Towards stronger precaution?

The opportunities for application of the Precautionary Principle in the NVWA's surveillance practice

MSc Thesis

Marijn Albus

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M. Albus
920831010060
Marijn.Albus@wur.nl

MSc Programme Food Safety
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Law and Governance Group
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Supervisors
Dr. H. Schebesta
Law and Governance Group
Wageningen University and Research

Ir. H.M. Laporte
Directie Strategie
NVWA

Mr. Ir. A.M. Vroegop
Directie Strategie
NVWA

Examiner
N. Bernaz PhD
Law and Governance Group
Wageningen University and Research

Preface

"If I have seen further it is by standing on the shoulders of Giants."[1]

Dear reader,

Imagine a young boy heading for school. Just before leaving, his mother warns him: “it might start raining today, perhaps you would like to pack an umbrella?”. An easily imaginable situation, which raises questions similar to the application of the precautionary principle: how do I manage risks when confronted with scientific uncertainty? There is uncertainty on whether it might rain or not (exposure uncertainty). There is also uncertainty on the dose-response relationship: suppose I get wet, how much would it trouble me?. To deal with this uncertainty, a possible measure is to bring an umbrella. However, what if this umbrella is huge, heavy and pink, and the boy would likely be embarrassed and burdened to be seen with it? Or, even heavier: what if the umbrella is not available, but can be rented for a certain amount of money? For a tiny amount, the boy might be willing to pay for the use of the umbrella, but it is not likely he will be willing to pay a substantial amount. Another relationship between this example and the precautionary principle is the notion that the measure will have to be revised within a reasonable amount of time. So, to discuss the precautionary principle in relation to food safety: what colour can the umbrella be? How heavy can it be? What willingness to pay can be concluded for the use of this umbrella? When will the measure be revised?

Before you lies a draft Thesis report, which is the conclusive milestone of my MSc study Food Safety Law. The report has been constructed in tight cooperation with the Netherlands Food and Consumer Products Safety Authority (NVWA). For the past eight months, I enjoyed the supervision by the departments of Policy Planning and Instrument Development (BPI) and Legal Affairs (JZ). My colleagues and supervisors at the NVWA have formed an indispensable source of information and inspiration. A word of gratitude towards these colleagues and all others who have enabled me to complete this project is therefore an excellent starting point for this report.

Firstly I would like to thank my Wageningen UR supervisor, Hanna Schebesta for her critical and constructive attitude towards the proposal and numerous draft versions we have discussed. Gonda Laporte, thank you for your time and effort dedicated to making me feel at home in the team and in the organisation. Thank you as well for your feedback, which has helped me to structure both the process and contents of my research. The same applies to Arjen Vroegop, whose legal knowledge provided highly necessary input to the report. Finally I would like to thank Dick Sijm for helping me select useful methodology.

Other people who deserve to be mentioned here are my colleagues from BPI, both for their company as well as their advice. My parents, who provided great support throughout the process and finally my girlfriend Janine. Thank you for your patience, understanding and continuous motivation.

As concluded in Utrecht, July 19th 2018.

[1] Newton, I. (1675) "Letter from Sir Isaac Newton to Robert Hooke"

Abstract

The Precautionary Principle is an important tool for risk management under scientific uncertainty. In the field of food safety, the principle is codified in article 7 of the GFL. The principle appears at various other levels (conventions, EU, WTO, national legislation) that relate to food safety as well and is both criticized and appraised. To allow for a more effective protection of the interest of public health, it is desirable to research when recourse to the Precautionary Principle can be made and which criteria pertain to measures based on this principle.

The approach followed is a literature study on risk regulation, a doctrinal analysis of the relevant legislation and an analysis of existing case law on the Precautionary Principle. This analysis uses the Communication from the Commission on the Precautionary Principle as a yardstick to interpret the factors that triggered recourse to the principle, the measures identified and whether the communication's guidelines were followed.

The research shows that the Precautionary Principle can be applied directly as well as indirectly. The indirect application is demonstrated by the finding that the Principle is frequently used as a framework to test the legitimacy of new or existing EU legislation upon. The case law found indicates that there has been limited application of the Precautionary Principle for food safety ever since its codification in the GFL. The case law on direct application also gives interesting limitations towards the obligations posed on risk managers and towards the degree to which third parties can derive rights.

In the discussion, it is demonstrated that article 7 GFL reduces the paralysing effect of the Precautionary Principle by attributing priority to the interest of public health over other interests.

The research provides the NVWA with a framework for consideration which should be followed when confronted with scientific uncertainty. This framework aims to identify the nature of uncertainty involved, which measures could be considered and finally which obligations should be followed.

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1 Introduction

Regulation 178/20002 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 (usually referred to as General Food Law (GFL) forms the basis for EU food safety policy and legislation[2]. In the Netherlands, the Netherlands Food and Consumer Products Safety Authority (Nederlandse Voedsel- en Warenautoriteit – NVWA) is the designated authority to enforce the GFL.

The NVWA's task[3] is surveillance on and enforcement of legal compliance in domains of legislation that are coordinated by the ministries of Agriculture, Nature and Food Quality[4] and Public Health[5]. In the field of food safety, it addresses any legal or natural person who is involved in the production, sale or supply of a food product to a consumer. The risk analysis framework on food safety has been formally introduced in EU law in the General Food Law and its preamble and the White Paper on Food Safety[6]. The GFL has also codified the Precautionary Principle, which is a principle to take risk management measures in situations where there is uncertainty on the exact scope, likeliness or dimension of risk. Apart from the GFL, the Precautionary Principle is expressed in many different formulations at different aggregation levels[7], such as EU, WTO or national legislation or in conventions and treaties.

1.1 Background

This thesis report touches upon the question on how risk managers could apply the Precautionary Principle as an instrument to take measures under circumstances of scientific uncertainty in decision making processes. In the response to various food safety incidents and crises occurring towards the finalisation of the 20th century, risk analysis and sound scientific principles have become an indispensable constituent of food law.

1.2 Problem definition

The Precautionary Principle appears in various forms and at various levels such as the WTO, EU, national legislation and UN-treaties. The GFL codifies the Precautionary Principle in relation to food safety, for the purpose of human health. The risk analysis framework however does not exactly define who can or should act as a risk manager in the Netherlands, based on this regulation. For the NVWA itself, it is not clear how the Precautionary Principle applies in the different domains in which this authority is active. Food safety is not the only public interest that it safeguards. Previous applications of the Precautionary Principle in the field of food safety have enabled the NVWA to take action under scientific uncertainty. To make this application more explicit, it is desirable for the NVWA to know how the Precautionary Principle can be applied and how this principle has been developed in case law.

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[2] Vos, E. (2000). EU Food Safety Regulation in the Aftermath of the BSE Crisis. *Journal of Consumer Policy*, 23, 227–255.

[3] As described in the NVWA's Organisational Reform Plan for 2020 (Organisatiebesluit NVWA 2020)

[4] Ministerie van Landbouw, Natuur en Voedselkwaliteit (LNV) (Ministry of Agriculture, nature and Food Quality)

[5] Ministerie van Volksgezondheid, Welzijn en Sport (VWS) (Ministry of Public Health, Wellbeing and Sports)

[6] Vignarajah, K. (2009). Reconciling Free Trade and Safe Trade: New Paradigms for Regulating Imports in the Twenty-First Century. *Journal of Wor*, *43*(4), 771–795

[7] Belt, H. Van Den. (2003). Debating the Precautionary Principle: "Guilty until Proven Innocent" or "Innocent until Proven Guilty"? *Editor's Choice Series on Agricultural Ethics*, *132*(July), 1122–1126. http://doi.org/10.1104/pp.103.023531.1122

1.3 Research questions and report outline

This thesis report aims to answer the following research question:
How can the Precautionary Principle, in the way it currently applies in the Netherlands, contribute to the broadening of the NVWA's activities in the field of Food Safety?

This main question is to be answered through several sub-questions.

Setting the context

- What is the task of the Netherlands Food and Consumer Products Safety Authority (NVWA) and in which fields is it active?
- Which instruments does the NVWA employ to perform its task?

Through this chapter, the reader is provided with an overview of what the NVWA does, how it is organised and how the regular[8] practice of enforcement and surveillance works.

Defining precaution from a legal perspective

- Who is addressed in the passive formulation of the Precautionary Principle in art.7 GFL?
- What is the legal basis for application of the Precautionary Principle in the Netherlands?
- Where on the continuum between weakest precaution and strongest precaution should we currently interpret the Precautionary Principle?

This chapter aims to provide insight in what the legal status is of the Precautionary Principle by describing its addressees and its place on the strong-weak continuum[9].

Describing precaution from empiricism

- To what degree is the Communication from the Commission on the Precautionary Principle applied in rulings by European and national courts?

This chapter aims to analyse practical applications of the Precautionary Principle from the perspective of the Communication of the EC[10]. The communication identifies factors, measures and guidelines that pertain to risk management based on the principle. By comparing the expression of these aspects between different cases, it becomes clear which aspects carry practical relevance and which do not.

Exploring precaution as an instrument

- Which options for application of the Precautionary Principle can be identified? Which conditions pertain to these options?
- How do these options for application differ per EU-member state?
- Do these options differ per public interest the NVWA serves?

[8] In this report, a "regular" situation is a situation where scientific certainty about a risk has been established, in contrast with a situation where there is scientific uncertainty.
[9] See chapter 3.2..3 for an exact specification of this continuum
[10] Commission of the European Communities. (2000). Communication from the Commission on the Precautionary Principle, 1–28.

In the concluding remarks, a framework for application is laid down. It shows which steps the NVWA should follow in order to correctly take risk management measures in situations of scientific uncertainty. From these practical insights, the possibilities for application are deducted and discussed in comparison with the popular critiques cast towards the Precautionary Principle.

1.4 Description of sources

1.4.1 Literature

Relevant literature has been obtained from sources Heinonline, Kluwer, WUR University Library database, and any other relevant piece of literature found through references of other publications, congresses, information provided by colleagues or through other ways. Search criteria comprised *"precautionary AND (principle OR approach) AND (EU OR European Union OR member state*) AND (food safety OR risk management OR risk regulation OR risk analysis)".* No specific time-related selection criteria were applied. The query was ran in December 2017 and March 2018.

1.4.2 Primary law

The relevant primary law used has been found in the literature described above. The sources in which a reference to the Precautionary Principle is made are the Treaty on the Functioning of the European Union (TFEU), article 191, and the World Trade Organisation agreement on Sanitary and Phytosanitary measures (SPS agreement), article 5(7).

1.4.3 Secondary law

Relevant secondary law has also been found in the literature described above. The sources in which a reference to the Precautionary Principle is made are regulation 178/2002[11], hereafter referred to as the GFL. The relevant articles of this regulation are preamble (20) and (21), article 6(3) and article 7.

1.4.4 Case law

Case law where either the Precautionary Principle has been used as the basis for risk management activities, or where the court has discussed the interpretation of the Precautionary Principle in relation to other regulations, has been selected using a query in Eur-Lex and rechtspraak.nl. The outcomes of these queries have been discussed with legal experts of the NVWA in order to determine their relevance and to interpret the NVWA's decision-making process in these cases.

1.5 Methodology

The found literature is assessed as a literature review in the Theoretical Framework. Relevant primary and secondary law is analysed doctrinally and the case law is analysed using the Communication from the Commission on the Precautionary Principle as a framework

1.5.1 The doctrinal method

The legal framework will be described through a doctrinal analysis of the relevant primary and secondary law, according to the approach described by Duncan & Hutchinson[12].

[11] REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January2002 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

[12] Hutchinson, T., & Duncan, N. (2012). Defining and describing what we do: Doctrinal legal research. *Deakin Law Review* 17(1) 83-119

1.5.2 Yardstick

The Communication from the Commission on the Precautionary Principle serves as a practical guideline for the implementation of this principle[13,14]. It specifies in further detail which circumstances pertain to the application of the principle and which criteria should be considered when applying. The circumstances and criteria are used to analyse the relevant case law. One of the factors in the communication, namely the concept of 'uncertainty', is analysed in further detail according to the identification of different kinds of uncertainty provided in the dissertation Precautionary Duties in Tort Law[15]. This scholar divides the possible types of uncertainty into uncertainty related to hazard, to the dose-response relationship, to the degree of exposure, to the situations in which exposure can take place, to the effect and to the effectiveness of the proposed measure. Using this characterisation, the uncertainty on which the existing case law is based, will become distinct.

