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Introduction

Technological developments and innovations punctuate the history of human civilisation, profoundly impacting the development of modern life. Inventions such as archery revolutionised hunting, with the wheel doing the same for transportation. The arch radically changed construction techniques, the loom revolutionised clothing, and printing transformed the storage and sharing of ideas. The steam engine led to industrial production, followed by the electric motor's democratisation of power. Vaccines and antibiotics profoundly altered health and medicine. The invention of the railway, automobiles, and airplanes revolutionised transport again; and the telephone, mobile communication, and the internet have made it as easy to talk to one another as if we all lived in one global village.

While all of these technologies greatly benefited humankind, they also sometimes brought about unintended negative consequences, which civilisations had to handle. They often disrupted life and social order, causing disarray and harm. Human society needed to learn how to make best use of innovation.

Technological development continues today, at an ever-accelerating pace. It is increasingly important for society and policy-makers to anticipate possible game-changing innovations, to start analysing potential benefits, as well as harmful effects, early on, and to develop a concerted response in order to maximise the good and minimise any damage.

Such anticipatory responses can take several forms: legislation regulating technologies (possibly prohibiting certain uses); public action supporting the development of technologies or facilitating their introduction through norms and regulations; education and outreach efforts to allow society to reap greater benefits; and compensatory measures for those sections of society that stand to lose from new technologies.

The European Union (EU) institutions, along with national institutions in the Member States and a growing array of international and global policy institutions, are a key source of policy-making in the 21st century. EU policies affect not only the lives of over 500 million Europeans, but increasingly also global trends and developments in issues such as climate change, resource efficiency and sustainability, trade, health care, regional conflict resolution, and reduction of poverty.

To work more effectively, the European Parliament often needs to look beyond the short-term political agenda, and search for longer-term developments, proactively launching discussions and developing early public policy approaches.

This proactive role is part of the daily life of the Parliament at many levels, in hearings organised by individual Members and in discussions within political groups or committees. The Science and Technology Options Assessment (STOA) Panel plays a pivotal role in this reflection process. STOA supports the work of parliamentary committees on long-term policy, at their request, with forward-looking studies, and proactively initiates work to identify technological developments that could have a profound societal impact that justifies inclusion on the political agenda.

The European Parliament's Directorate-General for Parliamentary Research Services (DG EPRS) published a study: 'Ten technologies which could change our lives – potential impacts and policy implications', in 2015, with each chapter highlighting a particular technology, its promises and potential negative consequences, and the role that the European Parliament could and should play in shaping these developments. This paper continues this line of reflection, presenting ten additional technologies that increasingly demand policy-makers' attention.

No pretence has been made to rank technological developments in any particular order of importance, impact, or urgency. Instead, the topics have been chosen to reflect the wide range of subjects on which STOA has decided to focus during the Parliament's eighth term.

The aim of this publication is not only to draw attention to these ten particular technologies, but also to promote reflection about other technological developments that might still be at an early stage, but that could, in a similar way, massively impact our lives in the short- or longer-term future.

Approach

For each topic, we briefly present the technological challenges and the solutions that are being developed, the current state of advancement and the likely further path of development. We then look at their possible intended or unintended impact on wider society. In the final section, we then try to identify the particular role that the European Parliament can play, as a supranational policy-making institution, to positively shape these technological shifts.

exceedingly heavy and therefore fuel-inefficient. This problem is further accentuated for electric cars, where the batteries often add another 33 % to the weight of the vehicle. Ironically, this means that a large part of the energy stored in the batteries is required simply to accelerate the increasingly heavy battery pack.

However, the younger generation is increasingly moving away from the traditional system of ownership of a single, 'personal', car, towards models of car sharing. Also, as car sharing companies offer their clients a choice of different vehicles, the individual vehicles will not need to be as multipurpose as privately-owned cars. They could instead be more diverse, much lighter and also mostly offer shorter driving ranges, requiring lighter batteries, therefore significantly increasing efficiency.

