

# A COMPARATIVE STUDY OF THE PRECAUTIONARY PRINCIPLE IN FOOD SAFETY LAWS AND REGULATIONS IN THE UNITED STATES OF AMERICA AND THE EUROPEAN UNION\*

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## Abstract

The precautionary principle emerged as a tool in food safety risk regulation to help risk manager in making decisions regarding scientific uncertainty. However, the vagueness of the principle has resulted in a variety of different applications of the principle in different jurisdictions.

This article examines the application of the precautionary principle in international trade law, the European Union and the United States laws and regulations in the area of food safety by a comparative study. The approaches toward the precautionary principle in the field of food safety are found to be different in the European Union and the United States both in the laws and legislations, and the implementation of the competent authorities. From the comparative study, the article demonstrates that there are several factors influential to the different approaches as the law and safety are the concept reflecting each society. The main factors influencing different applications are the differences in public perception, legislative tradition and institutional structures. It is suggested that the US-EU divergent

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approaches on the application of the precautionary principle in food safety regulation can be viewed as a lesson for a national application of the precautionary principle in food safety that would have to take these factors into consideration of balancing different values of the society.

**Keywords:** Precautionary Principle, Food Safety, Food Safety Regulations, Food, Precaution

## 1. Introduction

Precaution or the notion to carefully do something in advance in order to prevent something unpleasant from happening is a common pattern of behavior expressed through old folk wisdom like “Better be safe than sorry”, which reflects an ordinary human nature seeking for a security. However, as the notion has been developed into a principle or the so-called precautionary principle (PP) as a tool to manage new and rapid emerging risks, it has generated conflicting opinions on the application of the principle.

There are a variety of areas that the PP is applied as a tool in risk management decision-making, including the food safety decision making. Food safety control system is complex and multidimensional, a decision on food safety would require a number of factors into consideration in balancing different values of each society.

In the international arena, the concept of PP is recognised in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), but the interpretation concerning the use of PP in the World Trade Organization arena is not conclusive so there remains divergent approaches in different jurisdictions, especially between the EU and the US. The Divergence between the EU and the US gains attention internationally as their implementations of the PP are influential to other jurisdictions as well. Countries primarily export to the US are adopting the US position, while countries that rely on the EU market are supporting the EU position.<sup>1</sup>

Hence, this article attempts to examine the precautionary principle as applied in the EU and the US food safety system in order to identify the differences and factors relevant to such differences.

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<sup>1</sup> Joakim Zander, *The Application of the Precautionary Principle in Practice: Comparative Dimensions* (Cambridge University Press 2010) 33

## 2. What is the Precautionary Principle

The concept of precautionary principle is often said to be rooted from the German concept of *Vorsorge* or *Vorsorgeprinzip* that was initially defined as a new standard of environmental protection<sup>2</sup> and later spread to several other specific area of protection, especially the health protection.

### 2.1 Definition of the Precautionary Principle

There is no generally accepted definition of the precautionary principle.<sup>3</sup> Trouwborst described the PP in general international law to be reflected by the term *in dubio pro natura* or ‘erring on the side of environmental protection’.<sup>4</sup> However, there are definitions that are frequently cited such as the definition provided by the Bergen Ministerial Declaration on Sustainable Development 1990,<sup>5</sup> and the definition provided by the Rio Declaration on Environment and Development at the 1992.<sup>6</sup>

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<sup>2</sup> Julien Cazala, ‘Food Safety and the Precautionary Principle: The Legitimate Moderation of Community Courts’ (2004) 10(5) European Law Journal, 539

<sup>3</sup> Jonathan B. Wiener and Michael D. Rogers, ‘Comparing Precaution in the United States and Europe’ (2002) 5(4) Journal of Risk Research, 317-349

<sup>4</sup> Arie Trouwborst, ‘The Precautionary Principle in General International Law: Combating the Babylonian Confusion’ (2007) 16(2) Review of European, Comparative & International Environmental Law, 188

<sup>5</sup> The Bergen Ministerial Declaration on Sustainable development (1990), art 7 provides:

*“In order to achieve sustainable development, policies must be based on the precautionary principle. Environmental measures must anticipate, prevent and attack the causes of environmental degradation. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.”*

<sup>6</sup> The Rio Declaration on Environment and Development (The 1992 United Nations Conference on Environment and Development) Principle 15 provides:

*“In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”*

These definitions are different in details that could imply the degree of precaution and discretion given to the decision makers.

