Workshop on Reconciling Precaution and Innovation

Workshop Information Package

The RECIPES project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 824665

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Acknowledgments & Disclaimer

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The RECIPES project

The EU Commission strives to be on the forefront of scientific excellence and has as part of the EU Horizon 2020 research initiative launched the project RECIPES "REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders".

RECIPES aims to analyse how the precautionary principle is applied in the European Union and improve its future application with recourse to participatory methods. The RECIPES project intends to reconcile innovation and precaution by developing tools and guidelines to ensure the precautionary principle is applied while still encouraging innovation.

The project includes collaborators in more than 11 countries in Europe and beyond.

The Scenario Workshops are organized by the Danish Board of Technology Foundation (DBT). DBT is a non-profit, common good foundation, with more than 30 years of experience in stakeholder involvement in research and innovation.

For more information please visit recipes-project.eu/.

The workshop

1.1 Aim of the workshop

The overarching goal of the workshop is to identify new tools and guidelines for the EU and its member states to best govern uncertain risks related to innovation, with a focus on the precautionary principle

1.2 Method

For the workshop we use the method called 'Scenario Workshop'.

The scenario workshop is an instrument for participatory planning, based on dialogue and collaboration between stakeholders, experts, and policy makers. The method aims to stir dialogue, provide the opportunity for exchanging experience and knowledge about existing barriers and possible solutions, enhance the understanding on the central topic/problem of discussion, and facilitate consensus on proposed solutions among the involved.

1.3 The Scenarios

Central to the workshop are three scenarios that outline three different approaches to the implementation of the precautionary principle and how this may interplay with innovation.

The three scenarios should not be conceived as being mutually exclusive. Choosing and combining elements from the scenarios may help to construct a fourth scenario with an optimal combination of elements in a shared vision of a desirable future as well as to identify which actions are necessary to fulfil the vision.

1.4 Workshop structure

The workshop discussions will be structured in three phases, that all feed into each other:

Phase 1: Critical Discussion

What do the three scenarios lack? What aspects, values and perspectives are not included in the precautionary principle's current forms of implementation? What challenges does it bring?

Phase 2: Formulation of shared visions for reconciling precaution & innovation

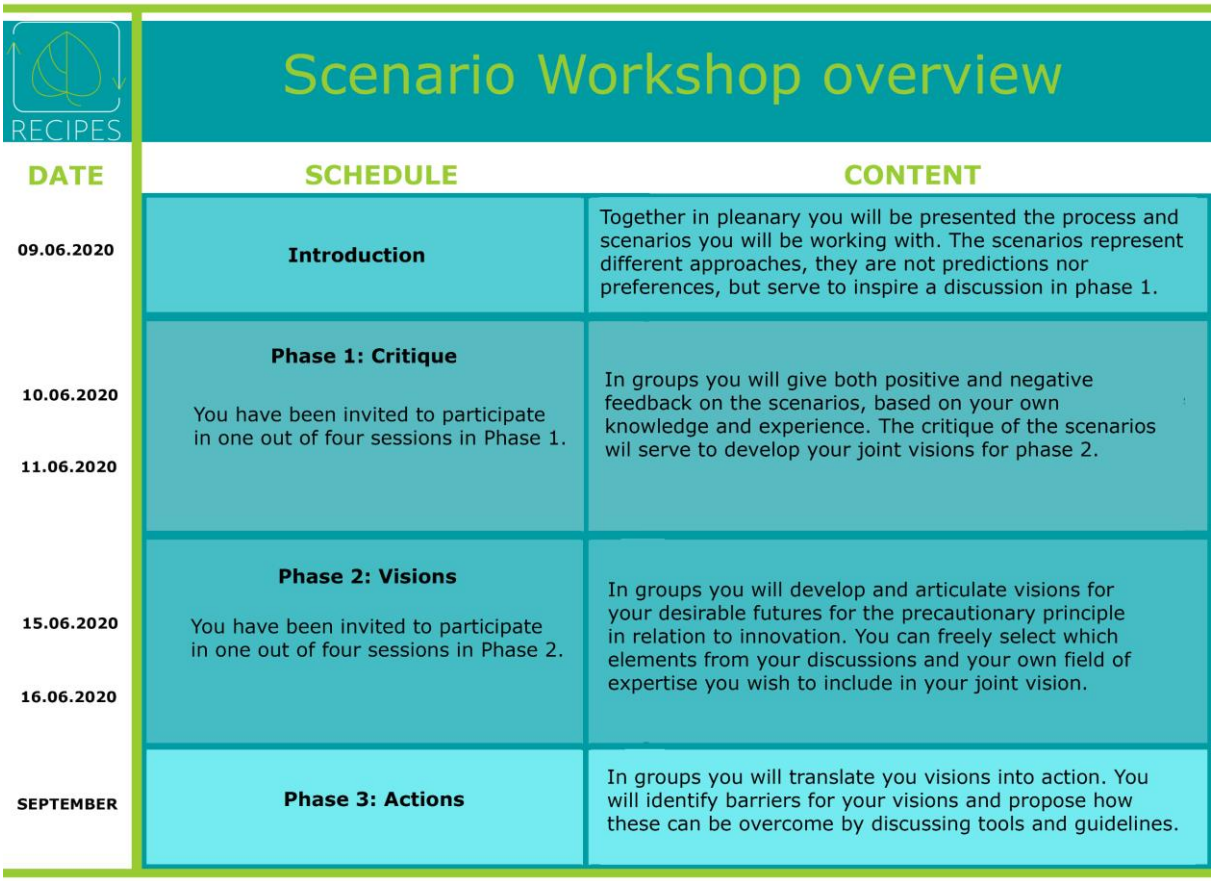
Based on the critique - How should concerns to innovation, the environment, societal issues be valued in the precautionary principle? What constitutes a good 'tool' and a 'guideline' in this context?

