Master thesis
Food Safety Law

Unsafe Casu Marzu

Can Casu Marzu be deemed safe according to article 14 of Regulation (EC) No 178/2002?

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Preface

In the beginning of 2017, I was starting with exploring my interests regarding thesis topics. I wrote down a web of several subjects and questions that were on my mind. However one subject has been staying on my mind. In the same period, an evening course called Insects and Society crossed my path. During this course, I learned about the wonderful world of insects and showed me how beneficial insects can act as food and feed. Casu Marzu was one of the examples of insects as food consumed within the European Union.

Several persons told me that you should do your thesis in a field that you are attracted to, otherwise it would be a very long and hard period. Since then, I noticed that Casu Marzu had to be the topic of my thesis. I wanted everything to be settled and agreed with the supervisor on this topic. The light was green and I was eager to kick off the thesis.

After working all the time on the same topic and diving into the materials regarding one specific case, enthusiasm can be cooled down easily. Luckily, during the whole thesis period, I have not had any regret with regards to the topic of Casu Marzu. Thanks to this enthusiasm, I am able to keep on searching and tending to find the answer on sub-questions and ultimately on the research question. In the end, I hope I will be able to transfer this enthusiasm to the readers of the report and attendants of the colloquium.

Thesis is an obligatory part of the master programme Food Safety Law at the Wageningen University. This thesis is conducted at the chair group Law and Governance. In a period of six months, in periods 1-3 of year 2017/2018, the student will conduct research, will write a thesis and will present a colloquium. This process is under the supervision of a superior in the chair group named above. Two examiners of the respective chair group will attend the colloquium and will read the thesis report, the student will be examined on both aspects. For more detailed information on the examination and/or procedural aspects during the thesis, can be referred to the Green Booklet.

List of contents

List of abbreviations

AMPH	N'-Acetyl-4-(hydroxymethyl)phenylhydrazine
AMR	antimicrobial resistance
Berger case	c-636/11 *Karl Berger v Freistaat Bayern*
BPA	bisphenol A
BSE	bovine spongiforme encephalopathies
Cfu/g	number of coliform units per gram material (in most cases food)
DES	diethylstilbestrol
E.coli	Eschicheria coli
EFSA	European Food Safety Authority
EU	European Union
FBO	food business operator
GABA	γ-aminobutyric acid
GFL	general food law, Regulation (EC) No 178/2002
LAB	lacid acid bacteria
MPN/100g	most probable number of units found per 100 gram material
NVWA	Nederlandse Voedsel- en Warenautoriteit (English: Dutch Food Safety Authority)
PAH	polycyclic aromatic hydrocarbon
PCB	polychlorinated biphenyls
P.D.O	protected designation of origin (Italian: DOP=denominazione origine protetta)
TSE	transmittable spongiform encephalopathies
WTO	World Trade Organization

Abstract

Casu Marzu, containing living larvae, is one of the most disputable cheeses as regards to safety issues. Article 14 of Regulation (EC) No 178/2002 states that food shall not be placed on the market if deemed unsafe. Further, this article describes unsafe as either injurious to health or unfit for human consumption. In this research, both aspects of unsafety are discussed with respect to Casu Marzu.

Can Casu Marzu be deemed safe according to article 14 of Regulation (EC) No 178/2002?

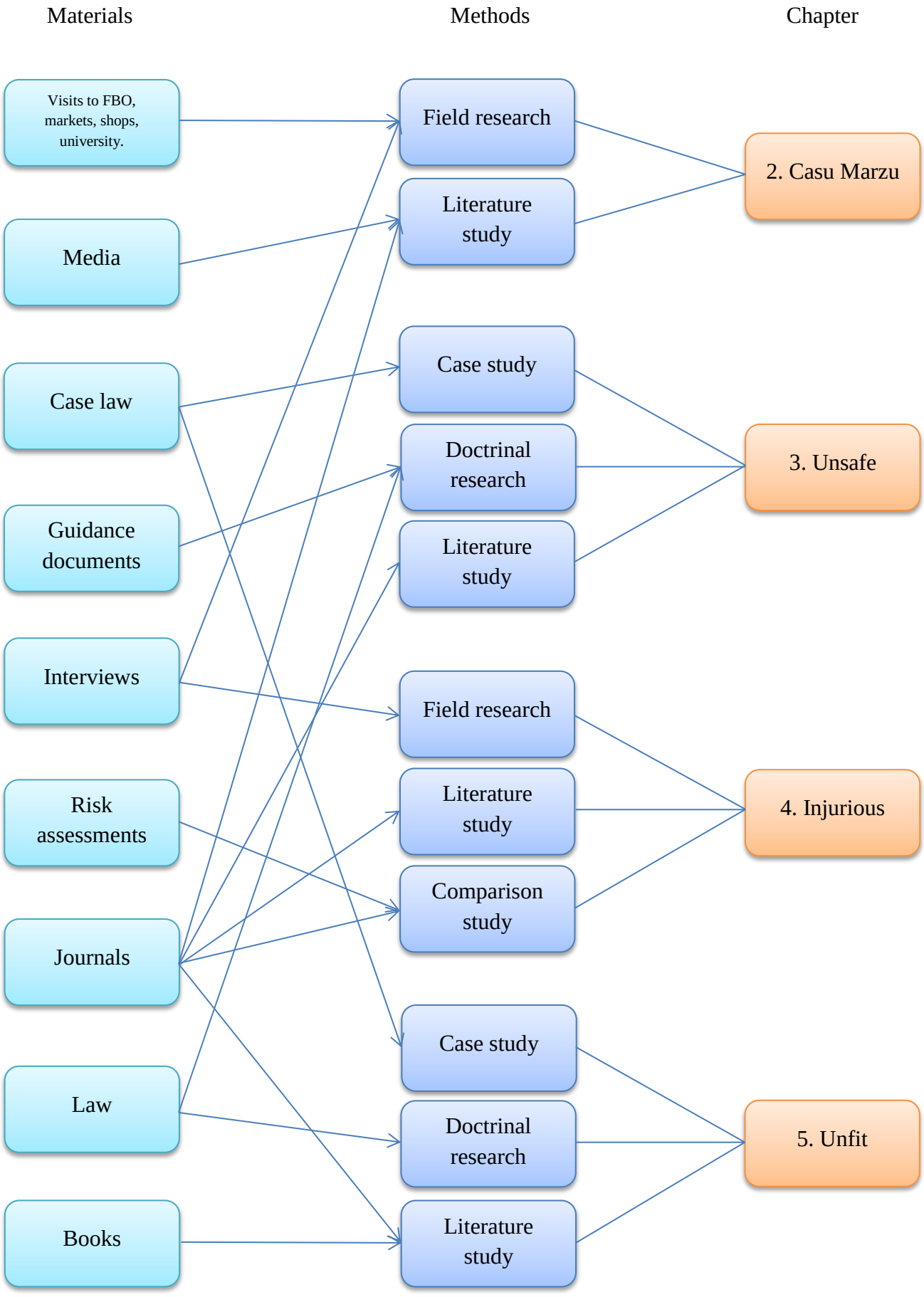
In order to be able to answer this question, methods like field research, literature study, comparison study and doctrinal research are conducted. According to article 5 of Legge 283 del 30 aprile 1962 of Italian law, Casu Marzu is forbidden to place on the market due to the infestation of the fly *Piophila casei*. Besides, Casu Marzu is not fully compliant to several provisions in EU-food law.

Hazards to health are identified in Casu Marzu, however exposure is low, what makes the health risks negligible. For many of the identified hazards, limits were not even established in food law at EU-level. For the biochemical hazard histamine, a limit is only set on fishery products and it is likely that the amounts consumed differ between these products. Looking to this limit, Casu Marzu would be incompliant. The comparison study teaches that other products, as deemed safe, can pose risks to health as well and even be breaching normative EU-food law. In addition, many food hazards in Casu Marzu can be diminished with standardising and monitoring the production process and thus legalising marketing of the food product.

Looking at the aspect of unfit for human consumption, the expectation of the consumer plays an important role. When the consumer purchases a product and consumes it and expectations are fulfilled, the product seems to be fit. Many cases have shown a default in the product or extraneous contamination, which is not expected when buying the product. In case of Casu Marzu, the product is expected to contain living larvae, which contribute to the particular taste, structure, odour and appearance the consumer is expecting from Casu Marzu.

Key words: Casu Marzu, food safety, unsafe food, injurious to health, unfit for human consumption, edible insects.

Methods & materials



1. Introduction

Casu Marzu is known throughout the world, but it can be seen as the most disputable cheese in the world as well. Casu Marzu is a cheese made of sheep milk and is produced and eaten in Sardegna, Italy. The cheese does not only contain milk, which makes it so disputable[1]. It namely contains living larvae that digest the cheese mass. This cheese is given several names, such as casu frazigu, casu becciu, casu fattittu, casu marzu, hasu muhidu, formaggio marcio[2], which all mean putrid cheese. In the current situation it is not allowed to place Casu Marzu on the market, since it is not conform national Italian law and is considered unsafe. However, local admirers of this cheese do not totally agree and argue that Casu Marzu has been eaten for over several generations and nobody showed any issues with regards to health[3].

When investigating at European Union level, article 14 of Regulation (EC) No. 178/2002 says that food shall not be placed on the market when unsafe. The same article furtherly explains that unsafe can either be injurious to health or unfit for human consumption and how these definitions should be determined in relation to food products[4]. Nevertheless, an important question that raises hereafter is whether the unsafety is to measure or to be perceived by the public? The case of Casu Marzu shows legal uncertainty. Therefore this thesis is subject to give clarification on the unsafety or safety of Casu Marzu.

The research question for this thesis is

'*Can Casu Marzu be deemed safe according to article 14 of Regulation (EC) No. 178/2002?´*

In order to find an answer on the research question and to clarify the boarders of the term ''unsafe'' in this case, sub-questions are formulated.

After this introduction, the report will be opened with the background on the product Casu Marzu. This chapter explains the manufacturing process of the product and its characteristics. The following chapter is named *3. Unsafe according to article 14*, in which an overview is given on the legal background and the meaning of the definition 'unsafe'. Furthermore, the definitions 'precautionary principle' and 'burden of proof' are discussed. Hereafter in chapter *4. Injurious to health*, a comparison study is conducted. In the comparison study, Casu Marzu

[1] Marika Luongo (for Leonarda.it News). 2016. *Il casu marzu è il formaggio più pericoloso al mondo*.

[2] Regione autonoma della Sardegna, assessorato dell'agricoltura e riforma agro-pastorale. N.d. *Prodotto tradizionale della Sardegna-Casu frazigu, formaggi*.

[3] Ministero delle politiche agricole alimentari e forestali for Italy. 2015. *Quindicesima revision dell'elenco nazionale dei prodotti agroalimentari tradizionali in attuazione dell'art. 3, comma 3, del decreto ministriale 8 settembre 1999, n.350.*

[4] European Parliament and Council for the European Union. 2002. *Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.*

is compared to several food products, which are widely marketed within the EU nowadays. Besides this comparison study, the risks related to health are identified for Casu Marzu and first of all an explanation on the meaning of injurious to health will be given. The next chapter is called *5. Unfit for human consumption* and answers the questions 'What is unfit for human consumption according to Regulation (EC) No. 178/2002?' and 'What is understood with the interest of the consumer (individually and collectively) as described in Regulation (EC) No. 178/2002?'