## 2.2 Nature of the Precautionary Principle

The central idea of the PP evolved from the conception that it will be too late to wait for scientific certainty in order to create effective responses to potential adverse effects.<sup>7</sup> An application of the PP would allow the competent authority to adopt a preventive measure, despite uncertainties of the risk, which is a step beyond the preventative principle that aims to prevent the adverse effect of a ‘known risk’. Hence, the principle is also deemed as an acceptance to take a higher cost at the present in order to guard against possible adverse effect in the future the same way as an investment or an insurance.<sup>8</sup> An apparent example of an application of the PP can be shown in the decisions concerning the use of genetically modified product that there are still scientific uncertainties about its long term effects on human health and the dosages linking to that effect. However, risk managers in various jurisdictions have made decisions to prevent the harm on the use of genetically modified product based on the scientific uncertainties, which is an application of the PP.

Generally, the core elements triggering the application of the PP can be extracted into three general elements, including probabilities of the harm which is the scientific uncertainties as to the consequences of an action; threat of harm which is the adverse effect caused by that action; and

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<sup>7</sup> Markus W. Gehring and Marie Claire Cordonier Segger, ‘Precaution in World Trade Law: The Precautionary Principle and its Implications for the World Trade Organization’ Research Paper <<http://www.cisdl.org/wp-content/uploads/2018/05/Precaution-in-World-Trade-Law-2003.pdf>> accessed 4 January 2019

<sup>8</sup> Andrew Jordan and Timothy O’Riordan, ‘The Precautionary Principle: A Legal and Policy History’ in Marco Martuzzi and Joel A. Tickner (eds), *The Precautionary Principle: Protecting Public Health, the Environment and the Future of Our Children* (WHO 2004) 32 <[http://www.euro.who.int/\\_data/assets/pdf\\_file/0003/91173/E83079.pdf](http://www.euro.who.int/_data/assets/pdf_file/0003/91173/E83079.pdf)> accessed 26 November 2019

action before strong proof of harm that give the regulator to take action in order to avoid the potential adverse effects even the scientific evidence of harm is still uncertain.<sup>9</sup> In several regulations concerning the application of the PP, these core elements are also complemented with several other detailed rules, guidelines and principles, for example, the proportionality principle, the non-discriminatory rules, and the provisional rules that the outcome of the application may vary greatly.<sup>10</sup>

### 3. The Precautionary Principle as Applied in Food Safety System

The concept of food safety has been developed since the ancient time,<sup>11</sup> and it is still evolving along with the development of food industry. Advanced technological innovation and globalisation introduce new food related risks to the society that are complex with the ability to travel broader and faster.<sup>12</sup> Therefore, the issue of food safety regulation in the current system of food trade is multidimensional, extranational and interdisciplinary social sector.<sup>13</sup>

There are several concepts used in controlling risk from food. The concept of risk analysis is generally recognized as one of the fundamental approaches behind the development of food safety control.<sup>14</sup> It helps providing regulators with the essential information for effective decision-making by three elements or three processes, namely, risk assessment, risk management and risk communication, which are three

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<sup>9</sup> UNESCO and Comest, *The Precautionary Principle* (UNESCO 2005)

<sup>10</sup> Markus Wagner, ‘Taking Interdependence Seriously: The Need for a Reassessment of the Precautionary Principle in International Trade Law’ (2012) 20 Cardozo Journal of International and Comparative Law, 718

<sup>11</sup> Dario Bevilacqua, *Introduction to Global Food-safety Law and Regulation* (Europa Law Publishing 2015) 15

<sup>12</sup> ibid 12

<sup>13</sup> ibid 7-8

<sup>14</sup> Theofanis Christoforou, ‘The Precautionary Principle and Democratizing Expertise: A European Legal Perspective’ (2003) 30(3) Science and Public Policy 205-212

separate but integrated processes. In a risk analysis, the PP is deemed to be applicable in risk assessment and risk management.<sup>15</sup>

The complexity of the PP has increasingly heightened with challenging issues as a result of globalisation and technological innovations under several competing priorities and economic pressure. The application of the PP in food safety regulation, thus, has to comply with the nature of the food safety regulation.