As urbanites increasingly shift towards <u>car-sharing options</u>, private ownership of cars might gradually fall to only suburbanite families living in private houses that increasingly produce their own electricity with photovoltaic (PV) roof systems. Such PV systems are complemented by battery systems that store the energy produced during the day and make it available in the evening. For such families, having larger battery systems both in their houses and in their cars might become redundant. Instead, maximum efficiency may mean keeping only a minimum number of batteries permanently installed in the car (to cover the needs of daily commutes) and leaving the rest of the batteries at home attached to the PV system, only plugging them into their cars for the occasional longer weekend or holiday trip.

The price of electricity has a major impact on the attractiveness of electric cars. In a worst-case scenario, thousands of electric cars all being recharged at the same time could further strain the electricity grid and render it more unstable, requiring additional investments into our electricity networks. On the other hand, in the context of smart grids, electric cars making use of excess electricity supply by charging at certain times could benefit from particularly low electricity costs and help to stabilise the grid.

Anticipatory policy-making

There is wide consensus that a successful switch to e-mobility will depend on public action, incentives and support programmes. Attention is currently focused on incentivising current car owners to switch to electric vehicles, and building charging infrastructures that allow consumers to use their electric cars almost in the same way as their current ICE cars.

Anticipatory policy-making may better focus instead on promoting the development of cars that we will want to drive in the future, for the new generation that may increasingly rely on car-sharing alternatives. Promoting the development of light-weight electric vehicles for car-sharing services might make more sense than subsidising the development of heavy electric vehicles for private users who want to emulate the performance of their current vehicles.

We should also focus on how e-mobility would best integrate with the way we live in 20 years, when even more private homes will be equipped with PV systems and battery storage systems. Our changes in mobility will furthermore not only be driven by the aim to reduce CO₂ and other pollutant emissions, but also by the increasing congestion caused by private cars in urban areas. If we want to keep our cities liveable in the future, a re-invigoration of public transport solutions may be inevitable. When developing electric vehicles for the future, it may therefore be appropriate to anticipate this development and focus on vehicles that complement rather than compete with public transport offers.

In conclusion, public action to promote e-mobility may be most effective if it is tightly coordinated with parallel efforts to develop new modes of mobility, and new ways to produce and distribute our electricity.

One option could be to aim at an intelligent traffic system giving absolute priority to surface-bound public transport such as buses or trams. Traffic signals along roads employed by public transport could be programmed in such a way that buses would never have to stop for a red light, nor for cars blocking the road. A major drawback of public bus services today is that their effective travelling speed in urban areas rarely exceeds 15 km/h, and that their frequent stops at bus stops mean that they move even slower than private cars.

With ITS, we could drastically change this situation, potentially even doubling the effective travelling speeds of buses, which also means that the same number of buses and drivers could transport twice as many passengers.

In other words, the most effective way to faster, more fuel efficient passenger car traffic might actually be an investment in the attractiveness of public transport. In addition to speed, the price of public transport is also a key aspect influencing individuals' transport choices. Many people find the price of a single ride ticket too expensive for occasional use, or find tariff structures too confusing to understand. Public transport authorities perhaps focus too much effort today in selling and controlling tickets, with ever more high-tech access control systems, rather than actually transporting their passengers. A bus driver who stops at a bus stop for a minute to sell a single-ride ticket for €2, while 60 passengers wait in the back, is a macro-economic nonsense.

If efficient public transport is considered to be a public necessity, we may need to think more fundamentally about who should pay for it, and how. Perhaps one might simply consider switching over to providing public transport for free as a rule, the same way in which we switched over to free public education decades ago. At the same time, we could re-assess whether cities should continue to provide free on-street parking spaces for residents. Charging residents for on-street parking could raise the necessary funds to make public transport free for all. Disincentivising parking of private cars on public roads could also make more public space available for even smoother public transport services. Also, instead of using increasingly sophisticated machines to sell and control tickets for people who travel to town by bus, we could use all of this technical ingenuity to install systems that control and charge motorists who drive to cities in personal cars, providing additional funds to improve public transport.