1.6 Definition

For the sake of this report, the Precautionary Principle is defined as follows[16]:

"The Precautionary Principle is a principle that enables the NVWA to take action against food safety related risks when the severity or likeliness of this risk are not fully certain[17]"

Of course, broader definitions of the Precautionary Principle exist as well. This definition is however the functional definition on the domain Food Safety. As definition for a general Precautionary Principle, I propose:

"the Precautionary Principle expresses the thought that measures to accomplish a regulatory goal, could also be taken under scientific uncertainty"

This definition is formulated in order to circumvent the other, specific formulations that will be discussed later in this report. The existing formulations however do comply with the definition above.

[13] Ladeur, K. (2003). The introduction of the Precautionary Principle into EU law: a pyrrhic victory for environmental and public health law ? Decision-making under conditions of complexity inmulti-level political systems. *Common Market Law Review*, 40, 1455–1479.

[14] Szajkowska, A. (2010). THE IMPACT OF THE DEFINITION OF THE PRECAUTIONARY PRINCIPLE IN EU FOOD LAW. *Common Market Law Review*, 47, 173–196.

[15] De Jong, E. R. (2016). *Voorzorgverplichtingen: over aansprakelijkheidsrechtelijke normstelling voor onzekere risico's*. Boom Juridisch. Chapter 13

[16] From the NVWA's factsheet on the Precautionary Principle (2018). Internal classified document.

[17] This is a translation by the author. The definition in Dutch is: "Het voorzorgsbeginsel is een beginsel dat de NVWA in staat stelt op te treden tegen risico's m.b.t. voedselveiligheid waarvan wij niet geheel zeker zijn van de ernst of de kans van voorkomen."

2 Organisation description

This thesis has been conducted at the request of the NVWA. This chapter describes relevant characteristics of this organisation, such as its mission, the domains on which it is active, the instruments it employs, recent developments and the organisational structure. It shows that the NVWA safeguards six public interests, that is has a vast body of both administrative and penal measures it can rely on

2.1 Mission and domains

The NVWA was formed in 2012 through a merger[18] between the Plant Disease Service (PKD), the General Inspection Service (AID) and the Food and Consumer Products Authority (VWA)[19]. It is the designated authority for a number of regulations that can be attributed to six public interests: Food Safety, Product Safety, Animal Health, Animal Welfare, Plant Health and enforcement of environmental law[20]. For the exact specification of legislation, please see Appendix 1.

The NVWA 2020 organisational plan describes the strategic goals for the following years. Currently, the NVWA's surveillance is divided into 23 fields of surveillance[21]

2.2 Instruments – the intervention policy

In general, measures can be of administrative nature of penal nature. Measures are also divided in punitive sanctions and reparatory sanctions. The NVWA's intervention policy[22], which can be seen as the toolbox that the NVWA's inspectors utilize when performing an inspection, specifies which measures ("interventions") can be used in which situation.

A selection of instruments that the NVWA could employ is listed below. Please refer to Appendix 2 for the complete overview as specified in the NVWA's *intervention policy*

- Inspections
- Compliance support
- Certification
- Blockage
- Storage
- Policy advice

These administrative interventions have a reparatory nature. A reparatory intervention aims to correct the underlying problem[23]. Other interventions that are specified in the intervention policy are sanctions of a punitive nature, which means that the sanctions are not targeted at 'fixing the

[18] The 2012 fusion was not the only organisational change in the history of the NVWA and its predecessors. Since 2004, the authority is considered an agency of the ministry of economic affairs instead of the ministry of health (http://wetten.overheid.nl/BWBR0015155/2003-06-20)
[19] NVWA Annual Plan 2012 (jaarplan NVWA 2012)
[20] Organisatiebesluit NVWA 2020
[21] The 23 domains ("toezichtsdomeinen") are: Meat chain and food safety; Fish chain; Industrial production; Animal by-products; Feed; Special foods; Horeca and artisan production; Microbiology; Product safety; Living animals and animal health; Animal medicines; Animal welfare; Animal testing; Crop protection; Phytosanitary; Manure; Nature; Alcohol and Tobacco; Export; Import; European subsidies; Cross compliance; Land-area based subsidies
[22] https://www.nvwa.nl/over-de-nvwa/hoe-de-nvwa-werkt/toezicht-maatregelen-en-boetes/interventiebeleid
[23] Kelk, C. (2008). *Constante waarden*. Den Haag: Boom Juridische uitgevers.

problem' directly, but at penalizing the offender. Punitive sanctions comprise an administrative fine, or criminal prosecution.

2.3 A special instrument: the reflective function of surveillance

This function is a recent development. It encourages surveillance authorities, such as the NVWA, to critically reflect upon its own tasks in order to identify risks that are possibly not covered by existing regulation[24]. In a more traditional framework, a surveillance authority was especially considered to be the executive agency of a ministry. Compliance with legislation is however not considered a goal *as such,* but rather as a means to achieve a certain goal[25]. Because of the NVWA's expertise with surveillance however, it is worthwhile to consider how surveillance and enforcement could and should contribute to the most effective risk regulation.

The reflective function of surveillance helps the NVWA to identify possible risks from different angles. For example, by the publication of *Integrale Risicoanalyses – Integrated Risk Asessments*, risks are approached from a chain perspective. By considering the entire food chain of for example eggs, poultry or red meat, the risks that are identified have a different and more complex nature than the risks observed as such. This increases the importance and relevance of the NVWA's ability to handle complex risks with uncertainty involved[26].

2.4 The NVWA as legislator

Although the NVWA is an executive authority for the ministries of Agriculture and Health, it has some legislative functions as well. This materialises in the form of *decentralised regulations*[27]*:* a regulation formulated at executive level and established by the Inspector-General of the NVWA. This regulation is formalised by publication in the *Staatscourant*, which is the Dutch regulatory publication body. Article 1.3.4. of the General Administrative Law[28], indicates that this regulation describes the weighing of interests, establishing facts or explaining legal instructions related to the capacity of an administrative body. In this thesis, one of these regulations is discussed in more detail, namely the regulation on treating meat contaminated with *E. coli* organisms, described in paragraph 3.2.2.

[24] Wetenschappelijke Raad voor het Regeringsbeleid. (2013). Toezien op publieke belangen - naar een verruimd perspectief op Rijkstoezicht. Amsterdam University Press, Amsterdam 2013. Chapter 5

[25] Ministeries van Volksgezondheid Welzijn en Sport en Economische Zaken. (2015). Toezichtkader NVWA: Leidende principes voor toezicht en handhaving. Den Haag.

[26] As explained in the NVWA's publication of the Poultry-IRA as found on https://www.nvwa.nl/over-de-nvwa/hoe-de-nvwa-werkt/integrale-ketenanalyses. Consulted June 3rd, 2018.

[27] Beleidsregel in Dutch

[28] The Dutch Algemene Wet Bestuursrecht describes this regulation as follows: "Onder beleidsregel wordt verstaan: een bij besluit vastgestelde algemene regel, niet zijnde een algemeen verbindend voorschrift, omtrent de afweging van belangen, de vaststelling van feiten of de uitleg van wettelijke voorschriften bij het gebruik van een bevoegdheid van een bestuursorgaan"

2.5 Organigram

This thesis research has been conducted within the Strategy Unit, as part of the activities of department BPI (Beleid, Planvorming en Instrumentontwikkeling) or policy, planning and instrument development. The research was also supported by members of the Legal Affairs division, to provide input on enforcement actions by the NVWA and the motives thereto. Below, an excerpt of the NVWA's organigram shows the layout of the Strategy Unit[29]. The two departments most involved with this report are circled.

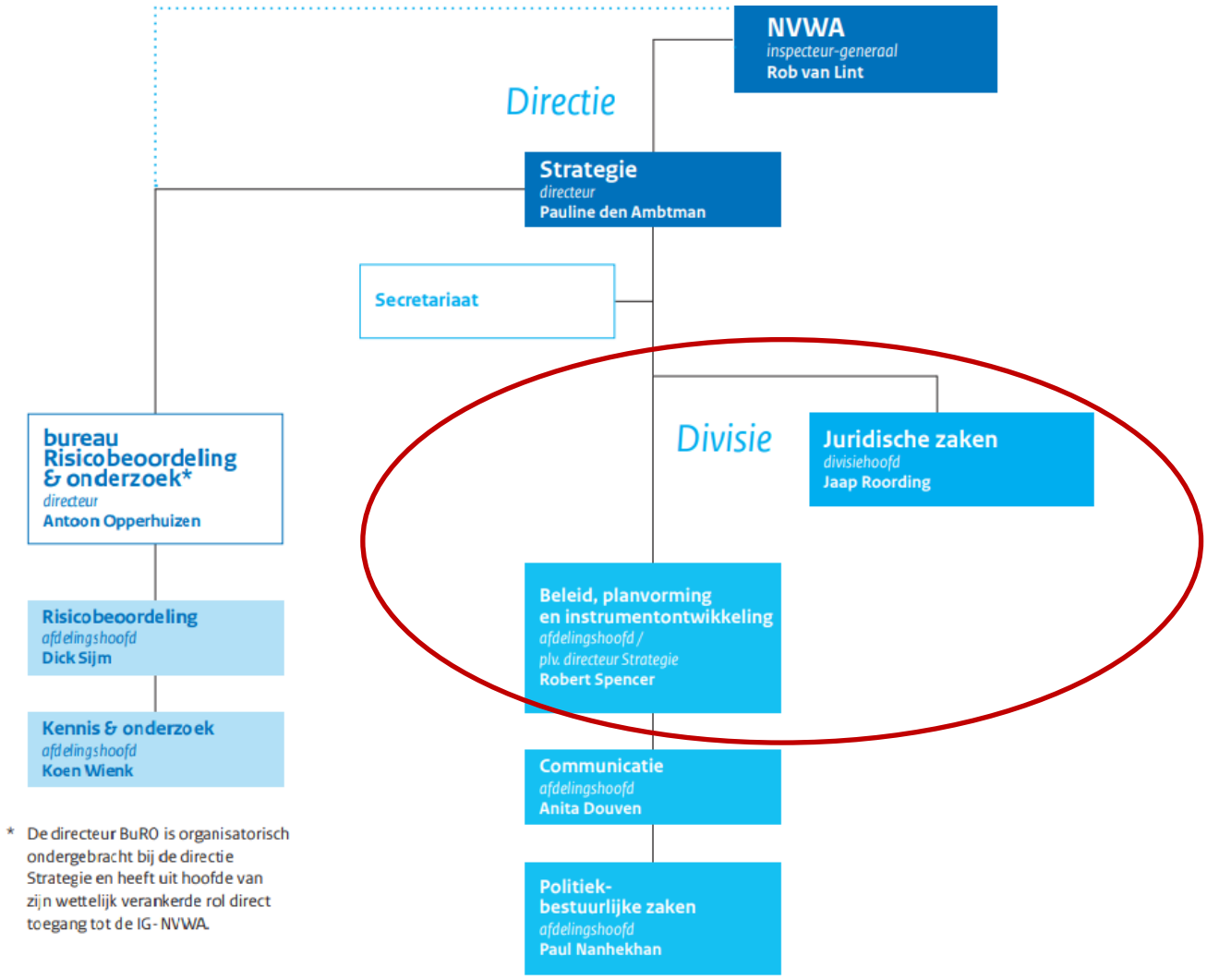

Figure 1: excerpt of the NVWA's organisational structure

[29] The full organigram could not be featured on an A4 page size. Please refer to https://www.nvwa.nl/documenten/nvwa/organisatie/opbouw/publicaties/organogram-nederlandse-voedsel-en-warenautoriteit to view the original file.

3 Theoretical Framework

This chapter describes relevant theoretical insights from literature. It discusses the critiques commonly cast towards the Precautionary Principle and the possible errors that can occur in its application. Finally, it demonstrates that by comparing different formulations of the Precautionary Principle and by finding the factors in which they differ, these formulations can be distributed amongst a continuum between weakest precaution and strongest precaution.

3.1 The Risk Analysis framework

In response to various food safety crises throughout the early nineties, the Commission decided to reform the legislation of food law. Many scholars have described the transition from free trade to science as the basis for food law. This started with the Green Paper on Food Safety in 1998, followed by the White Paper in 2000 and eventually the General Food Law in 2002, in which the shift to science as basis for food law was formalised in the form of Risk Analysis. Risk Analysis is defined in article 3.10 as "risk analysis means a process consisting of three interconnected components: risk assessment, risk management and risk communication". Risk analysis is the process of estimating the risk of a certain hazard. Risk management is clearly separated from risk assessment and is defined as "the process, distinct from risk assessment "(…) 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".