Phase 3 Actions[1]

Identifying barriers for your visions and propose how these can be overcome by discussing input and ideas for aspects to be included in tools and guidelines for the implementation of the precautionary principle in relation to innovation.

[1] Phase 3 takes place on the September workshop

1.5 Scenario Workshop Overview



1.6 Agenda for The RECIPES Scenario Workshop

Introduction to the RECIPES Workshop on Precaution and Innovation

Meeting	Place: Online event Date: June 9th 2020

09:50	You can enter zoom room.
10:00	Welcome
10:10	Introduction to RECIPES Project by Kristel De Smedt
10:20	Introduction to the Scenario Workshop and the different phases by Søren Gram
10:30	Introduction to the three scenarios by Søren Mark
10:45	Questions to the three presenters
10:55	Wrapping up.
11:00	Thank you and see you soon

Phase 1 Critique - A critical discussion of the three scenarios

Meeting	Place: Online event Date: June 10th and 11th, 2020

Morning Sessions 1 & 2	Afternoon Sessions 1 & 2	
09:50	13:50	You can enter zoom room.
10:00	14:00	Welcome and introduction
10:10	14:10	Critical discussion of the three scenarios
10:55	14:55	Break
11:10	15:10	Continuation of discussion
11:55	15:55	Wrapping up.
12:00	16:00	Thank you and see you soon

Phase 2 Vision - Formulation of shared visions for reconciling precaution & innovation

Meeting	**Place: Online event** **Date: June 15th and 16th , 2020**

Morning Sessions 1 & 2	Afternoon Sessions 1 & 2	
09:50	13:50	You can enter zoom room.
10:00	14:00	Welcome and Introduction
10:10	14:10	Discussion on desirable future visions on precaution and innovation
10:55	14:55	Break
11:10	15:10	Continuation of discussion
11:55	15:55	Wrapping up.
12:00	16:00	Thank you and see you soon