This thesis tends to find an answer on how to determine the concept of unsafe food within the jurisdiction of the European Union. This report stresses that this concept of unsafe food is partly about criterion, that can function as parameters for safe food. On the other hand, the concept of unsafe food can also be about a more philosophical approach to achieve the main objectives. The thesis represents an in-depth analysis on how to interpret food law at EU-level, in particular article 14 of Regulation (EU) No 178/2002, in light of the case of Casu Marzu.

2. Casu Marzu

2.1.Casu Marzu – Origin and tradition

Sardinia is with 24.090 km² the largest island situated in the Tyrrhenian Sea. Although the island falls under Italian jurisdiction, Sardinia is called an autonomous region. Sardinia consists of a hilly landscape limited by 1800 km of coast in Mediterranean climate, that together forms an often dry but fertile ground. This landscape makes a comfortable environment for herbal plants to grow (see figure 1). Sardinian specialties are often remarked by their spiced and herbal flavours. Sheep count for a significant part of the inhabitants of Sardinia, on the island live 1.650.000 humans[5] and approximately 6.000.000 sheep[6]. The hills together with the plants on those hills make a good living environment for the sheep. For this reason, plenty of sheep milk can be obtained, which results in several food products from ovine origin. Examples of these products are Fiore di Sardo, Pecorino Sardo, Granglona, Ricotta, crema di latte and Casu Marzu. This latter one can be considered as the most disputable one. Casu Marzu, meaning rotten cheese in Sardinian, is not allowed to be placed on the market due to safety reasons. Casu Marzu is a typical cheese made in Sardinia from sheep milk, like most of the other cheeses, but contains living larvae of the fly *Piophila casei* ingesting the cheese. However, many Sardinians have eaten the cheese since they were little and eating Casu Marzu is, among them, not experienced as odd. Contrarily, it is seen as a food product destined for special occasions.

Figure 1 Landscape Sardinia (Retrieved on 4-10-2017)

One of the raw materials of Casu Marzu, sheep milk, cannot be supplied throughout the whole year. Due to the life cycle of sheep, the lactation is spread over two periods. One group of sheep is pregnant in November, which is from then on starting the lactation cycle. The other group of sheep is pregnant in April, which will be lactating until the end of August[7]. This

[5] Kaart van Sardinie. Information retrieved on 06-10-2017 from www.sardinie.be.
[6] Oral source retrieved on 04-10-2017. Nino Feis in name of Caseificio San Pasquale, Nulvi, Italy.
[7] Oral source retrieved on 02-10-2017. Paolo Rosatelli in name of LAORE-Agenzia regionale per lo sviluppo in agricoltura, Sassari, Italy.

results in a stop of the supply of sheep milk in the months September, October and November, when no new cheese is manufactured[8].

The summer months give good potential to a lot of festivities and celebrations for taking place. A gathering with family and friends makes a nice occasion for sharing Casu Marzu accompanied with a good glass of Cannonau, typical red wine from Sardinia. The cheese is often offered as a gift among acquaintances.

2.2.Production process of Casu Marzu

The manufacturing process of Casu Marzu can differ strongly, which can result in differentiating safety and product characteristics. Casu Marzu is made of a cheese from sheep milk and is left for the access of flies. It does not have to be a particular kind of sheep milk cheese and can be a cheese, which is left over from the normal cheese production and left the cheese manufacturing site and thus the food business operator's (named FBO hereinafter) control. In the past, the herds made their own cheese at home right after milking. In this paragraph, a flow-chart renders the production process of Casu Marzu (see figure 2). Noteworthy here is that due to its illegality the production of Casu Marzu is not monitored and can vary in ways of production parameters and raw materials.

Legenda flowchart:

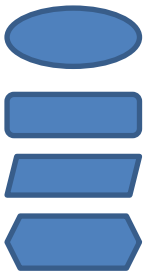


Figure 2 Casu Marzu (Source: Entomology department of Sassari University)

[8] Oral source retrieved on 04-10-2017. Nino Feis in name of Caseificio San Pasquale, Nulvi, Italy.


Milk from Sardinian sheep
Rennet (mostly ovine origin)
Coagulating
T= 34°C
Measures= size of rice
Pressing
t = 12 min.
Hardening
t = 12 min.
Cooking
T = 30 - 41°C
t = 1 – 5 min.
Putting curd in the mold
Salting
Be= 20%
t = 1 day
Maturing
t = 60 days (for 1,5 kG)
t = 12 (for 5 kG)
T = 20°C
Eggs of Piophila casei
Leaving in open air
Casu Marzu

9

The last step made by man in the process towards Casu Marzu, is to leave the cheese in freedom and let nature do its work. Much weight to objections for the cheese is obtained at this stage. The lack of traceability of the provider of the last ingredient, the fly *Piophila casei*, raises health concerns by the authorities. More detailed information on the harmful effects of *Piophila casei* will be given in chapter *4. Injurious to health*.

2.3.Pecorino Sardo

The start of Casu Marzu is producing a Pecorino Sardo, which is a cheese solely made of sheep milk originating from Sardinia. The name Pecorino Sardo is protected since 1996 as Regulation (EC) No. 1263/96 entered into force[10]. This regulation confirms the first application for the protection of the name, whereas a description of the product is included. The product is defined as a cheese made of whole sheep's milk, obtained by heating the curd up to 47°C-48°C. The cheese is cylindrical shaped and the mass is soft and elastic. The unique characteristic of this cheese is that the sheep, whereof the milk is obtained, have a broad plant variety to their access functioning as feed. The feed for the sheep contains for a great part these plants and less than half of the feed is given supplemental. The sheep eat and select the plants themselves, thus for a big share the feed is not monitored[11]. This variety in plants is typical for the island and therefore the autonomic region of Sardinia is defined as the geographical area for the origin of the product[12],[13],[14].

Pecorino Sardo is divided in two classes: Pecorino Sardo Dolce and Pecorino Sardo Maturo. In the product description is written that the curd of Dolce shall have the size of hazelnut whereas the curd of Maturo shall have the size of rice. This is from great influence on the taste in a later phase. When the curd is cut smaller and the curd is more broken, it leaves more possibility for cheese to lose lactose and become dryer. The more lactose a cheese contains the softer and sweeter it tastes. The Pecorino Sardo Dolce shall be matured between 20 and 60

[9] Several producers of Casu Marzu of which the identity cannot be given. *Scheda Tecnologica per rilevamento dei dati relative alla fabbricazione*. Information retrieved on 02-10-2017 as given by Paolo Rosatelli.
[10] Commission for the European Union. 1996. Regulation (EC) No 1263/96 of 1 July 1996 supplementing the Annex to Regulation (EC) No 1107/96 on the registration of geographical indications and designations of origin under the procedure laid down in Article 17 of Regulation (EEC) No 2081/92.
[11] Oral source retrieved on 02-10-2017. Paolo Rosatelli in name of LAORE-Agenzia regionale per lo sviluppo in agricoltura, Sassari, Italy.
[12] Associazione Produttori Pecorino Sardo. 1995. *Application for registration PDO - EEC No 6 IT/00018/930825.*
[13] Consorzio per la Tutela del Formaggio Pecorino Sardo for European Commission. 2010. *Amendment application according to Article 9 'PECORINO SARDO' EC No: IT-PDO-0117-0018-21.12.2000.*
[14] Consorzio per la Tutela del Formaggio Pecorino Sardo for European Commission. 2013. *Amendment application according to Article 9 'PECORINO SARDO' EC No: IT-PDO-0217-01127-04.07.2013.*

days, where the maturing step for Maturo takes more than 2 months. For the production of Casu Marzu, it is not preferable to leave a too matured Pecorino for the access of *Piophila casei*. When the cheese mass becomes too dry and too hard, it diminishes the good conditions for the larvae to develop and live.

2.4.Piophila casei

The last ingredient for the Casu Marzu is delivered by the fly *Piophila casei*, who lays her eggs in the Pecorino. This fly belongs to the Diptera class and Piophilidae family and is attracted by cheese and other dairy products. The appearance of this fly is similar to the well-known domestic fly, but smaller and slimmer (see figure 3). In its optimal living environment with relative humidity of 60% and temperature of 25°C the whole life cycle would be completed in 20 days. The stage of the larvae would take approximately 5 days, but can differ on environmental features. *Piophila casei* can stand cold temperatures even under zero and can tolerate upper temperatures up to 50°C. At this upper temperature, the life cycle will be accelerated and its life span is much shorter. For the larvae, this upper temperature can be fatal and they will not develop themselves anymore[15]. At lower temperatures than the optimal one, the development in the life cycle is decreased and the insect has to put in more energy and effort to develop itself into the next stage.

Figure 3 *Piophila casei* fly (Source: Entomology department of Sassari University)

The fly lays her eggs in the respective cheese and the eggs transform into larvae, who digests the cheese mass. For transforming cheese mass into 1 kG of Casu Marzu, 40.000 larvae need to be hosted in the cheese, for the cheese to be totally and homogenously ingested and fermented. For reaching this objective, the cheese should be free for access to 130 female *Piophila casei* on average to lay their eggs[16]. The access to the cheese will be easier for the fly in case the cheese has some irregularities and holes. The fly can access the cheese more to the internal side and lays her eggs there. Also for the larvae, in the internal of the cheese it is easier to find their way through the cheese instead of living on the crust, which is harder to digest for the larvae. The larvae need oxygen to live optimally and for that reason it is more preferable to have irregularities. These irregularities can be obtained by lactic acid bacteria

[15] E. M. Hegazfi, H. El-Gayari, A. Rawash and S. A. Ali. 1978. *Factors affecting the bionomics of Piophila casei (L.).*

[16] Oral source retrieved on 29-09-2017. Professor Andrea Lentini for Department of Entomology of University of Sassari.

(named LAB hereinafter) producing carbon dioxide[17]. In chapter *4. Injurious to health* more information on this process and these bacteria will be given.

2.5.Sensory attributes

Casu Marzu does not only have remarkable raw materials, but has remarkable sensory attributes as well. There are several sensory attributes, which together influences how the foodstuff is experienced by humans. These sensory attributes are channelled through sensory faculties for humans to receive and absorb the characteristics of the particular foodstuff. Mankind has five sensory faculties available; to see, to smell, to hear, to feel, to taste. Eyes are used for seeing the appearance of food, which is often used as a predetermination if food looks appealing at first sight. Colours of food can play an important role in this process. Then the nose helps the human body to receive the smell of a product, which is formed by volatiles[18]. The hearing occurs via ears, although the ears do not have a great influence on how the food is received, the ears can sometimes hear the texture. In some cases, with crunchy products for instance, the texture can be heard by the ears. Food enters the human body through the mouth where the last two sensory faculties occur; feeling and tasting, whereas the latter one happens with the tongue specifically[19]. The whole mouth can feel if the product has a velvety texture or rough texture. The tongue has the ability to taste five different flavours, namely bitter in the back of the tongue, sweet in front, sour on the back sides, salt on the front sides and umami all over the tongue[20].

