# Načelo predostrožnosti u europskoj politici sigurnosti hrane: između sigurnosti i inovativnosti

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# PRECAUTIONARY PRINCIPLE IN EU FOOD SAFETY LAW: BETWEEN SAFETY AND INNOVATION

Master Thesis

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## Authenticity Statement

I, Suzana Poljak, declare that my master thesis is an original result of my own work and that no sources other than cited in my thesis have been used in writing it.

## Izjava o izvornosti

Ja, Suzana Poljak, izjavljujem da je moj diplomski rad izvorni rezultat mojega rada te da se u njegovoj izradi nisam koristila drugim izvorima do onih navedenih u radu.

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## ABSTRACT

The precautionary principle is one of the general principles of EU law. In the time when we are facing challenges of survival in the conditions of the changing environment, the precautionary principle has come under scrutiny by the biotechnology sector. Innovations and technological developments have become increasingly important in society, and the prospect of newly developed products and techniques can be fascinating. However, it is important to remember that technology and innovations are not always good and that caution is necessary. Only an effectively applied precautionary principle can help balance an increasing need for innovation with the protection of the environment and human health. The application of the precautionary principle in the field of biotechnology in the EU is an example of the disruptive effects of the principle when applied improperly.

# INTRODUCTION

Food - a means of survival. Food production is a complex process that depends on the environment in which it occurs. Nowdays, fundamental changes to the environment consequently affect food production. In order to be able to continue with food production in the modified environment, the food production process has to adapt to new circumstances. This means that in order to keep producing certain plants and sustain animals in certain areas, those plants and animals have to adapt to a new climate. In the past, climate changes were gradual and organisms adapted in accordance with Darwin's principle of natural selection. There is no guarantee the environment will be able to adapt fast enough to sustain the current food production system. That being the case, investements in biotechnology are key to a more viable system. Unfortunately, innovations are not always safe.

The precautionary principle is one of the general principles of EU law. It deals with the mitigation of mitigation of risks from products and processes which have the potential to be harmful to the environment and human health. The precautionary principle strikes the balance between protecting Union fundamental values and enabling innovation. Thus it is of utmost importance to apply it in accordance with Union guidelines. However, when it comes to the regulation of biotechnology, that is not the case within the EU. In this thesis, I will attempt to provide a conducive argument that the negative image the precautionary principle has in the biotechnology industry is attributed to its improper application in the EU's biotechnology regulation system. The hypothesis is that the precautionary principle in the area of biotechnology is not applied adequately. If it were applied in accordance with the guidelines of its application, it would have positive effects not only to the environment and human health, which is the main objective, but also on innovation, economy, and employment. My aim is to defend the precautionary principle from the negative image it has acquired within the biotechnology industry because of its improper application in the EU.

Due to the inefficiency of the biotechnology regulatory system based on the precautionary principle, new principles are trying to be introduced in the hope that they will move the biotechnology industry forward. Currently, there are a few initiatives venturing to impose new ideas to the decisionmakers. EU institutions currently praise the innovation principle as a way

forward. Some EU institutions are very excited about the prospects of introducing to the innovation principle to EU law, but caution is advised when undertaking such actions.

This thesis is divided into three parts. Following this introduction, the central part is divided into three chapters. The first chapter is dedicated to the precautionary principle and guidelines for its application. The second chapter looks into the application of the principle in the EU legislation and case law. The innovation principle is discussed in the third chapter. Finally, the conclusion is a reflection on the initial hypothesis along with a few suggestions for further actions.

# 1) THE PRECAUTIONARY PRINCIPLE

## a) Definition

The European Commission described the precautionary principle as the decision whether or not to invoke the precautionary principle in situations where scientific information is insufficient, inconclusive, or uncertain and where there are indications that the possible effects on the environment, or human, animal or plant health may be potentially dangerous and inconsistent with the chosen level of protection.[1] The European Commission admits that there is no universally accepted definition of the principle, but it continues that it "would be wrong to conclude that the absence of the definition has to lead to legal uncertainty."[2] The Commission's position is that the Community authorities practical experience with the principle and its judicial review make it possible to get an ever-better handle on the principle.[3]

So, what is the Community experience with the principle?

The origins of the principle can be traced to the 1970s German environmental policy and introduction of "Vorsorgeprinzip" (foresight principle) in the German air pollution legislation. According to Alberto Alemanno, the manifestation of the principle in EU law occurred much earlier than 1992 and its official recognition by the Maastricht Treaty as one of the guiding principles of the EU (then EC) environmental policy. The "embryonic form" of the precautionary principle was formed by the ECJ in the 1980s as a question of free movement of goods. In situations of scientific uncertainty, the number of Member States invoking public health as a reason to justify the ban on the import of products containing specified substances began to increase[4] (e.g. Kaasfabriek Eyssen[5], Sandoz[6], Heijn[7] and Mirepoix[8] cases). The ECJ took a stand

[1] Communication from the Commission on the Precautionary Principle, Brussels, 2000, COM (2000) 1, p. 7
[2] ibid.; p. 9
[3] ibid.
[4] Alemanno, A., The Shaping of the Precautionary Principle by European Courts: From Scientific Uncertainty to Legal Certainty; Bocconi Legal Studies Research Paper No. 1007404, p. 1-2
[5] Case C-38/80; ECLI:EU:C:1981:35
[6] Case C-174/82; ECLI:EU:C:1983:213
[7] Case C-94/83; ECLI:EU:C:1984:285
[8] Case C-54/85; ECLI:EU:C:1986:123

that in case of scientific uncertainty the member states (MSs) should have a wide margin of maneuver and be allowed to take actions, including domestic prohibition of imported products, on the grounds of public health.[9]

A big step for the recognition of the principle came in 1992 when the principle was enshrined in the Maastricht Treaty[10] in the chapter related to the environmental protection, where it can still be found today:

"Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay. In this context, harmonisation measures answering environmental protection requirements shall include, where appropriate, a safeguard clause allowing Member States to take provisional measures, for non-economic environmental reasons, subject to a procedure of inspection by the Union." [11]

The problem with the placement of the principle in the environmental policy area was that the Treaty did not provide a legal basis for the application of the principle to the food law. The principle was extended to the food law and other areas by case law. the first judgments where the ECJ extended the application of the principle from the environment to the food law were the so-called "BSE judgments".[12] The ECJ took a stand that "Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent. That approach is borne out by Article 130r(1) of the EC Treaty, according to which Community policy on the environment is to pursue the objective inter alia of protecting human health. Article 130r(2) provides that that policy is to aim at a high level of protection and is to be based in particular on the principles that preventive action should be taken and that environmental

[9] Alemanno, A.; The Shaping of the Precautionary Principle by European Courts: From Scientific Uncertainty to Legal Certainty; Bocconi Legal Studies Research Paper No. 1007404, p. 1-3

[10] Treaty on European Union; OJ (1992) C 224; Art. 130

[11] The Treaty on the Functioning of the European Union; OJ (2012) C 326/49; Art. 191/2

12 Cases C-180/96; ECLI:EU:C:1997:447 and C-157/96; ECLI:EU:C:1998:191

protection requirements must be integrated into the definition and implementation of other Community policies."[13]

Some authors still claim that the legal basis for the application of the principle to food safety is non-existent in the Treaties because "food safety and environmental protection are not connected, in law or in fact."[14] However, since 2002, there is a clearer legal basis for the principle in the area of food law. Article 7 of Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (General Food Law)[15] gives the definition of the principle as follows:

"1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified, but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment."