Furthermore, besides focusing on the technical infrastructure, other options at the user level could make our transport system more intelligent. Daily commuters fill the streets at present, often travelling more or less similar routes in separate cars. ITS systems that would make spontaneous identification of options for ride sharing easier could reduce the need to use individual cars most of the time.

A lot of options exist therefore to make our traffic system more intelligent. Modern information technology offers tremendous opportunities in this field, but we will still need human ingenuity and imagination to harness its full potential.

connect capital cities with secondary cities, thus leading to a resurgence of secondary cities with maglev stations.

Maglev trains require dedicated infrastructure, which could trigger a rethinking of EU transport policy. The Trans-European Networks for Transport (TEN-T) is an EU programme that seeks, among other things, to fund railway infrastructure, aiming at building a comprehensive network across the Union. It targets bottlenecks, as well as cross-border and multi-modal infrastructures (connectivity of railway with ports and highways). As the network is based on traditional railways, maglev would create an opportunity for a major overhaul across the network.

In contrast, hoverboards are still a relatively new technology, but could eventually revolutionise the way in which people and goods move over shorter distances, providing a fast alternative to walking, driving, or public transport, or a more efficient way to move goods around a factory floor.

Maglev hoverboards would at first be expected to share spaces with pedestrians. As the technology improves, hoverboards could manage greater levitation distances and faster speeds, bringing about the possibility of installing hoverboard-dedicated lanes to ease the coexistence of pedestrians and hoverboard riders in public spaces.

Maglev technology could, however, also develop in completely different fields of application in the near future. The EU-funded <u>GABRIEL</u> project (FP7 funding programme for 2007-2013), investigates the <u>feasibility</u> of introducing maglev for aeroplane landing and take-off, leading to a reduction in energy consumption, cost and noise.

Anticipatory policy-making

One of the major stumbling blocks facing the introduction of maglev transportation is the fact that it requires a dedicated space and infrastructure, separate from current rail or road networks.

Commercial maglev trains currently only run in China and South Korea, but might begin operating in Japan in about a decade. The EU will need to evaluate whether it wants to remain involved in this emerging technology, by supporting the development of early commercial applications in selected locations, e.g. through the TEN-T funding programme. In the longer term, maglev trains will likely see their biggest potential in connecting metropolitan areas across national boundaries in Europe, and the EU could play a decisive role in creating the right conditions for such transnational links to become reality.

At the same time, the rising cost of fossil fuels has led to a renewed interest in using wood for domestic heating purposes. However, using insufficiently dried wood in insufficiently adapted open fireplaces can be a massive source of indoor and outdoor <u>air pollution</u>. If we want to exploit wood to make a positive contribution to the environmental impact of electricity and heat production, we need to optimise the way in which we collect and use the wood in decentralised power-plants and/or distribute the heat through district heating schemes, rather than a multitude of domestic fireplaces.

A renewed interest in wood as a primary material and renewable energy source will likely produce pressure to transform less productive agricultural land back into forests. This would then have to be compensated by increasing <u>productivity</u> on the remaining land, or reducing waste in food consumption.

While northern Europe already has relatively dense forest cover, a renewed interest in wood and an accompanying reforestation drive could have the biggest impact in southern Europe and northern Africa, where forests have been dwindling since the beginning of human civilisation.

Numerous <u>reforestation</u> projects in recent decades have demonstrated that the expansion of the <u>Sahara desert</u> region could be successfully reversed. These initiatives have so far, however, been limited regionally. A new, massive, coordinated campaign throughout southern Europe and northern Africa to reforest all available land could have a significant impact on the levels of CO_2 in the atmosphere. At the same time, it could potentially lead to the regional climate tipping from the current dry and hot conditions to a more humid and moderate environment, found in those latitudes in other parts of the world. For a relatively moderate cost, in the range of tens of billions of euro, reforestation could create millions of jobs and provide the catalyst for the development of a new wood-based sustainable economy in the wider Mediterranean region.