Casu Marzu can be distinguished by its strong smell and strong taste. Witnesses even describes the mouth feeling as strong, since the cheese forms a film on the tongue and therefore makes the taste lasting for a long time. Like all cheeses made from sheep milk, Casu Marzu has a salty character. The raw material larvae of *Piophila casei* gives a great contribution to the sensory attributes. Due to the ingestion of the cheese by the larvae, intrinsic enzymes of the insects break down lipids and protein in the Casu Marzu, which gives much more complex taste in return. Besides the contribution to the strong taste, the larvae also contributes to a major metamorphose in the texture of the cheese. Whereas a matured cheese normally gets more viscous in structure, Casu Marzu gets even more softened. This is declarable by the ingestion by the larvae, of which the intestinal tract transforms the cheese

[17] Oral source retrieved on 29-09-2017. Professor Nicoletta Mangia for Department of Microbiology of University of Sassari.
[18] M. Bergamaschi. 2016. *Volatile organic compounds in cheese production chain*.
[19] P.A. Luning & W. J. Marcelis. 2015. *Food quality management – Technological and managerial principles and practices*.
[20] NewScientist. 2000. *Vijfde smaak ontdekt*. Retrieved on 06-11-2017 from https://newscientist.nl/nieuws/vijfde-smaak-ontdekt/

into a softened substance. This process breaks down the structure of the cheese in such way that the product becomes spreadable[21]. This process is part of proteolysis and lipolysis, on which more detailed information will be given in chapter 4. *Injurious to health*.

2.6.Objections to market Casu Marzu

Currently, many objection towards Casu Marzu as food product persist. Many bloggers and news sites are writing about the adventurous experience with Casu Marzu. All stating that the European Commission banned the cheese from being placed on the market as food[22],[23]. However, in the reaction of Europe Direct[24] it seems that the European Commission does not mingle that much in the discussion whether to prohibit the marketing of Casu Marzu or not. The answer holds that Casu Marzu is listed as traditional Italian product, but does not deliberate on the legal status as food product within EU. One may notice the exploitation of the sovereignty principle in this answer. The sovereignty principle holds that each Member State should be able to govern its own and should be able to make objections to any act governed by the EU. In this case, the European Commission will stand by the decision of the Member State, Italy. Food law is established at Union level and Member States have to comply, but will not stress that much if a Member State goes beyond and being stricter upon some products from its own territory. It may be the case with Casu Marzu, that also the principle mutual recognition is used, but in the negative sense. The principle of mutual recognition holds that when a product is considered safe in one country, it shall be recognised as safe in any Member State[25]. When the product is unsafe and not allowed to be placed on the market within the jurisdiction of the own Member State, than it is also unsafe for other Member States and shall not be placed on the market.

For already a couple of years, Casu Marzu is officially listed as a traditional food product from the autonomic region of Sardinia in the category cheese[26]. Nevertheless, recognising a product being traditional is not the same as recognising that a product is in compliance with

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[21] Regione autonoma della Sardegna, assessorato dell'agricoltura e riforma agro-pastorale. N.d. *Prodotto tradizionale della Sardegna-Casu frazigu, formaggi*.

[22] Information retrieved on 17-07-2017 from http://www.express.co.uk/travel/articles/662167/cheese-maggots-illegal-sardinia-video

[23] Information retrieved on 18-07-2017 from http://www.foodqualitynews.com/Regulation-and-safety/Banned-foods-USA-vs-European-Union/(page)/1

[24] Europe Direct Contact Centre. Mail received on 26-10-2017. *Reference No. 101000212591*.

[25] H. Lelieveldt & S. Princen. 2015. *The politics of the European Union*.

[26] Ministero delle politiche agricole alimentari e forestali for Italy. 2015. *Quindicesima revision dell'elenco nazionale dei prodotti agroalimentari tradizionali in attuazione dell'art. 3, comma 3, del decreto ministriale 8 settembre 1999, n.350.*

article 5 of national food law and is, in that respect, legal to place on the market[27]. According to Professor Deiana of the Università degli studi de Sassari this article discusses the prohibition of the commercialisation of certain food products. Consuming a product is not the same as commercialising it and falls outside the scope of this article. This article does not prohibit production and consumption at domestic level[28].

Also in the Member State the Netherlands, objections towards Casu Marzu exist. In 2013, Casu Marzu was confiscated by the Dutch food safety authority (named NVWA hereinafter) at a food fair. After one day of being exposed to visitors of the food fair, the food product was taken by inspectors of the national competent authority. Exhibitioners were only allowed to show one sample of the product at the fair and were not allowed to offer the product as food anymore[29].

Due to a large supply of sheep milk on the hilly island Sardinia, many dairy products are produced from sheep milk, such as Casu Marzu. This cheese does not solely consist of milk, but contains living larvae as well and has strong sensory attributes. The larvae develops from the eggs of the fly *Piophila casei* and has accessed the cheese naturally. Although Casu Marzu is listed as a traditional food product, it is prohibited to sell Casu Marzu according to article 5 of national Italian food law.

[27] La Camera dei deputati ed il Senato della Repubblica for the Repubblica Italiana. *Legge 283 del 30 aprile del 1962 Disciplina igienica della produzione e della vendita delle sostanze alimentari e delle bevande*. Article 5.
[28] Giulio Brescia. 2016. *Casu marzu, un formaggio pericoloso… in attesa del marchio Dop*.
[29] EditieNL for RTLnieuws. 12-11-2013. *Kaas van madenpoep in beslag genomen (Engl.: Cheese of maggot poop confiscated).*

3. Unsafe according to article 14 of Regulation (EC) No 178/2002

In this chapter, a legal background in relation with Casu Marzu is given and the definitions of precautionary principle and burden of proof are explained. This chapter will provide guidance for understanding the following chapters more clearly. Important to note here, is that the EU has shared competence with regards to common safety concerns in public health matters and the internal market. To this extend, FBOs in Italy have to comply with Italian law and EU-law regarding food safety issues. However, the emphasis in this chapter will be on EU-food law.

3.1.Legal background

3.1.1 Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

The general objectives of this regulation are pursuing high level of protection for human health and life on one side and free movement of food on the other side. Furthermore, protection of consumers' interest is aimed with this Regulation, as well as it seems to be in the middle of both objectives. These objectives may also be contributing to the protection of consumers' interest. The general objectives already resembles complexity, noticeable on the controversial objectives standing in negative relationship. In many cases, it has shown that striving for one objective will jeopardise the other one. It is a tough job in achieving both at an equal level. Allowing Casu Marzu to be placed on the market can contribute to consumers' interest as in free movement of food, because there is demand for the product and consumers should be free to make choices. On the other hand, this could breach the protection for human health and life if Casu Marzu is deemed unsafe. Therefore it is important that with the help of law, a balance between the two objectives is sought.

Casu Marzu can fall under the definition of food, which is a condition for falling in the scope of this regulation. Casu Marzu contains living larvae and living animals are normally not considered as food as described in article 2. However, living animals can be seen as food when they are prepared for placing on the market. When Casu Marzu and more specifically the living larvae are prepared for placing on the market, Casu Marzu can be seen as food product.

This regulation shall apply, since it shall apply to all stages of production, processing and distribution of food and feed. Thus, unless Casu Marzu is made at home from raw milk on for own use and no further trade occurred, Casu Marzu falls under the obligations of EU food law. Exchanging or giving Casu Marzu in exchange for another foodstuff outside the private domestic environment would fall within the meaning of placing on the market. Placing on the market is described as any way of transferring food or feed for the purpose of sale, which can also occur without any charges. According to article 14(1) of this regulation, food shall not be placed on the market if it is unsafe. Casu Marzu, which is not made for private domestic use, may not exist when the product is deemed unsafe[30].

3.1.2. Regulation 852/2004 on the hygiene of foodstuffs

In this regulation, rules for official controls, registration, approval and guidance to good practices are laid down. Besides, the obligations for the food business operators are described, such as ensuring that the food under their control is satisfying the relevant hygiene requirements, referring to microbiological criteria and hazard analysis and critical control points. In the annexes of the regulation, rules are laid down on the establishments of the food business operators[31].

A shift has taken place with regards to food law, also for legal approach towards milk-products. In the past, milk and milk products was one of the first categories in food regulated by Directive (EEC) No 85/397 first and Directive (EEC) No 92/46 later on[32],[33]. It was the recognition of the necessity for a farm-to-fork approach, which resulted in the White Paper on food safety, that elevated the need for a horizontal approach in law-making rather than vertical. This means that laws are more designed in general requirements, which are applicable to a broad range of foodstuffs instead of laying down specific measures focused on one food category. As a result, the hygiene regulations are designed in order to cover all sorts of foodstuffs in general. Furthermore, these legislative acts in the past concerned directives,

[30] European Parliament and Council for the European Union. 2002. *Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*. Article 1, 2, 3 of Chapter I, article 14 of Chapter II.
[31] European Parliament and Council for the European Union. 2004. *Regulation (EC) No 852/2004 on the hygiene of foodstuffs.*
[32] Council for the European Economic Communities. 1985. *Directive 85/397/EEC on health and animal-health problems affecting intra-Community trade in heat-treated milk.*
[33] Council for the European Economic Communities. 1992. *Directive 92/46/EEC laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products.*

which first have to be implemented by every Member State. On the contrary, regulations, which are now mostly put in place in food law, are directly applicable[34].

In the case of Casu Marzu, one can state that the food product, as produced in artisanal way, is not fully conform hygiene requirements and therefore not compliant to this regulation. In case it is wanted to place Casu Marzu on the market, the food business operator shall comply to this regulation. Hygienic design of premises and equipment and the ability of cleaning thereof can be disputable, pending on different FBOs. However, every Casu Marzu is left to the natural access of the fly *Piophila casei*, which is not in accordance to paragraph 1(d) of Chapter II in Annex II of this regulation.

3.1.3. Regulation 853/2004 laying down specific rules for on the hygiene of foodstuffs

The regulation mentioned above is destined for food in general, whereas this regulation is specifically designed for the hygiene of foodstuffs originating from animals. The regulation sets rules on marking of animals and documentation. In annex I, definitions are given for several foodstuffs of animal origin. In annex II section IX, requirements are laid down for raw milk and dairy products.

The scope of this regulation is slightly differentiating from the scope of the GFL. When having regards to article 1, one can state that placing on the market of Casu Marzu falls in the scope of this regulation. However, in this regulations it is stressed that it shall not apply to direct supply of primary products from producer to final consumer. Primary products are defined as products that derive from primary production. In paragraph 3.1.1. one can read that production process of Casu marzu does not fall within the definition of primary production, so Casu Marzu is not a primary product. As a result, Casu Marzu cannot fall under the exceptions for applying to this regulation and the previous one.

Having regards to Casu Marzu, the FBO has to comply to the requirements specified in the annexes. For example, the temperature of the milk shall be kept equal or lower than 6°C. Nevertheless, as the milk is processed within 4 hours after milking, derogations on this requirement can be made. Derogations can also be made in case the or when the competent authority authorises a higher temperature for technical reasons for the manufacturing of the dairy product[35].