The Regulation follows the Commission's guidelines for applying the precautionary principle issued in 2000.[16]

### b) Guidelines for applying the precautionary principle

The lack of definition of the principle caused internal and international criticism[17] which led the Commission to issue the Communication on the precautionary principle. In its Communication, the Commission stated that the principle is relevant only in the event of a potential risk, even if this risk cannot be fully demonstrated or quantified or its effects determined

[13] Case C-180/96; §99-100

[14] MacMaoláin, C.; Food Law European, Domestic and International Frameworks, Hart publishing, 2015, p.137.

[15] OJ 2002 L 31/24

[16] Communication from the Commission on the Precautionary Principle, Brussels, 2000, COM(2000) 1

[17] see Alemanno, A. ., The Shaping of the Precautionary Principle by European Courts: From Scientific Uncertainty to Legal Certainty; Bocconi Legal Studies Research Paper No. 1007404, reference n. 33 and 34.

because of the insufficiency or inconclusive nature of scientific data.[18] As a triggering factor for the application of the principle, the Commission identified: identification of potentially negative effects resulting from a phenomenon, product or procedure, and scientific evaluation of the risk which because of the insufficiency of the data, their inconclusive or imprecise nature, makes it impossible to determine with sufficient certainty the risk in question.[19]

After the identification of the risk, the decision-makers have to select the appropriate course of action. The appropriate response is, according to the Commission, a result of an eminently political decision. The Commission stressed that there is a range of actions available under the head of the principle and that it is the ECJ's job to pronounce the legality of any measures taken by the Community institutions hence the measures may not be of an arbitrary nature.[20]

"Reliance on the precautionary principle is no excuse for derogating from the general principles of risk management. These general principles include: proportionality, non-discrimination, consistency, examination of the benefits and costs of action or lack of action, examination of scientific development."[21]

The measures should be maintained as long as the scientific data remains incomplete, imprecise, or inconclusive, and as long as the risk is considered too high to be imposed on society. The maintenance of the measures depends on the development of scientific knowledge. Measures should be reexamined and, if necessary, modified depending on the results of the scientific research and the follow up of their impact.[22]

### c) The General Food Law

The General Food Law Regulation establishes common principles and responsibilities, the means to provide a strong scientific base, efficient organizational arrangements, and procedures

[18] Communication from the Commission on the Precautionary Principle, Brussels, 2000, COM(2000) 1; p. 13.
[19] ibid., p. 14.
[20] ibid.; p. 14-15.
[21] ibid.; p. 17.
[22] ibid.; p. 20.

to underpin decision-making in matters of food and feed safety in order to assure a high level of protection of human health and consumers' interests and ensuring the effective functioning of the internal market.[23] General principles of food law according to the Regulation are: protection of human life and health, protection of animal health and welfare, plant health and environment, protection of consumers' interests, free movement of food and feed in the Community, risk analysis, precautionary principle, principles of transparency.

Definition of the principle was given in Article 7/1 of the Regulation:

"In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment."

The definition presupposes the existence of three triggering factors before the application of the principle: risk assessment[24], identification of possible harmful effect on health and the persistence of scientific uncertainty.

When the above-mentioned criteria for application of the principle are met, decisionmakers select the proper measures as a response to scientific uncertainty in the so-called "risk management phase."[25]

"Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of

[23] Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety; OJ 2002 L 31/24, Art. 1.

[24] According to Art. 3/11 of General Food Law Regulation "risk assessment means a scientifically based process consisting of four steps: hazard identification, hazard characterization, exposure assessment and risk characterization."

[25] "Risk management means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options." (Art. 3/12 General Food Law Regulation)

scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment."[26]

Just as the Commission's communication, the General Food Law Regulation limits the measures based on the precautionary principle. General Food Law Regulation demands that those measures are: proportionate, no more restrictive of trade than is required to achieve a high level of protection chosen in the Community, reviewed within a reasonable period of time in order to clarify scientific uncertainty and to conduct a more comprehensive risk assessment.

Measures based on the precautionary principle should be limited, periodically revised and used with precaution because "the limits of scientific knowledge may affect process of risk assessment influencing the overall level of attendant uncertainty and ultimately affecting the foundation for protective or preventive action."[27] It could be said that the general rule of application of the precautionary principle is: when the uncertainty stops, so should the measures based on the precautionary principle.

In my opinion, the EU still has a problem with the application of the precautionary principle. Not because of a lack of definition and guidance on how to apply it, but because of improper application. The EU is still facing international accusations about arbitrarily using the principle as a measure of protectionism. Such criticisms is relevant and should be addressed by EU institutions. Improper application of the principle can also lead to the EU falling behind the rest of the world in innovations in biotechnology. This could fatal in a rapidly changing environment where the continuation of production with current agricultural practices may soon become questionable and obsolete. Furthermore, I will try to prove that the EU institutions are not applying the precautionary principle according to the above-mentioned guidelines and the dangers of such approach.

[26] General Food Law Regulation; Art. 7/2
[27] Commission communication; p. 13.

## 2) APPLICATION OF THE PRECAUTIONARY PRINCIPLE IN BIOTECHNOLOGY

Food is a product of the environment in which it is produced, and as such food and animal feed production depends on the environment. Nowdays, the environment is facing fast changes that disable plants and animals, used as food, to naturally adapt to those changes. In order to keep the production of food and animal feed, scientists came up with various new ways to effectively produce plants and animals in a changing environment. Innovative ways of production raise questions about the safety of such foods. The precautionary principle comes into play in cases where the science is unclear or uncertain about the effects that the new process of food production can have on human and animal health and/or the environment. In this chapter, I will look at how the precautionary principle is applied to the new, potentially unsafe technologies in food production in the EU.

The hypothesis is that the precautionary principle in the area of biotechnology is not applied properly. If it were applied in accordance with the guidelines for its application, it would have positive effects not only to the environment and human health, which is the main objective of its application but also on innovation, economy, and employment. In my opinion, the problem is the lack of review of the measures based on the principle within a reasonable time-frame and consequently taking further actions according to the findings. I will try to prove my hypothesis by looking into rules that regulate GMO and Gene-editing technology.