Hence, Risk Management takes the risk assessment into account, but other relevant factors as well. Where Risk Assessment is supposed to be performed by scientific expert, Risk Management is a political process, to be performed by policy makers and politicians. In the Netherlands, the policy for food safety is developed at the Ministries of Agriculture and of Public Health, influenced by the people's representation in the Second Chamber. The execution of the developed policy is the task of the NVWA. In this execution, the NVWA also performs a process of weighing policy alternatives. Risk management therefore takes places at multiple levels

3.2 Theoretical perspectives to the Precautionary Principle

3.2.1 The paralysing effect

A society faces risks. Those who are assigned to mitigate these risks are obliged to consider which measures will provide society with the highest social utility[30]. Zero risk is neither feasible nor desirable, since the marginal investment will eventually outrun the marginal risk reduction[31].

Risks should not be considered as such, but rather in the complex context in which they appear: a risk is seldom a risk by itself, since the mitigation of one risk will often create another risk. The popular example is a risk manager considering a prohibition on Genetically Modified Organisms (GMO's). The Precautionary Principle can be used both to propagate the use of GMO's as well as to

[30] At least, when considering utility as the relevant output of risk regulation, as described in Fishburn, P. C. (1988). *Nonlinear preference and utility theory* (Vol. 5). Baltimore: Johns Hopkins University Press and in Rabin, M. (2013). *Risk aversion and expected-utility theory: A calibration theorem*. Handbook of the fundamentals of financial decision making: Part I (pp. 241-252).

[31] Abels, G., & Kobusch, A. (2010). Regulation of food safety in the EU: Changing patterns of multi-level governance.

prohibit this use[32]. The risk of detrimental effects to the environment is substituted by the risk of a shortage in the world food supply. Another example is that, when taking trade restrictions based on food standards, the risk that the economic interests of a consumer are harmed is substituted by the risk that an unfair restriction to trade is made[33], which again may pose harm to the consumer, business or society as a whole.

3.2.2 The subjective dimension of risks

Another important factor to consider is that risks have a subjective dimension. Risk perception is a crucial factor in the selection of risks to mitigate, and research has identified many factors that influence the discrepancy between actual risk and perceived risk[34] . Some of these factors are: natural vs. synthetic; availability heuristic[35]; catastrophic risk[36]; degree of in which a risk is avoidable and finally cultural, historical and religious factors[37]. In a properly functioning deliberative democracy, a government is the representative of its people and is appointed to execute the will of the people. Hence, risk management is not just a matter of dealing with risk, but also a matter of selecting those risks that society attributes value to. In the selection of risks, factors like social amplification are essential to consider as well.

The factor described before will differ amongst different communities. In general, different societies have different risks to which they attribute relevance[38]. In the field of food safety, the US tends to be less risk-averse than the EU. In practice, this means that US foods are considered to be safe unless the contrary is proven. The burden of proof lies with the antagonist of the (novel) foodstuff. EU foods however, usually are considered to be unsafe until the contrary is proven. This lays the burden of proof at the one pursuing economic benefit[39].

In practice however, EU foods can also be marketed without pre-market authorisation, as long as the criteria for safe food as laid down in articles 14 and 17 GFL are satisfied. This is the status quo; in case of scientific uncertainty however, the burden of proof is switched, resulting in the maxim “unsafe until safety is proven”. To add some nuance to this, there is a time-bound limit to the duration of “until”. A ban on a presumably unsafe food cannot be of permanent nature. So, in application of the Precautionary Principle, there is a mixed burden of proof. The risk manager is obliged to perform a risk assessment in order to provide evidence that the measure is justified, while the FBO is obliged to

[32] Sunstein, C. R. (2005). *Laws of fear: Beyond the Precautionary Principle* (Vol. 6). Cambridge University Press.
[33] Defares, K. J., & van der Meulen, B. M. J. (2009). Het voorzorgsbeginsel. Preadvies voor de Nederlandse Vereniging voor Levensmiddelenrecht. Sdu uitgevers.
[34] Sunstein, C. R. (2005). *Laws of fear: Beyond the Precautionary Principle* (Vol. 6). Cambridge University Press.
[35] Availability heuristic is the notion that people tend to perceive risks of which they can be easily imagined (i.e. “available” in the mind) more negatively than risks that are hard to imagine. As an example of an available risk, consider the risk on bacterial infection through a contaminated foodstuff. A less available risk would be the risk on long-term hepatic damage through chronic high-salt consumption in the diet. Although these risks constitute the same damage to society, public opinion is far more concerned about the first example than about the second.
[36] A catastrophic risk, such as a plane crash, is perceived more negatively than a risk of comparable damage that is less dramatic
[37] Hofstede values are a measure to stratify national perspectives towards these social factors
[38] Post, D. L. (2006). The Precautionary Principle and risk assessment in international food safety: How the World Trade Organization influences standards. *Risk Analysis*, *26*(5), 1259-1273.
[39] Van den Belt, H. (2003). Debating the Precautionary Principle: “guilty until proven innocent” or “innocent until proven guilty”?. Plant Physiology, 132(3), 1122-1126.

provide evidence that the contested food is safe for consumption. Failure to meet this requirement leads to the conclusion that the contested measure was in fact justified.

3.2.3 Errors in the application of the Precautionary Principle

In managing a risk, the existence of two possible errors can be reasoned. A false positive (type 1 error) is the situation where a risk is regulated which is not necessary to regulate. A false negative (type 2 error) is a situation where a risk is not regulated, while regulation would have been beneficial to society. The costs of an error are associated with the negative consequences for society[40,41,42] . This can be visualised in Malcolm Sparrow's model[43] on the overlapping circles. Situations that are regulated are represented by circle A, while undesirable situations are represented by circle B.

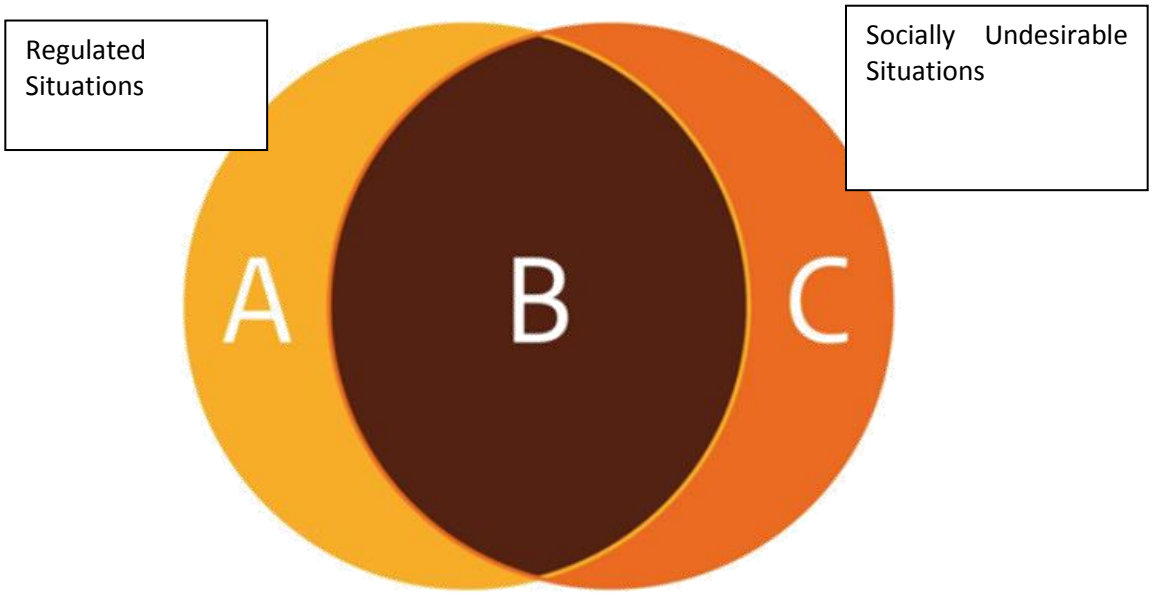

Figure 2: a visualisation of the possible errors in application of the Precautionary Principle

Here, the overlapping area labelled as "B" represents the ideal situation. A socially undesirable situation, such as a risk to public health or the environment, is covered by regulation. Area A represents a false negative: regulation is in place, but it is not covering a relevant risk. Area C represents a false positive: there is a risk, but it is not regulated.

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[40] van Asseldonk, M. A. P. M., Bergevoet, R. H. M., Bondt, N., & van der Meulen, H. A. B. (2014). *Ex-ante raamwerk overheid bij rampen en calamiteiten in de land-en tuinbouw* (No. 2014-023). LEI Wageningen UR

[41] Benedictus, A., Hogeveen, H., & Berends, B. R. (2009). The price of the Precautionary Principle: Cost-effectiveness of BSE intervention strategies in The Netherlands. Preventive veterinary medicine, 89(3-4), 212-222.

[42] Van der Meulen, S., & Van der Meulen, B. (2014). Riskjockeys en formele voedselveiligheid. Waar&Wet, 44(juni), 2–7.

[43] Idea taken from Sparrow, M. K. (2011). *The regulatory craft: controlling risks, solving problems, and managing compliance*. Brookings Institution Press.
Image taken from slide deck of Jan Meijer (directeur Keuren at the NVWA), presented at the 2018 edition of the Dutch annual food safety congress organised by consumer's organisation FoodWatch.

The simplicity of the above model characterises the relevance of the Precautionary Principle. The existence of a Precautionary Principle is aimed to prevent the situation where a socially undesirable situation cannot be acted against. Even in case it is not certain that a situation poses a relevant risk, a risk management may be adopted. This is to prevent false positives. On the other hand, the criteria that apply to application of regulation under the Precautionary Principle, such as measures being temporary and proportionate, prevent that a measure is aimed at a risk that is not relevant. This prevents occurrence of false negatives.

In contrast with the assumption raised above, it is relevant to consider the risk-regulation-response. This is the process of developing regulation in response to an adverse situation, while regulation might not be the effective means of mitigating the risk. A popular example in the Netherlands takes place in the municipality of Maastricht, where an incident occurred while volunteers from local sports associations were involved in collecting waste-paper in order to create some additional revenue to their tight funds. Two volunteers wounded themselves when jumping on a paper-collection truck wearing flip-flops. As a result, the municipality ordered that all volunteers should follow a training for the safe collection of waste-paper and were obliged to buy and wear safety boots. Since the associations carried part of the cost of the training and the safety boots, the revenue of the paper collection decreased by approximately 85%, while a less restricting measure might have yielded a similar regulatory goal.[44]

3.2.4 Strong precaution and weak precaution: a continuum?

The Precautionary Principle materialises in many forms and in many fields of legislation. Not every expression of the Precautionary Principle is unique. Although the formulation of the Precautionary Principle in regulation 178/2002 is *quite* clear, there is still room for interpretation. This invites me to consider other formulations of the Precautionary Principle as well, in order to determine the position of the "EU Food Law Precautionary Principle" relatively to its brothers.

The weakest form of precaution is found in principle 15 the Rio Declaration[45,46]. Here, an euphemistic formulation is chosen, stating that scientific uncertainty cannot be a reason not to take measures.

> **Rio Declaration Principle 15**
> 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.

It is salient to observe that this formulation refers to an "approach" rather than a "principle".

On the other extreme, we find the formulation that inadequately taking action in case of scientific uncertainty should lead to liability of the risk manager[47]. To put it simple, weak precaution gives risk

[44] Helsloot, I., & Scholtgens, A. (2015). Krachten rond de risico-regelreflex beschreven en geïllustreerd in 27 voorbeelden. Amsterdam: Boom-Lemma.
[45] Sachs, N. M. (2011). Rescuing The Strong Precautionary Principle From Its Critics. *University Of Illinois Law Review*, 4, 1285–1338.
[46] The Rio Declaration on Environment and Development, United Nations, 1992

managers the right to take action under scientific uncertainty, while strong precaution gives risk managers the (legally enforceable) duty to take action under scientific uncertainty[48]. Since the world isn't exactly black and white, the exact magnitude of the Precautionary Principle as it applies for food safety is somewhere in between these two definitions.

Other factors in which formulation of a Precautionary Principle can vary are the criteria that apply to said measures, and the circumstances under which they may be applied.

The image below visualizes how different formulations of the Precautionary Principle can be located along the continuum between week and strong precaution, using the burden of proof and the weight of evidence required as preliminary criteria.

