and in international guidelines, as well as under the European Clinical Trial Act. Yet, with the invention of CRISPR-Cas9, and its promise of safe and effective gene editing, critiques of an all-out ban on reproductive HGGE have intensified. Raising the question whether, if safe and effective editing

of the human germ line were indeed to become possible, certain medical applications should be allowed for, such as the prevention of severe heritable disease.

This project thus took place to the background of a restrictive national (and global) policy landscape that is being challenged in light of new gene-editing tools that entail the promise of safe and effective gene-editing. As well as a Dutch government that actively stimulated societal dialogues on medical ethical subjects and expressed their intention to weigh public perspectives in their decision-making.

TA Approach

Goal

The overall goal of the DNA-dialogue was to include a wide and diverse audience in the opinion-forming and decision-making on HGGE in The Netherlands, by:

- informing a diverse audience about the opportunities and uncertainties (e.g., relating to efficacy or safety) surrounding HGGE and about the societal and ethical issues it raises.
- inviting people to discuss their hopes, questions, wishes and concerns; and
- gathering and reporting a rich diversity of perspectives and considerations that can inform the political decision-making about HGGE and can stimulate further societal reflection.

An important aspect of reproductive HGGE that makes it particularly controversial, is that the genetic changes that are made will be passed down to future generations. When an embryo is genetically altered and develops into a human, all of his or her cells will contain these genetic changes, including the germ cells (sperm and egg cells). This means that these changes will be passed down to his or her (potential) future offspring, and all their offspring, and so on. And that making decision on the application of HGGE involves careful anticipation of future implications.

In the scientific and ethical discussions surrounding HGGE, therefore, it is widely acknowledged that HGGE could have far-reaching consequences[9]. Not only for those directly involved, such as the risks and benefits of prospective parents and the future child that is to be born through the HGEE procedure. But also for society at large: HGGE could impact the acceptance or discrimination of existing people with heritable diseases, exacerbate or diminish health inequalities, or (further) alter existing norms and practices surrounding reproduction.

The fact that the potential (long-term) consequences of reproductive HGGE are broad and far-reaching has informed the approach of the DNA-dialogue in two important ways. Firstly, it meant that within the DNA-dialogue, a wide audience was invited to participate in the dialogues, recognizing that the nature of HGGE warrants broad reflection. Lastly, it meant that the dialogues were future-oriented and facilitated discussion on the consequences HGGE could have for individuals and society in the long run.

Approach

The DNA-dialogue consisted of three phases: preparation (1), conducting dialogues (2) and analysing and reporting the results (3). Within these phases a wide variety of research, communication and public engagement activities took place.[10]

During the preparation phase, the Rathenau Instituut published a report that gave an overview of the societal and ethical issues surrounding HGGE and the political and public debate about HGGE in the Netherlands. The report concludes with ten lessons relevant to the design and contents of the dialogues. In addition, four techno-moral scenarios were drafted, that each imagined a different society in 2039 based on four application strategies for HGGE. These scenarios are a tool to specify and explicate potential

consequences of HGGE for individuals and society as a whole, and the underlying moral dilemmas. Three of these were transformed into short, animated movies that were used during the dialogues to provoke reflection and discussion. Besides these activities by the Rathenau Instituut, a communication and media strategy were developed, that outlines the media-outlets and strategies to be used to inform different groups about the topic of HGGE and invite them to participate in the discussion. The fact that the consortium was multidisciplinary meant that many different groups were represented in the consortium itself, which made it easier to invite different groups to participate.

In the second phase of the project 27 moderated dialogues were organized. In order to include a wide variety of perspectives in the dialogues, some were aimed at a broad, general audience, and others specifically targeted certain groups, such as patients, school children, medical professionals, the elderly and people with a migrant background or with lower literacy. Each dialogue was tailored to the target audience, for example by starting the discussion with a case study that is relevant to the specific group, or by using language that is easier to understand. Two versions have been made of the animated scenario's, including a shorter version with simpler language.

Analysing the results

Written reports were made during each of the 27 dialogues, which were qualitatively analysed in the last phase of the project. This resulted in the identification of six recurring themes:

1. Do we want to use HGGE and if so, for which purposes?
2. How should we shape the clinical practice in which HGGE is embedded?
3. What risks are connected to HGGE and how should we deal with them?
4. What organizational and ethical issues are connected to basic and clinical research of HGGE?
5. What societal implications could application of HGGE have?
6. What notions of the good life, reproduction and parenthood exist in relation to HGGE?

The discussion of these themes was then summarized in terms of the values, concerns, hopes and expectations of participants, and the conditions they formulated under which they deemed reproductive HGGE acceptable. Within the DNA dialogue quantitative research was conducted in the form of a questionnaire that was filled out by a representative sample of the Dutch society, complementing the qualitative results of the dialogues.

Use of TA outcomes

The results of the DNA-dialogue provide a rich insight into the various perspectives, considerations, questions, hopes and worries surrounding HGGE in Dutch society. They have been published in a final report, that also includes six recommendations to policymakers for further reflection and decision-making, which has been handed over to the minister of Health, Welfare and Sport in January 2021 (DNA-dialogue, 2021).[11] An article in CRISPR Journal gives the key findings and conclusions in English (Van Baalen, 2021).[12] Additionally, a 'consolidation report' was published that contained lessons learned and instructions for organizing successful societal dialogues in the future.

HGGE is one of five topics about which societal dialogues have been financed, and in some cases commissioned, by the Ministry of Health, Welfare and Sport.[13] These dialogues are part of a broader political re-evaluation of the Dutch Embryo law, that also includes the topic of creating human embryos for research purposes and expanding the indications for embryo selection. The formal political discussion about altering the Embryo law has not taken place yet, but the results of the societal dialogue on HGGE,

as well as the dialogues on other topics, will likely inform that discussion significantly. The results of these dialogues are included in the latest periodical evaluation of the Dutch Embryo law

How soon this political discussion will take place is still uncertain. For a big part, it depends on which parties will be part of the cabinet that is currently being formed and what agreements they make regarding to altering the Embryo law. The current cabinet consists of the same four parties that formed the previous cabinet. Thus, including the liberal party D66 and the Christian party CU, whose different perspectives on medical ethical questions resulted in the agreement of the previous cabinet not to alter the Embryo law before societal dialogue had taken place (interpreted by some as a means to postpone decision-making).

The impact of the Rathenau Instituut on the societal and political discussion on HGGE is not limited to our contributions to the DNA-dialogue. The Rathenau Instituut has monitored biotechnological developments closely for many years—including HGGE—and published several articles and reports on the matter. In several earlier publications on HGGE, the Rathenau Institute addressed that the societal discussion on HGGE focused too narrowly on the medical risks and benefits and failed to sufficiently recognize the impact HGGE could have on society and human rights. However difficult to pinpoint the exact causality, these publications have contributed to broadening the discussion of HGGE and the political recognition that HGGE warrants broad reflection and discussion, which in turn, likely contributed to the Ministry of Health financing the DNA-dialogues.

Thus, by providing TA-insights on a scientific or technological field over time, instead of through one-off TA-projects, the Rathenau Instituut is able have a long-term, (more) subtle and significant impact on societal debate and political decision-making. For an important part, this is made possible because the Rathenau Instituut is an impartial organization and receives structural financing to independently establish and carry out its working program.

Local and/or national TA context

Since over 35 years, the Rathenau Instituut is tasked with contributing to the societal debate and political opinion-forming on the impact of science, technology and innovation on society. It is specifically tasked to support the forming of political judgments in the Dutch and European parliaments.

The Rathenau Instituut receives structural funding by the Ministry of Education, Culture and Science, and independently establishes and carries out their own working program. We conduct research and organize dialogue both on our own initiative as well as commissioned by several national and European organizations, such as Ministries, governmental and societal organizations or the European Commission.

The Rathenau Instituut has grown from being a project organization into an organization that develops expertise programmatically. We actively share this expertise with parliament, policy-makers, journalists and (other) stakeholders.

4 Value-Directed Artificial Intelligence

Written by Petra Verhoef, with input of Linda Kool and Rinie van Est, Rathenau Instituut, The Netherlands

TA topic, purpose and audience

Introduction

Purpose & audience: The case study 'Value-Directed Artificial Intelligence' describes a period of roughly five years during which the Rathenau Instituut, a parliamentary technology assessment institute in the Netherlands, step-by-step urged the Dutch and European government and relevant societal stakeholders to build a governance system for using Artificial Intelligence (AI) in a value-based way, for purposes in various domains, ranging from care, justice or public administration. Hence, this case-study is not about a project, but it describes a series of studies and activities which were undertaken over time, partly based on a pre-defined strategy, partly in response to policy actions or news.

The audience was mainly stakeholders of the governance system regarding social and ethical aspects of digitalisation of society, i.e., the players who define social and ethical issues, put them on the policy and political agenda and translate them into actions, policy instruments, regulations and laws. Citizens were not targeted per se as audience at the start, but we engaged them later on.

The initiating factor for the series of (mostly) technology assessment studies performed by the Rathenau Instituut was a motion tabled by the Dutch Senate on 23rd of September 2014 asking the government to invite the Rathenau Institute to investigate the desirability of a committee that can advise on the ethical aspects of the digitization of society. The motion was based on the suspicion of members of parliament that digitization is compromising some important public values and human rights.

TA topic: Artificial Intelligence

Artificial Intelligence (AI) could be considered an enabling technology, as it has the potential to enhance other technologies. There are many applications of AI, some of which have already been integrated into our daily lives for quite some time: online search engines, spam filters in your mailbox, and the recommendations we get when watching favourite movies or series.

New possibilities of AI are presented to us in various domains. For example, a 'trained' algorithm that recognises skin cancer based on a picture of the skin better than a dermatologist would. Or AI-based image recognition helping to search seized data carriers of (suspected) criminal persons to find a particular object. These speeds up the work of detectives and makes the work more effective and efficient. Despite the evident value of these applications, society is confronted with the negative aspects too: smart software systems of public services or offices that turn out to discriminate or subtle algorithms which play a role in the distribution of disinformation.

In an article of March 2019, we gave a definition of AI: Nowadays, a distinction is often made between "rule-based AI" and "machine learning". Rule-based AI is based on programmed "if this, then that" instructions. Such a system doesn't learn from itself, but it does exhibit intelligent behaviour by analysing

the environment and taking action—with a certain degree of autonomy—to achieve specific goals (see the European Commission's definition of AI). Machine learning is based on detecting and learning from patterns in data. It involves developing software that improves its own performance, and it relies heavily on statistics. Deep learning is a type of machine learning based on neural networks (inspired by the biology of the brain). It involves combining weightings with input so as to classify and cluster that input.

Although public and political debate currently focuses mainly on forms of machine learning, it is important to understand that machine learning is only one type of AI. Machine learning and deep learning do not replace other types of AI; an AI system often involves a combination of multiple AI technologies, such as decision trees or logical reasoning (Jong, de, et al. 2019)

TA approach: steps and impact

The method applied was at first mainly parliamentary technology assessment to evaluate risks and ethical concerns on digitalization of society (such as robotics, big data, Internet of Things and of course, AI). In later stages we reported on AI separately, and not only wanted to influence the political agenda in the Netherlands, but also in Europe and worldwide. Quite recently we have started to organize dialogues among (international) stakeholders via blog series based on interviews, and among citizens via focus groups and small dialogue events.

Overall, we took a 'technology-centric' approach, the results of which should help improving the functionality of AI in various societal domains, ranging from care, justice or public administration. Safeguarding of public values is central to our advice of building and strengthening a governance system for using AI; we call it 'a value-directed application of AI'. We will describe the events from getting it on the political agenda, informing and educating the parliament and other stakeholders to the point of creating impact.