### a) Regulation of Genetically Modified Organism(s)

In biotechnology the expression GMO indicates several agri-food products which are created using different methods to slightly modify their genetic makeup (to recombine or splice one or few sequences of their DNA), often adding genes taken from other species (transgenesis). This is done through various techniques, in direct and more or less targeted ways, in order to cancel undesirable characteristics or to add useful traits. Such recombinant DNA (rDNA)

processes and products are part of the agri-food or biotechnology.[28] When the first GMO rules were adopted in the late 1980s, GMO products were not well known, and plant genomics was in its infancy.[29]

According to the Commission's website on GMO legislation: "The European Union has established a legal framework to ensure that the development of modern biotechnology, and more specifically of GMOs, takes place in safe conditions."[30] The main piece of GMO legislation is Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EC (GMO Directive),[31] which was amended in 2015 by Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC in regards to the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory (GMO Directive 2015).[32]

Article 1 of the GMO Directive, named "Objective", states that the objective of the GMO Directive is to approximate the laws, regulations and administrative provisions of the MS and to protect human health and the environment when placing product containing GMO on the market or releasing GMO into the environment for any other purpose, in accordance with the precautionary principle. Recital 8 of the GMO Directive also states that the precautionary principle has been taken into account in the drafting of the Directive and that it must be taken into account when implementing it. The definition of the precautionary principle is given in the General Food Law Regulation along with guidelines for its implementation. General Food Law Regulation applies to all stages of production, processing, and distribution of food and feed,[33] thus it is applicable to the GMO products and processes.

"Living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross-

[28] Tagliabue, G.; Ammann, K.; Some Basis for a Renewed Regulation of Agri-Food Biotechnology in the EU; J Agric Environ Ethics (2018) 31; p. 40.

[29] Davison, D.; Ammann, K.; New GMO Regulations for Old: Determining a New Future for EU Crop Biotechnology; GM Crops & Food, 8 (2017); p. 15

[30] GMO legislation. Available at https://ec.europa.eu/food/plant/gmo/legislation_en, last accessed on 9 September 2019.

[31] OJ 2001 L 106/1

[32] OJ 2015 L 68/1

[33] General Food Law Regulation; Art. 1/3

national frontiers thereby affecting other MSs. The effects of such releases on the environment may be irreversible."[34] The protection of human health and the environment requires that due attention be given to controlling risks from deliberate release into the environment of GMOs."[35] From the text of the GMO directive, it can be concluded that the GMO Directive and EU's GMO rules as a whole are a measure based on the precautionary principle, and for the purpose of this thesis we shall look at it as such.

As mentioned above (§1/b) in order to apply precautionary principle three conditions have to be met: risk assessment, identification of possible harmful effect on health/environment, and persistence of scientific uncertainty.

"The increasing cultivation of GMO crops has raised a wide range of concerns with respect to food safety, environmental effects, and socio-economic issues. From the food and health perspective, the main concerns are related to possible toxicity and allergenicity of GMO foods and products. Concerns about environmental risks include the impact of introgression of the transgenes into the natural landscape, impact of gene flow, effect on nontarget organisms, evolution of pest resistance, and loss of biodiversity. Adoption of GMO technologies has also evoked a range of social and ethical concerns about restricting access to genetic resources and new technologies, loss of traditions (such as saving seeds), private sector monopoly and loss of income of resource-poor farmers."[36]

In the next phase, decision-makers have to choose the appropriate measures to answer existing scientific uncertainty about GMO. Initially, the EU's approach to GMO rules was based on the premise that precaution would be gradually relaxed as more experience with GMO products was gained during experiments and field trials.[37] Unfortunately, we are witnessing witnessing an opposite trends occurring in the EU's GMO rules.

The measure, chosen by the decision-makers in a complex process, that must ensure the "protection of human health and the environment by controlling risks from deliberate release into

[34] The GMO Directive, Recital 4.
[35] The GMO Directive, Recital 5.
[36] FAO Statistical Yearbook, 2012, World Food and Agriculture; Food and Agriculture Organization of the United Nations; Rome 2012; p. 314. Available at http://www.fao.org/3/i2490e/i2490e04d.pdf, last accessed on 9 September 2019.
[37] Carr, S.; Ethical and Value-based Aspects of the European Commission's Precautionary Principle; Journal of Agricultural and Environmental Ethics, Vol.15 (2002); p. 32.

the environment of GMOs."[38] Still those measures have to be: proportionate, no more restrictive of trade than is required to achieve a high level of protection chosen in the Community, and reviewed within a reasonable period of time in order to clarify scientific uncertainty and to conduct a more comprehensive risk assessment. In the following chapters, I will look if that is the case with rules that regulate GMOs in the EU.

### i. Proportionality of the Measures and its Influence on Trade

The principle of proportionality entails a consideration of the costs and benefits of a measure enacted by an MS in the light of the different interests which Community rules deem worthy of protection. When reviewing the proportionality of a measure enacted by an MS, the ECJ applies one or more of three sub-tests: the suitability test, the necessity test and a review of proportionality "*stricto sensu*".[39] However, the review does not stop there. In addition to the assessment of proportionality described above, a measure enacted by an MS must not "constitute a means of arbitrary discrimination".[40]

The GMO Directive aim is to protect human health and the environment from the risk that the release of GMO poses to them.[41] For that purpose, the GMO directive regulates: environmental risk assessment, product approval procedure, post-market monitoring, and labeling requirements. Given the fact that the products produced by process of genetic modification were deemed different from the ones produced by traditional methods, and concerns about the safety of such products were raised, it was justified to introduce measures that decrease the possibility of adverse effect on human health and the environment. Measures introduced by the GMO Directive transfer the burden of proof that the GMO is safe for the environment and human health to the producer. Shifting the burden of proof to the producer, who claims that a/their product is safe, is one way of applying the precautionary principle, and it is applied to the products/procedures that

[38] GMO Directive; Recital

[39] Opinion of Advocate general Poiares Maduro, delivered on 13 July 2006; Case C-434/04; §23; ECLI:EU:C:2006:462

[40] ibid.; §28

[41] GMO Directive; Art. 1.

are considered *"a priori"* hazardous.[42] In case of the precautionary principle, when there is uncertainty about the risk the product causes, it is logical to shift the burden of proof to the producer who has access to information that would be difficult to obtain by the party that claims the product is not safe.[43]

In my opinion, measures introduced by the GMO Directive are in accordance with the proportionality principle. Environmental risk assessment, product approval procedure, post-market monitoring, and labeling requirements enacted by the GMO Directive are suitable to achieve the aim of the measure – protection of human health and environment. In the risk assessment procedure, it is possible to detect possible negative effects of the product/process, and post-market monitoring enables relevant authorities to react quickly in case the pre-market assessment failed to notice negative effects of the product/process. Labeling requirements are justified from the point of consumer protection. Some consumers do not want to consume GMOs, irrespective of their safety. Consumers have a right to make an informed choice, which is not possible without GMOs being labeled. The third sub-test of the proportionality test is the test of proportionality "*stricto sensu*". The test of proportionality *"stricto sensu"* can be expressed as the following rule: The greater the degree of detriment to the principle of free movement of goods, the greater must be the importance of satisfying the public interest on which the MS rely.[44] In my opinion, measures enacted by the GMO Directive do not, in theory, impose too big of a burden on the producers since they are crucial for the protection of human health and the environment.