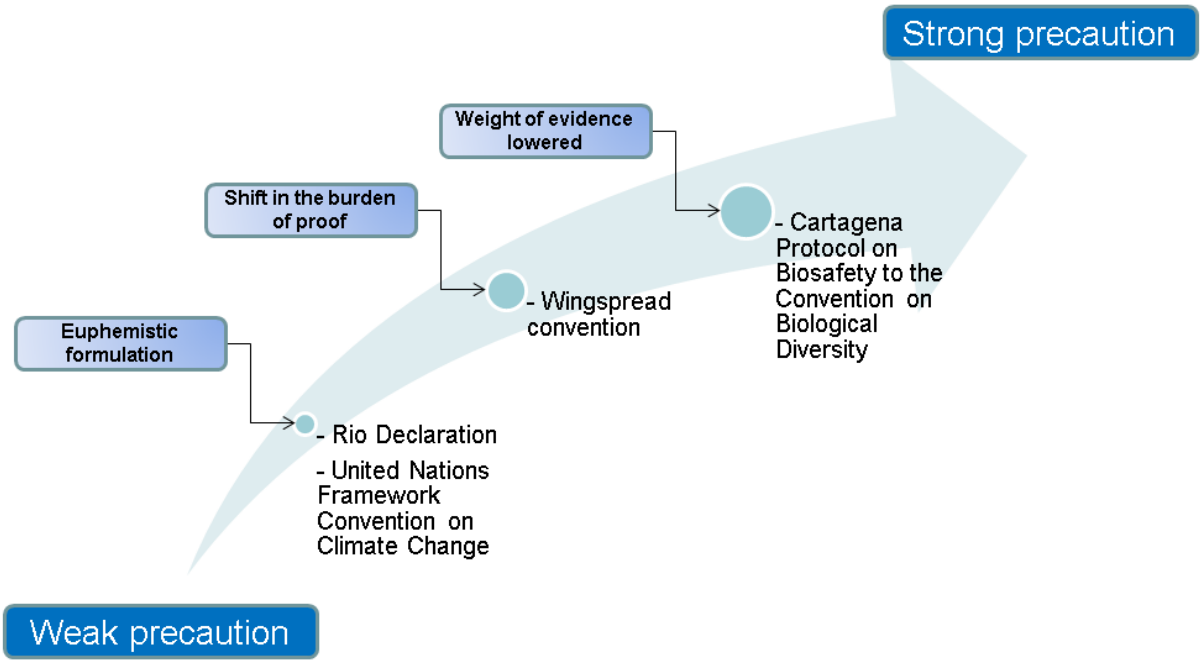

Figure 3: different formulations of the Precautionary Principle can be placed in the strong-weak continuum based on the burden of proof and the weight of evidence

[47] Tosun, J. (2013). *Risk Regulation in Europe: Assessing the Application of the Precautionary Principle.* SpringerBriefs in Political Science. Chapter 4

[48] Persson, E. (2016). What are the core ideas behind the Precautionary Principle? *Science of the Total Environment*, 557-558, 134–141.

4 Legal framework

This chapter describes the primary and secondary sources of law that provide various formulations of the Precautionary Principle and interpret these formulations in the light of the Risk Analysis framework.

4.1 Primary law

A common reference to the Precautionary Principle is article 191 (2) of the Treaty on the Functioning of the European Union (TFEU)

TFEU art. 191(2)
2. 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.

In article 191 (1), protection of human health is mentioned as one of the objectives of environmental protection.

TFEU art. 191(1)
1. Union policy on the environment shall contribute to pursuit of the following objectives:
— preserving, protecting and improving the quality of the environment,
— protecting human health,
— prudent and rational utilisation of natural resources,
— promoting measures at international level to deal with regional or worldwide environmental problems, and in particular combating climate change.

This incorporates the Precautionary Principle as a general principle of union policy. However, it cannot easily be used as a basis for enforcement and is more likely to be considered as a basis to develop policy upon, since a treaty does not provide enforcement mandate.

Article 5 of the WTO Agreement on Sanitary and Phytosanitary measures provides a formulation of the Precautionary Principle as well, although it does not mention the principle explicitly.

WTO SPS agreement art. 5(7)
7. 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.

This formulation has overlap with the Communication from the Commission on the Precautionary Principle: measures should be provisional and time-bound, the available scientific information should have been evaluated, and there is the requirement of performing additional research. Failure to base a measure on these conditions, has been the foundation for several disputes in front of the WTO

dispute settlement body. Hence, this article provides a basis for appeal to those (either WTO member nations or the EU) who are disadvantaged by the measure.

4.2 Secondary law

The General Food Law refers to the Precautionary Principle in recitals 20 and 21 of the preamble and in articles 6(3) and 7.

See below for the exact formulation, with emphasis added.

Regulation 178/2002: preamble
(20) The Precautionary Principle has been invoked to ensure **health protectio**n in the Community, thereby **giving rise to barriers to the free movement of food** or feed. Therefore it is necessary to adopt a uniform basis throughout the Community for the use of this principle.

(21) In those specific circumstances **where a risk to life or health** exists but scientific uncertainty persists, the **Precautionary Principle provides a mechanism** for determining risk management measures or other actions in order to ensure the high level of health protection chosen in the Community

The preamble of the General Food Law provides an interesting insight into the motives of the Commission at the time of constructing this regulation. The implication that barriers to the free movement of food or feed might be possible, shows parallels with articles 35 and 36 of the TFEU, which provide exceptions to the free movement of goods. One of these exceptions is the protection of human life or health. It is also interesting to observe that the Precautionary Principle is considered a **mechanism**: this shows that the legislator considers the principle as a regulatory tool that carries potential to practical implementation. It is also salient to observe that "other actions" than risk management measures should be possible, as long as the public health benefits from this action. Although the preamble does not provide a direct basis for enforcement, it does provide a relevant framework for how the rest of the regulation should be read.

Regulation 178/2002: article 6(3)
3. Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, other factors legitimate to the matter under consideration and **the Precautionary Principle** where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5

This article involves the Precautionary Principle within the framework of risk management. It shows that if the conditions in article 7(1) are met, risk management should take the Precautionary Principle into account. One of the general objectives is again the protection of human life and health, but the objectives mentioned in article 5 are not limited to that one objective. This gives an indication that the Precautionary Principle may be relevant for more interests than just public health.

Regulation 178/2002: article 7

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.

2. 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.

Article 7(1) provides the circumstances under which the Precautionary Principle may be invoked, while article 7(2) provides the criteria that pertain to this application. Article 7(1) recites the three conditions already established in the Communication from the Commission on the Precautionary Principle: possible harm has to be identified, yet there is scientific uncertainty, and steps must be taken to retrieve further scientific evidence in the form of a risk assessment.

The criteria given in article 7(2) are also related to the Communication: the measure should be proportional and of temporary nature. This triggers me to question what exactly could be considered a measure of non-temporary nature. Taking the instruments that the NVWA could apply for example, some of these could be considered permanent. This is the case of products that have a short shelf-life. When blocking a batch of fresh vegetables for example, the blocking itself is a temporary measure, while the quality deterioration of the vegetables that takes place during the blocking, is an irreversible process. A similar situation occurs for destruction of a batch of a product. The damage is irreversible, since the product cannot be recovered. In another framework of reasoning though, the decision “all incoming contaminated meat shall be destroyed until a risk assessment proves its safety for consumption” carries a temporary nature: it does not say that all incoming suspicious meat will indefinitely be destroyed, and hence, could be considered to be temporary.

5 Case law

This chapter provides an analysis of relevant case law. Through a search query in Curia for case law that refers to article 7 of regulation 178/2002, ran in May 2017, several relevant EU cases have been found. The Dutch case law has been found through a query in the digital archive of Dutch national case law on rechtspraak.nl. The applied query was *"voorzorgsbeginsel + (NVWA OR VWA OR warenautoriteit)* and yielded 7 results. Scanning these results led to the identification of three relevant cases. Cases were deemed irrelevant because the reference to the Precautionary Principle was not made explicitly or because there was no connection found between the Precautionary Principle and an enforcement action by the NVWA or its legal predecessors. The selected cases have also been suggested as material for analysis by the NVWA's legal officers involved in the cases.

5.1 Framework for analysis

Regarding the framework in which the selected case law is discussed, the communication from the Commission on the Precautionary Principle serves as a normative yardstick, as described in article paragraph 1.5.2. Hence, next to a general introduction and an overview of the case's history, each case is discussed in three parts

Firstly, the factors that triggered recourse to the Precautionary Principle are identified. According to the communication, these factors comprise three elements: the identification of potentially negative effects, scientific evaluation and scientific uncertainty. Next, the communication mentions the measures that could be considered to be applied. These are the decision whether or not to act and the nature of the action ultimately taken. Finally, the communication provides guidelines for application. In the codification of the Precautionary Principle in the GFL, some of these guidelines have become mandatory criteria that pertain to the applicant: measures taken based on the Precautionary Principle are obliged to be proportional, non-discriminatory and consistent also, further scientific developments should be examined. Article 7.1 obliges the risk manager to undertake efforts for a more comprehensive risk assessment. Article 7.1 also states that the measures should be of temporary nature. This restriction is also further specified by the obligation to reconsider the measure within a reasonable period of time. Other guidelines that are expressed in the communication, but not as such in the GFL itself, are the examination of costs and benefits of action and inaction and an indication to whom the burden should be attributed.

Hence, the case law will be analysed according to the following model:

1) Factors that triggered recourse to the Precautionary Principle: were the potentially negative effects identified? What was the result of the scientific evaluation? What kind of uncertainty is concerned here?
2) The measures that were identified: how was the decision whether or not to act taken? What is the nature of the action ultimately taken?
3) Whether the Guidelines for application have been followed: is the measure considered proportionate? Is it non-discriminatory? Is it consistent? Was it a temporary measure? Was it reviewed in due time? Has additional scientific evaluation been initiated? Were costs and benefits of action and inaction identified? Where lays the burden of proof?

5.2 EU case law

This chapter considers a number of cases in which either one of the parties or the court itself have referred to the Precautionary Principle. These cases are C-111/16 - Fidenato and Others (*Fidenato*), C-154/04 Alliance for Natural Health and Others (*Alliance for Natural Health and Others*), C-282/15 Queisser Pharma GMBH & co. KG v Bundesrepublik Deutschland (*Queisser Pharma*), C-601/11 P - France (Nutri-Link) v Commission (*France vs. Commission*), RBDHA:2016:2245 – Abbatoir Amsterdam, CBB:2015:398; RBROT:2014:6615; RBROT: 2013:BZ2463; RBROT:2012:BY1516 – Vleesimporteurs Rotterdam (*Vleesimporteurs Rotterdam*) and RBROT:2017:3571 - Solgar Vitamins (*Solgar Vitamins*). The search for relevant case law also yielded the case T-201/13 - Rubinum v Commission. The ruling and opinion of this case however could not be consulted via Curia or Eur-Lex. Therefor it has been decided, for the scope of this report, not to consider this case for analysis.

5.2.1 C-111/16 - Fidenato and Others

5.2.1.1 *General description*

This case considered preliminary questions from the Italian court, who had prosecuted farmers for cultivation of MON810, a GMO maize. This was prohibited by national Italian legislation. The plaintiffs alleged that the national legislation on basis of which they had been prosecuted conflicted with article 34 of regulation 1829/2003 and articles 53 and 54 of the GFL. The district court of Udine referred a number of questions to the Court of Justice, of which one question referred to the relationship between the Precautionary Principle and article 34 of regulation 1829/2003.

To quote the question in full:

> (3) May considerations relating to the Precautionary Principle which go beyond the parameters of serious and evident risk to human or animal health or the environment in the use of food or feed justify the adoption of interim emergency measures by a Member State within the meaning of [Article] 34 of [Regulation] No 1829/2003?

Regulation 1829/2003 is the "GMO-regulation", which lays down basic principles for the approval procedure of GMO crops on the EU market. Article 34 describes criteria for measures to be taken in case of an emergency. The question suggests a relationship between the Precautionary Principle and the adoption of emergency measures. Although no active recourse to the Precautionary Principle has been made in this case, i.e. no specific measure was taken with the Precautionary Principle as basis, the question still invites the court to shed light on the relationship between the general food law and a more dedicated regulation.

Facts

The maize which the plaintiffs had planted, MON 810, had been approved for placing on the market by the Commission on April 22, 1998. In April 2013, Italy requested the commission to prohibit cultivation of this maize, based on article 34 of Regulation 1829/2003. Their request was supported by scientific studies of two Italian research institutes: the Agricultural Research Council, (CRA) and the Institute for Environmental Protection (ISPRA). The Commission indicated that it did not see the necessity to take emergency measures, based on the scientific evidence provided. It did however request EFSA to conduct a more conclusive study (by May 29th, 2013).

Next, the Italian government issued a decree (by July 12th, 2013)which prohibits cultivation of MON 810. This was not based on the Precautionary Principle, but on article 54 GFL. EFSA indicated in its opinion 3371 that the scientific material provided by Italy did not provide any new evidence to justify the requested measures.

Process history

The three plaintiffs were faced with a penal order issued by the District Court of Udine for cultivating MON 810, which was an infringement of the decree issued in July 2013. In their opposition, the plaintiffs pled that the decree on basis of which they had been prosecuted, infringed article 34 of regulation 1829/2003 and articles 53 and 54 of the GFL. The District Court of Udine next referred prejudicial questions to the CoJ.