Steps and activities, including methods and tools

Since early 2017, our impact on the political and public debate became much more evident and far-reaching than before. We then published report called Urgent Upgrade (Kool et al. 2017) which discusses ethical and societal issues raised by digitalisation of society. The research, using the method of technology assessment, was done in response to the motion mentioned in the introduction. In hindsight, Urgent Upgrade turned out to be a pivotal publication, which initiated political and public debate on digitalisation like never before in the Netherlands. The report concluded that an urgent upgrade of the governance system for use of digital technologies, including AI, in societies is needed—a system in which ethical and social values are structurally secured. The Rathenau Instituut proposed a national action programme for a responsible digital society, which included the appointing an interdepartmental working group, drawing up a 'Digitization Agreement' formulating the commitments and responsibilities of businesses, government, and civil society actors, and holding regular political debates in the Senate and House of Representatives in the Netherlands on the governance of societal and ethical digitization issues.

With Urgent Upgrade, we had alerted politicians and other stakeholders in the governance system. We shared a clear, inspiring strategy for building a more stronger governance system that would be able to safeguard these and other important public values: privacy, autonomy, safety and security, control over technology, human dignity, equity and equality and balances of power.

At the end of 2017 and early 2018, Rathenau Institute together with the Social and Economic Council (SER, which advises the Dutch government and Parliament on social and economic policy) organised working conferences on public values and digitalization, involving companies, NGO's, ministries and regulators; with the aim of creating awareness and working towards principles or guidelines relevant for digital innovation. In that sense, we had an eye for the economical and innovation aspects as well. One

could say that the assessment perspective was widened to the stakeholders in the innovation ecosystem. However, this was meant mainly to involve and inform; not to drive the innovation per se.

In the summer of 2018, the cabinet presented their first National Digitalisation Strategy and the Rathenau Instituut published the follow-up of Urgent Upgrade: Directed Digitalisation (Kool et al., 2018). This report described how, between 1 January 2017 and 30 June 2018, work was undertaken in the Netherlands on a digital transition focusing on people and values. We noticed the impact of Urgent Upgrade, but we concluded that improvement was needed. We deemed that the position of regulating and supervising bodies should be strengthened further. We advised that the public sector, the private sector and civil society organisations must steer digital society in such a way that greater focus is placed on people and values. The aim should be a digital society in which no one is excluded.

In early 2019, our attention focused on AI. We observed that awareness on the ethical and societal aspects of AI was growing, and we hence wrote an article in the run-up to Netherlands Digital Day on March 21st of 2019. During this digital summit, parties from the business community, the scientific sector, government and civil-society organisations were going to discuss further development of the National Digitalisation Strategy and the question of how we can give shape to the digital transition. AI was the overarching theme for the digital summit. We took an EU-centred focus to widen our potential impact. And, importantly, we analysed what a value-based approach would mean for using AI in practice.[14] We spoke of “AI systems” rather than “AI” to acknowledge that we are dealing with automated decision systems used in all kinds of societal interactions and services. We phrased political questions, for example: who possesses the knowledge needed to take decisions? And, who determines who possesses that knowledge?

At that same time, we also made an inventory of all parties that have committed themselves to formulating and underwriting certain guidelines for the development and use of AI. We looked at statements, declarations, guidelines and codes regarding ethics and AI.[15] These commitments are each important, but also show the lack of alignment. Next to the advice to stop this proliferation of codes and principles, we advised to establish a link between innovation policy and public values more emphatically, including within the National Digitalisation Strategy; and to make the values perspective central to experimentation in actual practice.

In 2020, we made shorter, specific Briefs to the Parliament, addressing the scope of the Ministry of Economic Affairs and Climate Policy and the Ministry of the Interior and Kingdom Relations in the context of digitalization and AI in particular. In that same year, we responded to the European Commission's (EC) White Paper on Artificial Intelligence, with our publication *EU, ensure that AI makes us more sustainable, healthier, freer, and safer*.[16]

The Rathenau Instituut gave seven recommendations in its response to the EC. These include: connect excellent research with responsible AI innovations, take international responsibility and take into account local differences, especially in the public sector. We stressed to not only focus on the safeguarding of the public values but assess if and how AI can help reach important societal goals.

In 2020, at the request of the House of Representatives’ Temporary Committee on the Digital Future (established in 2019), we also investigated how the House can better manage the desirable and undesirable consequences of digitalization. In the report *More grip on digitization*, we scanned the working methods that parliaments in ten different countries employ to address digitalisation and used the outcomes of our study as a basis for identifying various ways in which the Dutch parliament can tighten its grip on this process (Rathenau Instituut, 2020).[17] One recommendation was to establish a standing Committee for Digital Affairs, which the House adopted in October 2020. The Committee was installed in 2021.

To give the standing Committee for Digital Affairs, an immediate agenda with attention points for use of digital technologies (including AI) in eight domains (including: news, public services, education, health care, platform economy and energy), we wrote a Brief to the Parliament (May 2021: *Grip on the digital society of tomorrow*)[18], based on research of the previous four years. In October 2021, we elaborated on

this in the report Status of the digital Netherlands, meant to give the new Members of Parliament a concrete agenda for their political work (Kool et al, 2021).

In 2021, we also advised the Upper House of Representatives on the use of AI within the government in a publication called *Grip on algorithmical decision taking in government.* The need for such advice was evident: the risk of AI dramatically affecting people's lives has painfully materialized with the 'allowance affair': between 2013 and 2019, the Dutch government wrongly accused an estimated 26,000 parents of making fraudulent child benefit claims, based on algorithms using demographic variables, such as migrant background. Families were ruined, financially and emotionally.

In the past two years, we have added dialogue approaches to the technology assessment: we have started to organize dialogues among national and international stakeholders via blog series based on interviews, and among citizens via focus groups and small dialogue events:

- Blogs on AI and manipulation (started in April 2022)[19]
- Blogs on international aspects of AI (between May 2020 and June 2021): e.g., we spoke to Karine Perset,[20] administrator of the OECD's AI Policy Observatory, part of the OECD Division for Digital Economy Policy in Paris and to Sally Radwan, the minister's advisor for artificial intelligence at the ministry of communications & information technology of Egypt.[21]
- Blogs based on interviews with 10 stakeholders on AI in health care (mid 2019 and early 2020).[22]

Together with the Dutch AI Coalition, we organized four citizen dialogues on AI in health care, using insights of our reports and above-mentioned blog series.

In addition, we assessed the application of the precautionary principle in AI-based Clinical Decision Support Systems as part of a H2020 project RECIPES.[23]

Use of TA outcomes

As historically described in the previous paragraph, we have used TA to identify social and ethical issues of AI, have successfully put them on the policy and political agenda and have subsequently, together with stakeholders, helped to put them into concrete actions. We have made a substantial contribution to the governance system of AI in the Netherlands by informing the National Digitalisation Strategy, helping with the establishment of a standing Committee on Digital Affairs, informing and educating the Upper and Lower Houses of representatives and by engaging with various stakeholders in the governance system of AI. We emphasized the importance of safeguarding of public values, but also informed strategies on innovating with AI to help reach important societal goals. Attention points for practical use for various domains gave actionable policy options and direction for parliamentarians.

The various ministries, in particular Education, Culture and Science, Economic affairs & Climate and Public Health, Welfare and Sports frequently use our reports and expertise and invite us to broaden their knowledge. This has noticeable, beneficial impact on policies, e.g., on AI for health or justice.

We have in the meantime created a firm connection to the standing Committee Digital Affairs. We have informed them recently on the role of social media platforms in societal unrest, polarisation, disruption and other unwanted impact on our democracy. The Committee recently also asked for a position paper on AI to help build a knowledge agenda and debate.

With our blogs and societal dialogue, we currently inform and engage citizens, international scientists and other institutes on our work and mission.

National TA context

For over 35 years, the Rathenau Instituut has been tasked with contributing to the societal debate and political opinion-forming on the impact of science, technology and innovation on society. It is specifically tasked to support the forming of political judgments in the Dutch and European parliaments. The Rathenau Instituut receives structural funding by the Ministry of Education, Culture and Science and independently establishes and carries out their own working program. Additionally, we conduct research and organize dialogue both on our own initiative as well as commissioned by several national and European organizations. Other parties inform the government or society on AI as well, but not per se from a parliamentary perspective. This makes the landscape on AI advice quite scattered, and alignment and partnering still requires attention.

5 Industry and Manufacture Agenda 2030

Written by Luis Humberto Viseu Melo, Instituto Superior Técnico (IST), Portugal

Following the Resolution of the Council of Ministers stating the “Commitment to Knowledge and Science: the Commitment to the Future”, the Ministry for Science and Higher Education, through the Foundation for Science and Technology (FCT), ensured the preparation of fifteen Thematic R&I Agendas.

One of those is the Industry and Manufacture Agenda 2030. These Agendas aim in particular to mobilize experts from R&D institutions and companies to identify challenges and opportunities in the Portuguese scientific and technological system, particularly in the medium- and long-term. These agendas are also expected to contribute to the development of research and innovation activities, contributing to finding answers to the problems or needs of different sectors of society.

The inclusive and dynamic process of preparing these agendas—involving experts from academia, research centres, companies, public organizations and civil society, within a framework of dialogue between different national actors—makes it possible to specify emerging and promising areas for Portuguese Research and Innovation, in a medium- and long-term perspective, until 2030.

The main goal of the agendas is to foster collective reflection about the knowledge base supporting the scientific, technological and socioeconomic development of the country in the areas in question.

Other goals of the thematic agendas are:

1. promoting dialogue between the scientific and business communities by articulating the skills and needs of researchers, citizens, companies, the Public Administration and civil society organizations
2. building a medium- and long-term vision for the Portuguese research and innovation system, as well as more promising R&I agendas to achieve this vision in each thematic area
3. contributing to the creation of information sources capable of inspiring and supporting decision-making processes, in particular regarding R&I internationalization strategies and the research agendas of institutions and their researchers.

The preparation of thematic R&I agendas favours an inclusive and bottom-up approach, involving scientific, technological and business communities, as well as other organizations. This process is inspired by international practices for the creation of strategic agendas capable of mobilizing research and innovation.

Each Agenda is prepared by groups of experts with representatives from the scientific and business communities. These expert groups were assembled by inviting the heads of R&D units and companies to appoint various specialists, as well as by sending direct invitations to different experts, thereby seeking to encompass each area's different points of view.

Although FCT offered the necessary technical and logistical support for the completion of the process, including a content structure proposal, it is the responsibility of each expert group to produce the content

of each agenda. Each agenda's internal structure is determined by the expert groups, which concurrently select the experts who will assume the positions of rapporteurs and coordinators.

This innovative and dynamic process aims to stimulate an exchange of ideas between the scientific and business communities in an ongoing dialogue focused on building a common agenda.

The Industry and Manufacture Agenda 2030 assessed different enabling (emerging and converging) technologies from the point of view of potential impact to Industry and Manufacture in the following years. In this way, the technology assessment process was approached from an applications perspective, trying to identify the potential impacts in the area in connection to the state of maturity of the technologies, as well as the challenges and goals to aim at. The main overall goal is fostering global competitiveness of Portuguese Industry.

Some main challenges were identified in order to foster innovation in Industry and Manufacture:

- investing in enabling technology in order to create a competitive advantage
- integrating Industry 4.0 and circular economy concepts in the industrial sector
- responding to the development of new products and advanced processes
- incorporating knowledge and technological development in Industry
- contributing to the European leadership in the global markets.

These challenges are embedded in a global context that shall have a strong impact in Industry, namely:

- climate changes, demographic changes, competition for natural resources
- digitalization of industry and new business models
- development of sustainable value chains
- optimization of performance and efficient use of resources
- societal impact and social responsibility, ethical issues
- strong international competition for attracting investment.

In short, this Agenda should be a tool for implementing economic and social development, reflected in an increase of productivity and employment through industrial modernization.

Considering these challenges, five broad domains were identified as strategic focal points for this agenda:

- advanced materials
- advanced industrial technologies processes
- efficient management of resources and processes in industry
- industrial robotics and intelligent manufacturing systems
- collaborative networks and human-centric industrial production.

Technologies were assessed within each of these domains, starting from the applications side. The impact, or potential impact, of these technologies to Industry was addressed and their level of maturity evaluated. Industry needs and requirements for the development of these technologies were also assessed.