Unfortunately, the measures adopted by the GMO Directive have proven to be burdensome in practice. The non-functioning mechanism for pre-market product approval, which lacks formal criteria and takes a long time to complete, is the problem.[45] The transparency of the pre-market approval process is impaired by the fact that high positioned officials ignore scientific evaluations by the European Food Safety Agency (EFSA)[46] and make their decisions on

[42] Commission communication, p. 20.
[43] Szajkowska, A.; The Impact of the Definition of the Precautionary Principle in the EU Food Law, Common Market Law Review, Vol 47 (2010); p. 192.
[44] Opinion of Advocate general Poiares Maduro; Case C-434/04; § 26
[45] see: Mastroeni, M.; Mittra, J.; Joyce, T.; Political Influences on Biotechnology-based Innovation for European Agriculture: Risk Assessment and Risk Management; Technology Analysis & Strategic Management, 2019
[46] Agency has a mandate to issue scientific opinions on products relating to GMO which should serve as scientific base for drafting and adoption of Community measures (General Food Law Regulation, Art. 22/5/c and Art. 22/6.)

approvals based on questionable grounds.[47] For me, the most problematic part of the GMO rules in the EU are the 2015 amendments to the GMO Directive.[48] The GMO Directive 2015 allows MSs to opt-out of cultivation of approved GMOs on their territory. Such a problematic application of the Directive has a disruptive effect on the trade with third countries and innovation. Who would want to invest in the GMOs if at the end of a (costly) approval procedure the product could not be produced in 19 (soon 18) out of 28 (soon 27) MSs?[49]

### ii. Review of the Measures Based on the Precautionary Principle

Once implemented, measures shall be reviewed within a reasonable period of time, depending on the nature of the identified risk to life or health and the type of scientific information needed to clarify the uncertainty and to conduct a more comprehensive risk assessment.[50] "The scientific evidence concerning the environmental and health impacts of GMOs is still emerging, but so far, there is no conclusive information on the definitive negative impacts of GMOs on health or the environment."[51] "The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not per se more risky than e.g., conventional plant breeding technologies."[52] The scientific community concluded that GMOs are as likely to be (un)safe as products obtained by

[47] In 2007 Commissioner for the Environment Stavros Dimas refused to approve cultivation of maize Bt11 despite the positive evaluation by EFSA (see: Mastroeni, M.; Mittra, J.; Joyce, T.; Political Influences on Biotechnology-based Innovation for European Agriculture: Risk Assessment and Risk Management; Technology Analysis & Strategic Management, 2019; p. 5.).

[48] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory (GMO Directive 2015); OJ 2015 L 68/1

[49] Restrictions of geographical scope of GMO applications/authorizations: EU countries demands and outcomes. Available at https://ec.europa.eu/food/plant/gmo/authorisation/cultivation/geographical_scope_en, last accessed on 9 September 2019.

[50] General Food Law Regulation, Art. 7/2.

[51] FAO Statistical Yearbook, 2012, World Food and Agriculture; Food and Agriculture Organization of the United Nations; Rome 2012; p. 314. Available at http://www.fao.org/3/i2490e/i2490e04d.pdf,, last accessed on 9 September 2019.

[52] A decade of EU-funded GMO research (2001-2010); Directorate-General for Research and Innovation - Biotechnologies, Agriculture, Food (2010); EUR 24473 EN; p. 16. Available at https://ec.europa.eu/research/biosociety/pdf/a_decade_of_eu-funded_gmo_research.pdf, last accessed on 9 September 2019.

traditional breeding techniques. The process itself does not lead to an increase in the risk that the GMOs pose to human health and the environment. Such conclusions from the scientific community should make GMO rules unnecessary because the general rule of the precautionary principle is that when the uncertainty stops so should the measures based on the principle. The confirmation of that rule can be seen in recital 17 of the GMO Directive: "This Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record."

Unfortunately, we witness the situation in which GMO regulation in the EU is persistent and has become even more restrictive.

In 2015 the GMO Directive was amended by the GMO directive 2015 which enables MSs to restrict or prohibit the cultivation of GMOs on their territory. From the perspective of the principles of EU law, such amendments are not justified. The measure adopted in the GMO Directive 2015 is not in accordance with the principle of proportionality and the precautionary principle. The GMO Directive 2015 enables MSs to ban the cultivation of GMOs, that have been approved by the relevant EU authorities, for part or all of the territory of MS. For the justification of the ban, MS should only use grounds with respect to environmental policy objectives which are distinct from and complementary to the assessment of risk to health and the environment, as assessed in the context of authorization procedure provided in the GMO Directive. Such grounds are: environmental policy objectives, town and country planning, land use, socioeconomic impacts, avoidance of GMO presence in other products, agricultural policy objectives, and public policy.[53] In short, the GMO Directive 2015 is introducing a new, unscientific base for the ban (the strongest possible measure in the arsenal!) on the cultivation of the GMOs, that have been approved in accordance with the GMO Directive. Moreover, the explanation for such a decision is not food safety, environmental safety/protection or protection of health but the fact that the "decision-making process has proved to be particularly difficult as regards the cultivation of GMOs in the light of the expression of national concerns which do not only relate to issues associated with the safety of GMOs for health and the environment."[54]

[53] GMO Directive 2015, Art. 1/2/3.
[54] GMO Directive 2015, Recital 7.

The GMO Directive 2015 is not in accordance with the precautionary principle because there is no uncertainty about the safety of the GMOs that are banned from cultivation. The GMO Directive 2015 enables MSs to ban the cultivation of GMOs that have, previously, been approved on the EU level. In order to be approved at the EU level, the GMO had to be proven safe for human health and the environment. If the GMO was proven to be safe, there is no triggering factor for the application of the precautionary principle because there is no uncertainty about the safety of the GMO.

Furthermore, the GMO Directive 2015 is not in accordance with the principle of proportionality. The test of necessity asks "whether an alternative measure is realistically available that would protect an MS's legitimate interests just as effectively but would be less restrictive."[55] The MSs cannot justify the ban on the cultivation of the GMOs on the grounds of protection of human health or the environment. In order to justify the ban, MSs can use one of the following grounds: environmental policy objectives, town and country planning, land use, socioeconomic impacts, avoidance of GMO presence in other products, agricultural policy objectives and public policy.[56] If the ban on the GMO is unnecessary on the EU level, I think it is highly unlikely that it is necessary on the level of an individual MS. However, for the sake of the argument, suppose that the ban is able to pass the necessity test because an MS "can demonstrate that adopting the alternative measure would have a detrimental effect on other legitimate interests"[57] The measure still has to pass the test of proportionality *"stricto sensu"*. The greater the degree of detriment to the principle of free movement of goods, the greater must be the importance of satisfying the public interest on which an MS relies. MSs rely on environmental policy objectives, town and country planning, land use, socioeconomic impacts, avoidance of GMO presence in other products, agricultural policy objectives and public policy to justify the ban on the cultivation of GMO on their territory. I think that above-mentioned interests cannot pass the test of proportionality because the functioning of the internal market and the position of the EU as a trading partner to the third countries are much more important than, for example, town and country planning.

[55] Opinion of Advocate general Poiares Maduro; Case C-434/04; § 25
[56] GMO Directive 2015; Art. 1/2
[57] ibid. note 56.