[34] H. Lelieveldt, S. Princen. 2015. *The politics of the European Union.*
[35] European Parliament and Council for the European Union. 2004. *Regulation (EC) No 853/2004 laying down specific hygiene rules for on the hygiene of foodstuffs.*

3.1.4. Regulation 2074/2005 laying down implementing measures for certain products under Regulation 853/2004

Derogations on hygiene obligations can be legally made under this regulation since 2005. As described in article 7, the right for leaving out the duty for complying to the hygiene regulation can be granted for traditional food by a Member State. Therefore ´food with traditional characteristics´ is defined in this article. Recognition under Regulation (EU) No 1151/2012[36] can be seen as protection of traditional food products by Community law as mentioned as third in article 7 of Regulation (EC) No 2074/2005. Furthermore, in the previous chapter *2. Casu Marzu* is described that the respective food product is recognised as traditional Italian product. This recognition can be a step closer to the chance of granting derogations under this EU Regulation by the Member State. However, uncertainty is still swaying the sceptre in the case of Casu Marzu.

The hygiene rules may derogate on the equipment and the room, where the product is manufactured. One can think of the design of floors, walls, ceilings, windows, doors and surfaces. When a Member State has granted the right for derogation on those hygiene rules, it has to notify the Commission and the other Member States within 1 year. This notification shall include a description of the requirements that have been adapted, a description of the food products and establishments and other relevant information[37]. In the case of Casu Marzu, derogations on the design of windows and doors would be helpful in order for the fly *Piophila casei* to have access to the cheese and to add the final ingredient for Casu Marzu.

3.1.5. Regulation (EU) No 2015/2283 on novel foods

The change in the novel food regulation has meant a shift in the approach toward insects in law. A food product can be defined as novel food when it is not significantly consumed within the EU before 15 May 1997 and when it falls within a specified category of food. In the former Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, only four categories were specified. In Regulation (EU) No 2015/2283 on novel foods, currently being in force, this number is elevated to ten categories. In the former novel food regulation, an insect-based product can be considered as food ingredients isolated from animals as discussed in category (e). Nevertheless, whole insects cannot fall within this category.

[36] European Parliament and Council for the European Union. 2012. *Regulation (EU) No 1151/2012 on quality schemes for agricultural products and foodstuffs*. Article 12, 13.

[37] European Commission for the European Union. 2005. *Regulation No 2074/2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004*.

Besides, it is not completely clear if the law-makers had taken insects into account with this regulation, when having regard to the recitals of the former novel food regulation. On the other hand, the current novel food regulation does take insects as food into account when having regard to recital 8. This recital explains that insects should be covered by the categories for the definition of novel food in order to keep up with the scientific and technological developments since 1997. Under this regulation, insects can fall within the definition of novel food via the category (v); food consisting of, isolated from or produced from animals or their part.

Regulation (EU) 2017/2470 establishing the Union list of novel foods, includes all the novel food products, which are authorised to be placed on the market within the EU. The Union list in the Annex of this regulation is a positive list, meaning that every product on the list can be marketed in the EU. However, the list exists of two tables and in the first table boundaries to the use of the novel food products can be set. One can think of maximum levels, defined food categories in which it may solely be used, labelling requirements or other requirements. In the second table, specifications on the novel food products are given.

Food products can be included in the Union list of novel foods via two ways: application for the authorisation of novel food or notification of traditional food from a third country. Whereas the notification of traditional food from a third country has to show history of safe use in a third country, the application has to show scientific evidence of the food not posing safety risk to human health. These procedures do not only differ on the content, also the timespan can differ strongly between the procedures. The notification procedure may be completed within 5 months, while the application procedure can take 17 months for completion.

Although Casu Marzu may fall within the definition of novel food, it cannot be seen as traditional food from a third country. Casu Marzu, a traditional food product, originates from the autonomous region Sardinia, which falls within the jurisdiction of Italy. Italy, being a Member State of the EU, cannot be seen as a third country. Casu Marzu can therefore not be included in the Union list of novel foods via a notification of traditional food from a third country.

Albeit Casu Marzu has been consumed significantly in Sardinia, one can state that Casu Marzu was not used for human consumption to a significant degree before 15 May 1997 when looking to the EU as a whole. For the second condition for falling under the term novel food, it would be more difficult to determine if it can fall within the definition. Two categories give

rise to doubts in light of Casu Marzu as novel food. The first category is ‘’food consisting of, isolated from or produced from animals or their parts etc.’’. With this category insects as a whole are considered with the addition of ‘’consisting of’’, however Casu Marzu as being the product does not solely consist of insects. Besides, Casu Marzu is not ‘’produced from animals’’, but produced with animals. This slightly difference in wording can result in that Casu Marzu does not fall under the definition of novel food. The second category is ‘’food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances’’. The production process of the fly laying her eggs in the cheese and the larvae to infest the cheese, can be seen as a process, which changes the structure of a food. Where the first condition uses the words; ‘’not used to a significant degree within the Union’’, this category just states ‘’not used’’. Casu Marzu is not consumed to a significant degree within the EU, nevertheless the production process is used earlier in Sardinia, so within the Union. Therefore Casu Marzu cannot fall under this category[38],[39].

Albeit Casu Marzu could not fall within the meaning of novel food, the recognition of whole insects as food in the current novel food regulation can be a step closer to the acceptance of food products like Casu Marzu. If larvae of *Piophila casei* specifically will be included in the Union list of novel foods, it is allowed to market these larvae as food product throughout the EU. Producers of Casu Marzu would be able to purchase the larvae as one of the ingredients of the food product. In this way the FBOs would be more able to fulfil the obligation of traceability as described in article 18 of GFL. Monitoring the production process and obtaining more harmonised production processes between different FBOs would be more convenient to achieve in this way.

3.1.6. Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs

In this regulation, microbial criteria for foodstuffs are laid down and as Casu Marzu falls within the scope of Regulation 852/2004 it falls in the scope of this regulation as well. Within this regulation, criteria are divided in two classes: food safety criteria and process hygiene criteria. Food safety criteria are set to define the acceptability for the food product being

[38] European Parliament and Council for the European Union. 2015. *Regulation (EU) 2015/2283 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001*. Recital 8, paragraph 2 of article 3, articles 10, 11, 12, 14, 15, 17, 18, 19.

[39] Commission for the European Union. 2017. *Regulation (EU) 2017/2470 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods*. Article 1, Annex.

placed on the market. Process hygiene criteria are defined as criteria, which indicate if the production process is functioning acceptable. Article 3 of this regulation says that FBOs shall ensure that foodstuffs comply to both kinds of criteria. In case incompliance with process hygiene criteria occurs, further actions should be followed up by the FBO. These actions can be improving the production process or carrying out other tests. This does not mean that products with unsatisfying results cannot be placed on the market. Nevertheless, it helps FBOs indicating the necessity for corrective actions in order to comply with food law. On the other hand, incompliance with safety criteria shall result in a recall of the product or of the batch with foodstuffs as described in article 7 of this regulation. Both kinds of criteria are laid down in Annex I.

Besides the criteria, also the foodstuffs are categorised in this annex. For knowing what to test for, one has to know the product and its production process well. Products from raw milk induce other hazards than that pasteurised products do. Some tests would be necessary for determining the safety of one products, but would be useless for other products. In Chapter I of Annex I of this regulation, two food safety criteria for two different food categories are applicable to cheese[40]. In the chapter 4. *Injurious to healh*, these criteria are applied in detail in the case of Casu Marzu.

3.1.7. Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs

Food products may not be placed on the market in case it exceeds the levels set for contaminants in the annex of this regulation. The maximum levels are laid down with respect to specific groups of food products. Furthermore, the levels categorised per contaminant group and the specific contaminant. The contaminants discussed in this regulation reflect chemical or biochemical hazards. Article 3 of this regulation stresses the prohibition of the use of foodstuffs, which exceeds limits, and thus the foodstuff shall not be put in place as an ingredient of a food product. Additionally, foodstuffs with too high values of certain contaminants may not be mixed with other foodstuffs, which do comply to this regulation.

When looking to the product Casu Marzu, this regulation is applicable, since the product falls within the groups of food products ‘milk for the manufacture of milk-based products’ and ‘dairy products’. The limits set for these groups of food products concerns the contaminants aflatoxin, lead and 3-monochloropropane-1,2-diol. Nevertheless, no data is available on the

[40] Commission for the European Union. 2005. *Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs*. Articles 1, 2, 3, 7, Annex I.

occurrence of these contaminants in Casu Marzu, therefore compliance with these limits cannot be checked in this research[41].

3.2.Unsafe

The term *unsafe* is defined in article 14 of GFL and it is divided in two classes; injurious to health and unfit for human consumption. The legal term *unsafe*, described in GFL, might be slightly different from the term, which the average consumer uses. The legal definition not only sees unsafe as a harmful effect on health but also unfavourable substances falling outside the measureable field. The first class can be seen as the measureable factor, which can be assessed in risk assessment. Risk assessment can be resulting in setting rules in order to prevent any harm on human health. Hereby the definition 'injurious to health' can be delimited and the meaning thereof is clear.

The second class, however, can be experienced as less measureable than the first one. On the definition of unfit for human consumption, the following is said in article 14 of GFL: 'In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.' This definition may seem logic, but the characteristics, on which the definition is pending, are quite hard to measure. When humans fail to measure characteristics, perception is put in place. However, from different cultures originate different consumers, having different perceptions. In such open definitions, like unfit for human consumption, different interpretations can be given to those definitions. Europe is known as a continent existing of plenty mini-cultures. The definition of unfit for human consumption can be interpreted in several manners, which can result in differentiating enforcement of law, considering a foodstuff unsafe or not.

Although both injurious to health and unfit for human consumption fall within the meaning of unsafe, it cannot be seen as the same or as indissoluble. In article 19 of GFL one can take notice of this, where both definitions explicitly are named in two different paragraphs. In the first one where FBOs have to recall the product in case it is found injurious to health and in the second where FBOs have to withdraw from the market as the product is found unfit. This is a clear example that both definition leads to the determination of unsafe food, but cannot be handled as one and the same.

[41] Commission for the European Union. 2006. *Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs*. Articles 1, 3, Annex.

Another contrasting fact in this regulation can be found in article 5 thereof. This article states that food law shall be based on risk analysis, wherein risk assessment can be seen as the starting point. Risk assessment, on its turn, shall be based on scientific evidence, which has to be undertaken in an objective manner. Imagining, assessing perception and wide definitions in an objective manner would be a tough task.

Article 14(7) describes that food shall be deemed safe when it complies to specific EU-law insofar EU-law reaches. When specific provisions are lacking for the food product, it shall be deemed safe when it complies to the national law where the product is marketed. With Casu Marzu that would be Italian law at first moment[42]. This is already a burden for the marketing of Casu Marzu, since Italian law prohibits the selling of this product. Furthermore, sometimes Casu Marzu is made in situations, which are not fully compliant with hygiene regulations like Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004. This implicates that Casu Marzu does not comply to specific EU-law and therefore cannot be deemed safe.