As a result of this process, it was possible to establish an overview of the most promising technologies to have a strong impact in Industry in the intended timeframe. This information is instrumental for all players in the field, in particular Industry and Policy, to design strategies for the next decade.

6 Biotechnology Assessment in Korea

Written by Jiyoung Suh, Science and Technology Policy Institute (STEPI), Republic of Korea

Introduction: The importance of strategic intelligence for "First Movers"

Korea has achieved rapid economic growth and industrial development in a very short period of time. From the standpoint of a latecomer, the goal of innovation is to adopt advanced technologies to speed up product development and foster industry. In Korea, this method of technological innovation has been applied as a dominant innovation paradigm for researchers and companies until the early 2000s. In this paradigm, the government's policy included the objective of quickly closing the technological gap with advanced countries and entering the leading group in the global market. In the process, the long-term impact on the health, lifestyle, ethics and environmental circumstances of members of society was somewhat neglected by policy makers.

In the 2000s, there was a growing awareness of the problem that Korea's strategy of following advanced countries could no longer be sustained. In the background, above all, there has been a change in the perception regarding the quality of life by members of Korean society. Demand for a healthy and happy life has increased among individuals, and this was viewed as a signal that the government should invest more resources and pay more attention to solving social problems such as the quality of medical services and environmental problems. However, externally, Korea has been experiencing difficulties due to the competitive pursuit of developing countries and strong position of advanced countries, and the need to gain a competitive edge in the global market could not be ignored.

Looking at Korean society now with 20 years having passed since then, the demands of members of society to resolve social problems have become stronger, and competition with advanced countries has intensified. In order to gain a global competitive advantage, the government and the private sector increased R&D funds, and the ratio of R&D expenditure to GDP in 2020 was 4.81%, the second highest in the world. The government is increasing R&D expenses in areas such as life/medical care, environment, and disaster areas, where private investment is difficult, and is making efforts to find growth engines that contribute to the improvement of social sustainability (MSIT, 2018; MSIT, 2019).

However, there is increasing awareness that the government's way of finding growth engines and supporting industries should be different from the past method of concentrating resources through 'picking the winner.' In designing an innovative policy, it is necessary to research in advance what kind of problem is to be solved through national resource input and what social and economic impacts may result, and to create evidence (Suh, 2023 forthcoming).

The importance of strategic intelligence to predict the socio-economic impacts that considers future generations in national policy establishment is growing, and interest in TA along with long-term future prospects and technology roadmaps is increasing.

Background & status of TA in Korea

Background of introduction of the Technology Assessment

Currently, in Korea, TA based on the Framework Act on Science and Technology has been implemented every year since 2001. In the 1990s, before the official technology impact assessment under the Framework Act on Science and Technology began, technology impact assessments were conducted by civic organizations such as the Citizen Science Center or the Korean National Commission for UNESCO (Ryu et. al., 2010)

Interest in 'genetic engineering' and 'gene manipulation' in the late 1990s played a major role in the institutionalization of TA in Korea. At that time, with the birth of Dolly the sheep, NGOs began to actively express concerns about the social side effects caused by science and technology, which led to a movement to enact laws on bioethics and GMOs. These concerns have expanded not only to biotechnology related to 'genes,' but also to Internet technology and nanotechnology, which were recognized as so-called 'promising technologies.' On the one hand, the economic and industrial impacts brought about by technological development in this field were presented in rosy colours, and on the other hand, concerns about various side effects, toxicity and ecosystem disturbances threatening the health of people and future generations continued to grow.

The government must implement a policy for fostering 'promising technologies' while responding to people's concerns about the risks of new technologies at the same time. In this situation, the government's response strategy was to 'enhance social acceptance' of science and technology. This is the background wherein the Ministry of Science and Technology, the department in charge of research and development of science and technology, enacted the Framework Act on Science and Technology, and stipulated the enforcement of TA as a law, and its purpose was mainly to ‘enhance social acceptance of technology.’

Status

In addition to the technical impact assessment of the Framework Act on Science and Technology mentioned above, the Ministry of Science and Technology enacted the Nanotechnology Development Promotion Act in 2002 and specified “NanoTA” in Article 19. The Ministry of Environment amended the Environmental Policy Framework Act in 2002 and institutionalized the “risk assessment of science and technology” for the environment. The Ministry of Agriculture, Food and Rural Affairs enacted the Agricultural Food Science and Technology Promotion Act in 2009 and specified “Evaluation of technological impact and technological level” in Article 16. The Ministry of Food & Drug Safety enacted the Food and Drug Safety Technology Act in 2015 and inserted the “Evaluation of technological impact and technology level” clause in Article 14.

The Ministry of Oceans and Fisheries enacted the Marine and Fisheries Science and Technology Promotion Act in 2017 and specified “technology impact and technology level evaluation” in Article 15. Recently, the Ministry of Food and Drug Safety has been conducting TA from 2020 with a focus on food and drug safety management. In 2021, through the revision of the Biotechnology Promotion Act, TA in the bio sector became regular. Although several ministries have enacted TAs, most of them are used for the purpose of identifying the demand for regulatory enactment/revision (the Ministry of Food and Drug Safety) or are not implemented regularly. It can be said that the Ministry of Science and Technology is the only ministry that conducts an evaluation of a wide range of social and economic impacts by utilizing the original purpose of TA.

Biotechnology Assessment

The most notable is TA in the bio field, which was implemented through the revision of the Biotechnology Promotion Act in 2021. In the case of biotechnology, it is in the spotlight as a technology that will greatly contribute to solving problems related to population aging, energy and environmental issues. However, from a technological point of view, biotechnology is recognized as having great potential to improve social sustainability, while social trust in technology is known to be low. In the early 2000s, intense debate among stakeholders took place over the extent to which research on cloned embryonic stem cells should be allowed. The negative perception of genetically engineered technology can also be seen in the recent debate over GM food labelling. The KFDA had formed a social consultative body to discuss the GM food labelling system in 2020, but there was a situation where the discussion was stopped (Consumers Korea, 2019). In fact, GM food labelling has nothing to do with the biotechnology that makes GM food. However, in the process of discussing the labelling system, a strong rejection of GMOs was revealed.

The government and high-level science and technology governance judged that it would be difficult to develop and apply biotechnology without solving the problem of 'understanding' and 'trust' of citizens. The government's expectations for TA are twofold. One is to create a social forum for biotechnology, and the other is to discover policy options in a manner that can increase the social value of innovation. In 2021, the Biotechnology Promotion Act was amended, and TA on biotechnology was institutionalized. In the bill, a clause is proposed that “TA on technologies that are expected to have a large social and economic impact among major technologies in the biotechnology field” should be implemented.

Challenges of BioTA

From instrumental TA for prediction to reflective TA for RRI

According to the Framework Act on Science and Technology, TA is defined as “the effect of the relevant technology on the improvement of the convenience of people’s lives and the development of related industries, the impact of new science and technology on the economy, society, culture, ethics and environment, measures to prevent this.” In addition, according to the government’s publications at the time, through TA, the government “contributed to the quality of life such as with regard to solving social safety issues in science and technology policies centred on economic performance, and analysed problems or negative impacts arising from the development of science and technology in advance and suitable countermeasures.”

In this context, it can be seen that so far, TA in Korea has been understood as a methodological tool to achieve two main objectives. First, TA is a methodology that detects the negative impact of new technologies early and searches for countermeasures. Article 23 (2) of the Enforcement Decree of the Framework Act on Science and Technology. Second, TA plays a role in preventing innovation from being hindered by the public's excessive concern about or rejection of new technologies. This shows that TA's policy function was understood as an 'early warning' and a 'tool' to enhance social acceptance of technology.

However, one thing to point out here is the vector of 'influence.' Here, it is technology that drives change, and society is in the position of being a passive object that must respond to change. If the policy function of TA is understood as 'early warning,' the success of TA is to prepare risk prevention measures according to the assessment results. This logical structure precludes the need for citizens to participate in the 'process' of technology development and policy formation (Suh, 2019; Suh, et. al., 2016).

In the face of welfare problems due to aging, energy problems due to climate change and environmental problems, it is not individual actors such as strong governments, outstanding researchers or CEOs of

companies with capital, but a shared vision to create a good innovation strategy that is essential. Such actors are Co-Creators who are in solidarity with each other in an effort to achieve a common purpose through various attempts.

For this, not only must the social impact of technology be understood, but also an open space for participation where members of society can influence technological innovation is needed. TA can serve to fulfil the function of such a space. In that space, from the perspective of future generations, sustainability, and quality of life, it is necessary to find out what has been overlooked in the practices of R&D and production sites so far.

Future TA should not be a tool for prediction but should play a reflective function role by reflecting the reality of the innovation ecosystem while mirroring social values and identifying directions to promote improvement.

Formation of commitment to innovation governance

The Korean government intends to support researchers and companies in the future so that they can transition from pursuing a strategy of seeking to catch up and become first movers. The government's role is, first, to provide accurate information about the domestic innovation ecosystem to innovators. It is necessary to analyse the changes in the ecosystem structure created by the interaction between innovators from a macro perspective to help innovators to have insights.

Second, the interests of Korean innovators can be reflected in the process of securing intellectual property rights and establishing standards for new technologies that are taking place at the global level. Until now, global technology governance has been led by the US or EU governments, or by global corporate giants. In the process, how technical standards and global trade norms affect the lives and business activities of citizens in developing countries and underprivileged countries has been overlooked.

In the future, TA should first serve as an intelligence function so that domestic research, industry and civil society can share and discuss issues related to the production of new knowledge and its industrialization that are being raised in the research-industry. In addition, TA should provide insights for the research community, industry and civil society to examine whether the research environment and industrialization process of new technologies are appropriate from the perspective of future generations and sustainability, and to reflect on current innovation capabilities and ways to improve the environment. In addition, if TA is conducted at the global level, it will be an opportunity for the socio-economic and ethical impacts of technology evaluated by domestic innovators to be reflected in global technology governance.

Strengthening societal challenge capacity

In the mid-2010s, as the social demand for the government to actively respond to the increase in medical expenses due to ecological changes due to climate change and the aging of the population increased, the development of energy sources to replace fossil fuels and production systems operated as by-products of fossil fuels were developed. The transformation of health care and the establishment of a health management system centred on prevention have emerged as the main goals of government policy. In the future, the government should make efforts not only to invest in R&D but also to enhance the social value of innovation for major technologies that are judged to contribute a lot to Societal Challenge.

From this point of view, biotechnology is one of the main technologies for which continuous TA should be conducted. In the ‘3rd Basic Plan for the Promotion of Biotechnology’ in 2017, biotechnology was presented as a promising technology for future job creation and market expansion (MSIT, 2017), and recently, it was selected as one of the 12 national strategic technologies such as AI and semiconductors (MSIT, 2022a). In the ‘4th Basic Plan for the Promotion of Biotechnology in 2022’ announced in November 2022, societal challenge through biotechnology was further emphasized (MSIT, forthcoming).

The government is of the view that 'breakthrough innovation' is necessary in the bio sector (MSIT, forthcoming). It is not just about securing technology, but that innovation with a big ripple effect that leads to changes in production methods and social culture throughout the industry must take place in the bio field. To make this possible, the R&D and Innovation Ecosystem must be designed so that social values can be created in the process of technology development and production.

it is necessary to examine whether an innovative ecosystem is in place in which the technological potential of new technologies can be realized in a manner that promotes improvements in the quality of life of members of society and enhances the sustainability of society.

If potential social risks are concealed with regard to technological progress and discourse on growth, efforts should be made to reveal the risks and explore what measures are needed to prevent them.

The method of innovation that contributes to solving major social problems is not 'formalized.' In a public forum such as TA, expectations and concerns about the technology that members of society have, as well as an understanding and a common vision for the innovation process should be taken into account.

Institutional environment for independent and stable TA

Korea's TA has been led by the 'administration'. Thus, the link between the results of TA and government policy is emphasized. This point is well shown in the contents of the laws on TA administered by each ministry below.