Outcome

The Precautionary Principle as codified in article 7 GFL cannot serve as the only legal basis to base emergency measures upon, as the conditions for emergency measures in article 34 of Regulation 1829/2003 have to be satisfied as well. Article 34 is seen as an expression of the Precautionary Principle dedicated to GMO's. According to the Advocate-General's opinion however, the requirement of an 'evident, serious risk' as laid down in article 34 places measures based on that article in a different system than measures based on the Precautionary Principle, where 'scientific uncertainty' and 'identification of possible harm' form a sufficient basis[49].

Hence, the Precautionary Principle is limited in its applicability. The court seems to follow the tendency to attribute predominance to *lex specialis* over *lex generalis*. Hence, when considering measures related to GMO foodstuffs, the general food law cannot be used to bypass the specific legislation for GMO foodstuffs.

5.2.1.2 *Analysis*

Factors

From this case, the negative effects that the legislator seeks to avoid using the implemented decree, do not come forward. It is apparent that Italy had doubts related to the safety of MON 810.This is made clear by their request to the Commission to take measures, by the fact that Italy provided scientific evidence and by the fact that Italy, ultimately, adopted a decree to prohibit MON 810 cultivation.

The result of the scientific evaluation is contradictory. According to Italy, their request for emergency measures is justified by the reports it provided. According to EFSA however, the reports do not provide any new scientific evidence and therefore EFSA relies on its previous conclusion in favour of approving MON 810 to be placed on the market.

It is unclear what kind of uncertainty is the case.

Measures

Based on deduction, I can identify two measures that were considered: measures taken by the Commission, or measures taken by the Italian Government, both with the aim to prevent MON 810

[49] Opinion of Mr Bobek – Case C 111/16 Fidenato E.A., at (68)

to be placed on the market. The measure finally taken was the second option, by accepting the decree to prohibit cultivation of MON 810.

Guidelines

Since the measure was not based on the Precautionary Principle, the guidelines and criteria for application of the Principle do not apply. The judge has not tested the contested measure for consistency with the Principle. However, since question three seems to hint at the possibility to actually base the contested measure on the Precautionary Principle, it may still be interesting to further consider the "PP-compliance" of the measure.

5.2.1.3 *Conclusion*

In its response to the third question, the judge noted that "(the precautionary) principle cannot be interpreted as meaning that the provisions set out in article 34 of Regulation NO 1829/2003 may be disregarded or altered, in particular by relaxing them". Ergo, for GMO's the requirement to take emergency measures upon, "evident", cannot be lowered to the PP's "harm identified but still uncertainty.

5.2.2 C-282/15 Queisser Pharma GMBH & co. KG v Bundesrepublik Deutschland

5.2.2.1 *General case description*

Facts and process history

A German court referred preliminary questions to the Court of Justice. The applicant of the German case, Queisser Pharma, had requested a derogation from the prohibition of bringing a food supplement to the market containing a certain amino acid, L-histidine. This request was rejected based on article 68 of the German Code on foodstuffs and animal feed, (*Lebensmittel- und Futtermittelgesetzbuch, LFGB)* which sets the criteria for a derogation of the prohibition to use non-approved additives as set out in paragraph 6(1) of the LFGB. Amino acids are considered additives based on paragraph 2.3 (3) LFGB. The criterion on which this rejection was based is found in paragraph 68 (3), which stipulates derogations are only allowed if it can be assumed there is no human or animal health risk. The health risk assumed was based on the fact that the supplement offered a combination of L-histidine and iron[50].

Queisser Pharma appealed to this rejection, after which the Federal Office for Consumer Protection and food safety (*the 'Office'*) granted a derogation for three years. Since Queisser Pharma held that it did not require a derogation at all. Hence, the German court referred preliminary questions to the CoJ to interpret the legitimacy of the German national legislation with EU legislation. One of the questions concerns the relationship between on the one hand, articles 6, 7 and 14 of the GFL and paragraphs 6 and 68 of the LFGB on the other hand.

[50] Judgement of 19.1.2017 – Case C-282/15 Queisser Pharma, at (25)

To quote the question in full[51,52]:

> (2) Does the scheme of Articles 14, 6, 7, 53 and 55 of Regulation [No 178/2002] mean that national bans on individual foods or food ingredients may only be issued under the conditions set out therein, and does this preclude a national statutory provision as set out at 1 above?

Outcome

In the answer to the preliminary questions, it was concluded that a positive-list system which only allows for temporary derogations in a limited number should be based on a substantial risk assessment, which was not the case for the German authorisation system.

5.2.2.2 *Analysis*

Factors

For the sake of analysis, I consider the existence of paragraphs 6 and 68 of the LFGB as an expression to the Precautionary Principle. Here again, the Precautionary Principle has not actively been invoked during the risk management activities taken by the office. The principle does however serve as a tool to test the legitimacy of the German legislation.

The potentially negative effects are not identified in the in the judgement or the opinion. The only notion of negative effects comes from the Office's "expressed doubts" on the safety of ingesting iron in combination with L-histidine. On a higher, more institutional level , the potential negative effects identified are risk to human or animal health, which is the objective of paragraph 6 of the LFGB.

The result of the scientific evaluation is the establishment of paragraph 6(1) LFGB, prohibiting non approved food additives, either unmixed or in mixture with other substances. No traces of a scientific examination dedicated to the specific supplement of Queisser Pharma can be found.

The uncertainty concerned here seems to be uncertainty towards the effect of the hazard and the dose-response relationship. The hazard concerned is a non-authorised additive in a mixture, the mixture of iron and the additive L-histidine in this case. The uncertainty is that a product might be placed on the market which is injurious to health.

Measures

The measure chosen was the implementation of a general prohibition of all non-authorised additives. In this specific case, the measure chosen was to refuse to provide a derogation to the producer. It is unclear how the decision to act or not to act has been taken.

Guidelines

According to the ruling, the implementation of a prohibition of non-authorised additives is not considered proportionate. The court holds that the fact that derogations have a maximum term of three years and are only renewable for three times, is too restrictive for the set objective of public

[51] *Idem,* at (32)

[52] The national statutory provision refers to a provision that prohibit food supplements with amino acid unless a derogation has been issued

health protection. No explicit reference is made to the criterion “non-discriminatory”, although the court does hold that it is disproportional to also require a derogation for products of which the safety is proven. This seems to discriminate between products that are proven to be safe and products which aren’t yet, which can be considered to conflict with the non-discriminatory criterion. The measure is not temporary and has not been reviewed in due time.

5.2.2.3 *Conclusion*

The court gives the following interpretations on the relation between the Precautionary Principle as codified in article 7 GFL and the German prohibition of non-authorised additives:
A system of prior authorization for all amino acids cannot be justified on a risk assessment of only a selection of amino acids. Also, the fact that a risk assessment brings practical difficulties cannot justify absence of a risk assessment as the basis of such a prior authorization scheme.

Finally, it is considered disproportionate to only allow temporary derogations without providing the opportunity for the producer to prove the safety of the propagated additives. Hence a system of prior authorization for products containing amino acids cannot be based on a risk assessment of only certain types of amino acids, and derogations to this system cannot be only temporary

5.2.3 C-154/04 - Alliance for Natural Health and Others

5.2.3.1 *General case description*

Facts and process history

This case refers to the legitimacy of Directive 2002/46, which establishes a positive list of nutrients that are allowed to be used in food supplements. The alliance for natural health, which represents a number of supplement producers, questions whether this directive complies with the criteria for EU legislation, under which proportionality. The CoJ judges whether the directive is to be considered proportional and refers to the Precautionary Principle in its ruling.

Outcome

The court judged that no factor was revealed that could affect the legitimacy of Directive 2002/46. The appeal was therefore rejected.

5.2.3.2 *Analysis*

Factors

It is unclear whether the potentially negative effects have been identified. The result of the scientific evaluation was the establishment of a positive list of additives to be used in food additives, instead of a negative list. It is unclear what kind of uncertainty is considered in this case.

Measures

The measure identified and implemented is a positive-list system. It is unclear how the decision to act or not to act has been taken.

Guidelines

The only guideline for application that has been tested by the court is the proportionality principle. The regulation is considered compliant to this principle. The other guidelines are not considered. The burden of proof is placed at the protagonist of the additive, by considering all additives outside of the positive list to be unsafe until their safety is proven.

5.2.3.3 *Conclusion*

The court considers a positive list as a good expression of the Precautionary Principle and considers a high level of protection of human health to justify such a system.

5.2.4 C-601/11 P - France (Nutri-Link) v Commission & T-257/07 - France v Commission

5.2.4.1 *General case description*

Facts & process history

In case T-257/07, the French government had referred preliminary questions to the General Court. In case C-601/11P, it appealed to the judgement by the General Court, essentially requesting a re-evaluation at the CoJ. The action that France appealed against was the implementation of Regulation (EC) No 746/2008 concerning the treatment of cattle in which Transmissible Spongiform Encephalopathies (TSE's) had been detected. The regulation allowed for a milder treatment of cattle infected with TSE's that were not associated with bovine species (Bovine Spongiform Encephalopathy, BSE). France objected to this regulation on the basis of the Precautionary Principle, since it reasoned the existence of the scientific uncertainty towards the safety for human health of TSE-infected cattle. According to France, the possibility that TSE's could transfer to humans, causing scrapie, could not be excluded. According to the Commission meanwhile, the odds of non-BSE TSE's transferring to humans were sufficiently low.

Outcome

The CoJ rejected France's appeal and confirmed the legitimacy of the existing regulation.

5.2.4.2 *Analysis*

Factors

The potentially negative effect identified was the transfer of non-BSE TSE's to humans. The results of scientific evaluation were contradictory. According to EFSA's report on which the Commission had based the regulation, the risk of transfer was sufficiently low, while a report issued by the French Food Safety Authority indicated that this risk could not be excluded. The uncertainty in this case relates to the effectivity of proposed measures. France sustained the argument that TSE transfer to humans could not be proven by discriminatory tests, while the Commission had sufficient trust in discriminatory tests as a method to prove transfer did not take place.

Measures

The measures considered by France were to tighten the regulation, leading to a more strict treatment of cattle infected with TSE's. No measure was taken eventually.

Guidelines

The court tested the proportionality of the existing regulation and considered it to be proportional. It did not test for the criterion that a measure should be non-discriminatory or whether it had been reviewed in due time. Neither did it test for the evaluation of costs and benefits of action and inaction. The measure was not temporary, but permanent and no additional scientific evaluation had taken place. The court judged that the existing scientific evidence was conclusive.

5.2.4.3 *Conclusion*

From this case, it can be concluded that it is not sufficient to establish scientific uncertainty purely based on the existence of several, contradictory risk assessments.

5.3 Dutch Case law

In the Netherlands, three sets of decisions have been appealed to by the receiver. These appeals referred to decisions to block a consignment of frozen beef, to order a recall on meat and to withhold a batch of vitamin D supplements. This paragraph describes the decisions taken on the basis of the Precautionary Principle, the ground for appeal and the considerations of the judge.

5.3.1 Abattoir Amsterdam

5.3.1.1 *General case description*

Facts and process history

In this situation, the NVWA informed the Abattoir Amsterdam, a slaughterhouse, that it had the duty to recall a batch of veal[53]. This was based on the presence of clenbuterol, a forbidden hormone, in hair samples of calves at the site of origin.

This duty was based on article 19 GFL. Interestingly, the judge ruled that appeal was not applicable, since *informing* on the duty to recall is not the same as *imposing* the duty to recall. However, the facts in this case still have a say on what kind of actions can be taken.

A second analysis, based on samples of actual veal that origined from Abattoir Amsterdam, the specific lot of calves processed by Abattoir Amsterdam showed no presence of clenbuterol. Abattoir Amsterdam therefore requested compensation of the damage it had suffered as the result of the unnecessary recall.

Outcome

The appeal was rejected and the applicant was ordered to carry the cost of the procedure.

5.3.1.2 *Analysis*

Factors

The potential harm was the suspicion of presence of clenbuterol, a forbidden hormone. This was based on hair samples at the production site of the veal's origin. The expected harm was identified, the fact that conclusive information was lacking, was also supported by the court's findings.

The kind of uncertainty here is not related to the hazard clenbuterol brings to human health, but to the presence of this substance. Hence, the uncertainty can be classified as uncertainty to the exposure to the harmful substance. This is confirmed by the judge in paragraph 4.3: "between parties there is no conflict that clenbuterol is a prohibited substance and that animals in which this substance is present, shall not be placed on the market. It has not been argued that any (scientific) uncertainty exists regarding the harmfulness of consumption of food containing clenbuterol".