3.3.Precautionary principle

‘’*Lack of evidence of harm is not the same as evidence of lack of harm.’’* (Stirling, 2013)

This citation tends to express that uncertainty shall not be denied, that if the evidence of the harm is missing partially it does not mean that potential harm does not exist. Precautionary principle holds decision-making to take measures seeming a necessity to diminish the possible risk without waiting on the development in science so that information on the risk is conclusive. The roots of the precautionary principle in politics can be found in the Rio Declaration adopted by the United Nations in 1992. In principle 15 thereof it was stated that States shall apply a precautionary approach for protecting the environment[43]. For the years coming, the precautionary principle was discussed solely in light of environmental issues.

The establishment of the World Trade Organisation (named WTO hereinafter) can be seen as a turning point in the application of the precautionary principle. When the WTO was established in 1995, the Agreement on the application of sanitary and phytosanitary measures came into force. Although the principle is not mentioned explicitly in this Agreement, it is discussed in paragraph 7 of article 5, saying that measures may be taken by a Member where relevant scientific evidence is insufficient yet. When looking back to article 2 of this Agreement, such measures may be taken for the protection of human, animal, plant life or

[42] European Parliament and Council for the European Union. 2002. *Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*. Paragraph 7, 9 of article 14.

[43] The United Nations Conference on Environment and Development for the United Nations. 1992. *The Rio Declaration on environment and development*.

health[44]. So with this Agreement, WTO already extends application of the precautionary principle to other fields outside the environmental field. Also within the European Union (named EU hereinafter) the precautionary principle firstly was only subject to environmental matters. The principle was solely covered in both the Treaty on the European Union article 174 and in Treaty on the Functioning of the European Union when it comes to environmental issues[45],[46]. However, the European Commission explains that it shall be applied in much more fields than only the environmental one.

A motive for the European Commission for applying the precautionary principle is nowadays' speed in communication diverged via several new channels. It has become more realistic that sensitivity to new risks by the public is augmented before science was even able to completely clear up the information on the risk. Therefore decision-makers shall have regard to these risk perceptions from the public and take preventive measures[47]. Here, precautionary principle can be seen as a tool in, as well as a result of risk communication.

In GFL, the precautionary principle is mentioned in article 7. When there is uncertainty in risk assessment, public authorities have to take measures out of precaution, in order to prevent any harm that is identified. Probably FBOs also have to deal with uncertainty in risk assessment. However the precautionary principle, as mentioned in article 7 of this regulation, is not addressed to FBOs[48]. Article 19 of this regulation, the responsibilities for food business operators are described. The precautionary approach towards the FBOs in this article can be seen in the first paragraph, which states that when a FBO has reason to believe that food is not in compliance with the food safety requirements shall initiate procedures to withdraw the food in question.

Where normally decisions are taken in risk management as a result of risk assessment, is in case of the precautionary principle decision-making even more in hands of risk managers. For instance, already making the decision whether or not to invoke this principle and in what way is solely on account of risk managers[49]. Some criticism argues that when political and economic forces are at stake, uncertainty in science is denied and so is the necessity for

[44] World Trade Organisation for all Members of World Trade Organisation. 1995. *Agreement on the application of sanitary and phytosanitary measures.*
[45] European Union for the European Union. 1997. *Treaty on European Union*.
[46] European Union for the European Union. 2012. *Treaty on the Functioning of the European Union.*
[47] European Commission for the European Union. 2000. *Communication from the Commission on the precautionary principle*.
[48] Bernd van der Meulen. 2014. *The core of European food law.*
[49] European Parliament and Council for the European Union. 2002. *Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*.

preventive measures. One tends to deliver scientific evidence rather than admitting uncertainty in order to avoid application of precautionary principle[50]

In risk management some general principles are set and these shall also be taken into account with invoking on the precautionary principle. The principles of non-discrimination, proportionality, consistency, the examination of benefits and costs of action and lack of action and the examination of scientific developments shall also be taken into account when considering preventive measures.

In the case of Casu Marzu, one cannot provoke the precautionary principle as discussed in article 7 of this regulation. A condition for provoke the precautionary principle is the persistence of scientific uncertainty. Having a closer look at one of the hazards identified in chapter 4. *Injurious to health*, biogenic amines, no scientific uncertainty persists as there is no uncertainty on how to test for the biogenic amines. However, precautionary principle can be invoked if it is uncertain how to establish at what dose the biogenic pose a risk for human health, for example.

3.4.Burden of proof

The burden of proof in unsafe food is in hands of several parties. Concerning food law, the burden of proof for FBO is proving that the food that he places on the market is not unsafe and is complying with article 14 (1) of GFL. The burden of proof for the national competent authorities would be to show that food being placed on the market is unsafe and therefore not complying with the article mentioned above. The burden of proof is the required weight for bringing forward arguments in order to persuade the other party of your position[51]. When one party is suing another party, one has to carry the burden of proof in showing what the other has or not has done in fulfilling his legal duties. An example hereof can be found in cases, where the European Commission brings a Member State to prosecution, because of failure in complying with EU-law. At that point, the European Commission carries the burden of proof; it has to show proof of the failure[52].

The burden of proof seems to become smaller for the competent authorities, since they have competencies in taking actions in order to achieve the general objectives of the GFL according to article 17 (2) thereof. These actions can hold informing the public on the risk that a food product may pose. Article 17 (2) states that the competent authorities shall take action

[50] Andy Stirling (for the Guardian). 08-07-2013. *Why the precautionary principle matters*.
[51] Douglas N. Walton. 1988. *Burden of proof.*
[52] Court (Third Chamber) for the European Union. 2015. *Case C‑29/14 European Commission v Republic of Poland.*

in order to enforce GFL. This can mean tending to achieve the general objectives of the GFL, such as high level of protection of human life and health, protection of consumers' interest, and even free movement of goods in the EU. Communication is one of the actions falling within this meaning. Thus looking to article 17, it is not a matter of having the right, but it is a matter of having the duty. Article 10 GFL, says that an authority has the right to inform the public on risks in case it is suspected that the product may pose a risk for human or animal health[53]. Whereas article 10 describes the competence of the competent authority, article 17 describes the obligation of the competent authority. Both articles can relate to the communication towards the public, but according the first article mentioned, the competent authority may inform the public and the latter article can be interpreted as shall inform the public. Besides, in article 10 it does not have to concern exclusively risk to health, as words as 'reason to suspect' and 'may present' are used in describing the conditions for the right to inform. For the competent authorities gives this wording more freedom in their reason to take action. The burden of proof for the competent authorities is smaller in taking such preventive measures.

Another example of a smaller burden of proof on the competent authority's side can be found in article 14 (8) of GFL. Here the right is given to competent authorities to take actions, such as imposing restrictions on placing on the market or requiring withdrawals from market. This right can be put in place when the competent authorities have reason to suspect that the food is unsafe, despite its conformity with specific provisions. So when the burden of proof on the FBO's side is fulfilled in showing the compliance with all respective food law, this proof can be subverted as yet by the suspicion of the competent authority.

Since the recognition of the increasing innovation and therewith the development of new products, also food products, the burden of proof has shifted. This recognition was the cause for the awareness of the importance for designing new legislation. This has been leading to Regulation (EC) No 258/97 on novel foods and novel food ingredients. From 15 May 1997 on every food not being placed on the market to a significant degree within the EU before this date shall pass an approval procedure first[54],[55]. The fact that a FBO, being applicant in this

[53] European Parliament and Council for the European Union. 2002. *Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*.
[54] European Parliament and Council for the European Union. 1997. *Regulation (EC) No 258/1997 on novel foods.*
[55] European Parliament and Council for the European Union. 2015. *Regulation (EU) No 2015/2283 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing*

situation, has to give evidence that their product is not unsafe, means that the burden of proof is on the side of the respective FBO. If it wants its product marketed in the EU, it shall show it is safe. Before the implementation of this regulation, all food was deemed to be safe in the first place and were allowed to be placed on the market without presenting first the history of safe use. In the past, this history of safe use had been showed by the experiences in the past and not with a particular risk assessment. Casu Marzu has not been showing adverse health effects and it can therefore be considered as history of safe use. Unfortunately, no record-keeping has been conducted regarding history of safe use. However this would be very contradicting, as the product has been having an illegal status and any recording of history of safe use, would be proof of incompliance to food law.

Another example of burden of proof in food law can be found in traceability. According to article 18 (2) of GFL the FBO should be able to archive records on its suppliers and also on its customers and should made those records available on demand of the competent authority. The burden of proof of traceability has to be carried by the FBO in order for the competent authority to be able to take appropriate measures. In the current situation in the production process of Casu Marzu, the FBO would not be able to fulfil the obligation of traceability. FBO do not know where all of the raw materials are originating from, in particular the larvae of *Piophila casei.* When the FBO is able to use reared *Piophila casei*, which are properly labelled, the traceability can be correctly fulfilled. Only then, FBO can carry the burden of proof in showing traceability data to the competent authority.

At the time of applying for a Protection of Designated Orginin (named PDO hereinafter), the group of producers carry the burden of proof in showing that the product deserves this status. The burden of proof in this example holds to show compliance with the following characteristics: the product originates from the specific area, the quality and the characteristics of the product is due to the geographical environment of that area and that the whole production of the product occurs in that geographical area[56]. Comitato promotore ‘’DOP formaggio marcio di Sardegna’’ started a project in order to make an application for the status of Protection of Designated Origin. The objectives of this project were to investigate and to standardise the production processes, to recognise and to structure the critical points of hygiene in the production and to investigate the demand for Casu Marzu. Getting closer to

Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.

[56] Council for the European Union. 2006. *Regulation (EC) No 510/2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs*. Article 2.

recognition of Casu Marzu and legalising the food product was not the only intention for the committee to start the project. The committee's intention was to standardise the production, with setting production and product requirements, and above all, setting hygienic measures to improve the safety of the product[57]. The nowadays' illegal status of Casu Marzu has seemed to be the greatest safety issue, since there is no control. In an environment where no requirements are laid down and there is no monitoring of the processing and product, diversity in products can occur. This is the case with Casu Marzu, the product is currently produced in several ways and is produced randomly. Due to the illegality of the product, but the existing demand for the product, consumers cannot rely on a consistent quality and with that safety of the product.

In case it is desirable to place Casu Marzu on the market within EU, the product and its production have to comply with several food law. The law applicable at EU-level concerns:

- **Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;**
- **Regulation (EC) No 852/2004 on the hygiene of foodstuffs;**
- **Regulation (EC) No 853/2004 on laying down specific hygiene rules for food of animal origin;**
- **Regulation 2074/2005 laying down implementing measures for certain products under Regulation 853/2004;**
- **Regulation (EU) 2015/2283 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001;**
- **Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs;**
- **Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs.**

Lack of data, as often occurs in the case of Casu Marzu, cannot be put forward as an argument to provoke the precautionary principle as discussed in article 7 of GFL. It can be invoked when it is uncertain how an hazard must be assessed. The burden of proof seems to have been shifted more to the side of FBOs and less to the competent authorities, having regard to all competencies of these authorities and the novel food regulation. The burden of proof in traceability would be difficult to fulfil for FBOs of

[57] Comitato promotore ''DOP formaggio marcio di Sardegna''. 2004. *Relazione tecnica illustrative del progetto – descrizione del progetto*.