1.7 List of participants

Name	Surname	Title	Organisation	Country
Carolina	Vigo	Adviser	BusinessEurope	Belgium
Nina	Holland	Researcher	Corporate Europe Observatory	Belgium
Jock	Martin	Head of Integrated Assessments for Sustainable Programme	European Environment Agency	Denmark
Howard	Chase	Chairman	European Risk Forum (ERF)	Switzerland
Angela	Simone	Project Manager	Fondazione Bassetti	Italy
Denise	Schuetz	Doctor	German Chemical Industry Association (VCI)	Germany
Andrea	Carta	Senior Legal Strategist	Greenpeace, European Unit	Belgium
David	Santillo	Senior Scientist	Greenpeace Research Laboratories	UK
Maike	Niggemann	Policy Adviser	IndustriAll Europe	Belgium
Marie-Valentine	Florin	Executive Director	International Risk Governance Center (EPFL)	Switzerland
Steffi	Ober	Doctor	Naturschutzbund / Nature And Biodiversity Conservation Union (NABU)	Germany
Pál	Goda	Doctor	Research Institute of Agricultural Economics	Hungary
Angeliki	Lysimachou	Science Policy Officer	Pesticide Action Network Europe	Belgium
Véronique	Fraigneau	Advocacy & Communication Manager	PlasticsEurope	France
Christian	Prip	Senior Policy Analyst	The Fridtjof Nansen Institute	Norway
Florian	Part	Doctor	University of Natural Resources and Life Sciences	Austria
Maria Gabriella	Stanzione	Assistant professor and tenured researcher	University of Salerno	Italy
Elbert	de Jong	Doctor	Utrecht University	Netherlands

The Scenarios

Introduction to the Scenarios

Precaution is a well-known concept in the EU of today. The way it is currently implemented reflects today's balances in legislation and practices between protection of public health and environment and considerations for technological and commercial development.

The precautionary principle plays a significant role in several global and regional treaties and conventions (e.g. on climate, chemicals and biodiversity) and it was formally adopted in EU as an overarching environmental legal principle in the Maastricht Treaty in 1992.

Today it is integrated into the Treaty on the Functioning of the EU (Article 191(2)) and in a number of both EU and member states policies, strategies, regulations and practices.

In the year 2000 the EU Commission released a communication to guide the EU and its member states on the implementation of the principle of precaution (4). The communication provided, and still provides, a common framework and interpretation of important elements related to invocation and implementation of the precautionary principle.

Thirteen years after the release of the communication the European Environment Agency, however, based on a large number of case studies mostly related to chemicals, public health and environmental protection, made a strong call for both stronger and earlier implementation of the precautionary principle in the EU (7).

New studies performed as part of the EU-funded RECIPES project on Precaution, Innovation and Science have further found that there is much variation in how the principle is implemented in the different economic sectors within the EU, as well as in the way the principle is managed in the member states. The studies also find that this in some cases may lead to regulatory disharmony and to uncertainty for suppliers and users (3, 14, 15).

As we presently navigate in the Anthropocene, where the climate and biodiversity crises are at the top of the political agenda both globally and in the EU, some argue that there is an evident need, as emphasized by the new European Green Deal, to develop new, innovative and more sustainable ways of production and consumption while at the same time to review, revise and improve the implementation of the precautionary principle.

Some representatives from the private sector have advocated for the introduction of a new concept, the "innovation principle" in the EU *acquis*, which is a suggestion that has been positively received by the EU Commission.

Originally the "innovation principle" was introduced to promote economic growth and job creation by balancing the precautionary principle. Generally, however, when the principle occurs in EU contexts today it is meant not to counter-balance precaution but to promote innovation-friendly policies and regulatory frameworks by ensuring that when new policies or developments take place the impacts on innovation are assessed and addressed (8, 16, 17).

So far, the "innovation principle" lacks a recognized and agreed definition, and it is still to be seen how it in reality may impact and interplay with the implementation of the precautionary principle.

Scenario approach

In the following pages we present three scenarios that represent different practical elaborations of viewpoints on how to improve the implementation of the precautionary principle. They are based on RECIPES results from a stocktaking exercise[2], citizen's meetings, internal project workshop, and reviews from the RECIPES Advisory Board[3]. In addition, nine case studies on the complexities of applying the precautionary principle in the context of different technologies have contributed to the specifications of challenges faced in each scenario.[4]

The scenario method is used to help think outside the box, develop mutual understanding, and work towards shared solutions. The scenarios are there for you to challenge and improve. They are not different versions, let alone predictions, of the future. Importantly, they should not be conceived as being mutually exclusive- elements of the scenarios can co-exist. In fact, choosing and combining elements from the scenarios may help to construct a fourth scenario with an optimal combination of elements. This shared vision can make it possible to identify solutions to current challenges experienced with the implementation of the precautionary principle. This way, the three scenarios will feed into the RECIPES process of designing new tools and guidelines for the precautionary principle in respect to reconciling precaution and innovation.