Salient to observe is that the reference to the Precautionary Principle in the court proceedings was not made by the NVWA, but by the abattoir. The arguments provided by the abattoir related to the duties the NVWA would have when basing a measure on the Precautionary Principle. The court did not decide whether or not the actions by the NVWA could be considered to be based on the Precautionary Principle. It did however test which obligations would be placed on the NVWA should it have based its measures on this principle.

[53] RBDHA:2016:2245 – Abbatoir Amsterdam

Measures

The nature of the action ultimately taken is the obligation to perform a recall. The decision whether or not to act was based on the risk assessment of clenbuterol. The consideration of a measure less restrictive than a recall is not mentioned by the NVWA or the court. The applicant however held that a lighter measure might have been implemented

Guidelines

The court ruled that the applicant's argument that the NVWA would have the duty to perform further research to prove compliance with specific provisions on the safety of a party of veal. The NVWA was correct in posing the burden of proof on the FBO. It was also concluded that the NVWA had assessed the available scientific material and that it had taken temporary measures, while taking steps to initiate a new risk assessment. The court did not test for proportionality of this measure however. Neither did the court test for a non-discriminatory nature of the measure and consistency.

5.3.1.3 *Conclusion*

It is salient to observe that neither the NVWA, neither the court referred to notion that all calves in the same lot could be considered unsafe, based on the article of the general food law that states that when a product in a batch is considered unsafe, the entire batch shall be deemed unsafe. This article also places the onus of proof at the food business operator: by proving the safety of the batch, the predicate "unsafe" could be released again.

The NVWA's action was based on article 19 GFL, which obliges an FBO to prevent products expected to be unsafe from being placed on the market. The court concluded that the research which proved the safety of the batch of abattoir Amsterdam could as well had been performed by the abattoir itself. Also, the fact that the abattoir had not made use of the possibility to take an insurance against the damage imposed by an unnecessary recall, indicated for the court that the abattoir had apparently not considered an insurance to be necessary[54]. The risk of an unnecessary recall therefore was voluntarily taken by the abattoir and should be considered an ordinary operational risk.

Hence, article 7 cannot be used to place obligations on the NVWA when the NVWA takes action on the basis of article 19 GFL.

5.3.2 The Vleesimporteurs Rotterdam cases

5.3.2.1 *General case description*

Facts and process history

Vleesimporteurs Rotterdam refers to a number of cases that all concern a blockage of frozen beef from Argentina[55]. The decision of the NVWA to block these batches, has been appealed at various levels (voorlopige voorziening; CbB) and by various stakeholders.

The decision to block several containers was based on microbiological sampling that indicated that E. coli bacteria carrying STx genes were present in the meat. STx is a highly pathogenic toxin. The

[54] RBDHA:2016:2245 – Abbatoir Amsterdam, at (4.3)
[55] CBB:2015:398 – Vleesimporteurs Rotterdam;
RBROT:2014:6615 – Vleesimporteurs Rotterdam;
RBROT: 2013:BZ2463 – Vleesimporteurs Rotterdam;
RBROT:2012:BY1516 – Vleesimporteurs Rotterdam

scientific debate concerning this pathogen however focuses on the question whether mere presence of genes that codify for STx is sufficient to treat the product as if STx itself is present. This question is based on the thought that the presence of genes does not necessarily trigger expression of the gene. It could very well be present in a fraction of the DNA that does not come to expression, since over 95% of DNA does not come to expression.

The NVWA employs a decentralised regulation that states that the presence of STx genes is sufficient to treat the product as if the genes would come to expression. The recourse to the Precautionary Principle was made as an additional substantiation of this rule and the resulting decision.

Outcome

The court decided that the blockage was proportional. The importers should have taken action by requesting the release of the blockage and to provide arguments for that. Hence, it is interesting to observe that here again the onus of proof within the principle of proportionality was placed on the FBO.

5.3.2.2 *Analysis*

Factors

The potentially negative effects identified are health risks as a result of possible STx gene expression. The result of the scientific evaluation is the policy instrument "refusal of imported products", which forbids any product imported from a third country infected with pathogenic *E. coli* serotypes to be placed on the market without further processing[56]. The kind of uncertainty concerned was uncertainty to the likeliness of occurring

Measures

Blockage was the only measure identified by the NVWA. Re-treatment, which would be a less restrictive measure, was suggested by the importers.

Guidelines

The contested measure was tested for proportionality but not for the criteria non-discriminatory and temporary. The measure was considered to be proportional.

5.3.2.3 *Conclusion*

Arguments of the appellant were especially focussed on the disproportionality of the measure. Their claim was that by blocking the batch, its receivers (Vleesverwerkers Rotterdam) were not able to use the meat for other purposes, such as treating it as a lower-class type of meat and hence processing it through a heat treatment. This would ensure that the meat would be safe to consume, however, its economic potential would decrease from the treatment. The court refused this claim, since the receivers had not taken substantial action to initiate that process.

5.3.3 The Solgar Vitamins case

5.3.3.1 *General case description*

Facts and process history

[56] Policy as published on the NVWA's website: https://www.nvwa.nl/documenten/import/veterinair/ks-documenten/bip-procedures/bpr-22-vgc-weigeren-van-producten. Consulted April 12th, 2018

The question in this dispute between the Minster of Public Health and Solgar Vitamins Haarlem B.V. was whether 100 mg of vitamin D would be a too high value to ensure public health[57]. The norm for this vitamin was set on 75 mg per unit of consumption. The upper limit for safe consumption was, based on risk assessments by the RIVM and by EFSA set on 100 mg

The NVWA therefore decided to block the vitamin supplement containing 100 mg of vitamin D per consumption

Outcome

The court considered that there was no urgent need to perform a recall and hence rejected the NVWA's decision to order the recall. It did however not reject the NVWA's decision to order the withholding. The crucial argumentation to reject the recall was based on the court's observation that the NVWA had not taken any other steps to execute the recall.

5.3.3.2 *Analysis*

Factors

The potentially negative effects identified are health risks as a result of excessive amounts of vitamin D consumption. The result of the scientific evaluation was that different opinions existed on what would be a safe value for vitamin D to be consumed daily. The kind of uncertainty concerned here is uncertainty related to the dose-response relationship.

Measures

The measures were to order the producer, Solgar Vitamins, to withhold their product from the market and to execute a recall. The producer was also faced with a charge under penalty (*last onder dwangsom* in Dutch) for breaking the withholding or for not executing the recall.

Guidelines

The measures were considered not fully proportional since the recall was considered unnecessary. Adversely, the measure was not tested for the criteria that it should be non-discriminatory and consistent. The measure was considered temporary and had been reviewed in due time, namely after the appeal had been filed to the court. Additional scientific evaluation had taken place. The burden of proof to prove the unsafety of these specific supplements was placed at the NVWA.

5.3.3.3 *Conclusion*

According to the court, if the recall had been necessary, the NVWA could have taken more initiative to execute the recall.

[57] RBROT:2017:3571 - Solgar Vitamins

6 Results and conclusions

This chapter describes the interpretations from case law, what the legal status is of the Precautionary Principle in the Netherlands and gives a conclusion in the form of both a framework for application as well as other policy recommendations.

6.1 Inferences from case law

The framework for analysis has distinguished three elements that are relevant for application of the Precautionary Principle . These are, *ex* ante: factors that trigger recourse and measures identified. *Ex post*, there is the element of examining whether the guidelines have been followed. This paragraph provides a schematic overview of the analysed case law.

6.1.1 Factors triggering recourse to the Precautionary Principle

Table 1: overview of court's interpretation of the factors in EU case law

Case name	Potentially negative effects identified	Result of the scientific evaluation	Kind of uncertainty concerned
Fidenato and Others	N/A	Different conclusions between EFSA and Italy	Unclear
Queisser Pharma	"expressed doubts" on the safety of ingesting iron in combination with L-histidine	No scientific examination dedicated to the specific supplement	The uncertainty concerned here seems to be uncertainty towards the effect of the hazard and the dose-response relationship.
Alliance for Natural Health and Others	N/A	Establishment of a positive list of substances to be used in food additives	Unclear
France vs Commission	non-BSE type TSE might transmit to humans	France: transmission cannot be excluded; EFSA: chances at transmission is sufficiently low	Uncertainy regarding the reliability of discriminatory tests, hence, uncertainty towards the effectivity of proposed measures

Table 2: overview of court's interpretation of the factors in Dutch national case law

Case name	Potentially negative effects identified	Result of the scientific evaluation	Kind of uncertainty concerned
Abattoir Amsterdam	Clenbuterol might be present in the food chain. Clenbuterol is injurious to health	Presence of clenbuterol	Uncertainty related to the presence of clenbuterol in the suspected batch. Hence, uncertainty of exposure
Vleesimporteurs Rotterdam	Health risks as a result of possible STx gene expression	STx is injurious to health	Uncertainty related to the likeliness of STx genes actually coming to expression. Hence, exposure-uncertainty

Solgar Vitamins	Health risk as a result of a too high exposure to vitamin D	100 mg of vitamin D may be above the safe limit for consumption	Uncertainty related to the dose-response relationship

These tables show that in two cases, namely *Alliance for Natural Health* and *Fidenato*, the type of uncertainty concerned was not identified in court. This does not mean that the type of uncertainty has not been identified at all, but it is salient to observe that for the outcome of the case, the type of uncertainty was not considered relevant. In these two cases, the identification of potentially negative effects was not treated in court either. The table also shows that the types of uncertainty occurring in case law are related to the dose-response relationship, the effectivity of proposed measures and towards the exposure.

6.1.2 Measures identified

Table 3: overview of the court's interpretation of the measures in EU case law

Case name	Decision to act/not to act taken?	Nature of the action taken
Fidenato and Others	Unclear	Action by either Commission or Italy to prevent MON 810 to be placed on the market.
Queisser Pharma	Unclear	Implementation of a general prohibition of all non-authorised additives
Alliance for Natural Health and Others	Unclear	Positive-list system
France vs Commission	Not acted because the court rejected France's appeal	Inaction

Table 4: overview of the court's interpretation of the measures in Dutch national case law

Case name	Decision to act/not to act taken?	Nature of the action taken
Abattoir Amsterdam	Unclear	Instruct FBO to perform a recall
Vleesimporteurs Rotterdam	Action was based on the NVWA's policy for meat contaminated with E. coli carrying STx genes	Blockage
Solgar Vitamins	Unclear	Instruct FBO to perform a recall

Here it is especially salient to observe that it is unclear in all cases except for *France vs. Commission* and *Vleesimporteurs Rotterdam* how the decision to act or not to act has been taken. Apparently, this is not a relevant ground of consideration in court. In *France vs. Commission*, no action was taken at all, while in *Vleesimporteurs Rotterdam*, the decision to act was based on the execution of already existing policy.

6.1.3 Guidelines

Table 5: overview of both EU and Dutch court's interpretation of the guidelines.

Case name	Proportionality	Non-discriminatory	Consistent	Temporary	Reviewed in due time	Additional scientific evaluation	Costs and benefits of action and inaction	Where lays the burden of proof?
EU case law								
Fidenato and Others	Not tested	Not tested	Not tested	Not tested	Not tested	Not tested	Not tested	Italy
Queisser Pharma	The measure was considered not proportional	No .Discriminatory because even products of which the safety is established cannot easily be placed on the positive list	Not tested	No	No	Not tested	Not tested	FBO
Alliance for Natural Health and Others	Tested, measure was considered proportional	Not tested	Not tested	No, permament	No	Not tested	Not tested	With the protagonist of the additive
France vs Commission	Tested, regulation was considered proportional	Not tested	Not tested	No	Not tested	No, scientific evidence was considered to be conclusive	Not tested	France
Dutch National case law								
Abattoir Amsterdam	Tested, measure was considered proportional	Not tested	Not tested	Yes, but irreversible	Not applicable	Yes	Not tested	FBO
Vleesimporteurs Rotterdam	Tested, measure was considered proportional	Not tested	Not tested	Yes, but irreversible	Not applicable	Yes	Not tested	FBO
Solgar Vitamins	Tested, proposed measures were considered not proportional	Not tested	Not tested	Yes	Yes, after court action	Yes	Not tested	NVWA

In the table above, the criteria that either have not been tested or which did not comply to the Communication, have been colour coded in light red, to visualise these criteria.

Proportionality is a criterion regularly tested in court. The criterion that measures should be *non-discriminatory* however is usually not tested. The one case were it is tested, *Quiesser Pharma*, the finding that a measure is discriminatory is used to underline the non-proportionality of this measure.