Casu Marzu, since the origin of one of the raw materials is unknown and hard to monitor in the current situation. Nowadays, there are no requirements on Casu Marzu and the production thereof is not monitored. Therefore, the diversity of Casu Marzu is high and the product can differ massively.

4. Injurious to health

Injurious to health is the first part of the definition *unsafe* in article 14 of GFL and will be explained in this chapter. Afterwards an insight will be given on the potential health benefits and health risks related to the consumption of Casu Marzu. Due to a lack of risk assessment on the product as foodstuff, a comparison will follow of several food products, which are generally recognised as safe. Characteristics of Casu Marzu, which are disputable in their safety to human, are linked in this comparison to those of other food products considered safe for humans.

4.1.Injurious to health

Injurious to health is specified in three divisions in article 14 (4), which all should cover the meaning of the definition. This paragraph is laid down that a product does not have to fit all the conditions mentioned in this paragraph. It means that if a product fits one or more of these divisions, the product shall be determined as injurious to health.

The first division defining injurious to health embraces the overall adverse health effects and is referring to any adverse health effect. This division is pointing out on the fact that adverse health effects can occur in the human consuming the product, but also in generations following up the actual consumer relating to the consumption of food. This division of injurious to health stresses that this may not be left out of sight when having regard to food unsafety[58].

A noteworthy example of adverse health effects on subsequent generations is the synthetic oestrogen diethylstilbestrol (named DES hereinafter). DES has been posing not only high risks of breast cancer for the consumers, but also vaginal and cervix cancer, miscarriage, premature labour and infertility for the generation following up the consumer. For 33 years in 20th century, DES was prescribed to pregnant women in order to prevent miscarriage and premature labour. Nevertheless the opposite was reached, when between 5-10 million cases were reported with these consequences in subsequent generations.

It was found in the research to the injuriousness of DES that the synthetic oestrogen Bisphenol A (named BPA hereinafter) can also lead to detrimental consequences for human

[58] European Parliament and Council for the European Union. 2002. *Regulation (EU) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*. Article 14.4(a).

health over generations[59]. BPA is an elastomer, making plastic material softer and more flexible. Knowing this, a regulation in EU-law was devoted especially on the use of BPA in infant feeding bottles. Regulation (EU) No 321/2011 proscribes the use of the respective substance in manufacturing infant feeding bottles[60]. Currently, legislative procedure is ongoing for stricter regulations on the use of BPA in food contact material in general. The specific migration limit will be 12 times as strict as the current limit. For many years business-to-business pressure was already limiting the use of BPA in any form of food contact material. A reason for this could be the stricter national law from several Member States, like France which disallowed all uses of bisphenol in food contact material, not only for the focus group of infants or young children[61].

The second division relates to probable cumulative toxic effects. This division highlights that some substances may not have an immediate toxicity, but may pose a risk on health later on. These substances have the ability to accumulate in the human body and are harmless when present in small doses. However the accumulation in the body can result in an high dose of the substance and may cause harm at this stage.

Particularly in law concerning food contact materials, the cumulative toxic potential to the human body of certain substances is considered. In Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, is recognised that monomers and other small plastic substances can migrate from the main material into food. In this way, these substances are ingested by humans indirectly. Before 2011, only an overall migration limit was set, but also specific migration limits are affixed since the enforcement of this regulation. Business operators in plastic materials should only use articles allowed by Annex I and test on the potential for migration of the specific substances in their material towards the food that is packed in it[62].

The last division describes injurious to health with regards to sensitivities that can occur to the human body, but has displayed not to be occurring to every human. For this matter, this point

[59] Kavita Mistry. 2009. *Determining the effects of Desplex* in Yale Scientific. Retrieved from http://www.yalescientific.org/2009/02/determining-the-effects-of-desplex/

[60] European Commission for the European Union. 2011. *Regulation (EU) No 321/2011 amending Regulation (EU) No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles*.

[61] Joseph James Whitworth. 2017. *EU bans BPA in packaging for 0-3 year olds* in FoodQualityNews. Retrieved from https://www.foodqualitynews.com/Article/2017/10/10/European-Commission-tightens-bisphenol-A-regulation

[62] European Commission for the European Union. 2011. *Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food*. Article 5, article 11, article 12, annex I.

is referring to a specific category of consumers and not to the average consumer. Food sensitivities exist of food allergens, food intolerances and food aversions.

A clear example of this division of injurious to health can be found in not declared information concerning food allergens. Many recalls in nowadays' food industry can be derived from this division, having the default of missing information or wrongly declarations. This often occurs, as food products are packed in the wrong packaging or as the ingredient list is incomplete. When an ingredient can cause a food sensitivity, one can consider not to consume the food product containing that specific ingredient, if right informed by the packaging. This latter situation is discussed earlier in paragraph 3(b) of article 14, where it says that the provisioning of information towards the consumers should be taken into account in determining unsafety of food[63]. Not mentioning a specific kind of substance significantly triggering sensitivities, can be seen as a failure in the provisioning of this information. As a result, the specific group of consumers is not capable to avoid the respective food product. In more detail are the provisions in Regulation (EU) No 1169/2011 on the provision of food information to consumers. In article 9 of this regulation it is described what particles are obligatory to provide to consumers. The third point of this article emphasises the need for declaring any substances causing allergies or intolerances. These substances are named in Annex II of the regulation and shall be emphasised in the list of ingredients in accordance to article 21[64].

4.2.Health hazards of Casu Marzu

Risks can be seen as the probability of a hazard occurring. Hazards can be divided in four categories, like biological hazards, biochemical hazards, chemical hazards and physical hazards. For the first category, one can think of pathogenic micro-organisms, for the biochemical sort, one may think of proteins triggering an allergic reaction. Examples of the third sort of hazards are too high amounts of acrylamide or Polychlorinated Biphenyls, which can be derived from process contamination in the first example or environmental

[63] European Parliament and Council for the European Union. 2002. *Regulation (EU) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*. Article 14.4 (b) & (c), article 14.3 (b).

[64] European Parliament and Council for the European Union. 2011. *Regulation (EU) No 1169/2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004*. Article 9, article 21, annex II.

contamination in case of the latter. A piece of glass in a food product can pose a risk due to a physical hazard[65].

When looking to cheese, the potential of biological hazards is commonly present. Biological hazards are pathogenic bacteria, viruses and parasites. Cheese manufacturing requires fermentation and fermentation requires bacteria. Fermentation is the process where sugars are converted into other compounds. It is yeast in wort that convert sugar into alcohol and carbon dioxide, making it a beer[66]. Bacteria help mankind in creating tasty food products. It is for the LAB, making milk more viscous and transform the raw material into a smooth yoghurt. This is also through fermentation, the LAB, like *Lactobacillus delbrueckii* and *Streptococcus salivarius*, eat the lactose in the milk and produce lactic acid[67].

LAB, generally recognized as safe, play a key role during fermentation and ripening process of the cheese, in particular they have the ability to produce lactic acid during homo- or heterofermentative metabolism. Heterofermentative *Lactobacillus brevis*, *L. fermentum* and, under certain conditions also *L. plantarum* and *L. casei*, convert lactose into ethanol/acetic acid and carbon dioxide as by-products. The presence of carbon dioxide, making small holes in the cheese, together with several volatiles, which are contributing to the sensory attributes[68].

During the fermentation of cheese, the acidifying activity of LAB (for example L. lactis) limits the development of the acid-sensitive spoilage microflora and favors the activity of the rennet enzymes. All this has a direct positive influence on the microbiological and technological quality of cheese (for example on its structure). Moreover, *L. lactis* can produce different bacteriocins, which are peptide compounds active against many spoilage and potentially pathogenic microorganisms.

A study on Fiore Sardo cheese, a PDO cheese made from sheep milk, highlights the importance of mesophilic lactococci and lactobacilli in cheese-making processes that utilize raw ewe's milk. On the other hand, Fiore Sardo cheese showed a high number of

[65] P.A. Luning & W. J. Marcelis. 2015. *Food quality management – Technological and managerial principles and practices*.
[66] L. Alba-Lois and C. Segal-Kischinevzky. 2010. *Yeast fermentation and the making of beer and wine* from Beer & Wine Makers. Nature Education.
[67] H. McGee. 2006. *McGee on Food & Cooking: An Encyclopedia of Kitchen Science, History and Culture.* Nieuw Amsterdam uitgevers, Amsterdam. P. 58-60.
[68] N.P. Mangia, M.A. Murgia, G. Garau, F. Fancello, P. Deiana. 2013. *Suitability of selected autochthonous lactic acid bacteria cultures for Pecorino Sardo Dolce cheese manufacturing: influence on microbial composition, nutritional value and sensory attributes*.

autochthonous LAB in raw milk with a reduced number of spoilage microorganisms especially during the fermentative phase and the first part of the ripening[69].

Many LAB were detected in raw sheep milk, such as *Lactococcus lactis*, *Streptococcus thermophilus*, *Lactobacillus casei*, *Lactobacillus plantarum*, *Lactobacillus brevis*, *L. pentosus*, *Enterococcus spp.*, as dominating species. Furthemore, a range of pathogenic bacteria may be present in a raw milk, one can think of coagulase-negative *Staphyloccus*, *Salmonella enterica*, *Escherichia* and *Listeria*. These bacteria are generally associated to the lack of good hygienic practices and have to be avoided in the end-product in the food industry. In order to minimise the risks on illness due to the consumption of cheese, measures on the maximum numbers of bacteria are set. As described in chapter *3. Unsafe according to article 14*, legislative acts are not destined for a particular product category anymore. Regulations are designed nowadays in a way that they are applicable for all kind of foodstuffs.

In Regulation (EC) No 2073/2005 microbiological criteria are set, also for product categories covering Casu Marzu. Cheeses, butter and cream from raw milk or milk that has undergone a lower heat treatment than pasteurisation should be tested on *Salmonella.* During the shelf-life of the product, this bacteria shall be absent in 25 grams of each of the 5 samples tested. Some cheeses made at a manufactory, which are pasteurised, are used as starter for making the Casu Marzu. Others can be made of Pecorino DOP, which is thermised instead of pasteurised[70]. Casu Marzu can also be made in artisanal way, where heat treatment in the production process does not reach pasteurisation. Considering the worst case scenario for the current situation, this criteria shall apply to Casu Marzu. Nevertheless, data on the absence of *Salmonella* in Casu Marzu is lacking. One should know if the production process includes pasteurisation, in order to be able to rule out tests, which are not necessary to conduct in order to achieve a high level of safety. *Salmonella* is killed when pasteurised, since the bacteria are killed at temperatures of 70°C within a minute[71]. In case Casu Marzu is produced from pasteurised cheese, one does not have to test for *Salmonella.* It must be mentioned again that the production process of Casu Marzu occurs in several ways.

Since Casu Marzu is considered a ready-to-eat product, the food safety criterion for *Listeria monocytogenes* must be met. This criterion sets a limit of 100 cfu/g on the bacteria during the

[69] N.P. Mangia, M.A. Murgia, G. Garau, M.G. Sanna, P. Deiana. 2008. *Influence of selected lab cultures on the evolution of free amino acids, free fatty acids and Fiore Sardo cheese microflora during the ripening.*
[70] Oral source retrieved on 04-10-2017. Nino Feis in name of Caseificio San Pasquale, Nulvi, Italy.
[71] Institute of Environmental Science and Research for New Zealand Food Safety Authority. 2001. *Data sheet – non-typhoid Salmonellae*.

shelf-life, and it shall be absent in 25 gram of product at the time the product leaves the producing FBO's immediate control.