Anticipatory policy-making

In contrast to agricultural crops, growing trees and forests requires a much longer-term vision and approach. Furthermore, reforestation campaigns will only be successful in the long run if a new wood-based economic sector is created in parallel. Policy-making could play a crucial role at several levels. A reforestation campaign would initially require public money to be made available, and information and communication campaigns to ensure the participation of local populations in the wider effort. Popular support could be further fostered by organising a systematic transfer of technology that would allow better use of the growing forests.

A wider use of wood as building material in the construction industry requires that building codes be swiftly updated as wood technology evolves.

A wider use of wood as biomass for renewable energy production could benefit from a more efficient system of locally collecting available wood resources, while discouraging individual households from burning wood for heating or cooking purposes.

In the context of the growing world population, it would be problematic to expand the areas set aside for growing forests at the expense of agricultural land used for food production. Instead, the focus should be on areas that are unsuitable for agricultural production, e.g. more arid localities. Public research programmes could optimise tree species for cultivation in these less favourable environments, and satellite technology could help monitor the reforestation programmes and optimise their impact on the regional and global climate.

The general assumption under which globalisation has transformed our economies into knowledge economies is also valid for agriculture. New skills would need to be learned for widespread uptake of PA. Various types of skills are required for farming using PA, such as technological, environmental and managerial skills. Young farmers need to be equipped with the right mix of both job-specific and crosscutting core skills to be able to access PA, and thereby the farming profession might become more attractive to young people. In addition, PA technologies could really boost the education level in rural areas.

PA could also contribute to changing the way our countryside looks today. The use of smarter technology would reduce the need for large, monotonous, fields dominating the landscape, allowing a transformation to a more varied landscape of fields, trees, bushes, and natural areas. It could also have a significant environmental impact, as it would allow for more selective removal of the most sensitive ecological areas from the agricultural production process.

However, when considering PA in the EU, we also have to consider that <u>farming</u> across the EU-28 is heterogeneous in many respects. This diversity includes aspects such as business models, production sectors, farming practices, employment as an absolute number and as a ratio of the working population, farmers' education and skills levels, and farming output. The societal impact of PA would be greatest in those countries with the largest percentage of workforce employed in agriculture.

Anticipatory policy-making

The wide diversity of agriculture throughout the EU, particularly regarding farm size, types of farming, farming practices, output and employment, presents a challenge for European policy-makers. European policy measures should differentiate between the Member States, considering that the opportunities and concerns differ greatly from one country to another.

Irrespective of what the economic context might be in the next decades, PA will be needed by EU farmers to improve their yields with less available arable land.

Research and development will be a key driving force in bringing about the agricultural jobs of tomorrow. Accordingly, substantial shifts from the Common Agricultural Policy (CAP) (2021-2027) to enhanced R&D in agriculture could be envisaged. More money could, for instance, be invested in cutting-edge technologies such as biosensors, robotics, spectrograph and imagery.

The EU could enhance its rural development policy, financing agricultural and forestry innovation through measures which could support the creation of operational groups, innovation services, investments or other approaches. Such programmes promoting PA practices could also serve other societal goals, such as a balanced territorial development, or life-long learning.

Another possible policy option is to create a third pillar within the CAP 2021-2027, dedicated to environmentally sustainable technologies.

materials, where it is currently necessary to create and test a new substance to find out how useful or harmful it would be. Another possible application is in artificial intelligence, although what improvements a quantum computer would offer in this area remains unclear.

While quantum technologies can help solve a range of problems, they can also potentially create new ones. One possible scenario is that in the future, quantum computing could allow others to break our existing cryptography protocols. This threat in turn provides considerable motivation for the development of quantum cryptography, which would provide protection from such an attack. The continued safety of our encryption systems may thus depend on advances in quantum cryptography staying abreast of advances in quantum computing.

However, a future quantum computer could be used not only to decrypt future transmissions, but also data that was intercepted and recorded in previous decades. Therefore, unless quantum computing is demonstrated to be completely infeasible, organisations who want to keep their current information secure in future decades will likely maintain an interest in quantum cryptographic systems.