The decision to amend GMO rules and enable MSs to ban cultivation on their territory is an arbitrary decision that is contrary to the principles of the EU law. To amend an important piece of GMO legislation in order to pander to interests of certain MSs is not in accordance with the EU law and it is bad for the reputation of the EU as a trade partner. Such decisions of the EU institutions that are not based on scientific facts give fuel to international accusations of using the precautionary principle as an instrument of protectionism.

### iii. Non-scientific Factors in the Decision Making Process

Public perceptions about GMOs in food and agriculture are divided with a tendency toward avoiding GM food and products in many developed and developing countries.[58] It should be noted that some authors praise the opt-out clause introduced by GMO Directive 2015 because, in their opinion, it establishes a balance between an authorization procedure based on risk assessment and the option for an MS to express the concerns of their citizens without having to rely on scientific evidence or to take into account other MS.[59] According to them, because society shares the burden of any unforeseen consequences, the scientific risk assessment should be set in a context of a wider discussion of the possible social and ethical implications.[60] The problem with such an approach is that it disables the uniformity of European legislation and has a negative effect on the solidarity among MSs. Furthermore, it is hypocritical that MSs that decide to use the opt-out clause still use the GMO products, but don't share the (alleged) ethical and moral costs of its production.

I disagree with the idea that the opinion of the citizens is not considered during the decision-making process. The Commission has confirmed its wish to rely on procedures as transparent as possible and to involve all interested parties at the earliest stage possible, which

[58] FAO Statistical Yearbook, 2012, World Food and Agriculture; Food and Agriculture Organization of the United Nations; Rome 2012; p. 314. Available at http://www.fao.org/3/i2490e/i2490e04d.pdf, last accessed on 9 September 2019.

[59] Petetin, L.; The Precautionary Principle and Non-scientific Factors in the Regulation of Biotech Foods; European Journal of Risk Regulation, Vol. 8 (2017), p. 110.

[60] Carr, S.; Ethical and Value-based Aspects of the European Commission's Precautionary Principle; Journal of Agricultural and Environmental Ethics, Vol.15 (2002); p. 35.

should assist decision-makers in taking legislative measures which are likely to achieve the society's chosen level of health or environmental protection.[61] Such position is further developed in recital 19 of General Food Law Regulation that recognizes that scientific risk assessment alone cannot provide all information on which a risk management decision should be based on and that other factors, relevant to the matter, should be taken into account including societal, economic, traditional, ethical and environmental factors.

In order to include public in the decision-making process, the Commission consults the public on GMO food and feed authorization applications. Before a GMO can be approved, the public has 30 days to comment on the summary of the applications, and on the risk assessment done by the European Food Safety Authority (EFSA). After the consultation, the Commission sends the comments received for the submitted applications directly to the lead competent authority for the analysis. Scientific comments received for the applications are sent to EFSA who checks their impact on the EFSA scientific opinion. The results of public consultation can be found on the Commission's website. [62]

### iv. Proposition for Changes to the GMO Rules

Today, technological progress is exponentially growing. What was new yesterday is old news today. In the field of biotechnology, changes are happening fast, and new technics that play with the genetic structure of organisms are constantly emerging. In such a dynamic environment, with the non-profitable procedure for approval of new GMO techniques, the EU is at risk of faltering in making considerable contributions to the innovations in the field of biotechnology. The Commission recognized the importance of biotechnology by making its life sciences and biotechnology strategy part of the Europe 2020 strategy and the Innovation Union flagship

[61] Commission communication, p. 16

[62] Public consultations on GM food & feed authorisation applications. Available at https://ec.europa.eu/food/plant/gmo/public_consultations_en, last accessed on 9. September 2019.

program. The European Commission aims to identify and remedy obstacles in the biotechnology industry.[63]

In order to help the biotechnology industry, the Commission should revise the GMO directive. Some authors pose the question of the efficiency of the system, such as the GMO Directive, that is process- and not product-based. Those authors propose a regulatory framework which would concentrate on potential environmental and health risks of a product rather than focusing on the process through which the product was created.[64]

If we were to accept such changes to the regulatory system, I believe that we would not need the GMO Directive at all. There is already a functioning system of tracking food safety of GMO products in the EU - The Regulation (EC) No 1830/2003 on the traceability and labeling of genetically modified organisms (GMOs) and the traceability of food and feed products produced from GMOs (GMO Regulation).[65] "The GMO Regulation provides a framework for the traceability of products consisting of or containing genetically modified organisms (GMOs), and food and feed produced from GMOs, with the objectives of facilitating accurate labeling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products."[66] Currently, The GMO Regulation rules apply to the GMOs that are approved and placed on the market in accordance with the GMO Directive. From the recital 2 of the Regulation it is evident that the Regulation was a reaction to non-functioning mechanisms derived from the GMO Directive: "Differences between national laws, regulations and administrative provisions concerning traceability and labeling of GMOs as products or in products as well as traceability of food and feed produced from GMOs may hinder their free movement, creating conditions of unequal and unfair competition. A harmonized Community framework for traceability and labeling of GMOs should contribute to the effective functioning of the internal market." The Regulation puts in place rules to ensure pre-approved products containing GMOs and food and animal feed derived from them can be traced on all stages of the production and distribution

[63] Biotechnology. Available at https://ec.europa.eu/growth/sectors/biotechnology_en, last accessed on 9 September 2019.

[64] Morris, S. H.; Spillane, C.; GM Directive Deficiencies in the European Union; EMBO Reports, Vol 9., No. 6. (2008), p. 500.

[65] OJ 2003 L 268/24

[66] GMO Regulation; Art. 1.

chain.[67] This Regulation provides a framework for monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products.[68] The regulatory system based on the GMO Regulation and General Food Law Regulation would be more open to the new GMO products but would still ensure the safety of such products by allowing competent authorities to invoke the precautionary principle when necessary. This would enable the application of the precautionary principle when there would not be a pre-approval procedure of the GMOs, which is currently regulated by the GMO Directive.

[67] Summary of: Regulation (EC) No 1830/2003 on the traceability and labelling of genetically modified organisms (GMOs) and the traceability of food and feed products produced from GMOs. Available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:l21170, last accessed on 9 September 2019.

[68] GMO Regulation, Art. 1.

### b) New Breeding Techniques (NBT)

According to the Commission web page: "The European Commission follows the continuous progress in modern biotechnology, to consider how the EU can benefit from innovation in the food and agricultural sector while maintaining high safety standards. In the last decade, a variety of new techniques has been developed, based on advances in biotechnology."[69] In this chapter, I will concentrate on a mutagenesis technique called "genome editing" and on the question whether the regulation of genome editing in the EU is in accordance with the precautionary principle.