Another food safety criteria for cheese is on Staphylococcal enterotoxins for which amounts of the coagulase-positive *Staphylococci* are exceeding 100.000 cfu/g. This food safety criteria is a result from incompliance with a process hygiene criterion. Regarding the process hygiene criteria for this matter, improvements in the production process should be made when the bacteria is in amounts higher than 10.000 cfu/g. The product should be tested at the point where the amount of the bacteria is expected to be at its highest amount. In a study to Fiore di Latte, an amount higher than the limit is found, however data on Staphylococcal enterotoxins in a sheep milk cheese is lacking.

Besides large numbers of several bacteria, biological hazards can result in another class of hazards as well, biochemical hazards. During fermentation in cheese-making, proteins and lipids are broken down in smaller particles during fermentation. As well milk indigenous bacteria as exogenous bacteria have the ability to catalyse proteolysis. Proteolysis is the hydrolysing process responsible for fragmenting proteins in smaller compounds, such as peptides and free amino acids. Casu Marzu is exposed to a second catabolic transformation of the free amino acids, named decarboxylation, which result in biogenic amines. Bacteria with aminoacyl decarboxylase activity, which are present in cheese, split the carboxyl group from the rest of the amino acid. The biogenic amines specifically found in Casu Marzu are histamine, tyramine, β-phenylethylamine, cadaverine, putrescine, spermine, spermidine and tryptamine[72].

From all the biogenic amines found in the cheese, cadaverine and putrescine can be transformed into nitrosamines with the help of nitrite, which are found carcinogenic. In order to understand the dose-response relationship between nitrosamines and carcinogenicity, a body weight should be determined. Considering that it is unlikely that Casu Marzu is eaten by infants and children under the age of 3 years and the biggest group of consumers is above 18 years old, a value of 70 kg is used for the body weight[73]. Although, no legal limit in EU-law is established for the occurrence of nitrosamines in food, a study found that carcinogenicity can be induced by *N*-nitrosodimethylamine (named NDMA hereinafter) starting from 0,01 mg/kg body weight per day. This makes a threshold of 0,7 mg intake of NDMA per day. This same

[72] G. Manca, A. Porcu, A. Ru, M. Salaris, M. A. Franco, E.P.L. De Santis. 2015. *Comparison of γ-Aminobutyric Acid and Biogenic Amine Content of Different types of Ewe's Milk Cheese Produced in Sardinia, Italy*.
[73] EFSA Scientific Committee for the European Food Safety Authority. 2012. *Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data.*

study affirms that the specific nitrosamine is found in dairy and cheese products in the range of 0,001-0,006 mg/kg[74]. Despite of the lacking figures of nitrosamines actually found in Casu Marzu itself, it can be written that the predecessors are present in the range of 63-4707 mg/kg for cadaverine and 83-1658 mg/kg for putrescine. These amines have to be converted with the help of nitrate to become nitrosamines. Important to note here, the strength of this metabolism is unknown and further calculations cannot be made in order to determine the actual number of NDMA in Casu Marzu.

Headaches, high blood pressure and hypertension can be caused by values of 25 mg tyramine[75]. These symptoms can also be induced after intakes of β-phenylethylamine. An average of 202,7 mg β-phenylethylamine was present in 1 kg Casu Marzu and the average was 1521,9 mg/kg for tyramine. For example, when eating a normal Pecorino Sardo PDO, this dose-response amount would be reached with eating more than 1,5 kg of the cheese. Looking to the average amount of tyramine tested in Casu Marzu, this level would be reached with the consumption of approximately 16,4 gram[76]. Important to note here, consumers, who take certain medicines (monoamine oxidase inhibitors to be precise), are much more vulnerable for this hazard in comparison to normal consumers.

Histamine intoxication can result in nausea, sweating, headache, hyper- and hypotension[77]. These symptoms are similarly to the symptoms of an allergic reaction. This is no coincidence, since histamine is also released after mast cell degranulation in the human body in response of an oversensitivity for a certain substance. The similarity in symptoms is often reason of misdiagnosing. Where the symptoms are in most cases explained due to an allergic reaction, where the patient actually has consumed too high amount of histamine and actually undergoes a food poisoning. Every human body has a detoxification system, which is able to detoxify the functions of biogenic amines. However, the effectivity of this system differs between individuals and can be decreased by medicines and also by alcohol [78]. The tradition of eating Casu Marzu, which is often accompanied with wine, can exert the negative characteristics of biogenic amines.

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[74] A.R. Tricker, R. Preussmann. 1991. *Carcinogenic N-nitrosamines in the diet: occurrence, formation, mechanisms and carcinogenic potential*.
[75] T.S. Sathyanarayana Rao, V.K. Yeragani. 2009. *Hypertensive crisis and cheese*.
[76] G. Manca, A. Porcu, A. Ru, M. Salaris, M. A. Franco, E.P.L. De Santis. 2015. *Comparison of γ-Aminobutyric Acid and Biogenic Amine Content of Different types of Ewe's Milk Cheese Produced in Sardinia, Italy*. Italian
[77] A. Halász, Á. Baráth, L. Simon-Sarkadi, W. Holzapfel. 1994. *Biogenic amines and their production by microorganisms in food.*
[78] B. ten Brink, C. Damink, H.M.L.J Joosten, J.H.J. Huis in 't Veld. 1990. *Occurrence and formation of biologically active amines in foods*.

Noteworthy, histamine is listed as a food safety criterion, but only in the category fishery products, manufactured from fish species associated with a high amount of histidine. Hereby, the criterion is established on 100 mg histamine per kg food[79]. An average 372,7 mg/kg on histamine is found in Casu Marzu. Although the food safety criterion is not established for a food product category, which covers the cheese, the product would be exceeding the limit set for fishery products.

Casu Marzu contains milk and insects, both ingredients can trigger an allergic reactions in specific groups of consumers. This is risk for those specific groups of consumers due to a biochemical hazards. Therefore, it is important that those consumers have the informed choice to avoid the product. To this extend, the ingredients milk and insects should be mentioned on the label as allergens.

The last step in the production process towards Casu Marzu raises concern regarding traceability. This last step holds that the fly will come to the cheese naturally to lay eggs and the larvae are not intentionally added as an ingredient. In this way, traceability is diminished and raw material brought in uncontrolled. *Piophila casei* is mostly attracted by dairy products (see figure 4). However, in case no dairy is in the nearby surrounding, the fly can also be attracted by cadavers. These cadavers may carry some transmittable diseases and the *Piophila casei* can act as a vector of these diseases. When no insource controlling takes place, it cannot be noticed if any transmission of diseases is occurring.

Figure 4 Fly attracted by Pecorino cheese (Retrieved on 30-09-2017)

Therefore the concern on the risk of TSE in Casu Marzu via the *Piophila casei* exists. This concern finds its roots in the BSE-crisis, where it was found that Creutzfeldt-Jakob Disease[80] could be linked to bovine spongiform encephalopathies (named BSE hereinafter). With a relatively high mortality rate, Creutzfeldt-Jakob Disease has been taking the lives of 28

[79] European Commission for the European Union. 2005. *Commission Regulation (EU) No 2073/2005 on microbiological criteria for foodstuffs*. Article 2, article 3, article 7 and annex I.
[80] L.J.M. van Keulen. N.d. *Creutzfeldt-Jakob*. Retrieved on 10-11-2017 from http://www.wur.nl/nl/show/Ziekte-van-Creutzfeldt-Jakob.htm

persons in the United Kingdom in 2000[81]. This was a great concern of the European Union and measures were taken upon the risk of transmissible spongiform encephalopathies (named TSE hereinafter), of which BSE was a variety. Not only were measures taken regarding feed for bovine species, but a monitoring system for every Member States should diminish the risk on TSE. In case the monitoring system resulted positive for TSE the Member State could be classified that no feed of any animal origin is allowed[82].

Monitoring does not occur with regards to the fly, therefore it is not known if carries any TSE. When a wild animal in the hills of Sardinia dies, this will not be monitored. Noteworthy, in this case cadavers do not act in any way as an ingredient or feed to an ingredient. Nevertheless, when a fly of *Piophila casei* has been visiting the cadaver and providing the last ingredient of Casu Marzu at the same time, it can act as a vector transmitting diseases from cadavers to the cheese. This would pose a risk due to biological hazards.

In order to tackle this traceability issue and get better insight into the life cycle of *Piophila casei*, a research was conducted by the Entomology department of the Sassari University. The objective of the research was to find out if the *Piophila casei* can be reared under controlled conditions and are still applicable in processing Casu Marzu. Findings of the research are that it is possible to rear *Piophila casei* in a way that raw material for Casu Marzu could be tested before entering the cheese[83]. Besides it was found that in order to obtain a Casu Marzu, which is homogenously ingested by the larvae, a great number of female *Piophila casei* was needed as described in chapter *2. Casu Marzu*.

The larvae (see figure 5) are expected to cause some physical damage in the human body, in particular myasis. Myasis can be seen as micro perforation in the human intestines. Nevertheless, it is important to note that no case of myasis is reported related to the consumption of Casu Marzu. Consuming Casu Marzu often occurs with the larvae still alive in the cheese. The larvae of the insect *Piophila casei* have the capability to survive acidy environments, as well as the acid found in the stomach of humans for 120 hours.

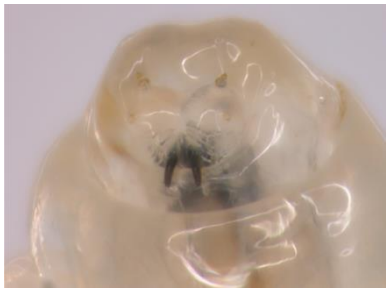

Figure 5 The head of *Piophila casei* larvae (Source: Entomology department of Sassari University)

[81] World Health Organization. 2012. Variant Creutzfeldt-Jakob disease – factsheet No 180. Retrieved on 10-11-2017 from http://www.who.int/mediacentre/factsheets/fs180/en/

[82] European Parliament and Council for the European Community. 2001. *Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies*. Article 7, annex II.

[83] Oral source retrieved on 29-09-2017. Professor Andrea Lentini for Department of Entomology of University of Sassari.

Considering the small size of the larvae and even the smaller teeth of the larvae (<0,1 millimeter), if the larvae are still alive the damage would be nihil. More research could be conducted on the topic of myasis in relationship with the consumption of Casu Marzu in order to shut down the possibility of the hazard occurring in humans.

4.3.Comparison study

In order to obtain a more relativized view on Casu Marzu as a food product, a comparison study is performed. In this comparison study, assessing insects as food partly contribute to the assessment of Casu Marzu, since Casu Marzu partly consists of insects. The relation between Casu Marzu and insects is positive. This holds that when the assessment for insects concludes that risks, associated with the consumption of insects, are low, the risks for a part of the Casu Marzu would be low. After insects, the food products gorgonzola, oysters and mushrooms will follow in this comparison study. The latter three products are commonly consumed and the marketing thereof is allowed within the EU. If these products pose high risks for health, it can be questioned, why these are allowed and Casu Marzu not.