All scenarios are different possible interplays between technological innovation and the structures and practices for the implementation of the precautionary principle.

- The first scenario describes business as usual, the current situation.
- The second scenario puts more emphasis on the furthering of innovation to benefit sustainability.
- The third scenario focuses on democratic aspects of innovation, promoting a stronger, wider and more inclusive implementation of the precautionary principle.

In the following sections, each scenario is introduced further, followed by a summary of the main challenges of each approach to the implementation of the precautionary principle.

Please read the scenarios carefully. After reading try to think of max. 3 points/elements you find the most essential in relation to your field or sector, and why. What do the three scenarios lack? What aspects, values and perspectives are not included in the precautionary principle's current forms of implementation? What challenges does it bring? We will start our Phase 1 discussion with your inputs.

Thank you for reading and we look forward to your inputs!

[2] https://recipes-project.eu/results/taking-stock-precautionary-principle-2000
[3] https://recipes-project.eu/about/advisory-board & https://recipes-project.eu/partners
[4] https://recipes-project.eu/results/recipes-case-studies-aligning-precaution-and-innovation

Scenario 1 Current practices and challenges - baseline

Since the year 2000 the implementation of the precautionary principle in the EU has been guided by a Commission communication (4).

Although the communication was only a guiding document, it constituted an important codification of the EU institution's understanding and agreement on the principle at the time it was adopted.

The communication states that three prerequisites should be established before invocation of the principle:

- the identification of possible negative effects;
- the performance of a scientific evaluation;
- the existence of scientific uncertainty.

The Commission also provides guidelines in the communication on precautionary measures, to be followed by policy-makers. The precautionary measures should be:

- proportional to the chosen level of protection;
- non-discriminatory in their application;
- consistent with similar measures taken;
- based on an examination of the potential benefits and costs of action and inaction;
- subject to review in light of new scientific data;
- capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

There can be little doubt that the implementation of the precautionary principle, underpinned by the Commission´s communication, has played a positive role in avoidance and/or reduction of many and multifarious health and environmental hazards.

However, several studies, including studies undertaken by the European Environment Agency and recently by RECIPES, show that the principle is not always interpreted and implemented consistently in the various regulatory sector schemes in the EU (chemicals, GMOs, pesticides, biocides, foods, cosmetics, etc.) and that there are sometimes inconsistencies in how the guidelines are interpreted and implemented by the EU and the member states' authorities in specific cases (7, 14, 15).

The inconsistencies in the implementation can create uncertainties for producers and consumers, and there is general agreement that a more systematic and consistent implementation is desirable and could provide for a fairer and more sustainable implementation.

The recent launch of the European Green Deal and the soon to come 8th European Environment Action programme (8th EAP) offer relevant frameworks for updating and for further developing and reshaping guidelines, regulations and practices related to the precautionary principle (1, 3, 16, 17).

The need for such adjustments is further emphasized by the fast and massive development of new and emerging technologies (e.g. artificial intelligence, nanotechnology, precision

gene editing, synthetic biology) which are only partly regulated and pose new kinds of risks and regulatory challenges.

Also, new EU policies and strategies for innovation and the current discussions on the "innovative principle" underscore the need for further clarification and for establishment of guidelines and regulatory frameworks for the interplay between precaution and innovation (5, 10, 16, 17).

Among the first steps in moving in the direction of more consistent implementation of the precautionary principle and clarification of the interplay between innovation and precaution could take the form of a new strategy from the Commission to supplement the communication from 2000.

Challenges

This section will present some of the current and immediate challenges to the implementation of the precautionary principle. The challenges are mainly identified in and extracted from the RECIPES case studies.

The RECIPES case studies describe how the precautionary principle is currently applied in relation to both well-known products and technologies and to new and potent emerging technologies. The products and technologies analysed represent a wide range of potential risks and impacts and are in very different stages of development and implementation of the precautionary principle.

A total of 9 in-depth RECIPES case studies were undertaken and focussed on: Glyphosate, neonicotinoids, endocrine disruptors, microplastics in food products and cosmetics, genetically modified organisms, new gene-editing techniques with focus on CRISPER-Cas9 gene drives, nanotechnologies, use of artificial intelligence in healthcare, and on precaution and financial risks in relation to urban waste water treatment (14).