"Gene editing (GE) is a technique where the modification of organisms takes place by deleting, disrupting, or enhancing parts of the genome of a single species without injecting external genetic material. The technique setting the pace in gene editing is "CRISPR-Cas9". Effectively a "molecular scissors", it can alter the genetic structure of organisms in ways that can improve their immunity, resilience, yield, and other characteristics. By not crossing the "species barrier", the modifications associated with the technique could occur naturally. This characteristic, claim its advocates, means that it should not be subject to the procedures and rules associated with transgenic GMOs. Opponents, however, argue that the process is nonetheless risky since unforeseen changes associated with gene editing have occurred"[70]

From the definition of gene-editing, we see that we are dealing with new technology that may pose a risk to the environment and human health. First studies have shown that products of gene editing could have unintended consequences on the environment and human health. Scientists involved in the development of gene-editing technology are aware and are warning about the risks that products of such techniques can cause once they were released into the environment. Caution is needed before the commercialization of the products of new breeding techniques. For example, researchers on malaria resistant mosquitoes raised concern that gene drives used in GE have the potential to alter entire populations and therefore, entire ecosystems. They could also, in theory, negatively affect human health by causing the malaria parasite to

[69] New Techniques in Biotechnology. Available at https://ec.europa.eu/food/plant/gmo/modern_biotech_en, last accessed on 9 September 2019.

[70] INTERNATIONAL: EU will be cautious on gene editing, OxResearch Daily Brief Service, 30 August 2018, p. 1.

evolve to be more virulent or to be carried by another host. This technology has the potential to be immensely powerful and to change the course of things that we may not be able to predict.[71] In such circumstances where, following an assessment of available information, the possibility of harmful effects on health or environment is identified, but scientific uncertainty persists, risk management measures necessary to ensure the high level of the protection chosen in the EU may be adopted, pending further scientific information for a more comprehensive risk assessment.[72] In short, we should be able to apply the precautionary principle on GE products. The Precautionary principle allows decision-makers to choose from a set of various, more or less restrictive, measures depending on the imposed risk. "In areas harmonized under EU law, those measures are to be taken on the basis of secondary law provisions giving specific expression to that principle, for instance, safeguard clauses or other provisions dedicated to the handling of new information with regard to risks to health or the environment presented by a certain product. In the absence of harmonization, the precautionary principle may also be relied on autonomously, to justify the adoption of restrictive measures."[73]

The debate on how to regulate new breeding methods, that includes GE, was abruptly stopped by the decision of the ECJ in the case C-528/16 from 25 July 2018. The ECJ, in its judgment, decided that organisms obtained by means of techniques/methods of mutagenesis constitute genetically modified organisms within the meaning of the GMO Directive. The judgment C-528/16 submitted NBT to GMO rules. Considering what we already wrote about the defaults of GMO rules in the EU, the negative reactions from scientific and investment circles to the decision does not come as a surprise. The criticism related to the EU genetic engineering legislation's unlikelihood of doing justice to the opportunities and challenges of GE technologies and warnings that the ECJ ruling could paralyze funding and force an exodus of talent from Europe to places where there are not the same onerous restrictions were predominant after the ruling[74]. Although I agree that the Court's decision and explanation are not very convincing and that the interpretation of the same contested provision in the Opinion of AG Bobek makes more

[71] Scudellari, M. ; Self-destructing mosquitoes and sterilized rodents: the promise of gene drives; Nature International journal of science. Available at https://www.nature.com/articles/d41586-019-02087-5, last accessed on 9 September 2019.

[72] General Food Law Regulation, Art. 7/1.

[73] Opinion of Advocate General Bobek delivered on 18 January 2018, Case C-528/16, § 48. ECLI:EU:C:2018:20

[74] Kelly, É.; Scientists urge new EU rules on gene editing crops; Science/Business. Available at https://sciencebusiness.net/news/scientists-urge-new-eu-rules-gene-editing-crops, last accessed on 9 September 2019.

sense, the ruling is binding and the Commission expressed its commitment to the implementation of the Court's ruling.[75] However, that does not mean that the GMO Directive cannot be changed in order to reflect changes in technology. "EU health Commissioner Vytenis Andriukaitis said new plant breeding techniques need new EU legislation that takes into account the latest technological advances. Andriukaitis said the ECJ had been asked to interpret a law, the EU's GMO Directive, which was adopted 20 years ago and does not reflect the technological progress achieved since then in this area. It is a quite sensitive issue for ministers and society. Different MSs have different views, and different approaches to the GMOs and the core EU legislation on this has been in place since the 1990s, and it was only updated in 2001. But I expected that a new initiative will be required in the next Commission."[76]

During the procedure, some interesting questions about the precautionary principle came up, and it is important for the future development of the principle to look into them.

### i.) Lessons for the Precautionary Principle

In the case C-528/16, the Court refused to answer the question related to the validity of Art. 2 and 3 of the GMO Directive concerning the precautionary principle. Articles 2 and 3 read with Annexes I A and I B of the GMO Directive defined GMO techniques that are exempt from the application of the GMO Directive. In its question to the ECJ, the referring court asked: "May the validity of Articles 2 and 3 of and Annexes I A and I B to Directive [2001/18] with regard to the precautionary principle guaranteed by Article 191(2) [TFEU], in that those provisions do not subject [GMOs] obtained by mutagenesis to precautionary, impact-assessment and traceability measures, be called into question, taking account of the development of genetic engineering processes, the appearance of new plant varieties obtained by means of those techniques and the current scientific uncertainty as to their impacts and the potential risks they represent for the

[75] New Techniques in biotechnology. Available at https://ec.europa.eu/food/plant/gmo/modern_biotech_en last accessed on 9 September 2019.

[76] Fortuna, G.; Commission in search of 'robust response' to gene editing challenge, Euractive. Available at https://www.euractiv.com/section/agriculture-food/news/commission-in-search-of-robust-response-to-gene-editing-challenge/, last accessed on 9 September 2019.

environment and human and animal health?"[77] In short, referring court asked can the absence of surveillance, together with the absence of conclusive scientific data proving that organisms obtained by mutagenesis are safe, amount to a breach of the precautionary principle thus potentially justify the annulment of articles that exempt mutagenesis techniques from the scope of the GMO Directive.[78]

The ECJ found that the answer to the referring court's question is not necessary because the mutagenesis techniques are in the scope of the GMO Directive.[79] Therefore, because the potentially unsafe mutagenesis techniques are ruled by the GMO Directive there is no breach of the precautionary principle and no need for the annulment of relevant articles.