“The government shall evaluate in advance the impact of the development of new science and technology on the economy, society, culture, ethics, environment, etc. and reflect the results in policies” (Framework Act on Science and Technology, Article 14).

“Technical impact assessment may be conducted in advance on the impact and ripple effects of new marine and fisheries science and technology on the marine and fishery-related industries, and the results may be reflected in the master plan” (Marine and Fisheries Science and Technology Promotion Act, Article 15).

The purpose of the Korean government's institutionalization of TA in various laws is to reflect the results in government policies and basic plans. As mentioned above, there is a risk of turning TA into a political instrument, but the high linkage between TA and policy itself does not need to be viewed as a problem.

Unlike many other countries where TA is led by the National Assembly, in Korea, the administration takes the lead. When administration-led TA is carried out, there is an advantage that not only are improvements in macro aspects such as establishment or revision of policy directions realized but also new projects can be attempted at a fast pace or even more detailed parts of the system can be improved. In the bio TA, a promotion system should be devised to make the most of these advantages.

However, there are some concerns given that the executive agency is the one that actually performs the technical impact assessment of the executive branch, and the agency and the government department have a close business relationship (cf. Kwon, 2014; Suh, et. al., 2014; Lee et. al., 2015). It is also pointed out that there is a lot of room for the government to intervene in selecting the evaluation target for TA or setting the evaluation direction (National Assembly Legislative Research Office). In planning future bio TA, it is important to consider the appropriate budget and manpower so that the independence and stability of TA can be secured.

TA that responds in a timely manner to the trend of technological development

Today, technological innovation is proceeding at a very fast pace by utilizing deep technologies such as AI and Big Data. At the same time, the complexity of the innovation ecosystem in the bio sector is

increasing day by day. According to the data presented in the biotechnology promotion implementation plan, the bioindustry in Korea has recorded an average annual growth rate of 7% since 2015, exceeding the sum of the three major export industries (semiconductors, automobiles and chemical products), and the bioindustry (R&D+facility) investment is growing at an average annual rate of 7.0% (approximately $2 billion) compared to 2016 (MSIT, 2021). In addition, the number of core research personnel increased from 1 998 in 2013 to 2 855 in 2019. The number of workers in the bio industry increases by an average of 6.5% annually, reaching 53 546 in 2020 (MSIT, 2021).

If a biofoundry is built in the future and advanced AI manpower is nurtured, the speed of such technology development and industrial growth is expected to accelerate. In 2022, the Korean government has established the “Korea Synthetic Biology Development Council” (KSBA), a privately led cooperative organization, and has expressed its will to promote the introduction of deep-tech in the bio field and lay the foundation for genome research. In line with the rapidly developing trend of biotechnology, it is necessary to evaluate the social and economic impact of technology.

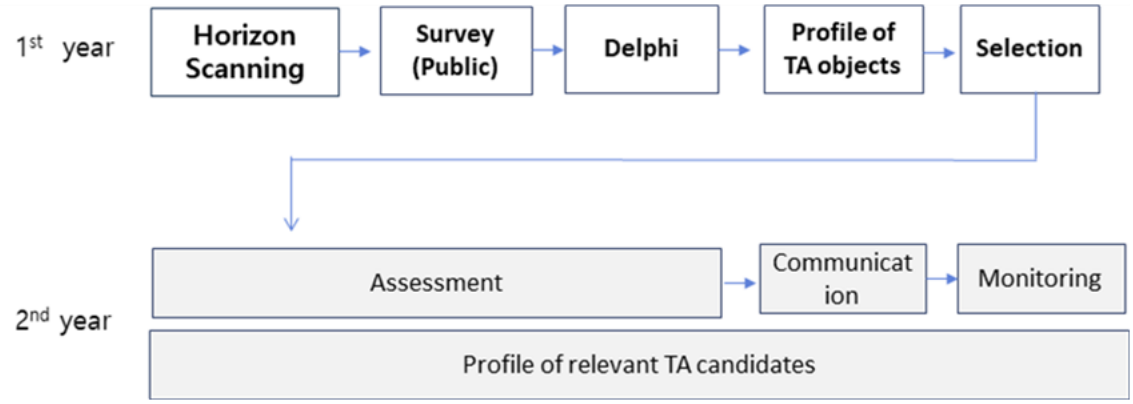
It was also pointed out that TA based on the existing Framework Act on Science and Technology lacks timeliness because all technologies are placed as assessment candidates and an assessment object is selected from among them. This is also the reason for separately promoting TA in the bio sector.

Bio Technology Assessment Plan

Implementation cycle: bi-annual

The TA will be conducted every two years. This is because assessment itself is important, but communication activities that enable policy stakeholders to understand TA and take interest in assessment are just as important. A communication strategy for TA is necessary both before and after implementation. In particular, after the assessment, the needs of stakeholders identified through sharing and communication will be fed back to the next TA. For this purpose, it seems appropriate to have a biennial cycle.

Figure 5. Cycle of TA



In the year when the assessment would not be conducted, a brief expert centred assessment of the socio-economic impacts of promising biotechnologies will be conducted and a short profile will be provided on an online platform. This has two purposes. One is to help a wide range of stakeholders understand new technologies, and the other is to produce the materials that will help select the subject and object (target)

of TA for the next year. Through a short profile, each stakeholder could have an opportunity to build his/her own perspective in each position.

TA Implementation Strategy

Establish a delivery system for policy governance

In order for the results of the TA to be used as 'strategic intelligence' for the establishment and improvement of innovation policies, it is necessary to establish a delivery system that delivers the results of TA to the governance organizations of the administration and the National Assembly. In addition, it is necessary to support policy stakeholders in citizens, industries, and academia to participate in TA or learn about policy issues and indirectly participate in national policy governance.

The policy governance of the executive branch may include governance organizations such as the Science and Technology Advisory Council and the Bioethics Committee (under discussion). As a communication partner of the research organization of National Assembly is expected to play an intermediary role (under discussion)

In the process of carrying out the TA, it is desirable to directly or indirectly participate in the stakeholder consultative body related to the bio innovation policy. Currently, the Biotechnology Policy Research Center (NBPRC), an agency under the Ministry of Science and Technology, operates the "Bio Regulatory Policy Forum" to discuss bioregulatory policy issues, and the Ministry of Industry has initiated the Korea Synthetic Biology Development Council (KSBA). The two stakeholder consultative bodies include researchers in the bio sector, industry stakeholders, and law and policy researchers.

Parallel research to understand the innovation ecosystem and policy stakeholders

After the implementation of TA was institutionalized based on the Biotechnology Promotion Act, a plan was established to actually implement it. STEPI was in charge of establishing a technology impact assessment plan. In this work, STEPI determined that it is necessary for academia and policy stakeholders to share their understanding of TA and presented an analysis of theoretical concepts and challenges of TA that should be attempted in Korea. In 2022, we plan to select the target of assessment for the pilot project scheduled to be implemented in 2023 and derive the main issues to be assessed.

In order for a TA to have policy implications, it must be possible to clearly reveal the perceptions shared by policy stakeholders and conflicting perceptions through the assessment. For this, it is important to understand the stakeholder's perception of technology in advance. In addition, structural elements of industry, institution and the scientific knowledge production structure that are related to stakeholders' perceptions of technology should be identified. These tasks are collectively called Horizon Scanning and are intended to be implemented prior to the TA.

For Horizon Scanning, biotechnology, industry, and domestic and foreign policy trends should be identified based on previously published literature data. It is also important to understand public perceptions by conducting a public survey on major technologies and innovation methods based on important trend information. As NBPRC continuously collects and analyses information on bio policy, industry, and technology trends, it has useful data for basic trend analysis of horizon scanning. Through horizon scanning we will not only analyse the trends, but also examine the gap between the perceptions of citizens and the perceptions of experts and industries (to be implemented in December 2022). For a more in-depth analysis of social and economic impacts, workshops and Delphi surveys with experts in the research, industry and policy sectors and citizen representatives will be held (only Delphi will be conducted in 2022).

Sharing the TA results with stakeholders through continuous communication

The results of the TA should be communicated not only to the administrative and parliamentary policy governance, but also to citizens of various classes and regions. To this end, the results of the TA should be reconstructed in a format that is easy for everyone to understand. In addition to documents, various media such as various media such as public conferences and exhibitions should be utilized.

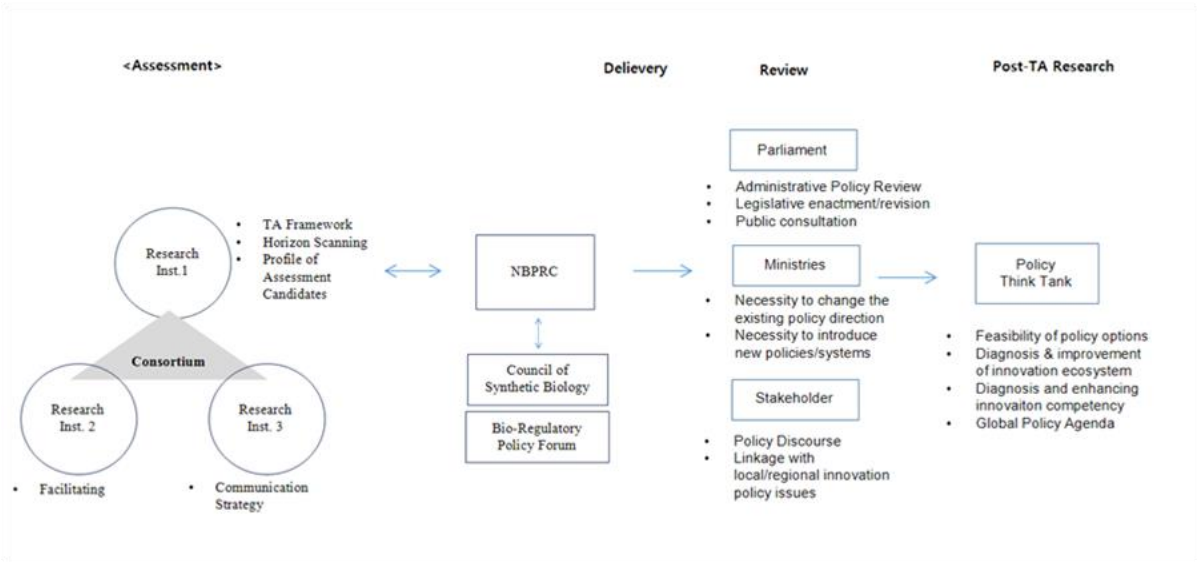
Promotion system and process

Hub & Spoke

BioTA will be conducted in a Hub-Spoke relationship between the Biotechnology Policy Research Center, an affiliate of the Ministry of Science and Technology, and the TA Research Institute.

There is no research institute specializing in TA in Korea. Therefore, a consortium type in which a Policy Think Tank such as STEPI (Science & Technology Policy Institute) and research centre of a university is linked would be suitable for conducting a TA (under discussion).