### 3.1 The Precautionary Principle and The International Food Safety Regulations

The rise of the international food trade and the creation of global food chain call for the need to manage food safety on the international level. International food safety regulations imply both the need to protect human health and to promote trade liberalization which is functioned through two main bodies, which are the WTO and the Codex Alimentarius Commission (CAC).

The WTO's mechanism on food safety is the SPS Agreement, which establishes a framework of rules and disciplines to specifically direct the use of sanitary and phytosanitary (SPS) measures of the Member States to prevent disguised trade barriers in the form of sanitary measures.<sup>16</sup> By this, the SPS Agreement also encourages Members to base their national standards with international standard provided by the 'relevant international organizations' such as the CAC,<sup>17</sup> which publishes standards and Code of Practices based on scientific concepts.<sup>18</sup>

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<sup>15</sup> Akawat Laowonsiri, 'Application of the Precautionary Principle in the SPS Agreement', (2010) 14 Max Planck Yearbook of United Nations Law 576

<sup>16</sup> Jaruprapa Rakpong, *WTO Laws: Interpretation and Analysis* (1<sup>st</sup> edn, Thammasat University 2017) (ຈາຽປະກາ ຮັກພົງໝົງ, ກວ່າມາຍແຫ່ງອົງກົດກຳໂລກ: ກາຣີຄວາມແລກກາຣວິເຄາະທີ່ບໍບັນຍຸດືສຳຄັນ ໂຄຣງກາຣຕໍາຮາແລກເອກສາຣປະກອບກາຮສອນ ດັນນິຕິສາສຕ່ຽມທະວິທາລີຍຮຽມຄາສຕ່ຽມ ພິມເພື່ອຮັງທີ່ 1 2017))

<sup>17</sup> The SPS Agreement, art 5.1 provides:

Rapid growth of new technologies highlights the significance of the PP in managing food-related risks. The CAC recognised precaution as “an inherent element of risk analysis”<sup>19</sup>, but do not explicitly codify the PP in its text, while the SPS Agreement embedded the concept of action before scientific sufficiency in Article 5.7,<sup>20</sup> which reflects the idea of PP. Under Article 5.7, the requirements for an adoption of a precautionary measure can be classified into two pre-conditions and two obligations. Pre-conditions

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*“Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal, or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.”*

<sup>18</sup> Decision of the 21<sup>st</sup> Session of the Commission in 1995 provides that “the food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.”

<sup>19</sup> Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius provides that:

“Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health.”

Working Principles for Risk Analysis for Food Safety for Application by Governments (1<sup>st</sup> edn) provides that:

“Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health.”

<sup>20</sup> The SPS Agreement, art 5.7 provides:

“In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.”

are insufficiency of scientific evidence and available pertinent information basis, while the two obligations are the obligation to seek for more information and the obligation to review the adopted measure within a reasonable period of time. These conditions are set to ensure the necessity of the adoption of the PP-based measure.<sup>21</sup>

Since the concept of PP as reflected under Article 5.7 of the SPS Agreement is quite vague, it is up to the interpretation of the adjudicator to decide whether an adopted measure is in accordance with the obligations under SPS Agreement or not. For example, the interpretation of the term “relevant scientific evidence is insufficient” that the degree of relevancy and insufficiency may vary in different cases.

### 3.2 The Precautionary Principle and The European Union Food Safety Laws and Regulations

The EU food safety control system is highly impacted from previous experience of food scares in the Community, especially the bovine spongiform encephalopathy (BSE) crisis. A reform on both the legislation and institutional structure across Europe took place as a consequence to ensure a satisfactory level of health protection in the community.<sup>22</sup>

The reform explicitly introduced the application of the PP in EU law, both in the Treaty and the General Food Law. Article 7 of the Regulation 178/2002 or the General Food Law (GFL)<sup>23</sup> places the PP as a part of the risk

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<sup>21</sup> Fu Jiangyuan and Joanne Blennerhassett, ‘Is Article 5.7 of the SPS Agreement an Application of The Precautionary Principle?’ (2015) 10(2) *Frontiers of Law in China*, 276-82