A much more interesting discussion about the precautionary principle can be found in the Opinion of AG Bobek. According to AG Bobek: "there is a constitutional duty for legislation to be relevant, in the sense of being technically and socially responsive, and, provided that it is necessary in view of later evolution, to be updated. The legislature is obliged to keep its regulation reasonably up to date. This does not necessarily mean, in a legal order of attributed competence, that there is a duty to legislate, a duty to cover new ground. But there is certainly a duty to nurture the ground already covered".[80] Bobek continues: "Failing to keep the instrument up to date could result, in extreme cases of technical or social lack of responsiveness, in a potential declaration of invalidity of the specific legislative provisions because of inactivity, namely, because of the failure to amend. I wish to underline the very exceptional nature of such a step, which could only be contemplated in cases of clear and paramount dissonance between changed reality and effectively obsolete legislation."[81] "The specific role and value of the precautionary principle is that in those areas and issues covered by that principle, that duty becomes crucial. In the sensitive areas covered by that principle, extra caution and vigilance is called for, which translates into the need for regular updates and review by the legislature."[82]

In the previous chapter of this thesis, I made it very clear that revision of the measures based on the precautionary principle is part of the proper use of the principle. The problem is that

[77] Judgement C-528/16, §25; ECLI:EU:C:2018:583
[78] Opinion of Advocate General Bobek delivered on 18 January 2018, Case C-528/16, § 130.
[79] Judgement C-528/16, § 84.
[80] Opinion of Advocate General Bobek delivered on 18 January 2018, Case C-528/16, § 139.
[81] Opinion of Advocate General Bobek delivered on 18 January 2018, Case C-528/16, § 140.
[82] Opinion of Advocate General Bobek delivered on 18 January 2018, Case C-528/16, § 141.

the failure of that obligation does not have any legal consequences. The GMO regulation in the Union has not been revised at all from the position of the precautionary principle in the time of its existence. Since 1990 until today, technology and scientific research came to some valuable conclusions on the safety of GMOs, but in the EU, those findings have been ignored. Having one of the most severe sets of GMO regulations in the world and hostile legal and political climate resulted in an almost insignificant amount of GMO crops being cultivated in the Union.[83]

In the most controversial part of the judgment, the crucial role for determining whether the mutagenesis technics is or is not exempt from the scope of the GMO Directive was played by the precautionary principle. The difference between the Court's and the Advocate General's opinions on the time limit of the precautionary principle became crucial for determining that just those mutagenesis techniques which have conventionally been used in a number of applications and have a long safety record are exempt.

In his Opinion, the Advocate General states: "It would appear to me that if one wishes to remain in the realm of legal interpretation, the precautionary principle is likely to play a different role. As in other cases of legal interpretation, that principle can be used to interpret uncertain notions or categories, where there is doubt about their meaning within reasonably acceptable semantic limits of the written text — where there are several (equally plausible) options on the table. It cannot lead, however, to rewriting the provisions of the legal text against their wording, that is, "*contra legem*". What the Applicants are effectively asking for is not an interpretation of the GMO Directive but a judicial redrafting of it, more specifically the redrawing of the scope of the exemption of Article 3(1) and Annex I B, against the wording of the legislation, seeking an insertion through a judicial medium of categories which are clearly not provided for in the legislation itself."[84]

The court invoked recital 17 of GMO Directive that states: "This Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record." As I mentioned before, the general rule is that once the uncertainty stops, so should the measures based on the principle. If the method was proven to be safe, measures based on the precautionary

[83] Davison, J.; Ammann, K.; New GMO Regulations for Old: Determining a New Future for EU Crop Biotechnology; GM Crops & Food (2017) Vol 8.; p. 13.

[84] Opinion of Advocate General Bobek delivered on 18 January 2018, Case C-528/16, § 103. and 104.

principle should be revoked. With that in mind, the ECJ ruled that: "Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B to that directive and in the light of recital 17 thereof, must be interpreted as meaning that only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are excluded from the scope of that directive."[85]

[85] Judgement C-528/16, § 54.

## 3) INNOVATION PRINCIPLE

Opponents of the precautionary principle argue that by concentrating on unknown risks and ignoring benefits, priorities are distorted and beneficial developments prevented, with potentially harmful consequences, and innovations are stifled. On the other hand, proponents of the principle point to research that suggests that the application of regulation may stimulate innovation in technology, products, and processes. [86] For example, despite the EU inability to make progress in the adoption of GMO crops, from 2007 through 2011, more than 35% of genome editing publications came from Europe.[87] The fact that the GMOs were unprofitable shifted the industry to the development of new technologies. The same happened in the 1970s in Germany, when the first rules based on the precautionary principle were introduced to the German environmental policy. "German industry was willing to accept that it had little option but to embrace improved environmental standards and that in doing so it could strengthen its international competitive position by being first to develop more environmentally sustainable technologies."[88]

The general perception is that the EU is not competitive when it comes to innovations, especially in the field of biotechnology. One of the reasons for lack of EU's competitiveness is a regulation that is sometimes lacking and in other times over-regulating. In order to tackle the issue of regulation, the Commission came up with "the better regulation" agenda. "The better regulation agenda is about designing and evaluating EU policies and laws transparently, with evidence, and backed up by the views of citizens and stakeholders. It covers all policy areas and aims for targeted regulation that goes no further than required, in order to achieve objectives and bring benefits at minimum cost. To achieve better results, the Commission is opening-up policy and law-making and listening more to the people it affects. Better regulation relies on evidence and a transparent process, which involves citizens and stakeholders (for example, businesses, public administrations and researchers) throughout. The Commission identifies areas for

[86] Garnett, K; Parsons, D.J.; Multi-Case Review of the Application of the Precautionary Principle in European Union and Case Law; Risk Analysis (2017) Vol. 37, No. 3; p. 504.

[87] Wolt, J.D.; Wang, K.; Yang, B.; The Regultory Status of Genome-edited Crops; Plant Biotechnology Journal (2016) Vol. 14; p. 516.

[88] Woolcock, S.; The Precautionary Principle in the European Union and its Impact on International Trade Relations; CEPS Working Document No. 186, October 2002; p. 3.

improvement to the existing body of EU legislation. And when proposing new policies and laws, the Commission is focusing on the things that really do need to be done by the EU, and makes sure they are done well." [89] The Second Commission initiative in the field of better regulation is "Responsible research and innovation" (RRI). "RRI is an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation."[90]

In such a climate, the "innovation principle" was introduced. The innovation principle was written by members of the European Risk Forum. According to the information on their web page, The European Risk Forum (ERF) is an expert-led, non-profit think tank, which promotes high-quality risk assessment and risk management decisions by the EU institutions and raises awareness of risk management issues at the EU level.[91] "The innovation principle has the support of BusinessEurope, the European Roundtable of Industrialists and the European Chemical Industry Council (Cefic). It is telling that the vast majority of ERF members come from the biotech, pharmaceutical and agri-sectors and include, among others, AiCuris, Airbus Group, Arthur D. Little, Aurubis, BASF, Bayer, Dow AgroSciences, the Dow Chemical Company, Henkel AG, IBM Europe, Novartis, Royal Philips, Solvay, Syngenta, and Yara International. All are industries that have struggled with the EU over the authorization and licensing of their innovative products and who arguably have a natural suspicion of the precautionary principle and the resulting risk assessments this principle requires of them."[92] Therefore, it is to be expected that while they are calling themselves an "expert-led, non-profit think tank", others are calling them "corporate lobby platform".[93] I think that the industry has a right to propose measures that would help them achieve the goals of their industry. In my opinion, lobbying is a legitimate way of making your voice heard by policy-makers. The fact that the innovation principle is proposed by such a group does not mean that the principle should be "*ab initio*" discharged as the anti-precautionary principle legislation proposal. However, when the decision-makers think about

[89] Better regulation: why and how. Available at https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en, last accessed on 9 September 2019.