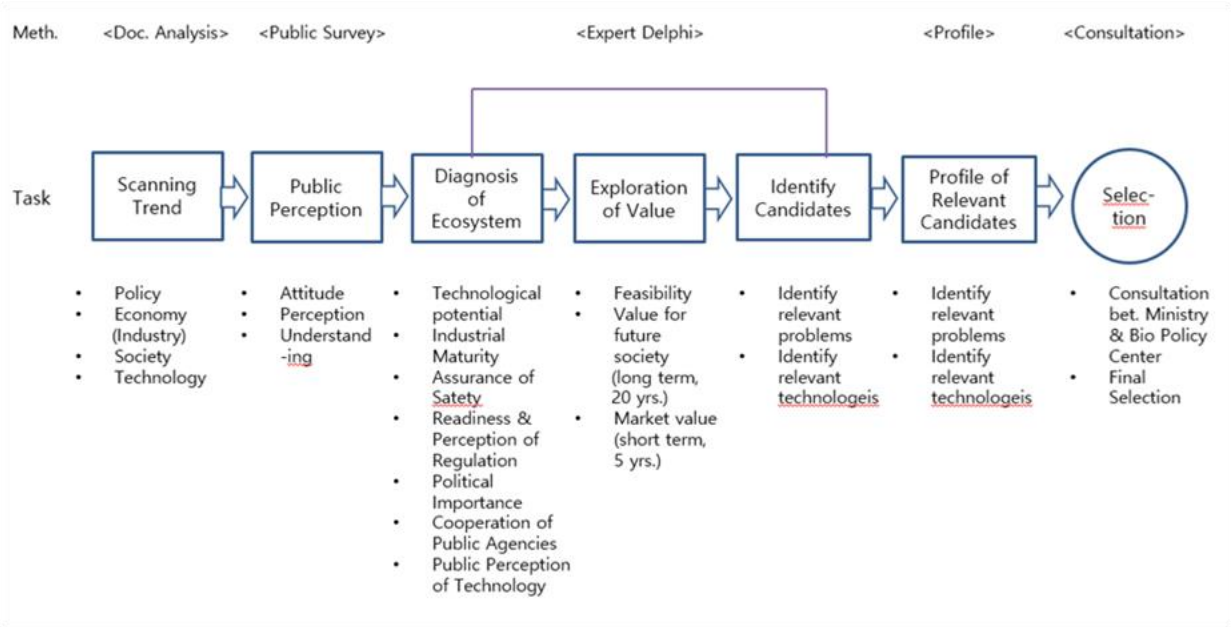
Figure 6. TA system



Process

In consideration of these various aspects, the TA will proceed as follows (possibly revised).

Figure 7. TA process



7 Novel and Exceptional Technology and Research Advisory Committee (NExTRAC)

Written by Irene Gadani, National Institutes of Health, USA

TA topic, purpose and audience

Introduction

The Novel and Exceptional Technology and Research Advisory Committee (NExTRAC) is the U.S. National Institutes of Health (NIH) Director's go-to advisory committee for advice and transparent discussions regarding emerging biotechnologies and any potential scientific, safety, ethical or social issues associated with their development and application. With the advice from the NExTRAC, NIH is well positioned to continue ensuring that its policies, guidance and oversight systems keep pace with the rapid and exciting landscape of biomedical research and technologies. This case study narrative will review the NExTRAC structure, past and current charges, the proposed framework for the Committee's work and the value of public engagement.

There is a long history of and ongoing efforts in technology assessment across the NIH and U.S. Government, and NExTRAC represents only one of many mechanisms. Prior to the establishment of the NExTRAC in 2019, the NIH Recombinant DNA Advisory Committee (RAC) was charged with in-depth review and public discussion associated with gene therapy research. As recombinant DNA technology became increasingly integrated into biomedical research, and in light of U.S. Food and Drug Administration's increasing regulatory authority and institutional oversight of gene therapy trials, NIH proposed removing the duplicative oversight of gene therapy research. In turn, this allowed NIH to re-envision the RAC into the NExTRAC, so as to align more closely to its original focus; serving as a public forum for discussing challenging questions that potentially arise with the emergence of new biotechnologies.

NExTRAC structure and makeup

NExTRAC consists of up to 25 voting members appointed by the NIH Director. A majority of the voting members are knowledgeable in relevant emerging scientific fields (e.g., data science, gene editing, synthetic biology). The Committee also includes persons knowledgeable in fields such as public health, laboratory safety, occupational health, protection of human participants in research, the environment, ethics, law, public attitudes or related fields. Members are typically external to the federal government but are employed by NIH as Special Government Employees to monitor potential conflicts of interest and

ensure balanced representation. As necessary, subcommittees and ad hoc working groups may be established.

Meetings of the full Committee are held approximately two times within a year. The meeting agendas are available to the public ahead of the meeting and the meetings are open to the public (rare exceptions may apply) with opportunities for public comments. Subcommittees and ad hoc working groups may meet more regularly when tasked with a specific charge.

NExTRAC Working Group efforts

The NIH Director issues charges to the NExTRAC, which have been varied in scope. Previous and current NExTRAC working groups and their charges include the following:

- Working Group to Establish a NExTRAC Framework (charge issued December 2019; report with findings published December 2020)
  - Describe effective approaches for prospectively identifying emerging biotechnologies or specific applications with reasonable potential to have important scientific, safety or ethical considerations; and
  - Conceptualize a framework for NExTRAC deliberation of issues surrounding emerging biotechnologies and applications.
- Gene Drives in Biomedical Research Working Group (charge issued December 2019; report with findings published September 2021)
  - Consider whether existing biosafety guidance is adequate for contained laboratory research utilizing gene drive technology; and
  - Outline conditions (if any) under which NIH could consider supporting field release of gene drive-modified organisms.
- Data Science and Emerging Technologies Working Group (charge issued June 2021, deliberations underway)
  - Define and characterize the types of research questions that require increasing granularity and aggregation of data about individuals that are likely to be addressed through emerging technologies; and
  - For those questions/technologies, consult with stakeholders to discuss and assess the value of and potential implications for individuals, groups, and society.

NExTRAC framework

To launch the work of the Committee, the NIH Director established a working group to describe effective approaches for horizon scanning and develop a framework to guide the NExTRAC and the NIH in its consideration of emerging technologies. The framework identified features of a biotechnology that may benefit from public deliberation and outlined a process for the NExTRAC's future work. The framework of this group, published in December 2020, also helps inform the NIH Director as he/she considers which topics and tasks merit the attention of the Committee, such as those with a reasonable potential to have important scientific, safety or ethical considerations within the NIH mission. Additionally, the framework is an effective tool for the Committee itself when considering any given charge provided by the NIH Director. Some topics that the working group discussed include:

- applications of emerging biotechnologies,
- components of horizon scanning approaches,
- features of biotechnologies and their applications to serve as "prompts" for public deliberation, and

- strategies for committee engagement and soliciting feedback.

Figure 8. Desired components of NIH approach(es) to prospectively identify emerging biotechnologies or specific applications

	Components
The horizon scanning focuses on and identifies…	…emerging biotechnologies and applications that fall within or are related to the NIH mission space.
	…input from diverse groups.
	…"convergence" (i.e., when technologies that were previously separate or distinct begin to align) as a harbinger of an emerging biotechnology or application.
	…early indicators of issues that would require an NIH response.
The horizon scanning process…	…integrates and builds on previous work of others to detect emerging technologies/research and gaps.
	…is iterative.
	…includes both (1) continuous horizon-scanning processes in strategically important areas and (2) stand-alone projects/processes designed to answer explicit questions.
	…includes explicit and deliberate strategies for recognizing and mitigating the effects of biases and psychological heuristics.
	…appreciates time frame appropriately tied to the purpose (likely 5-10 years).
	…has periodic re-evaluation of approaches to identify weak spots and gaps.

Source: Novel and Exceptional Technology and Research Advisory Committee. Report to Establish a NExTRAC Framework. 2020. https://osp.od.nih.gov/wp-content/uploads/NExTRAC-Framework-Report_FINAL_508.pdf.

The prompts are not meant to be all encompassing or in priority order, and they are not intended to be used as a checklist. In fact, a truly novel issue could arise falling within the scope of just one or two of the following prompts, and still be a high priority for discussion.

Figure 9. Set of prompts for public deliberation to help inform the NIH Director as he or she considers which topics and tasks merit the attention of the Committee

Source: Novel and Exceptional Technology and Research Advisory Committee. Report to Establish a NExTRAC Framework. 2020. https://osp.od.nih.gov/wp-content/uploads/NExTRAC-Framework-Report_FINAL_508.pdf.

In the report, the NExTRAC recommended that relevant technologies and applications include those that overlap and interface with the NIH's mission, such as artificial intelligence used specifically in to improve the conduct of biomedical research. The proposed scope of horizon scanning is not necessarily limited to NIH-funded technologies but would align with research supported by the NIH mission. The Committee also recommended that it would be helpful for the NIH to prospectively identify emerging biotechnologies or specific applications through horizon scanning processes that appreciate a 5-10-year time frame. In terms of the appropriate time frame, key questions include how long until an important impact is anticipated to occur, and, in some cases, when the technology is likely to enter clinical trials or the healthcare system.

Technology Assessment process: A benefit to risk-based approach

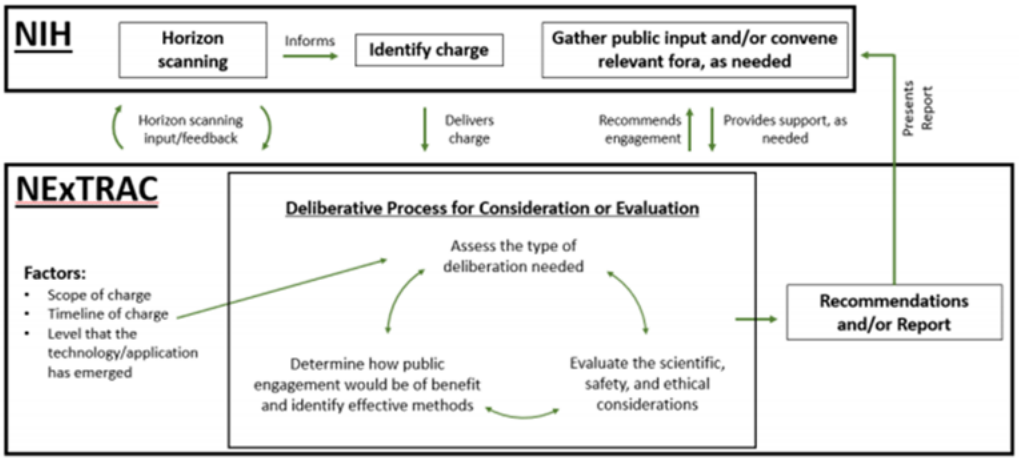
Charges delivered by the NIH Director may be scoped narrowly or widely, and a variety of approaches may be needed in different circumstances. The Committee recognized that it is not possible to anticipate all future possible charges, or specific approaches to address those charges. Indeed, attempting to anticipate all possible emerging technologies or applications may impose unnecessary bounds on the thinking of the group. As such, the Committee suggested the following process steps, which can occur iteratively and non-sequentially, where one step can inform another. The proposed process is intended to provide a flexible framework for future NExTRAC consideration or evaluation that can be applied in a charge-specific manner (Figure 11).

1. Assess the type of deliberation needed.
2. Evaluate the scientific, safety and ethical considerations.
3. Determine how public engagement would be of benefit and identify effective methods.

When the NExTRAC is given a charge by the NIH Director, it (or a working group of the Committee) will likely first assess the type of deliberation that is needed. The process of deliberation may depend on number of factors, such as the charge's scope, timeline and the level that the technology has emerged.

The Committee/working groups should also evaluate the relevant scientific, safety, and ethical considerations and how those considerations may be addressed by current or future policy/regulation. Such evaluation can be done through desk research of existing resources, workshops and meetings with field specific experts, etc. This assessment can also help inform how public engagement would be of benefit and identify effective methods of soliciting feedback and engaging the community. For example, during the Gene Drives in Biomedical Research Working Group deliberations, the Working Group reviewed the current state of gene drive technologies and experiences with other technologies involving field release of genetically modified organisms. They considered the adequacy of existing biosafety guidance and strategies for biological and environmental risk mitigation for both laboratory and field release research, assessing potential harms and potential benefits, and identifying and engaging stakeholders. The Working Group consulted with subject matter experts in these areas including at a public NExTRAC workshop, Gene Drives: Biosafety Guidance and Conditions for Field Release Research. Public comments were also considered by the NExTRAC as part of the workshop and deliberations on the draft report presented by the Gene Drives in Biomedical Research Working Group.

Figure 10. Potential deliberative process for NExTRAC consideration or evaluation



Source: Novel and Exceptional Technology and Research Advisory Committee. Report to Establish a NExTRAC Framework. 2020. https://osp.od.nih.gov/wp-content/uploads/NExTRAC-Framework-Report_FINAL_508.pdf.