<sup>22</sup> Anna Szajkowska, ‘Regulating Food Law: Risk Analysis and The Precautionary Principle as General Principles of EU Food Law’ (Doctoral thesis, Wageningen University 2012) 53

<sup>23</sup> The Regulation 178/2002, art 7 provides:

*“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*

analysis methodology, specifically as a risk management tool to guide decision making process of the risk managers under situations of scientific uncertainty on the PP basis. In the implementation of the PP, the principle is recognised and supported under the new institutional structure, which separates the risk assessment body from the risk management body. In practice, it is reported that many provisional risk management measures were taken on the grounds of the PP,<sup>24</sup> however, the degree of precaution is varied in each case. For example, the principle is applied to genetically modified products in a very strong degree of precaution comparing to other products making the EU system concerning GM products one of the strictest in the world.<sup>25</sup>

The EU Courts also play an important role regarding the interpretation of the PP in the EU food safety. Generally, the EU courts have affirmed the application of the PP as the general principle of EC law. However, the EU Treaty does not provide clear indication regarding the standard of review, so the EU courts have also implemented distinct level of intensity in their judicial review.<sup>26</sup> In the *Pfizer* decision, the Court held

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*high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.*

*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 scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.”*

<sup>24</sup> Maria Christodoulou, ‘Study on the Evaluation of Regulation (EC) No 178/2002 (“the General Food Law Regulation”)’ (Final Report 2015) European Commission 109 <[https://ec.europa.eu/food/sites/food/files/gfl\\_fitc\\_external\\_study\\_gen\\_part\\_gfl.pdf](https://ec.europa.eu/food/sites/food/files/gfl_fitc_external_study_gen_part_gfl.pdf)> accessed 26 November 2019

<sup>25</sup> *ibid*

<sup>26</sup> The European Risk Forum, ‘The Precautionary Principle Application and Way Forward’ (2011) The ERF Study, 41

that in balancing between the economic losses resulting from the adopted measure and the objective of the Community in protecting public health, the Court has to allow the competent authority to take such a decision on risk management and uphold the measure.<sup>27</sup>

Therefore, it can be seen that the PP is highly supported in the EU through all the legislation in the Treaty and the GFL, the implementation of the principle by the risk assessment and risk management bodies and the judicial review of the implementation processes by the Court.

### 3.3 The Precautionary Principle and The United States Food Safety Law and Regulation

The initial rules concerning food matters in the US were in place primarily for the purpose of governing interstate commerce at the time of great expansion after the Civil war.<sup>28</sup> The issue of adulteration is later recognised, which led to the establishment of the Chemical Division of the United States Department of Agriculture to address specifically on the issue.<sup>29</sup> The space era technologies also have a part in designing food safety system in the US, as foods for astronaut's consumption have to be safe. However, the scientists and microbiologists at that time found problems concerning the assurance of food safety. Consequently, the monitoring of critical control points and strict record keeping procedures was introduced, which has later become the underlying concept of the HACCP in the US

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[http://www.riskforum.eu/uploads/2/5/7/1/25710097/erf\\_pp\\_way\\_forward\\_booklet.pdf](http://www.riskforum.eu/uploads/2/5/7/1/25710097/erf_pp_way_forward_booklet.pdf)  
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<sup>27</sup> *Pfizer Animal Health v. Council of the European Union* (2002) Case T-13/99, ECR II-3305

<sup>28</sup> Kevin J. Fandl, *Law and Public Policy* (Routledge 2019) 258

<sup>29</sup> Committee to Ensure Safe Food from Production to Consumption, *Ensuring Safe Food from Production to Consumption* (National Research Council, National Academy 1998)

food industry.<sup>30</sup> The US food safety system is also responsive to various scandals in the society, such as the food additives scandals that lead to three legislative amendments that aim to improve the ability to assure the safety of novel materials added to foods or used in the production of foods, including, the Pesticide Control Amendment of 1954, the Food Additives Amendment of 1958, and the Color Additives Amendments of 1960, and the series of E.coli outbreaks that lead to the enactment of the Food Safety Modernization Act (FSMA).