Disparate regulation

The case studies demonstrate that different categories of products and technologies often have many different forms and properties, have wide ranges of sources and are used in multiple ways. This for instance is the case for endocrine disruptors, microplastics and nano-materials which today are regulated in the EU under several different regulatory schemes.

Endocrine disruptors for instance, depending on their use, are regulated under EU directives and regulations on food, pesticides, biocides, chemicals, and cosmetics. Approaches to the implementation of the precautionary principle vary between these schemes as does the definition of what constitutes an endocrine disruptor.

The current complexity of the regulatory framework in some instances results in replacement of refused or banned products with other products with the same or even higher risks.

An example of this is when new crop plant varieties with the same genetic make-up (DNA) become subject to either minimal risk assessment procedures or very strict and demanding requirements depending on whether the plant is a result of traditional breeding or modern gene-editing.

Another example is when a "regrettable substitution" occurs when one endocrine disruptor (bisphenol A) is substituted by another less stringently regulated endocrine disruptor (bisphenol S), although the latter has the same or higher level of risk.

Decisions made on products or technologies can further vary when approval decisions are under the authority of the individual EU member states. Some products can therefore be banned in some member states while being lawfully applied in others. This for instance is the case for some pesticides and biocides.

Although much effort goes into ensuring and improving regulatory coordination the case studies demonstrate that the complexity of the current regulatory schemes in some cases leads to inconsistent processes and decision-making.

Scientific uncertainty

Many of the new technological products analysed in the case studies have very complex and partly unknown routes and fates in organisms and the environment and may pose potential direct or indirect negative health or environmental impacts (e.g. neonicotinoids, endocrine disruptors and microplastics). In all the cases, although to a varying degree, there is scientific uncertainty about potential risks and how to manage these.

In some cases, the scientific knowledge on possible risks and acceptable thresholds is very limited (e.g. human health impacts from microplastics in foods and impacts of endocrine disruptors in humans, including on reproductive health) while there is much scientific evidence available in other cases, though no conclusive or concordant conclusions on risks (e.g. on the human health risks of glyphosate).

As scientific uncertainty about the risks is a main trigger for the invocation of the precautionary principle and is at the same time often very difficult to define and put on formula, further analyses of cases and identification of best practices may be helpful and used to update and develop more detailed guidelines on how to manage scientific uncertainty.

Timely implementation of the precautionary principle

Many of the case studies undertaken by the European Environment Agency have demonstrated that the invocation of the precautionary principle has been instrumental to avoid hazards to human health and the environment, but also that earlier invocation of the principle should have taken place and would have saved humans and the environment from serious harm (e.g. asbestos, PCB and lead in gasoline).

The RECIPES case studies further reveal that the precautionary principle over time has become an increasingly important issue in several cases and that it in some instances may be expected to be invoked and become implemented more in the future. This could for instance be the case for endocrine disruptors, neonicotinoids, and glyphosate.

To illustrate, glyphosate, which for several decades has been the most commonly used active substance in herbicides in the EU (and the rest of the world) was only granted a 5-year renewal in the EU in 2017 while earlier renewals were for 10 or 15 years.

A number of member states, including Germany and France, hold the position that glyphosate should be phased out or banned due to its negative impacts on nature (decline of biodiversity) and its potential negative impact on human health (potential carcinogenic properties). Thus, glyphosate may be banned in the EU or is at least likely to be subject to stricter risk management requirements after 2022.

While glyphosate has been lawfully applied until now and has a track record of being cost effective, not many useful alternatives have been developed, which could have stimulated innovations related to integrated pest management and organic farming.

For microplastics an EU ban (under REACH) is on its way for intentionally added microplastics in cosmetic products and several companies have already started to use healthy alternatives. Intentionally added microplastics in cosmetics, however, only constitute a minor part of the pollution with microplastics and more prevention and/or implementation of the precautionary principle may be expected in the future.

All in all, it seems that both consumers and innovative researchers and producers in many instances could benefit from earlier invocation and implementation of the precautionary principle.

Scenario 2 Sustainable Innovation with Precaution

This scenario focuses on the interplay between innovation and the precautionary principle.