Anticipatory policy-making

There is already considerable public and private interest in developing quantum technologies. <u>The Netherlands</u> and the <u>United Kingdom</u> have programmes in this area that have attracted hundreds of millions of euro in funding, both from public bodies and from industry. The European Commission recently announced a plan to invest €1 billion in a <u>quantum technologies flagship</u> initiative.

As with many new technologies, it is important to consider how to bridge what is known as the 'valley of death', between scientific research and commercial application. The science behind quantum technologies is widely believed to be well-understood, and research is now moving beyond demonstration experiments towards building useful devices. However, as commercial application of many of these technologies is still some way off, investment from private companies remains a fraction of that in their conventional counterparts. Public investment programmes will be important for bringing quantum technologies closer to commercial viability, and the effectiveness of current programmes should be monitored in this regard.

One particular aspect that may need large public investment is the infrastructure required for quantum cryptography. This technology is likely to require special optical fibres to transmit single photons (particles of light) in such a way that their quantum state is maintained. There are already initiatives to develop this infrastructure in China, Japan and the USA, as well as some Member States. To allow quantum communication across the EU, as well as around the world, an uninterrupted network is required. Another option would be the development of new 'post-quantum' encryption protocols with no known quantum algorithm that could be used to break them.

For quantum computers, the question of what they would be able to do is still an active area of research. The ability to break existing cryptography protocols is one application that could have negative consequences, and it is possible that more harmful applications will be developed in the future. Possibilities include the ability to hack other security protocols that are currently considered to be secure against a quantum attack. Therefore, it may be prudent to regulate access to such devices. However, a likely business model for this emerging industry would be to allow users to submit problems online, therefore such regulation may not be feasible. In addition, regulation may stifle the potential for a huge acceleration in technological progress, reducing the corresponding benefits for society.

Quantum technologies offer fascinating possibilities, which have yet to be fully explored, and progress in this area could be accelerated by increasing public investment. However, policy-makers need to devote a considerable amount of attention to the field as progress unfolds, in order to minimise the possible negative consequences resulting from these technologies.

ranges may be relatively long under certain conditions but, on the other hand, not having batteries means that they are required to use the power coming from the carrier signal provided by the antennas connected to the reader. Also, UHF is prone to malfunction in the presence of liquids (that absorb the energy) or metals (that reflect the signal creating interference). All of this results in readers being necessarily quite costly and conspicuous (e.g. as a reading arch in a shop) even if tags are not.

Another implication of the requirement for such simple tags (to use very little energy), is that the communication protocols implemented in them are rather basic. This means that they are not secure, as they do not include encryption or any other measures of protection. Further research is currently underway in these areas, but for the moment the information can be tampered with in several ways (counterfeiting, eavesdropping, cloning, spoofing, jamming etc.).

As well as basic UHF RFID tags, there are other tags that are also very common and even simpler, as is the case for those using <u>near field communication</u> (NFC) technology. NFC uses lower frequencies and tags can only be read at very short distances (usually by a hand-held device) and one at a time. The advantage is that they require only a cheap and simple reader. On the other hand, many other types of tags with improved capabilities also exist, as by adding a battery (to make 'active tags'), they may become sufficiently complex for many different applications. Active tags can include sensors, actuators and a large memory, and make extended communication ranges possible. All of these capabilities again contribute to public concern regarding the applications of this technology.

Anticipatory policy-making

It is important to note that the small tags that may be hidden in everyday objects are currently always simple, passive devices, with quite limited capabilities (the more powerful ones are usually bigger and far more conspicuous). Therefore, it is always difficult to read a tag, and even more so in the EU, where the power of readers has been limited to two watts by law (while four watts are allowed in the USA). This means that reading ranges are usually limited to about two metres. Furthermore, as readers work in a very similar way to radar, they are easily detected and controlled by the authorities. However, it is important to keep in mind that these tags have been designed for simple consumer goods. Therefore, even if the possibilities associated with their use are rather broad, it is unlikely that the tags will be used by any hypothetical 'Big Brother'.