Value of public engagement

Public engagement into NIH processes has value independent of any charge. As needed, NIH can gather public input for the Committee/working groups to consider or NIH can convene relevant fora to allow the Committee to engage directly with relevant stakeholders. This public engagement and input may take a variety of forms, including forums, workshops, Requests for Information, listening sessions, public broadcasting of the Committee's or working group's charge, progress and results, etc. Most NIH advisory committee meetings are open to the public by default, and public comments are solicited on draft reports. The NExTRAC recommended that the Committee/working groups should also identify a timeline and strategy for optimal public engagement on a charge-by-charge basis. For example, the NExTRAC Data Science and Emerging Technologies Working Group was charged in 2021 to consult with stakeholders and to consider the "attitudes and perspectives about sharing participant data to advance biomedical

research, specifically through the lens of balancing research risk (e.g., privacy, autonomy) with research deliverables." This working group is due to engage in discussions and stakeholder engagement in 2022 and findings are expected to be shared in 2023.

8 GAO's assessment of vaccine development technologies and the challenges of addressing infectious diseases

Written by Sarah Harvey, Government Accountability Office (GAO), USA

Introduction: TA background, purpose and audience

Background

In June 2020, GAO began an assessment of technologies and approaches that could increase the speed and reduce the cost of vaccine development. At the time, the U.S. had just over 2 million reported COVID-19 cases and 103 000 deaths. Americans had begun to see the spillover effects on the economy as millions lost their jobs because of stay-at-home orders and business closures. Vaccines, which protect people from disease by preparing the body to respond to an infection, were acknowledged to be an important tool for individual and public health and the U.S. Department of Health and Human Services (HHS) had allocated nearly $5.5 billion to support efforts related to COVID-19 vaccines and therapeutics.[24]

Rapid growth in basic scientific understanding—in areas such as genomics and structural biology that are supporting a new era in vaccine development—is poised to help the international community prepare for potential future epidemics and pandemics. Yet vaccine development continues to be a difficult, complex and costly endeavour. Vaccine developers face numerous technical challenges related to the biological complexity of some infectious diseases and the lack of maturity of new vaccine technologies. Other challenges include long development time frames, high rates of clinical trial failure and the lack of investment incentives. Economists told us that the benefits that vaccines provide have not necessarily provided a commensurate return on investment associated with developing or manufacturing them.[25]

Purpose and audience

GAO's main goal is to provide Congress, federal agencies, policymakers and the public with non-partisan, objective and reliable information to help the federal government save money and work more efficiently and effectively. GAO assists congressional decision makers and other policymakers in their deliberations by furnishing them with analytical information on various issues through its product lines, which include performance audits, technology assessments (TA) and other products.

Science and technology (S&T) issues figure prominently in problems that Congress confronts. One way that GAO provides objective, reliable S&T analysis is through the production of TAs that offer insights and

foresight on the effects of technologies and corresponding policy implications. Our Vaccine Development TA is part of GAO's response to the CARES Act, which requires regular reporting on government-wide issues related to the COVID-19 pandemic.[26] [27] The objectives of our Vaccine Development TA, as established at the onset of the study, were to identify and describe the technologies, approaches, and associated challenges for vaccine (1) research and development, (2) testing and (3) manufacturing, as well as (4) the economic factors that affect vaccine investment. The report was issued on 16 November 2021 to the nine Congressional Committees that authorized the CARES Act. GAO briefed staff from each of these committees prior to public release of the report. A full copy of the report can be found at https://www.gao.gov/products/gao-22-104371.

Vaccine Development technologies

In our TA we describe 16 innovative technologies and approaches that may enhance the nation's ability to respond to high-priority infectious diseases. The technologies and approaches have differing levels of maturity and applications. We focused on describing key factors that can affect each technology's ability to enable vaccine development and key challenges that may hinder its adoption.

For example, next-generation vaccine platforms, such as nucleic acid (e.g., mRNA and DNA) and viral vector platforms, can help speed development—particularly when new pathogens emerge—because they start with the genetic information that codes for the pathogen's antigens. This eliminates the need to grow the pathogen and then purify the antigens. These platforms are also highly adaptable to multiple pathogens, as the genetic code for the identified antigens may be quickly incorporated into various delivery vehicles, such as lipid nanoparticles or viral vectors. However, key challenges such as inherent technological limitations and the need for sufficient levels of highly trained personnel may hinder the adoption of next-generation vaccine platforms.

We also reported on the economic challenges that hinder vaccine development, such as market failures (i.e., market interactions that fall short of what would have been socially beneficial). Experts told us that market failures may result from underinvestment. There may be numerous reasons for underinvestment in vaccines; though one reason cited is that vaccines fail to capture their full benefit in the price. This stems from the fact that vaccines benefit both paying customers who are vaccinated and unvaccinated members of the population who receive some level of protection through herd immunity. Knowing that the full benefits cannot be returned discourages investment, which then contributes to market failures.

We identified three options for policymakers that could help address this and other challenges:

1. Conduct a systematic evaluation of factors that discourage developers from investing in new vaccines.
2. Evaluate the effectiveness of different mechanisms to incentivize vaccine investment and determine what circumstances or time frames may make some mechanisms more or less useful.
3. Assess whether relevant federal agencies have the authority to use mechanisms to incentivize vaccine development and, for any identified gaps, consider providing such authority.

Approach: Perspectives and processes for the TA

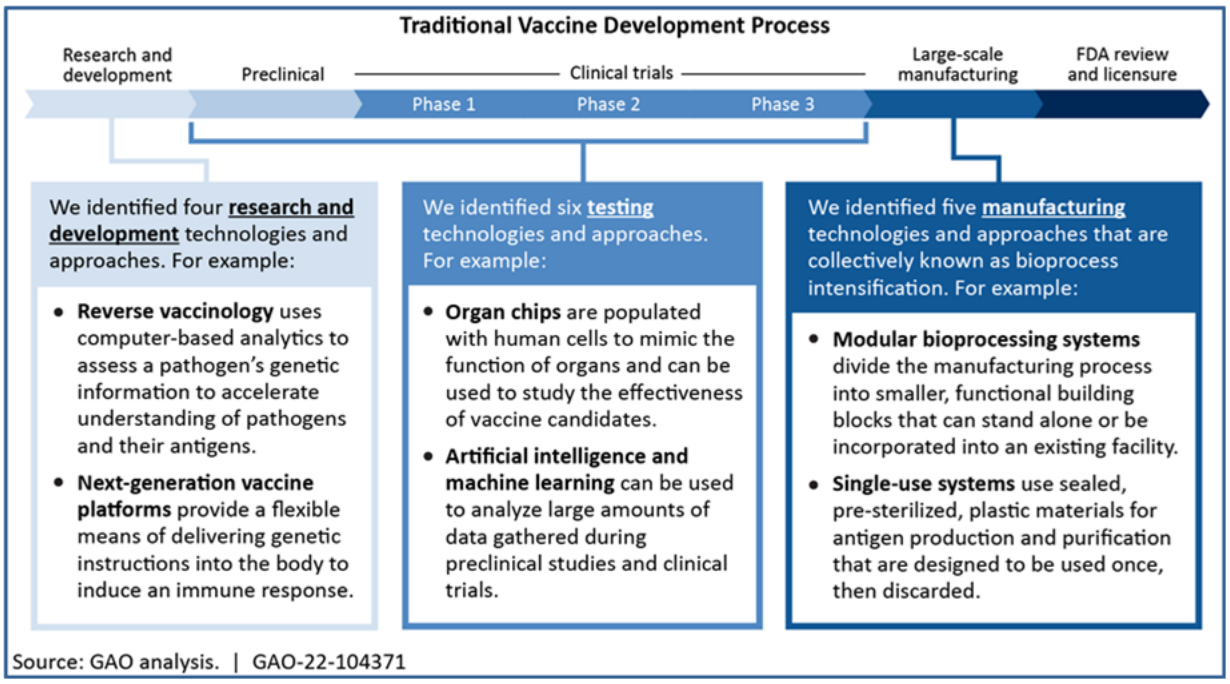
Perspective on assessing vaccine development technologies

With its primary focus on the innovation ecosystem, the Vaccine Development TA mapped each innovative technology to a phase in the vaccine development life cycle (Figure 11 below). Three chapters of the TA were devoted to describing the technologies, key challenges and related policy options for each life cycle

phase. The final chapter described the economic landscape of vaccine development and the policy options that may address related challenges.

This technology assessment is illustrative of at least four key dimensions for TAs that are described in Section 4 of this report: legitimate and trustworthy, clear granularity and scope, smart and inclusive participation and producing useable strategic intelligence.

Figure 11. Vaccine technologies and approaches used during vaccine development



Note: Note: Our TA also discussed the use of monoclonal antibodies, a technology typically used as a therapeutic that may also be leveraged as a preventative. Because a monoclonal antibody is not a vaccine, the TA did not map this technology onto the vaccine development life cycle and instead discussed it within the context of research and development.

While the TA's focus was on the overall landscape of vaccine development, we felt it was also important to provide a technology-centric view. Because of the large number of technologies discussed in the TA, we decided to provide technical information in short S&T quick reads—a series of one-page technology descriptions—as appendices to the report. These one-page descriptions were based on GAO's Science & Tech Spotlights.[28] This approach allowed policymakers and the public to quickly reference detailed information about each technology, including its level of maturity, how it works and potential applications. See Figure 12 below for an example of an S&T quick read included in the TA.

Figure 12. Example of a technology quick read from our Vaccine Development TA

Next-Generation Vaccine Platforms

Next-generation platforms allow vaccines to be developed based on the pathogen's genetic information, instead of first growing the pathogen (e.g., a virus) in the lab. As a result, next-generation platforms are highly adaptable, and can potentially accelerate vaccine development.

What is it?

Next-generation platforms use an interchangeable system of components, allowing vaccines to be developed in a plug-and-play fashion. Next-generation platforms use a carrier to deliver genetic instructions for an antigen—the substance that stimulates an immune response—into the body. Platform based approaches can be scaled up more rapidly, potentially accelerating vaccine development, and can target multiple pathogens (table 1).

Table 1: Examples of next-generation vaccine platforms

Vaccine Platform	Description
 DNA	DNA vaccines use synthetic DNA coding for an antigen. The synthetic DNA is inserted into a DNA vector, which delivers it into the body. The body's cells then convert the DNA to mRNA which, in turn, is converted into the antigen.
 mRNA	Messenger RNA (mRNA) vaccines are encapsulated genetic instructions that allow the body's cells to directly produce the antigen and stimulate the immune system. Since mRNA is naturally unstable, it is first stabilized and then packaged in a carrier molecule. Lipid nanoparticles—tiny spherical capsules made of lipids—are the most frequently used carriers.
 Viral vector	Viral vector vaccines use other viruses—genetically engineered to remove their disease-causing aspects—as the carrier to deliver the DNA code for an antigen into the body. Viral vector vaccines that reproduce themselves result in more antigen production and thus stimulate a stronger immune response.

Source: GAO analysis. | GAO-22-104371

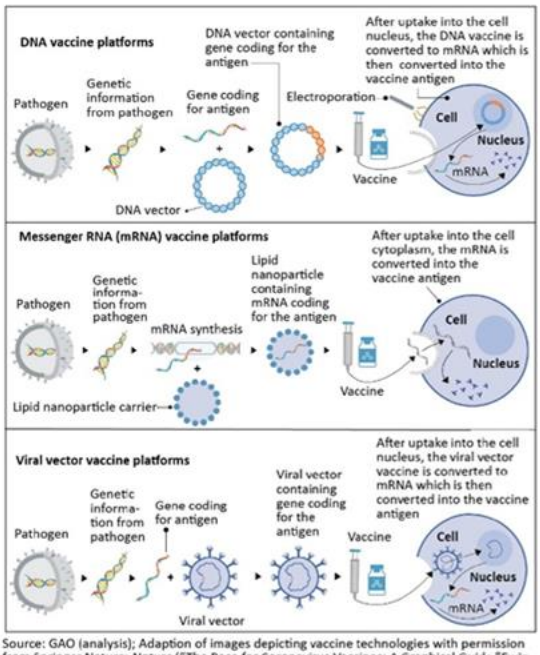
How mature is it?