[90] Responsible research & innovation. Available at https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation, last accessed on 9 September 2019.

[91] European Risk Forum. Available at http://www.riskforum.eu/, last accessed on 9 September 2019.

[92] Garnett, K.; Van Calster, G.; Reins, L.; Towards an Innovation Principle: an Industry Trump or Shortening the Odds on Environmental Protection?; Law, Innovation and Technology (2018); p. 2.

[93] The 'innovation principle' trap - Industries behind risky products push for backdoor to bypass EU safety rules; Corporate Europe Observatory. Available at https://corporateeurope.org/en/environment/2018/12/innovation-principle-trap, last accessed on 9 September 2019

introducing such a proposal into legislation or official documents, they should bear in mind its origin.

ERF phrased innovation principle (IP) as:

"whenever policy or regulatory decisions are under consideration, the impact on innovation should also be fully assessed and addressed."

Innovation is defined as "the process of translating discoveries and ideas into technologies, processes, products, and services and bringing these to market so that society can benefit from them."[94] (Supposed) Necessity of IP, ERF explained: "Innovation has been and remains a high priority for the EU, however, tends to be more on funding than on the regulatory environment. Nevertheless, over the past two decades, the EU institutions have put in place important and far-reaching risk assessment and risk management functions. The innovation Principle proposes to continue this development by establishing a new and positive policymaking framework in support of innovation. By promoting the innovation principle, the European Risk Forum and the CEOs who signed the letter to President Jean-Claude Juncker seek to ensure that policy-makers are able to protect innovation as well as continuing to protect health and the environment. Policies which simply attempt to identify and avoid technological risk may appear to protect health and the environment but could in the longer-term cause much greater harm by sending messages to innovators that they had better invest in other parts of the world."[95] "The innovation principle is not intended to undermine or reduce the importance of the precautionary principle. In fact, the two principles are complementary. The innovation principle should be used alongside the precautionary principle, taking into account the need to protect society and the environment and also to protect Europe's ability to attract and benefit from technological innovation. The innovation principle aims to stimulate investment in innovation by increasing the confidence of innovators in the regulatory system."[96] However, some academics warn that "an unqualified innovation principle focusing exclusively on jobs and growth, and with the force of law behind it, would certainly be one way out of the existing impasse and a potential tool capable of freezing the precautionary principle. Thus, it is fair to suggest that the innovation principle as

[94] Innovation Principle Q&A. Available at http://www.riskforum.eu/innovation-principle.html, last accessed on 9 September 2019.

[95] ibid.

[96] ibid.

proposed by the ERF could pose a serious threat to the precautionary principle and act as a "joker in the pack", thwarting long-established and settled EU environmental principles."[97]

In the EU, there are calls against the "*status quo*" when it comes to the precautionary principle. I applaud all initiatives aimed at changing the rules that are obviously not working, especially when it comes to the regulation of biotechnology. However, I do not think that all initiatives that are currently being praised will fix the problems that the EU has with the application of the precautionary principle in biotechnology. The precautionary principle demands from the decision-makers to conduct a cost-benefit analysis before they introduce measures based on the principle. The innovation principle in its proposed form is nothing more than the cost-benefit analysis. I am not convinced that problems of EU's improper use of the precautionary principle can be fixed by adopting the "opposing" principle. The end of such a battle of principles would be the application of the proportionality test. I am not sure that the proportionality test would be very kind to the innovation principle when, on the other side, human health and environmental protection is in question. As mentioned before the real problem with the application of the precautionary principle lays in improper use and lack of regular review process. Initiatives, such as the innovation principle, that come from the biotechnology sector might be counter-productive if taken at face value.

[97] Garnett, K.; Van Calster, G.; Reins, L.; Towards an Innovation Principle: an Industry Trump or Shortening the Odds on Environmental Protection?; Law, Innovation and Technology (2018); p. 12.

# CONCLUSION

The idea for the thesis came from the question: how GMO rules based on the precautionary principle compare to a need for innovation? I have to admit that when I first heard of the precautionary principle, I was skeptical about it. My first thoughts were that it is a principle that could have negative effects on progress and innovation in the time that we need them more than ever. I thought that the innovation principle as a counterbalance to precaution is necessary. But after studying the precautionary principle in more detail, I changed my initial position. Innovations are presented as something magical that enables progress without any consequences. The new breeding techniques sound great when presented with all the possibilities that they offer. What is not noticeable at first are the potential effects the NBT could have on human health and the environment. The excitement I see in the EU about the innovation principle and new technologies is the same I experienced when introduced to the NBT techniques and the innovation principle. However, after elaborate research, I concluded that caution is necessary when something sounds too good to be true. If we take a stand that the innovation is "*ab initio*" good, as suggested by the innovation principle, we might do more harm than good. When the consequences of innovation have a real potential to be harmful, the precautionary principle balances our inclination for innovations with the need for safety. Now, that we are facing consequences of climate change, we need the precautionary principle more than ever. The biggest misconception I had was that caution and innovation do not go together. Innovation and precaution can go together if the precautionary principle is applied correctly, which is not always the case.

The hypothesis was that the precautionary principle in the area of biotechnology is not applied adequately. If it were applied in accordance with the guidelines of its application, it would have positive effects not only to the environment and human health, which is the main objective, but also on innovation, economy, and employment. My aim was to defend the precautionary principle from the negative image it has acquired within the biotechnology industry because of its improper application in the EU. The negative image of the principle is a consequence of misuse of the principle by the EU institutions, and not the principle itself.

My research shows that the main problem with the measures based on the precautionary principle is the review process. The GMO rules imposed for the first time in the 1990s have not been updated in accordance with new scientific findings on GMOs. Measures based on the precautionary principle should be temporary. Measures based on the precautionary principle are imposed because there is scientific uncertainty about the risks the product/process causes, the principle demands further research in order to resolve that uncertainty. In the EU legislation, new findings on the safety of GMOs have been ignored, and there was no review of the measures based on the precautionary principle. In the 1990s, the GMO Directive acknowledged that some techniques of genetic modification did not lead to unsafe products and exempted those techniques from the scope of the Directive. The ECJ in judgment C-528/16 confirmed that techniques which have conventionally been used in a number of applications and have a long safety record are excluded from the scope of the GMO Directive. The problem is that the EU still insists on pre-approval procedure for techniques of genetic modification that have a long safety record and are conventionally used in the rest of the world. Such restrictiveness caused almost no cultivation of GMO in the territory of the EU. The review of the GMO rules in the EU would enable production and further investments in techniques that have been proven safe while the techniques that raised concerns about its effects on human health and the environment would be further researched. Regarding the precautionary principle it can be said that when one door closes the other one opens. Germany proved that the precautionary principle could have a positive impact on the economy if the industry and the government cooperate in finding an alternative for the products/processes whose use has been limited by measures based on the precautionary principle. Finding a substitute for the product or the process that is potentially unsafe has a positive effect on the economy because it demands the creation of new jobs and innovation. In the end, restrictive GMO rules in the EU led to the development of NBT in the EU.

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