"Innovation" can be defined in multiple ways but is generally understood as the creation of something new, that provides value for someone. While innovation may provide benefits to some, it may, however, also have no impact or even negative impacts on others (3, 5, 16, 17).

Evidently, some innovations can contribute to achieving for instance the UN's sustainable development goals (SDGs) or the objectives of EU's new Green Deal while other innovation may have the opposite effect.

This scenario looks into challenges and options for adjusting precautionary requirements towards further stimulation of desirable innovations.

Some private sector stakeholders including the "European Risk Forum", a think tank which works for 10 multinational companies and 16 trade associations, started in 2013 to advocate for the introduction of an "innovation principle" in the EU *acquis* to help create "a more innovation-friendly regulatory regime" and to balance the principle of precaution. Thus, the forum asked that for whenever policy or regulatory decisions would come under consideration, that the impact on innovation as a driver for jobs and growth should be considered and addressed (3, 8, 10).

The European Risk Forum expressed that unclear and long-lasting processing of product applications and a too stringent implementation of the precautionary principle in decision-making lead to weakening of European companies' competitiveness compared to counterparts in other countries with faster and/or less stringent precautionary regulations. This, the forum stated, hampered technological innovation, and in some instances also green transformation, by de-motivating both investors and researchers to engage in development of needed products and new technologies.

The EU Commission has supported the concept of the innovation principle. Accordingly, the principle, although still not well-defined, was recently and for the first time introduced in an EU legal text, i.e. in the "Horizon Europe Regulation and Program" which succeeds "Horizon 2020" and lays out the future rules for financing the EU's research and innovation program (3, 6, 11, 17).

Concerns have been raised by the EU Parliament, consumer associations, green NGOs and some think tanks that the introduction of the innovation principle could lead to a de-regulatory approach that could weaken the precautionary approach. They argue that the principle must be defined and managed in a way that fully respects the precautionary principle and stimulate technological innovations which are safe and fulfil public health, environmental and societal objectives (3, 16).

The critics have further emphasized that there exists no solid evidence that the precautionary approach hampers innovation in Europe and that studies and analyses document the opposite, namely that the precautionary approach can help to stimulate desirable technological innovation.

The relationship between precaution and innovation is one of the issues analysed in the RECIPES case studies and while some of the case studies find that precaution may hinder innovations (e.g. GMOs) other case studies find that precaution seem to stimulate technological innovations (healthy alternatives to microplastics, emergence of initiatives such as Green Chemicals etc.) (14).

Proponents of the innovation principle argue that the current rules and practices for implementation of the precautionary principle can be adjusted to become more innovation-friendly and to underpin sustainable technological development further.

A number of projects and training and education activities for "Responsible Research and Innovation" (RRI) have taken place under Horizon 2020 and will take place under the Horizon Europe Regulation and Program. The aim of these efforts is to involve a broad range of relevant stakeholders in dialogue on science and innovation in the early phases of development ("upstream") (3, 11, 17).

This involvement and open dialogue amongst innovators and citizens are to help alignment of innovations with the values of society and thus to establish a positive interplay between precaution and innovation.

Challenges

In the following section focus is on how sustainable technological innovation can be stimulated more by adjustments to the way the precautionary principle is currently implemented. The presented challenges are mainly based on lessons learned from the RECIPES case studies.

Long duration of risk assessments and decision-making processes

Several of the RECIPES case studies are about technological products which have been subject to risk assessment for several decades (e.g. endocrine disruptors, GM crop plants, glyphosate and neonicotinoids).

Long-lasting and unresolved risk assessment and approval processes is not only a problem for investors and researchers but also create uncertainties for citizens who may use products which may be banned at a later stage (e.g. endocrine disruptors, glyphosate and secondary microplastics).

The case studies suggest that faster decision-making in such situations, based on the best possible current knowledge, could help to reduce uncertainties and, in cases where decision-making results in non-approval, also the risk of ultimately unproductive and unsuccessful investments.

In some instances, the cases also establish that new scientific knowledge is not considered (e.g. 30 years of safe use experiences from cultivation of GM crop plant cultivation in many countries outside of the EU). This demonstrates that there is a need for consideration on how new scientific knowledge is more consistently acknowledged and taken into account.