Next-generation vaccine platforms are a recent development. As of October 2021, the Food and Drug Administration (FDA) had licensed two next-generation viral vector platform vaccines for use in humans—one for dengue and one for Ebola, and had issued an emergency use authorization (EUA) for a viral vector COVID-19 vaccine. FDA had also issued EUAs for two mRNA vaccines for COVID-19, and one of these vaccines had also been licensed for certain individuals. FDA had not licensed any DNA vaccines for use in humans, but had licensed one vaccine for use in animals.

How does it work?

DNA vaccine platforms contain genetic instructions that induce the cell to make the antigen. The gene encoding the antigen is plugged into a DNA vector to make the vaccine. mRNA vaccine platforms contain synthesized mRNA encoding the vaccine antigen, which is then encapsulated in a lipid capsule to make the vaccine. Viral vector vaccine platforms contain copies of genes encoding the vaccine antigen. The gene is plugged into a viral vector to make the vaccine (fig. 1).

Figure 1: Vaccine platforms



Source: GAO (analysis); Adaption of images depicting vaccine technologies with permission from Springer Nature: *Nature* ("The Race for Coronavirus Vaccines: A Graphical Guide," Ewin Callaway) © 2020 and MariLee/fizzgig/Sir.Vector/stock.adobe.com. | GAO-22-104371

Source: Davizro Photography/stock.adobe.com (header). | GAO-22-104371

Process used for the Vaccine Development TA

We followed GAO's Technology Design Handbook, which outlines key steps and considerations for TA design, in developing the Vaccine Development TA (GAO 2021). The process consisted of four key phases: initiation, design, message development and external review. See Table 4 below for a summary of these phases.

Table 4. Summary of GAO's Technology Assessment process

Phase	Steps
Initiation	• Discussion with Congressional request, if applicable, regarding scope and focus of the work • Consideration of technology state, relevant stakeholder expertise, and potential policy implications • Consideration of whether policy options may be appropriate for inclusion
Design	• Performance of initial research • Consideration of relevant sections of GAO's quality standards and methodological and technical standards and guides • Consultation with GAO subject matter experts and internal stakeholders, as needed • Discussion with agency officials and experts • Identification of and consultation with external experts, such as science, policy, and industry experts, who may also serve as external reviewers • Identification of policy options, if appropriate
Message development	• Collection and analysis of evidence • Assessment of evidence and research results • Development of draft findings • Ongoing engagement with external experts • Conduct and discuss policy options assessment, if appropriate
External review	• Request views from relevant third parties, if applicable, and request comments from relevant federal agencies, as appropriate • Request comments from external experts, and other as appropriate

Source: GAO-21-347G. https://www.gao.gov/products/gao-21-347g.

The team that developed the Vaccine Development TA followed this four-step process from beginning to end. For example, during the initiation phase, the team identified key stakeholders from government, academia, and industry to inform their initial considerations, identified the four objectives and began discussions about whether policy options would be appropriate for this TA.

The team then transitioned to the design phase during which they began their research, started consulting with subject matter experts and outlined their methodology. The methodology centred on a literature review, which included scientific articles and government reports, and interviews with stakeholders and experts who have a diverse set of perspectives on the science, administration and economics of vaccine development. A key part of the methodology was our collaboration with the National Academies of Sciences, Engineering and Medicine to hold a three-day expert meeting.

Box 1. Defining scope

To define and delineate scope, teams may consider:

- type, part or level of maturity of the technology
- time frame, economic sector(s) or geography
- types of effects and outcomes

- institutional considerations, such as previous work by GAO and other organizations
- availability of information, including possible proprietary nature of information.

Another key design step was determining the scope of the work. Scoping allowed the team to develop an initial understanding of the technology and the context around that technology, such as social, political, legal and economic factors. The team reviewed scientific literature describing current and developing tools; interviewed experts from government, academia, the non-profit sector and industry; and collaborated with internal and external stakeholders. Key limitations were also identified. Specifically, the team decided to focus their assessment on U.S. vaccine development, though pandemics pose a global threat. Also, the technologies and approaches to vaccine development and the economic incentives selected by the team were not an exhaustive list. Instead, the team selected those that were most promising based on the literature review and expert interviews. The team also chose to not include technologies and approaches related to vaccine distribution.

Engaging with internal stakeholders early and throughout the work was key to confirm soundness and reach agreement on each phase. For the design phase, stakeholders provided key input on the criteria, information required and sources, scope and methodology and limitations. As work progressed through data collection and analysis, stakeholders provided key input on whether additional work was needed. As the team moved into the message agreement phase, stakeholders helped assess whether evidence collected was sufficient and appropriate to support findings and conclusions reached for each objective. Once sufficient evidence was collected and analysed, the team discussed how the evidence supported potential findings and shared these findings with stakeholders during a formal message agreement meeting. Finally, as the team developed the product and prepared it for external release and distribution, internal stakeholders reviewed the draft for methodological and legal sufficiency.

The team also engaged with federal agency officials and external stakeholders to discuss findings and potential policy options and give them the opportunity to comment on the draft. The team provided a draft to the Department of Defense (DOD) and Health and Human Services (HHS) for review. DOD concurred without comment, and HHS provided technical comments, which were incorporated into the final product as appropriate. Nine participants from the expert meeting also reviewed a draft of the product, and their technical comments were incorporated into the final report, as appropriate.

As noted earlier, the Vaccine Development TA was part of GAO's larger body of work on the COVID-19 pandemic. GAO's TA products may be either single reports or part of a series, depending on the topic and congressional interest. An example of a series is GAO's series of TAs on Artificial Intelligence, which includes:

- Artificial Intelligence: Emerging Opportunities, Challenges, and Implications (GAO-18-142SP)
- Artificial Intelligence in Health Care: Benefits and Challenges of Machine Learning in Drug Development (GAO-20-215SP)
- Artificial Intelligence in Health Care: Benefits and Challenges of Technologies to Augment Patient Care (GAO-21-7SP)
- Artificial Intelligence in Health Care: Benefits and Challenges of Medical Diagnostic Technologies (GAO-22-104629) – anticipated issuance in July 2022.

Outcomes: GAO's role in U.S. science policy

GAO provides members of Congress and their staff with trusted, nonpartisan information on the performance of federal programs. Over the years, GAO has worked to make science and technology (S&T) analysis a priority. Policymakers need reliable, timely information on S&T topics as rapid developments increase complexity and affect the economy, national security and more. GAO responds to this need by

examining S&T issues government-wide and providing Congress with foresight and insight into emerging trends through its government oversight reports and TAs.

Technology presents opportunities and challenges that may vary, depending in part on the policy context in which they are assessed. We include policy options in our TAs to assist policymakers in addressing the challenges associated with a technology. Policy options can be used to articulate a range of possible actions that may enhance benefits or mitigate challenges. These options are addressed to policymakers broadly, not to a specific agency or entity. Although policy options do not endorse a particular course of action, GAO's analysis of multiple feasible alternatives is intended to demonstrate that various policy options have trade-offs, with each potentially fulfilling certain goals more than others. This information can help policymakers consider these trade-offs in light of the goals they hope to achieve and take action, if they so choose.

In our Vaccine Development TA, we proposed nine policy options that may help improve U.S. vaccine development capabilities by addressing challenges that hinder the adoption of relevant technologies or address economic challenges. To develop the policy options, the team compiled a list of 19 possible options that were based on their review of the scientific and economic literature, interviews with experts and the vaccine development expert meeting. The team analysed these options and removed ideas that were either redundant, not feasible to implement or did not fit into the overall scope of the work. The team then analysed each policy option by identifying potential benefits and considerations of implementing them. See Table 5 below for selected examples of the policy options.

Table 5. Selected policy options to address challenges in vaccine development

Policy Option	Opportunities	Considerations
Improve preparedness Policymakers could provide support for public-private partnerships to strategically address potential pandemic pathogens identified as priorities. These partnerships could, for example, develop and test vaccine candidates that may provide protection from pathogens with pandemic potential.	This early development could provide a coordinated foundation that can be mobilized in an emergency. Such an approach could speed vaccine development as well as potentially reduce risk for vaccine researchers and developers concerning questions of safety, efficacy, and manufacturability.	The lack of certainty of the commercial market and government funding for vaccines against pathogens with pandemic potential may be too risky for the private sector to undertake.
Further support development of data standards Policymakers could further support coordinated efforts to obtain the views of all stakeholders and to develop standards for health data and their use in clinical trials	Integrating researchers' needs into the standards development process could better ensure the necessary data are available. Access to high-quality data in a standardized format may allow streamlined patient recruitment for clinical trials	Expanding access to patient heath data requires attention to ensure privacy. Developing and implementing standardized data formats and IT infrastructure is time-consuming and costly.
Evaluate factors that inhibit vaccine investment and mechanisms to increase it Policymakers could collaborate across sectors, such as government, academia, and industry, to conduct a systematic evaluation of factors that inhibit developers from investing in new vaccines	A clear understanding of the range of factors discouraging vaccine investment would provide the basis for effectively addressing those factors	Collaboration between policymakers and other stakeholders to obtain all relevant viewpoints can be time-consuming and it may be hard to reach a consensus

Source: GAO-22-104371.

Local and national context for TA

GAO has conducted S&T work for nearly 50 years, including technology assessments for almost two decades. In 2018, Congress encouraged GAO to form an S&T-focused team, recognizing that the scope of technological complexities continues to grow significantly and that there is a need to bolster capacity of, and enhance access to, quality and independent S&T expertise for Congress. On 29 January 2019, GAO formally created the Science, Technology Assessment, and Analytics (STAA) team by pulling together and building upon existing elements within GAO. Since then, STAA has provided over 78 products to Congress, including technology assessments covering a wide range of science, technology and information technology issues. STAA has also worked collaboratively with other teams at GAO numerous products since its creation. STAA works collaboratively with other S&T organizations, including the National Academies of Science, Engineering and Medicine, Office of Science and Technology Policy, Consortium for Science, Policy & Outcomes at Arizona State University, Center for Innovation Policy at Duke University, and the American Association for the Advancement of Science.

9 The National Nanotechnology Initiative's strategic planning process and use of TA to select nanotechnology challenges: A case study

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Introduction to the National Nanotechnology Initiative

The National Nanotechnology Initiative (NNI) was launched in 2000 as a U.S. Government research and development initiative.[29] Federal departments, independent agencies and commissions participating in the NNI work together toward the shared vision of "*a future in which the ability to understand and control matter at the nanoscale leads to ongoing revolutions in technology and industry that benefit society*." Nanotechnology now spans a wide variety of science and engineering disciplines, and nanoscale solutions contribute to areas as diverse as medicine, energy generation and storage, water purification, smart materials, sensors, consumer electronics, high performance computing, food and agriculture and quantum information sciences.

Due to the breadth of nanotechnology, the NNI involves the related activities of more than 30 Federal entities with a range of research, development and regulatory roles and responsibilities. Funding support for nanotechnology R&D stems directly from NNI member agencies based on their missions and authorities, totalling nearly $40 billion since its inception.[30] Beyond the involvement of the Federal entities, the NNI community includes academia, industry, state and local government representatives, international collaborators, teachers and students and the broader public.

The 21st Century Nanotechnology Research and Development Act (P.L. 108-153), the legislation that established the NNI, created organizations and structures to support an engaged and coordinated nanoscale science and technology community.[31] The Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the National Science and Technology Council (NSTC) is the body that brings all of the agencies participating in the NNI together. The National Nanotechnology Coordination Office (NNCO) was established to provide administrative, logistical and technical support to NSET and to provide public outreach and engagement on behalf of the NNI.

The NNCO uses its convening power to bring together members of the NNI community to address needs, share information and best practices and identify areas of emphasis in order for Federal resources to be

better leveraged towards nanoscale solutions. For example, current and historical areas of focus include nanomanufacturing, nanoelectronics, nanosensors and water nanotechnologies.