Interestingly, the criterion *consistency* has not been tested in any case. This can be explained by the fact that consistency is not stipulated in the article 7 GFL. Many measures have a permanent rather than a temporary nature. The court however does not usually consider this in its argumentation. It is salient to observe that the measures introduced in the Dutch cases *Abattoir Amsterdam*, *Vleesimporteurs Rotterdam* and *Solgar Vitamins* all had a temporary nature. These were also the cases where additional scientific evaluation has taken place and where the court considered this additional scientific evaluation in its argumentation. The EU-court cases have in common that neither the temporary nature of the measure nor the evaluation of additional scientific evidence has been examined.

6.2 Defining precaution from a legal perspective

6.2.1 The Dutch addressee of the passive formulation of the Precautionary Principle in art.7 GFL

Based on the context of article 7 GFL, any institution that has the right or duty to take risk management measures could base an activity on the Precautionary Principle. Since the broad definition of risk management, the NVWA should not consider itself to be the only addressee of the formulation in article 7 GFL. Risk management is a process for which various institutions are responsible. On the field of food safety, the NVWA should see itself as executor of risk management decisions, but the responsibilities of policy makers at the ministry of Agriculture and the ministry of public health can be considered risk management decisions/actions as well. Article 7(2) lays down the criteria that should be followed upon application, thereby addressing the risk manager.

6.2.2 The legal basis for application of the Precautionary Principle in the Netherlands

The GFL is not the sole legal source of the Precautionary Principle. In the TFEU, a general means of application of the Precautionary Principle is provided in article 191 (2). Also, the Precautionary Principle can be seen as one of the principles for adequate governance (ABBB's), as it is mildly codified in article 3.2 of the Algemene Wet Bestuur, a basic administrative regulation[58]. This articles poses the obligation for decision-makers to gather knowledge on the relevant facts and the interests at stake in order to base their decision upon. Naturally, this obligation also counts when applying the Precautionary Principle. The difference between "certain" situations and "uncertain" situation is that in the latter case, there is a limitation towards the availability or existence of relevant facts.

[58] The Dutch formulation is "Bij de voorbereiding van een besluit vergaart het bestuursorgaan de nodige kennis omtrent de relevante feiten en de af te wegen belangen.", or in English: "When preparing a decision, the administrative institution gathers the required knowledge with regard to the relevant facts and the interests at stake."

The obligation to care for public interests comes from the "assigning letter" (toewijzingsbrief)[59] in which the ministries of Agriculture and Public Health assign the task to the NVWA to enforce the relevant legislation on its six domains.

6.2.3 The Precautionary Principle on the continuum between weakest precaution and strongest precaution

When paying close attention to the exact formulation of the law, we find that provisional risk management techniques may be taken. "May" implies that it is allowed to do so, but there is not a defined duty. In practice however, there are duties expressed for the NVWA in Dutch law. The minister can be held accountable, should the NVWA fail in fulfilling its legal task[60]. It is however unclear to which extent the duty to enforce on the basis of the Precautionary Principle can also be a legal requirement.

It is relevant to pay close attention to the distinction between accountability and liability. Although these two concepts both connect a result or a moral verdict to a certain act or inaction, accountability is more likely to be associated with a cause-effect relationship while liability is more likely to be associated with the question who is responsible for compensation of the damage. Many scholars however have further explored the question whether a risk manager can be held liable in case of failure to fulfil its task[61]. Liability however, requires a certain victim who has suffered a certain damage. In the general risk management framework, the risk manager (in the form of a governmental institution or its representative) acts against the source of the risk, which is usually the economic activity of a business. One of the characteristics of strong precaution is that third parties (i.e. consumers) could derive rights on the basis of the Precautionary Principle[62]. Let us observe the fictive example where a consumer organisation such as Greenpeace demands action from a governmental institution to mitigate an uncertain risk, with the Precautionary Principle as justification. Inaction by the authority to heed this demand might lead to the government being accountable, or liable because of neglect. A condition to condemn an agent as liable is that the damage is known or can be estimated and that the victim is clearly identified. This pleads towards accountability rather than liability.

Another complicating factor is that the Precautionary Principle and other legal varieties of mitigating uncertain risk do not have solely governmental institutions as addressee. Numerous Dutch cases exist where employer liability is based on the Precautionary Principle. Hence, the "generic" Precautionary Principle is applicable to businesses as well and consumers or people in an employer-employee relation can derive rights from it. In case law however, it customary to refer to the "duty to care" (with neglect being the opposite of the duty of care) than to the "Precautionary Principle" itself.

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[59] Tweede Kamer der Staten-Generaal. Instellen van de Nederlandse Voedsel- en Warenautoriteit (NVWA) als baten-lastendienst; Brief regering; Voorhangprocedure instellen baten-lastendienst Nederlandse Voedsel en Waren Autoriteit (NVWA).

[60] Kjærnes, U., Harvey, M., & Warde, A. (2007). *Trust in food: A comparative and institutional analysis*. Springer.

[61] De Jong, E. R. (2016). *Voorzorgverplichtingen: over aansprakelijkheidsrechtelijke normstelling voor onzekere risico's*. Boom juridisch.; van Velthoven, B. C. J., & van Wijck, P. W. (2008). Proportionele aansprakelijkheid vanuit ex ante perspectief. *Aansprakelijkheid, verzekering en schade*, 11.

[62] Lyon, J. D. (1998). Coordinated food systems and accountability mechanisms for food safety: A law and economics approach. *Food & Drug LJ*, *53*, 729.

There has been no evidence found where negligence is assumed as a result of inaction by the risk manager. Therefore, the Precautionary Principle as it applies in the Netherlands, is not the strongest form of precaution possible. The weight of evidence required is however quite low and the additional requirements are not very restrictive. Therefore, application of the Precautionary Principle may be strengthened.

6.3 Conclusion

In this report, two types of application of the Precautionary Principle can be identified. The first is the Precautionary Principle as a general point of reference for the development of law and policy. I refer to this as "indirect application". This implies that the principle does not serve to base an enforcement activity upon, but as a means to test compliance of new regulatory instruments. Examples of cases where the principle was applied indirectly, are *Fidenato and others*, *Queisser Pharma*, *Alliance for natural health and others vs Commission* and *France vs Commission*. The second type of application that can be identified is the "direct application", where the principle is used as a basis for enforcement activities. This has been the case in *Vleesimporteurs Rotterdam*, *Abattoir Amsterdam*, *Solgar Vitamins*.

6.3.1 A procedure for application of the Precautionary Principle

To answer the main question, "How can the Precautionary Principle, in the way it currently applies in the Netherlands, contribute to the broadening of the NVWA's activities in the field of Food Safety?", I propose a procedure for the NVWA to be followed when confronted with scientific uncertainty.

This procedure covers three parts: firstly to assess the circumstances in order to determine whether the Precautionary Principle could or should be invoked, secondly to determine the criteria that pertain to measures based on the principle (*material conditions*) and thirdly additional steps that are obliged to be followed upon application (*procedural conditions*).

6.3.1.1 *Determining whether the Precautionary Principle should be invoked*

From the legal framework, the analysis of case law and other results, it follows that three factors justify recourse to the Precautionary Principle: potentially negative effects must be identified, scientific evaluation of the available knowledge must have taken place, and scientific uncertainty remains. Next, possible measures should be considered.

The first two factors are usually combined in a preliminary risk assessment of the status quo. The scientific uncertainty can be identified using the framework for classification of uncertainty. The possible classifications are uncertainty related to hazard, to the dose-response relationship, to the degree of exposure, to the situations in which exposure can take place, to the effect and to the effectiveness of the proposed measure. The type of uncertainty is important for the identification of possible measures and to the decision whether or not to implement these measures.

6.3.1.2 *Criteria that pertain to measures*

When considering measures, it is important that these measures comply with the criteria of proportionality and non-discriminatory. The criterion of proportionality that pertains to measures taken on the basis of the Precautionary Principle has been tested in all court rulings. In most cases, the proposed measure was found to be proportional. To prove non-proportionality the burden of proof lays with the antagonist of the measure.

The criterion of a measure being non-discriminatory has not been tested in court. It does however remain an inevitable criterion for enforcement practice, not only because of the codification of the Precautionary Principle in the GFL, but also since it is a general principle of public governance in the Netherlands.

There are limitations towards the duration of a measure however. This is shown in the ruling of Queisser Pharma, where the court judges that a system of limited derogations in a positive list system would conflict with the GFL. Hence, measures based on the Precautionary Principle cannot be of permanent nature, and a system of limited derogations, without the option to establish a permanent derogation or addition to the positive list, would be illegitimate.

6.3.1.3 *Procedural conditions*

Having implemented measures, there are additional procedural requirements. These requirements are that the measure is considered in due time and that additional scientific evidence will be evaluated.

The criterion of the measure being revisited in due time has not been tested, and various examples show that "in due time" does not imply a formal duration. In all Dutch case law, additional scientific material has been evaluated and the court has payed close attention to this material.

6.3.2 Recommendations for future research

The recommendations for future policy development can be divided in three domains: knowing the environment (recommendations 1) and 2)), intragovernmental communication (recommendation 3)) and further development of guidelines (recommendation 4).

1) For policy makers, in the interest of the NVWA, it is recommended to translate the Precautionary Principle from the domain "Food Safety" to the other domains in which the NVWA is active. An exploration into the legal framework on precaution in these other domains could be a start. This translation is a harmonisation effort which helps the NVWA to apply the Precautionary Principle in a uniform matter. It is also desirable to perform an exhaustive assessment aimed at identification of the Precautionary Principle in all its forms, both in *Lex specialis* as well as in *Lex Generalis*.

2) Several EU member states indicated in the REFIT[63] programme that there is no national basis/guidance on the use of the PP, and Article 6 constitutes the main legal basis, with Article 7 less well understood. Hence it is advisable to consider the founding of a Dutch working group to establish a national guideline on application of the Precautionary Principle in risk management. The question "how should we deal with scientific uncertainty?" is relevant to the general public interest, exceeding the sole domains in which the NVWA is active. Scientific uncertainty can never fully be excluded, and should not impair risk regulation.

[63] Fitness check on the General Food Law, as provided on https://ec.europa.eu/food/safety/general_food_law/fitness_check_en. Consulted on March 12th, 2018

3) In the 2015 REFIT survey, the Netherlands answered “no” or “I do not know” on question 32 o the GFL: “Have any provisional risk management measures been taken by Member States at national level on the basis of the Precautionary Principle (Article 7)?”. This thesis shows the answer to that question should in fact have been “yes”. Therefore, it is recommended to improve the communication within the various departments of the Dutch government that are involved with risk management.

4) As stated in REFIT: “Article 7 constitutes the only detailed legal reference to what the Precautionary principle is in EU law and, as it stands, has the merits of a general wording that allows implementation in differing contexts particularly in such a highly complex technical area as food safety. The Commission has provided guidelines on the use of the PRECAUTIONARY PRINCIPLE more generally. **However, in the absence of further specific guidelines on Article 7/178 , whether at EU or at national level, the inherent challenges of applying the PRECAUTIONARY PRINCIPLE across EU policies are also evident in its application in the food safety policy area”**. This calls for an EU-wide competence research to identify which rights and duties other EU member states have taken upon them, based upon the Precautionary Principle.

7 Discussion

This chapter discusses the results in comparison to the findings of the theoretical framework, to show whether the critiques of the paralysing effect of the Precautionary Principle and the subjective dimension of risks are justified. The chapter also describes the limitations of the research which are found in the selection of examples of application, in the variability in formulations of the Precautionary Principle and in the desirability to apply the Principle.

7.1 Discussion of the results

This chapter confronts the findings on application of the Precautionary Principle with the critiques cast especially in Sunstein's essay against the Precautionary Principle and other literature described in the theoretical framework. The main points of critique identified here are the paralysing effect of the Precautionary Principle and its unscientific nature. By asking the question which factors attribute soundness to the critique, a balanced view can be deducted on the PP's potential and pitfalls.

7.1.1 Critique 1: the paralysing effect

The paralysing effect materialised from the thought that in risk management, each action has inevitable consequences. Taking measures against a risk will have other risks as its consequence. Taking actions against a potential unsafe food leads to the risk that the world food supply becomes insufficient, yielding hunger as a result. Taking precautions against a terrorism suspect leads to the risk of restricting an innocent human in its basic freedom. Hence, the Precautionary Principle as such is not an effective instrument to mitigate risks. To dispute this preliminary conclusion however, it is relevant to consider the regulatory goal identified in article 7 of the GFL and in recital 20 of its preamble. Here, a clear reference is made to the intention of application of the Precautionary Principle, namely the protection of the high level of food safety in the European Union. Hence, this article provides a guideline towards the acceptability of risks that emerge from application of the Precautionary Principle. Considering the Precautionary Principle as a means to substitute, divert or deflect risks, it provides a selection criterion on which risks should have priority to be dealt with.