These findings seem to call for intensification of resources and capacities to undertake risk assessments and perform decision-making by relevant authorities and to undertake and update risk assessments and decisions when new and relevant scientific knowledge becomes available.

One-size-fits-all risk assessments or a more gradated approach

The private sector has also raised concerns about authorities' request for huge amounts of costly research data for their risk assessments (8, 10).

This may deter smaller companies and small research institutions to get involved in research and development and in some instances leave the playing field to only a few and large multinational companies. This in particular seems to be the case for development of GMOs and other products stemming from modern gene technologies.

One possible approach to reduce these problems could be to gradate the requirements of data for risk assessments and in this way move away from a "one-size-fits-all approach" of risk assessments, which today is prevalent for some kind of products.

For instance, today genetically modified crop plants are all subject to the same requirements of year-long testing and provision of comprehensive research data independently of their new characteristics, there capability to interbreed with wild plant relatives, or their survivability outside cultivated fields.

A more gradated approach to risk assessments could therefore be considered and be based on an initial screening for potential risks and establishment of risk classes with different levels of requirements of provision of data.

Products with similar characteristics to previously approved products with safe track records or with minimal or moderate risk characteristics could then enter less demanding and faster application procedures.

Consideration of more than potential environmental and health risks

In many of the RECIPES case studies other concerns than the potential health or environmental risks play a major role for member states' positions and decisions although the rules and regulatory framework does not cater much for such concerns to be considered, investigated or addressed (14).

For example, citizens' discomfort with the present status of and future development pathway for agricultural technology in the EU plays a major political role when it comes to glyphosate and genetically modified crop plants.

Similarly, concerns about citizens' rights play a role in the discussion on the precautionary principle related to artificial intelligence.

Also, broader concerns about the biodiversity and climate crises may play a role while such consequences are not yet directly addressed in most of the EU and member states' schemes for risk assessments.

Inclusion of such considerations, however, is generally asked for by the public, by green NGOs and some think tanks and, to an increasing extent, also by decision-makers as expressed in EU strategies such as the Green Deal and EU's 8th Environment Action Programme.

Scenario 3 Stronger, wider and more inclusive implementation of precaution

This scenario emphasizes the need for development of a significantly stronger and more widespread implementation of the precautionary principle in the EU.

Proponents of this view also often find that the principle should be used more and in a way that enables and encourages more inclusive, transparent and thus democratic decision-making processes (3, 12, 13, 15, 16).

The conclusion in the European Environment Agency's analyses of case studies in 2013 is that there is a need for more frequent invocation of the precautionary principle as well as for stronger implementation of precautionary measures. The Agency further emphasised that the implementation of the precautionary principle should have been invoked earlier in many cases and that it only rarely has been applied in cases where it later showed that risks were not significant (7).

The proponents of a stronger implementation of the precautionary principle further find that earlier and more stringent implementation of the precautionary principle will help investors and researchers to set ambitious targets and spur sustainable innovation (3, 15).

One positive example of such innovation is the emergence of "Green Chemicals", a movement which took off in the mid-90s in Europe amongst private sector companies and in research societies. It aims to design chemical products and processes that reduce or eliminate the generation and use of hazardous substances.

Presently, as it has become clear that major changes are needed for production and consumption patterns in the EU in order to achieve political goals related to the climate and biodiversity crises, the precautionary principle with its overt recognition of uncertainties and its negotiated nature of decision-making can be reckoned to be more important than ever.

Updated guidelines for stronger, wider and more inclusive implementation of the precautionary principle could be introduced in a new communication from the EU Commission replacing the communication on the principle from 2000.

Challenges

Some of the most important challenges to applying a stronger, wider and more inclusive implementation of the precautionary principle are presented below. The identified challenges are mainly extracted from the RECIPES case studies (14).

Emerging technologies – guidelines

The RECIPES case studies demonstrate that application of the existing regulations and guidelines for health and environmental risk assessments related to chemicals, foods, cosmetics, GMOs etc. cannot automatically be considered to be relevant and sufficient to be used in relation to developments within new and emerging fields (such as CRISPR Cas9, gene drive, artificial intelligence and nanotechnology).

Development is fast in these fields and may pose different kinds of risks, which may often be related to socio-economic or ethical issues.