Background, purpose and audience

The 21st Century Nanotechnology Research and Development Act also calls for the development of and regular updates to the NNI Strategic Plan. The NNCO supports the development of the plan with member agencies and in consultation with the broader NNI community. Public engagement and raising awareness of nanotechnology, including assessments of the current status and future directions, are important aspects of the NNI, especially during the strategic planning process.

The NNI Strategic Plan identifies goals and objectives for the initiative and guides the activities of the agencies participating in the NNI, individual and collective, to advance nanotechnology R&D in the U.S. The NNI Strategic Plan is a required document submitted to Congress as part of its oversight of the initiative, but another critical role of the plan is to communicate the NNI goals and priorities with academia; industry; Federal, state and local governments; non-governmental organizations and other interested parties. The plan, along with the annual NNI report, highlight the priorities of member agencies with regard to nanotechnology including their anticipated areas for interdisciplinary R&D support and methods to translate that research into the private sector.

Various aspects of the NNI focus on the 5 areas identified during the course of the Technology Assessment—strategic intelligence for policies on emerging and converging technologies project: 1. better technology (a techno-centric focus); 2. building better innovation ecosystems (industrial and innovation focus); 3. transforming systems to align with sustainable development goals; 4. build trust, transparency and inclusion with citizens (public awareness focus); 5. Envisioning desirable and undesirable futures (society focus).

Approach and processes for TA

The process for developing the 2021 NNI Strategic plan took a clean-slate approach and evaluated both the current state of technology and priority areas going forward. The envisioned outcome was the establishment of an operational framework to best support the entire nanotechnology R&D community. Key technology focus areas will be dynamic and will be identified via broad community engagement.

The strategic planning process actively sought input from every corner of the nanotechnology community through engagement at a wide variety of conferences, workshops and other meetings; one-on-one conversations, an Office of Science and Technology Policy (OSTP) Request for Information (RFI); and a dedicated public workshop to identify how to best support the nanotechnology R&D community now and into the future.[32] NSET created five strategic planning teams comprised of representatives from NNI-participating agencies. Each team focused on a different goal of the NNI: research and development, commercialization, physical and cyber infrastructure, education and workforce development, and responsible development. Through regular meetings, the strategic planning teams developed the RFI content and identified speakers, panellists and discussion topics for the public workshop.

This process resulted in the 2021 NNI Strategic Plan which identifies five interconnected goals and introduces new mechanism to better support the entire nanotechnology community.[33] The five goals are: 1) ensure that the United States remains a world leader in nanotechnology research and development; 2) promote commercialization of nanotechnology R&D; 3) provide the infrastructure to sustainably support nanotechnology research, development and deployment; 4) engage the public and expand the nanotechnology workforce; and 5) ensure the responsible development of nanotechnology. For each of

these goals, several objectives are identified as well as Federal actions and opportunities for the NNI community to participate and engage. The plan also identifies new mechanisms to better connect and support the nanotechnology R&D ecosystem, including National Nanotechnology Challenges (NNCs). The NNCs are intended to inspire the nanotechnology R&D community, and help make connections to broader efforts and resources, to focus on solutions to world challenges.

Selection of National Nanotechnology Challenge

The planning process that produced the strategic plan did not identify the specific scientific or technical priority areas for the new NNCs. The TA approach for the selection of NNC topics is best aligned with a mission-oriented focus. It is important to note that while the NNC mechanism itself does not provide funding, the expectation is that by focusing on a significant global challenge facing society where nanotechnology can be part of the solution, the collective efforts of the NNI community, including those of Federal funding agencies, will more quickly lead to solutions. Also, with greater communication, coordination, and community attention, these efforts will be more fully leveraged, and opportunities will be better known.

Possible challenge topics must be broad enough to be relevant to a significant number of NNI member agencies, align with the priorities of the Administration, have a sense of urgency in order to engage stakeholders beyond the U.S. government and represent a near-term opportunity for impact utilizing advances in nanotechnology. Specific NNC topics are selected by NSET, based on the interests and priorities of the NNI-participating agencies, in collaboration with the broader nanotechnology R&D community and informed by public input. For example, the request for information released during the strategic planning process explicitly asked the public for input on potential topics for “moonshots” and to identify world challenges where nanotechnology is likely to significantly contribute to solutions.

Once a potential topic is selected, an internal challenge group consisting of representatives of the relevant agencies is assembled to further refine the topic. The purpose of the internal group is not to fully develop an action plan and metrics of success—something the broader NNI community should do—but to scope the challenge. To maximize broad awareness and engagement, timing of the public announcement of a challenge should take advantage of existing activities. For example, National Nanotechnology Day (October 9th) is an annual celebration featuring a series of community-led events and activities to help raise awareness of nanotechnology. In 2022, a press release from the White House OSTP celebrating National Nanotechnology Day featured the announcement of the first NNC, Nano4EARTH, which focuses on climate change.[34] This was amplified through social media, and mailings/newsletters, and has been a regular talking point for leadership across the NNI community.

Once a NNC is public, the broader NNI community can address the challenge in different ways. Public workshops, panel discussions and talks at conferences may be developed. Working groups to address identified barriers and communities with specific interests may form. Also, existing community events can adopt the challenge topic to provide additional focus on the challenge’s greatest opportunities.

In the case of Nano4EARTH, a two-day workshop open to the public is being developed, featuring high profile thought leaders from the Federal government, academia and industry. Panel discussions will be focused on the nanotechnologies that are best positioned to make an impact on climate change in the near term (~4 years), the resources available to address barriers and ways to track and maintain forward momentum. These panel discussions, as well as input provided by all workshop participants, will form the foundation for a strategic planning session at the end of the workshop. A report summarizing the identified priorities and future directions, will be developed and broadly disseminated and communicated by NNI leaders. A journal article authored by representatives from a diverse group of NNI-participating agencies is also likely. It is anticipated that more focused activities will follow, which would assemble subject matter

experts on the identified nanotechnology solutions to map out paths forward towards the greatest needs of the challenge area.

National and international context

The NNI Strategic Plan highlights the collective vision, goals and objectives for the upcoming five years and provides the framework for national efforts. International collaboration is emphasized as an important part of NNI efforts. The NNCs are intended to address significant challenges and expected to inspire and mobilize researchers the world over to participate and help solve these important problems.

Endnotes

[1] The studies which are the subject of this paper have been conducted at the request of the Panel for the Future of Science and Technology (STOA) and have been managed by the Scientific Foresight Unit, within the Directorate-General for Parliamentary Research Services (EPRS) of the Secretariat of the European Parliament. The authors were at the time of these studies working for the Scientific Foresight Unit.

[2] For more information on STOA's foresight methods, see STOA publication: "Guidelines for foresight-based policy analysis." Lieve Van Woensel, July 2021.

[3] The terms new genetic techniques (NGTs) and genome editing are used interchangeably.

[4] Court of Justice of the European Union, Press Release No. 111/18: "Organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by the GMO Directive." 25 July 2018.

[5] European Group on Ethics in Science and New Technologies: "Ethics of Genome Editing" 2021.

[6] European Commission, Press Corner: "Biotechnologies: Commission seeks open debate on New Genomic Techniques as study shows potential for sustainable agriculture and need for new policy." 29 April 2021.

[7] European Commission, Have Your Say portal: "Legislation for plants produced by certain new genomic techniques."

[8] The following organizations constituted the consortium that organized the Dutch 'DNA-dialogue': the Dutch National Information Center on Heredity (Afrocentrism), the department for clinical genetics at the Erasmus Medical Center, Rathenau Instituut, NEMO Kennislink, NPV – Zorg voor het leven, the National Institute for Public Health and the Environment (RIVM), Center for Media and Health (CMG), Netherlands Association for Community Genetics & Public Health Genomics (NACGG), Patient Alliance for Rare and Genetic Diseases (VSOP), Dutch Clinical Genetics Society (VKGN), the section Community Genetics & Public Health Genomics and the Center for Reproductive Medicine at Amsterdam UMC.

[9] See for example the reports of the Nuffield Council on Bioethics (2018) and the German Ethics Council (2020).

[10] For a detailed description of these activities see https://www.rathenau.nl/en/social-and-political-debate-bioethics/dna-dialogue-analysis-and-outcomes (last accessed 11.11.2022).

[11] Zo denken Nederlanders over het aanpassen van embryo-DNA | Rathenau Instituut (last accessed 11.11.2022).

[12] The DNA-Dialogue: A Broad Societal Dialogue About Human Germline Genome Editing in the Netherlands | The CRISPR Journal (liebertpub.com) (last accessed 11.11.2022).

[13] The other topics are the creation of embryos for research purposes (1), expanding the possibilities for embryo selection (2), growing human organs in animals (3) and creating synthetic embryos (4).

[14] https://www.rathenau.nl/en/digital-society/how-we-put-ai-practice-based-european-values (last accessed 11.11.2022).

[15] https://www.rathenau.nl/en/digital-society/overview-ethics-codes-and-principles-ai (last accessed 11.11.2022). (last accessed 11.11.2022). (last accessed 11.11.2022).

[16] EU, ensure that AI makes us more sustainable, healthier, freer, and safer | Rathenau Instituut (last accessed 11.11.2022).

[17] More grip on digitisation | Rathenau Instituut (last accessed 11.11.2022).

[18] Grip op de digitale samenleving van morgen | Rathenau Instituut (last accessed 11.11.2022).

[19] New blog series on AI and manipulation | Rathenau Instituut (last accessed 11.11.2022).

[20] 'Policy experiments are important to provide controlled and transparent AI systems' | Rathenau Instituut (last accessed 11.11.2022).

[21] Worldwide harmonisation AI can harm regional values | Rathenau Instituut (last accessed 11.11.2022).

[22] Artificial intelligence in healthcare: deciding together is crucial | Rathenau Instituut (last accessed 11.11.2022).

[23] Case Study 8: The use of Artificial Intelligence in Healthcare | RECIPES (recipes-project.eu) (last accessed 11.11.2022).

[24] GAO, COVID-19: Opportunities to Improve Federal Response and Recovery Efforts, GAO-20-625 (Washington, D.C.: June 2020).

[25] For further support, see Gouglas et al., "Estimating the Cost of Vaccine Development against Epidemic Infectious Diseases: A Cost Minimisation Study," The Lancet Global Health, vol. 6, no. 12 (2018): e1386-e1396.

[26] Pub.L. No. 116-136, § 19010, 134 Stat. 281, 579-81 (2020).

[27] GAO's next government-wide report can be found on GAO's website at https://www.gao.gov/coronavirus.

[28] GAO launched a new line of S&T quick read summaries to complement its more in-depth evaluations and assessments. Science & Tech Spotlights summarize emerging innovations and the relevant policy context. These two-pagers are available at https://www.gao.gov/science-technology. To see them as soon as they come out, subscribe to GAO's Science and Technology email updates.

[29] More information regarding the National Nanotechnology Initiative can be found at https://www.nano.gov.

[30] The NNI Supplement to the President's Budget serves as the initiative's annual report to Congress and details agency investments in nanotechnology R&D, provides highlights of progress toward the NNI goals, and outlines agency plans and priorities. The 2022 supplement can be found at https://www.nano.gov/2022BudgetSupplement.

[31] 21st Century Nanotechnology Research and Development Act available at https://www.govinfo.gov/app/details/PLAW-108publ153/summary.

[32] The RFI can be found at https://www.federalregister.gov/documents/2020/10/13/2020-22556/request-for-information-national-nanotechnology-initiative-strategic-planning, and workshop details are available at https://www.nano.gov/2021stakeholderworkshop.

[33] 2021 National Nanotechnology Initiative Strategic Plan available at https://www.nano.gov/sites/default/files/pub_resource/NNI-2021-Strategic-Plan.pdf.

[34] White House Office of Science and Technology Policy Marks National Nanotechnology Day 2022 available at

https://www.whitehouse.gov/ostp/news-updates/2022/10/07/white-house-office-of-science-and-technology-policy-marks-national-nanotechnology-day-2022/.