7.1.2 Critique 2: the unscientific nature of the Precautionary Principle

When scientific uncertainty exists, the risk that a measure is taken based on unscientific grounds becomes eminent. The unscientific nature of the Precautionary Principle is caused by the way a society perceives risks. As was discussed in this report's theoretical framework, risks cannot be perceived 100% objectively. Differences in cultural preferences and knowledge lead to different degrees of risk attitudes. In a properly functioning deliberative democracy, it is legitimate that a government takes these differences in risk attitude into account in the decision making process. Risk attitudes are also influenced by the availability heuristics. This leads to a more negative perception of catastrophic risks than a fully rational attitude would have rendered. By the legal requirement that a preliminary risk assessment is to be completed before any enforcement measure can be taken, the degree of subjectivity in the risk management process is decreased. This does however still allow for societal preferences to be reflected in the risk assessment. It is therefore important for risk managers to be aware of the distinction between *real* risk and *perceived* risk.

7.2 Limitations of the research

The most prominent limitation is found in the applied sources. The selection of examples has been based on criteria of accessibility. Since most of the examples used have been found in case law, it is

reasonable to assume that these examples may have been the *tip of the iceberg*. Only one other example of enforcement based on the Precautionary Principle has been found, namely the TTX contamination in shellfish. The decision to select these cases for analysis has been made because it has not been technically feasible to derive an exhaustive list of all enforcement actions where the Precautionary Principle has implicitly or explicitly been considered in the decision making process. The examples used can be used for the proof of concept, but it is possible that a more elaborate evaluation of PP-based-actions would provide new insights with a stronger extrapolation potential.

Another relevant limitation is found in the lack of consistency in the formulation of a Precautionary Principle. At the time I started this thesis, no one-term-fits-all definition of the Precautionary Principle was available. Hence, the Precautionary Principle has been defined both in general terms as well as in domain-specific terms. This underlines the need to have Precautionary Principle defined in *lex generalis*, which still enables codification of a Precautionary Principle in more domain-specific legislation in *lex specialis*. Since the definition of the Precautionary Principle adopted by the NVWA has been developed at a later stage, the scope of the research might have been different taking this definition as a starting point.

Another limitation has been found to be the usage of the Communication from the Commission on the PRECAUTIONARY PRINCIPLE as a yardstick for analysis. Although the communication provides a useful framework for analysis, it has no legal value. This limits the degree to which it is actually a relevant tool, since another framework, not carrying any legal value either, might be just as relevant and effective. The decision to use the Communication as a yardstick was based on the notion that this communication is associated with the codification of the Precautionary Principle in EU law and that it provides a clear, accessible framework. Another researcher might have selected a different framework and consecutively, would have derived different results using the same input.

Finally, an important limitation of this research lies in the *why* of the desire to apply the Precautionary Principle. This research is focused on the *when* and the *how* but has failed to provide an answer to *why* the Precautionary Principle should be applied. Critiques cast in the context of the risk-regulation response show that the decision not to act can be a legitimate decision as well. The existence of a false positive, i.e. introducing a form of regulation that does not actually render social utility, can occur. The question whether it is actually useful to apply the Precautionary Principle or to strive for a stronger application, should therefore be a topic of discussion in the dialogue between policy makers, consumers, safety authorities, industry and other stakeholders. Regulation can be an answer, but it is not always the answer.

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Appendices

Appendix 1 – overview of legislation for which the NVWA is the dedicated authority

Inventarisatie wetten waar de NVWA op toeziet
Versie 15 januari 2018

	Algemene wet	ministerie	
	Algemene wet bestuursrecht		
	Wet op de Economische delicten		
	Wetboek van Strafvordering		
	Wetboek van strafrecht		
	Algemene wet op het binnentreden		
	Wet openbaarheid van bestuur		
	Wet bescherming persoonsgegevens		
	Algemene Verordening Gegevensbescherming (Avg) + Uitvoeringswet Avg		
	Wet bescherming politiegegevens (Wpg) + EU richtlijn voor opsporing en vervolging		
	Gezondheidswet		
	Burgerlijk wetboek		
	Wet onafhankelijke risicobeoordeling Nederlandse Voedsel- en Warenautoriteit		
	Arbowet / Arbobesluit		
	Arbeidstijdenwet /arbeidstijdenbesluit		
	Specifieke wet		Toezicht en handhaving
	Warenwet (WW)	VWS	- Artikel 25; - Regeling aanwijzing toezichthoudende ambtenaren ex artikel 25 van de Warenwet; - Warenwetregeling taakverdeling toezichthouders Warenwet voor levensmiddelen; - verschillende besluiten en regelingen
	Tabaks- en rookwarenwet	VWS	- Artikel 13 - Tabaks- en rookwarenregeling, artikel 7.1.
	Gezondheidswet	VWS	--
	Geneesmiddelenwet	VWS	- Artikelen 100-116; - Besluit Staatstoezicht op de volksgezondheid
	Wet publieke gezondheid, Artikel 47a (inwerkingtreding 1-1-2018)	VWS	- Artikel 64; - Besluit Staatstoezicht op de volksgezondheid
	Gezondheids- en welzijnswet voor	LNV	- Artikelen. 114-120;

	dieren		- Regeling aanwijzing ambtenaren Gezondheids- en welzijnswet voor dieren
	Wet dieren	LNV	- Artikelen 8.1, 8.10-8.12; - Besluit aanwijzing toezichthouders Wet dieren
	Meststoffenwet	LNV	- Artikel 47; - Uitvoeringsregeling Mesttsoffenwet, artikel 129
	Plantenziektenwet	LNV	- Artikel 10; - Besluit aanwijzing toezichthouders Plantenziektenwet
	Wet gewasmiddelenbescherming en biociden	LNV	- Artikel 82; - Regeling gewasmiddelenbescherming en biociden, artikel 9.1; - Besluit mandaat, volmacht en machtiging hoofd van de afdeling Bestuurlijke & Juridische zaken NVWA inzake de Wet gewasbeschermingsmiddelen en biociden
	Visserijwet 1963	LNV	- Artikelen 54 a-62; - Besluit aanwijzing toezichthouders 2016 Visserijwet 1963
	Uitvoeringswet Visserijverdrag 1967	LNV	Artikelen 9 en 12 Toezicht niet bij NVWA
	Landbouwwet	LNV	- Artikel 48 a; - Besluit aanwijzing toezichthouders Landbouwwet
	landbouwkwaliteitswet	LNV	- Artikelen 15 en 18; - Landbouwkwaliteitsregeling 2007, artikel 26
	Wet op de dierproeven	LNV	- Artikel 20 en 26; - Besluit aanwijzing toezichthouders Wet op de dierproeven
	Kaderwet EZ-subsidies	LNV	- Artikel 8; - Besluit houdende aanwijzing toezichthouders Kaderwet EZ-subsidies 2014
	Wet implementatie Nagoya protocol	LNV	- Artikel 4; - Besluit aanwijzing toezichthouders Wet implementatie Nagoya Protocol
	Wet verbod pelsdierhouderij	LNV	- Artikel 5; - Regeling uitvoering Wet verbod pelsdierhouderij, artikel 4
	Zaaizaad- en plantgoedwet 2005	LNV	- Artikel 89; - Besluit aanwijzing toezichthouders Zaaizaad- en plantgoedwet 2005
	Wet natuurbescherming (inwerkingtreding 1-1-2017) (trekt Boswet, Flora- en Faunawet en Natuurbeschermingswet 1998 in)	LNV	- Artikel 7.1; - Regeling natuurbescherming, artikel 6.1
	Wet implementatie EU-richtlijnen energie-efficiëntie	LNV	- Artikel 31; - Besluit aanwijzing toezichthouders Wet implementatie EU-richtlijnen energie-efficiëntie

Appendix 2 – interventions as specified in the NVWA's Intervention Policy

Bijlage B – Overzicht interventies

Overzicht van sanctionerende interventies

• bestuurlijke boete (bestuursrecht);

• Bestuurlijke strafbeschikking

• Straf opgelegd door de strafrechter; dit wordt gestart door middel van een proces-verbaal dat bij het Openbaar Ministerie (OM) wordt ingediend (strafrecht)[64];

Overzicht van mogelijke corrigerende interventies (niet limitatief)

• Waarschuwing[65];

• schorsen of intrekken vergunning;

• officiële inbewaarneming

• bestuurlijke inbeslagname;

• vrijwillig afstand doen;

• weigering afgifte exportcertificaat

• oplegging waarschuwing consument;

• opleggen product recall;

• aanbrengen merk van afkeur;

• stilleggen productie;

• schorsing of intrekking van erkenning of registratie;

• ingrijpen in het productieproces van erkende/geregistreerde bedrijven;

• vernietigen productie/zaken;

• de invoering van hygiëneprocedures of andere noodzakelijk geachte maatregelen om de veiligheid van diervoeders of levensmiddelen, of de naleving van de desbetreffende wetgeving en van de voorschriften inzake diergezondheid en dierenwelzijn te garanderen;

• het beperken of verbieden van het op de markt brengen, invoeren of uitvoeren van diervoeders, levensmiddelen of dieren;

• monitoring en, waar nodig, het terugroepen, uit de handel nemen en/of vernietigen van diervoeders of levensmiddelen;

• de machtiging om de diervoeders en levensmiddelen aan te wenden voor andere doeleinden dan die waarvoor zij oorspronkelijk waren bedoeld;

• schorsing of sluiting van het betrokken bedrijf, hetzij geheel, hetzij gedeeltelijk, voor een bepaalde periode;

• maatregelen inzake zendingen uit derde landen ('speciale behandeling'): een behandeling of verwerking om de diervoeders of levensmiddelen in overeenstemming te brengen met de eisen van de communautaire wetgeving, of met de eisen van een derde land ingeval van terugsturen, met inbegrip van desinfectering, indien noodzakelijk, meer met uitsluiting van verdunning; verwerking op enige andere passende manier voor andere doeleinden dan menselijke of dierlijke consumptie);

• verbod op het vervoeren, be- of verwerken en in het verkeer brengen;

• verbod op het vervoederen aan dieren;

• verplichting tot tijdelijke opslag;

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[64] De meeste zaken worden door een OM-transactie afgedaan.

[65] Een waarschuwing is in tegenstelling tot de andere interventies geen besluit, maar wel gericht op het doen opheffen van eenovertreding.

• verplichting tot vernietiging of uit de handel nemen;
• verplichting tot ontsmetting, of een andere passende behandeling;
• verplichting tot terugzending naar het land van oorsprong;
• verplichting om (vermoedelijke) houders onverwijld en op doeltreffende wijze op de hoogte te stellen;
• verplichting om in het verkeer gebrachte producten op te halen en centraal op te slaan;
• verplichting tot identificeren en registreren van producten;
• verplichting dat de dieren evenals de van deze dieren afkomstige producten het bedrijf waar deze dieren worden gehouden niet verlaten dan met toestemming van de minister;
• verplichting dat de dieren opgestald worden of de stallen niet verlaten dan met toestemming van de minister;
• verplichting dat de dieren opgehokt worden of het hok niet verlaten dan met toestemming van de minister;
• verplichting dat de dieren op een aangewezen plaats worden gehouden en deze niet verlaten dan met toestemming van de minister;
• opleggen herstel geconstateerde inbreuken;
• schorsen vergunning of certificaat van goedkeuring van vervoermiddel;
• schorsen of intrekken getuigschrift vakbekwaamheid;
• opleggen verbod dieren te vervoeren;
• opleggen maatregelen ter bescherming dierenwelzijn zoals:
a) Verandering van bestuurder of verzorger;
b) Reparatie van vervoermiddel teneinde letsel aan dieren te voorkomen;
c) Overladen partij;
d) Terugzending dieren;
e) Onderbrengen dieren in geschikte huisvesting.
• andere maatregelen worden getroffen, voor zover de maatregelen zijn voorgeschreven bij een communautaire maatregel;
• een andere maatregel die de bevoegde autoriteit passend acht.

Appendix 3 – an exploration of the precautionary principle in other domains than Food Safety

8.1.1.1 *Product Safety*

Article 21 of the Warenwet (commodities act)
EU Regulation on product safety

8.1.1.2 *Animal Health*

Preamble of the Dutch animal law

8.1.1.3 *Animal welfare*

Preamble of the Dutch animal law

8.1.1.4 *Plant Health*

No actual enforcement practices that can be based on plant health regulations. Since there are little enforcement instruments as such – even in situations of scientific certainty-, the existence of a Precautionary Principle – to enforce in situations of uncertainty – is unlikely.

8.1.1.5 *Nature Conservation*

No specific principle identified, but the general principles (TFEU 191(2), WTO SPS art. 7) might be applicable