On the other hand, there is a real concern on the part of the developers about the safety of this technology for certain applications. To begin with, it would be important to ascertain a realistic limit to the power used by the readers, as this creates a serious limitation. While two watts seem to have very little effect on the human body, it is important to take into account that UHF uses the same wavelengths as microwave ovens. Therefore, there is a concern regarding the possibility of 'hot spots' appearing in certain locations that may affect biological products. For example, UHF RFID tags are being used in hospitals to track bags of blood, but there does not seem to be any specific research on the effects that the readers may have on the preservation of these products.

There are still many possible improvements around RFID, but the technology is already available, and the possible applications are many. It is true that the technology is not completely guaranteed to be fault-free and tamper-proof, but the simple tags designed to identify consumer goods cannot be compared with the devices that could be used to track a person, such as smartphones. Nevertheless, the use of this interesting technology can certainly help solve the many problems that appear along supply chains, affecting consumers. It may be preferable to accept the remote possibility of the authorities knowing what you are eating, than to risk food poisoning.

that sensors in cars already monitor eye-blinking rates to warn the driver of sleepiness, sensors we wear in our clothes could, in the future, warn us if the risk of a heart attack is particularly high, or if our immune system is particularly weak and we are in danger of contracting influenza.

While these new technologies promise great <u>healthcare</u> advances, they also pose a number of <u>challenges</u> <u>to society</u>, notably in terms of data protection.

Data protection is already a key issue to take into account in any clinical study. If researchers share these datasets even more extensively in future, it is even more important that data privacy standards provide effective protection for study participants. Due adherence to informed consent procedures will also be paramount, when the data provided by human subjects (patients or controls) is used in research other than that for which it was initially obtained.

The increasing number of sensors that accompany us in our daily life, and already today gather an increasing number of parameters about our health and well-being, will pose additional challenges. Mobile phone manufacturers, telecom operators and internet search engines already collect considerable amounts of health-relevant data about their clients today, without yet being perceived as actors in the health sectors. This will become even more critical when simple devices like mobile phones become able to derive a complete assessment of their users' health from the increasing number of parameters they collect.

Anticipatory policy-making

Besides the need to continuously update data protection and privacy rules as technology develops, wider issues must be considered regarding who should benefit from all of these technological advances. As an example, will sensors we wear on our body enable us to detect cancer at an earlier stage, increasing the chances for healing and lowering the cost of treatment; or will those technologies mainly help companies to increase insurance rates for those diagnosed with cancer?

Although data protection rules are continuously being updated, in an increasingly interconnected world it might become more and more difficult to hide the fact that one is affected by a particular disease such as cancer. We will need to find the right balance between an individual's interest in confidentiality concerning their health, and the benefit society could reap from easier access to anonymised medical data that could hold the key to medical innovations and breakthroughs.

Since even the best laws might not be able to guarantee privacy under all circumstances, and we therefore have to consider that a condition such as cancer might be made public, law-makers could provide an extra layer of protection by enacting legislation that minimises the potential for discrimination. For example, a system that provides for sharing of cancer patients' treatment costs between all health insurance companies will reduce the likeliness that an individual patient is discriminated against by an insurance company on the grounds of a history or propensity of developing cancer.

embryonic development, or may even be transplanted into people to replace diseased or failing natural organs. Organoids have also been used to study what goes wrong, such as in neurons derived directly from patients with Alzheimer's disease.

Alongside the benefits organoids could provide in terms of helping researchers to understand how real organs develop, and what can go wrong with that process, the scaling-up of organoids into reproducible and user-friendly systems and commercial manufacturing entails safety and ethical risks, given that <u>culture methods</u> are still in their infancy. <u>Personalised organoids</u> may facilitate the deployment of <u>personalised medical trials</u>, which may in turn pose new risks, and affordability concerns.

Similar conflicts may arise when considering the type of tissue being generated. The closer scientists come to making a human brain, the greater the ethical issues. The concepts of human integrity in this context could be placed under significant threat.