The emerging technologies presently deliver products that are mostly regulated under existing EU sector regulations for older technologies. For example, many nano-materials

and products are regulated under REACH and the EU regulation on chemical classification, labelling and packaging (CLP) while new organisms developed by CRISPR Cas9 are regulated under EU's GMO directives.

However, for nano-materials for instance there exists no agreed specification of what defines nano or nano-scale, and there is therefore uncertainty as to whether relevant and sufficient risk assessment and risk management requirements can be generally anticipated as a result of the present regulation.

Similarly, there has been controversies about a recent decision by the European Court of Justice in which it was determined that new organisms developed by modern gene editing methods (e.g. CRISPR Cas9) are to be considered to be GMOs and regulated under the GMO regulatory framework.

Some critics have argued that such organisms are genetically well-defined, do not contain new DNA and pose no significant risks and should therefore not fall under the strict GMO regulatory schemes. At the same time other critics have emphasized that entirely new, and hitherto unknown organisms could be developed in near future by application of CRISPR Cas9 in combination with other modern synthetic biological technologies and that such organisms should not be compared to GMOs and may pose different kinds of risks.

For organisms to be developed with gene drive, which presently are also regulated according to the existing GMO regulations, these are fundamentally different from previous GMOs in the sense that they are deliberately designed to spread their new genetic traits to their offspring and following generations in laboratories or in the wild. Such spreading of genes is usually avoided by risk mitigation measures for GMOs and may pose very complex and entirely new kinds of risks assessment challenges.

As such technologies progress, they may result in new products that will no longer belong under the already existing sector regulations and instead need to be regulated under either revised and expanded existing schemes or under new specific regulatory schemes, which may better reflect the specific risks they present and precautionary measures they require.

Further analyses of how fast and to what extent such developments can be expected to take place seem needed to establish timely precaution.

Transparency

In the RECIPES case study on glyphosate it is found that lack of access for the public to health data provided by the producer to the EU authority responsible for undertaking the risk assessment (The European Food Safety Authority, EFSA) has resulted in public mistrust of both the applicant and the authority.

Meanwhile good governance, broad participation and in particular transparency in relation to the developments in nanotechnologies and in waste water infrastructure development in Milan resulted in less conflict and more sustainable solutions (14).

Participation

The case studies on genetically modified plants and nano-materials describe very different situations in terms of participation. Whereas participation has been limited and first started late when products, such as genetically modified crop plants, were ready for marketing approval the development of nano-materials have from the outset been characterized by more open and inclusive dialogues and participation of a broad range of relevant stakeholders.

Much of this dialogue and inclusion happened under the umbrella of RRI activities in Horizon 2020 and can be expected to continue under the Horizon Europe Regulation and Program.

The RRI approach aims to ensure systematic and adequate multi-stakeholder participation and responsible research and innovation through assessment of potential implications and societal expectations with regard to research and innovation (3, 9, 11).

The present negative public sentiments towards genetically modified plants and the more nuanced public perceptions of nano-materials may to some extent be caused by these differences in approach to dialogue and inclusion.

That this could be the case is underlined by experiences with citizen participation related to genetically modified crops undertaken by the Danish Board of Technology. In 1999 the board held a so-called consensus conference where randomly selected citizens during three weekends discussed the pros and cons of different forms of and potential uses of GMOs with experts and other stakeholders (2).

As part of the process regarding drafting of Danish legislation in the field of GMOs the citizens agreed on a long list of recommendations to the Danish parliament containing their views on the most controversial issues regarding GMOs.

The citizens ended up being not generally against GM crop plants. While many of the participants were against cultivation of pesticide-tolerant crops they looked more positively on possible approval of crops made less dependent on pesticides, e.g. on fungus-resistant potatoes, if these had first been subject to risk assessments and found to pose no significant risks.

Another positive example of participation and innovative solutions is from the RECIPES case study on neonicotinoids where Italian farmers collectively established an insurance scheme against yield losses from no use of neonicotinoids in maize fields. It turned out that yield losses in general were minimal but that the scheme could be helpful in bad years (14).

Based on the general experiences from the RECIPES case studies it seems relevant to strengthen RRI and other relevant approaches, in order to experiment with and develop models for more transparency and more systematic and qualified stakeholder participation in the future implementation of the precautionary principle.

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