The exact term of PP is not explicitly mentioned in any of the US food safety laws and regulations. It is actually the element of the PP that is embedded in the detailed laws and regulations of the US in the form of precautionary approach in its risk management.<sup>31</sup> The concept of foresight, prevention and authority to take action to prevent the probability of harm before it is proved have incorporated in the US food safety system and expressed through measures such as the establishment of the pre-market approval system.<sup>32</sup>

The US food safety control system employs the multiple agency system that the main authorities are the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA). Responsibilities of the two agencies are separated on the basis of commodity lines. These independent agencies have the role in all the risk analysis processes, including the risk assessment, risk management and risk communication, as

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<sup>30</sup> Jennifer Ross-Nazzal, ‘“From Farm to Fork”: How Space Food Standards Impacted the Food Industry and Changed Food Safety Standards’ (Societal Impact of Spaceflight) 220-236 <<https://www.history.nasa.gov/sp4801-chapter12.pdf>> accessed 26 November 2019

<sup>31</sup> European Environment Agency, ‘Late Lessons from Early Warnings: The Precautionary Principle 1896-2000’ (2001) 22/2001 Environmental Issue Report, 12

<sup>32</sup> Terra Bowling, ‘Facing Uncertainty: Local Government and the Precautionary Principle’ (National Sea Grant Law Center) <[http://www.precaution.org/lib/local\\_govts\\_and\\_pp.081224.pdf](http://www.precaution.org/lib/local_govts_and_pp.081224.pdf)> accessed 26 November 2019

they are deemed as the expert in that specific matters. The US food safety system also includes high participation by the private establishment to create their own safety plan under inspection of the agencies.

The Courts are mostly limited themselves to the procedural dimension of the food safety regulations as they are deferential to the agencies' expertise in the substantive decision.<sup>33</sup>

In sum, there are various factors shaping the food safety system in the US. Though the US positions itself as opposing to the application of PP in the international arena, and terms related to PP or precaution are absent in the texts, the precautionary approach and attitude are reflected through its food safety control system, such as the enactment of FSMA that grants broad power to expertise agencies to oversee the food safety matters demonstrates the precautionary approach in the US food safety system.

#### 4. Conclusion

The PP is a principle that is becoming increasingly important in the current global food safety system in order to protect public health as there are several new emerging risks that its safety cannot be concluded scientifically. Food safety system in each jurisdiction is shaped by a variety of factors in that society. The difference in the food safety laws and regulations concerning the PP is apparent in the US and the EU. As the PP is explicitly included in the laws and regulations at the Community level in the EU, including Article 191 of the Treaty on the Functioning of the European Union and the specific Regulations concerning food safety in Article 7 of the Regulation 178/2002. While the term PP is not explicitly referred to in any of the US federal food safety regulation. Another difference is found in the implementation of the PP. Apart from the explicit inclusion of the term PP in the laws and regulations, the application of the PP in the EU is also highly supported by the EU institutions, including the European Commission that have published the Communication of the

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<sup>33</sup> Neal D. Fortin, *Food Regulation: Law, Science, Policy, and Practice* (Wiley 2017) 10

European Commission on the application of PP, which is like a guideline on the application of the PP. The Communication is also influential to decisions of the EU judicial bodies in considering cases. There are several cases that the Courts granted wide discretionary power to the competent authority in adopting a precautionary measure. On the other hand, as the PP is not explicitly stipulated in the US laws and regulations, but several duties are imposed on the competent authorities in protecting public health. However, the relevant authorities take a different approach. For example, the FDA determined that GM foods are not substantially different from those of non-GM foods, so they regulate the GM and the non-GM food on the same basis. The FDA sees the GM as harmless because there is no scientific proof that GM products are harmful. The US federal Courts are also quite restricted themselves to consider only on the procedural deficiency matter of the agency so the role in supporting the implementation of the PP is not evident.

It can be seen that the divergent application is a result of all the different historical background, legislative tradition, institutional structures in the EU and the US regime. Furthermore, even in the same regime the applications of the PP are varied among specific food products and specific dimensions. Hence, the concept of PP is linked with the concept of safety in a society that reflects various values of the society so each jurisdiction may apply the PP differently.

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