Anticipatory law-making

Although many of these technologies are still relatively new and require further validation and characterisation, the fact that organoids derived today from living tissues cultivated from participants' stem cells may be stored for a very long/virtually infinite period of time underlines the urgency to deal with these issues now. Privacy requirements; terms and conditions of inclusion of participants in research/clinical trial settings; storage and use of organoids; and dissemination of results including incidental findings, all require attention. Informed consent is a major issue regarding inclusion of participants and the collection of their stem cells from residual tissue. Organoid biobanking also requires the development of tailor-made informed consent procedures that address the challenges associated with the fact that organoids are actually living mini-organs that could be used for a wide range of purposes, as well as the lack of an EU-wide legal framework on biobanks.

The use of organoids may complement or even reduce animal testing and the involvement of humans in an experimental setting, which may in turn trigger the modification of the existing medicinal testing, clinical trial and chemicals' authorisation framework.

Another central issue is the question about ownership and commodification of bodily material, as well as how true to life an *in vitro* model of human development needs to be in order to be both scientifically valuable and ethically acceptable. As interest in organoid technology grows, the commercial development of more standardised, validated organoid culture media will also be valuable in ensuring that the organoid system becomes accessible to a wide range of academic and clinical scientists, thereby helping to maximise its potential.

changes to the human genome. For instance, the application of CRISPR as a pest control technique may produce unintended effects and mutations, which may lead to the dispersion of gene drive, the disappearance of a whole animal population, accidental releases and/or the irreversible disturbance of entire ecosystems. In fact, research activities intended to modify the genetic heritage of human beings which could make such changes inheritable are not financed under Horizon 2020, the EU framework programme for research and innovation.

Taking the non-maleficence principle into account in risk assessment, and distinguishing the clinical and therapeutic aims of gene editing from its enhancement applications/uses, have also become major sources of concern. Another important problem is the efficient and safe delivery of CRISPR-Cas9 into cell types or tissues that are hard to transfect and/or infect. Further <u>concerns</u> include the prospect of irreversible harm to the health of future generations, and concerns about opening the door to new forms of social inequality, discrimination and conflict, as well as to a new era of eugenics.

Anticipatory law-making

The rapid pace of scientific developments in the field of gene editing makes regulatory oversight particularly challenging. Moreover, there is a debate over whether CRISPR-Cas9 should be regulated as a gene editing technique, or whether its products should rather be controlled ad hoc with a result-based approach. International discussion on the regulatory status of genome editing techniques has focused on whether current definitions of genetic engineering or genetically engineered organisms could also apply to these recently discovered genetic editing tools.

The European Commission is currently working on a legal interpretation of the regulatory status of products generated by new plant-breeding techniques, to <u>minimise legal uncertainties</u> in this area. Such an interpretation may pave the way for a decision on whether gene editing technologies should fall under the scope of the EU legislative framework on the contained and deliberate release of genetically engineered organisms.

Patenting CRISPR-Cas9 for therapeutic use in humans is also legally controversial. In February 2017, the US Patent and Trademark Office (USPTO) issued a <u>decision</u> on who should hold the patent on using CRISPR-Cas9 to edit genes, defining the terms and conditions for profit generation from this technology in the years to come.

The risks of hereditary, unpredictable genetic mutations raise questions regarding the <u>safety of the technique</u> and the attribution of liability in case of damages. In a recent <u>report</u>, the US National Academies of Sciences, Engineering and Medicine urged caution when releasing gene drives into the open environment and suggested 'phased testing', including special safeguards, given the high scientific uncertainties and potential ecological risks. Safety measures are necessary to avoid dissemination of organisms that may cause ecological damage or affect human health.

In fact, many scientists caution that there is much to do before CRISPR could be <u>deployed</u> safely and efficiently. In particular, CRISPR might create <u>additional challenges</u> from a risk assessment standpoint, in that organisms produced by these methods may contain more pervasive changes to the genomes of living organisms than traditional genetic modification techniques.