To be able to select opponents in the comparison study, the characteristics of Casu Marzu are used as found in the chapter 2. *Casu Marzu*. These characteristics are put in place as parameter and risk assessments of food products with the same characteristics, which are generally recognised as safe, are revised. With the help of mind mapping, these characteristics are linked to the food products discussed underneath. The mind map, as used in the preparation for this chapter, is depicted in *Annex I* of this report.

4.3.1. Insects

The next category of food products, discussed in this paragraph, is insects. At the time Casu Marzu is tend to be eaten, larvae are present in the product. With this given, one can conclude that larvae are one of the ingredients of Casu Marzu. Larvae is a stage in the whole life cycle of Diptera class insects as written in chapter 2. Casu Marzu. When talking about consuming larvae, one can refer to the consumption of insects in general.

Where insects as food already have a long history over the world[84], that history within the EU seems just about to start. Within the EU, insects are now being seen as contamination when talking about food, also by legislators. A clear example of the desirably avoidance of insects in food processing can be noticed in Regulation (EU) No 852/2004 on the hygiene of foodstuffs. In chapter II of Annex II of this regulation, requirements on the production sites and places of production of food are laid down. In particular in paragraph 1.d. it is described

[84] Y. Jongema. 2012. *List of edible insect species of the world*.

how windows should be designed in a way that a screen is easy to place and easily removable, that will prevent insect from intruding[85]. Similarity in this position towards insects can be found in article 5 of Legge 283 del 30 aprile del 1962, where it is written that it is forbidden to sell food, which was accessible by intruders[86]. In the case of Casu Marzu, the fly of Piophila casei entering the cheese can be seen as the intruder discussed in this article and thus is seen as something that has to be avoided in food processing. Insects as food are considered to be subject to Regulation (EU) No 2015/2283 on novel foods [87].

EFSA conducted risk assessment on edible insects, so did the competent authorities of some Member States [88],[89],[90]. Looking to the biological hazards of edible insects, it differs from those of mammals, like pork. For example the bacteria naturally occurring in pork can be pathogenic to humans, for indigenous bacteria in insects are entomopathogenic. This means that they can be harmful for insects in large numbers, but are not that harmful for humans. This can be explained on behalf of the phylogenetically difference between mammals and insects. In spite of this difference, insects can still function as vectors of bacteria pathogenic for humans. One can think of cross-contamination during rearing of edible insects. In this perspective, high values of Enterobactericaea were found in reared insects. The NVWA believes that insects should be treated as food and with that should comply to standards as any other food should comply. For 65% of all samples had values higher than 10.000 cfu/g, which exceed the process hygiene criterion set for raw meat in the Netherlands. However no exceeding numbers were found for any food safety criteria [91]. Additionally, bacteria would be replicated in the intestinal tract of mammals, but not in insects. For instance, a study suggested that Campylobacter can only survive for 3 days in insects [92] as well as it is shown

[85] European Parliament and Council for the European Union. 2004. *Regulation (EC) No 852/2004 on the hygiene of foodstuffs.* Paragraph 1.d of Chapter II of Annex II.

[86] La Camera dei deputati ed il Senato della Repubblica for the Repubblica Italiana. *Legge 283 del 30 aprile del 1962 Disciplina igienica della produzione e della vendita delle sostanze alimentari e delle bevande*. Article 5.

[87] European Parliament and Council for the European Union. *Regulation (EU) 2015/2283 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001*. Recital 8, paragraph 2.a and 2.b of Article 3.

[88] Nederlandse Voedsel- en Warenautoriteit. 2014. *Advies over de risico's van consumptie van gekweekte insecten.*

[89] Scientific Committee of Federal Agency of the Safety of the Food Chain (Belgian competent authority). 2014. *Food safety aspects of insects intended for human consumption*.

[90] Agence nationale de securité sanitaire de l'alimentation, de l'environment et du travail (French competent authority). 2015. *Opinion on the use of insects as food and feed and the review of scientific knowledge on the health risks related to the consumption of insects*.

[91] Nederlandse Voedsel- en Warenautoriteit. 2014. *Advies over de risico's van consumptie van gekweekte insecten.*

[92] European Parliament and Council for the European Union. *Regulation (EU) 2015/2283 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing*

that E.coli disappeared on the 4th day in the insect Musca domestica as known as the house fly [93].

However, as some bacteria may not accumulate in insects, antibiotics can, which induce another biological hazard named Antimicrobial resistance (named AMR hereinafter). AMR is an increasing issue and many deaths in the past few years are ascribed to this concern. In 2009, EFSA concluded that Methicillin Resistant Staphylococcus aureus was harboured in food-producing animals and with that in food as well[94]. The number of deaths throughout the EU due to AMR is estimated on 25.000 each year[95].

Good housing conditions and proper hygiene can mitigate several risks in insects. This counts for the risk of AMR, but also for the risk of mycotoxins and aflatoxins, viruses and parasites. For AMR the hazard occurs particularly with the overuse of antibiotics, which can be done to save reared insects from bacterial infections. Therefore the use shall be minimised in order to diminish the risk of AMR.

In the class biochemical hazards, a hazard that cannot be left out with considering edible insects is the potential of insects causing allergies. Some human bodies can react hypersensitive when coming in contact with a certain substance of a food product. Humans that are sensitive to dust mites, crustaceans and molluscs, have a great chance of reacting to insects as well. The protein, triggering the allergic reaction in these products, is identified as trypomyosin.

The chemical hazard cadmium is a potential risk in insects. Cadmium intoxication causes bone demineralisation and cancer, but it can cause spontaneous abortion and low birth weight of the child when the mum is intoxicated. Cases of cadmium intoxication due to the consumption of foodstuffs are reported with diarrhoea and vomiting[96]. Out of 5 Musca domestica tested, the cadmium level in 3 flies were found exceeding the limit for feed of 0,5 mg/kg[97],[98]. The level of cadmium differs per stage in the life cycle of the insect. In most of the

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Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001. Paragraph 2.a and 2.b of Article 3 of Chapter I, Article 14 and 15 in Section II Chapter III.

[93] M. Kobayashi, T. Sasaki, N. Saito, K. Tamura, K. Suzuki. 1999. *Houseflies: not simple mechanical vectors of enterohemorrhagic Escherichia Coli O157:H7*.

[94] European Food Safety Authority Panel on Biological Hazards. 2009. *Scientific opinion - Assessment of the Public Health significance of methicillin resistant Staphylococcus aureus (MRSA) in animals and foods*.

[95] European Food Safety Authority. 2016. *Antimicrobial resistance and food safety*. Retrieved on 12-12-2017 from https://www.efsa.europa.eu/en/topics/topic/antimicrobial-resistance.

[96] J. Godt, F. Scheidig, C. Grosse-Siestrup, V. Esche, P. Brandenburg, A. Reich, D.A. Groneberg. 2006. *The toxicity of cadmium and resulting hazards for human health.*

[97] A.J. Charlton, M. Dickinson, M.E. Wakefield, E. Fitches, M. Kenis, R. Han, F. Zhu, N. Kone, M. Grant, E. Devic, G. Bruggeman, R. Prior, R. Smith. 2015. *Exploring the chemical safety of fly larvae as a source of protein for animal feed.*

cases, larvae contain higher levels than adults, since they have the capability of accumulating cadmium. Larval faeces even scored higher in cadmium levels than larvae, which can be explained with the off stream of chemicals through faeces[99]. Since the larvae and their faeces is eaten within the Casu Marzu, it would not be a redundancy to consider cadmium in risk assessment of Casu Marzu. However, important to note here is the significance of the substrate, where the larvae are living from. The larvae can accumulate cadmium, but when this heavy metal is not available to them, it will not be present in the larvae spontaneously[100]. Having regard to Regulation (EC) No 1881/2006 no limit is set on cadmium for the product group of milk-products[101]. This may imply that cadmium is not present in milk-products and therefore does not pose a risk in cheese. Knowing that the substrate matters, it is unlikely that high levels of cadmium are obtained in Casu Marzu.

Some insects produce indigenously toxins, these are called Phanerotoxics. One can think of bees and ants injecting poison into the host as defence[102]. However, these kind of insects are not considered as edible for the purpose for being placed on the market within the EU[103]. In the case of Casu Marzu, Piophila casei is not a Phanerotoxic and therefore are indigenously produced toxins not taken into account in this report.

4.3.2. Gorgonzola

Casu Marzu shows resemblances with Gorgonzola in several manners, such as sensory attributes, the country of origin and high values in micro-organisms. Casu Marzu may have high amounts of bacteria, which results in high amounts of biogenic amines. Gorgonzola, on the other hand, has an extensive high amount of moulds. Gorgonzola is made of pasteurised cow's milk and during maturing the cheese is injected with Pennicilium roqueforti, the mould responsible for the blue veins in the cheese. Gorgonzola has a protection of designation of origin and can only be produced in northern regions of Italy[104],[105].

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[98] European Parliament and Council for the European Union. 2002. *Directive 2002/32/EC on undesirable substances in animal feed*. Paragraph 1 of Article 4, Annex I.

[99] S. Diener1, C. Zurbrügg, K. Tockner. 2015. *Bioaccumulation of heavy metals in the black soldier fly, Hermetia illucens and effects on its life cycle*.

[100] L. Lindqvist. 1992. *Accumulation of Cadmium, Copper, and Zinc in Five Species of Phytophagous Insects*.

[101] Commission for the European Union. 2006. *Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs*. Annex.

[102] M. Blum. 2012. *Chemical defenses of Anthropods.*

[103] Scientific Committee of European Food Safety Authority. 2015. *Scientific opinion - Risk profile related to production and consumption of insects as food and feed*.

[104] Consorzio per la tutela del formaggio Gorgonzola. 1993. *Application for registration.*

[105] Consorzio per la tutela del formaggio Gorgonzola. 2014. *Amendment application in accordance of article 9 'Gorgonzola' - EU-nr.: IT-PDO-0217-01214 — 18.3.2014.*

Listeriosis is a microbiological hazard present in Gorgonzola. Listeriosis is caused by the pathogenic micro-organism Listeria monocytogenes, which is often associated to pose a risk in milk and milk products[106]. Listeriosis is often remarked by the symptoms nausea, fever, muscle pain and diarrhoea, but can also cause meningitis and spontaneous abortion (in pregnant patients)[107,108]. In 2015, the number of deaths reported in the EU as a result of Listeriosis was 270, which was the highest fatality rate among those of all zoonoses[109]. One year before, 30 notifications of Listeria monocytogenes in milk and milk products were made in Rapid Alert System for Food and Feed. Hereof were 9 notifications related to the pathogen found in Gorgonzola[110].

Listeria monocytogenes is known for its capability to grow in low temperature environment. For instance, simulations made based on worst case scenarios, showed that the level of Listeria monocytogenes already exceeded the limit of 100 cfu/g after 15 days at temperature of 4°C[111]. Considering that many households fridges can reach temperatures of 7°C, a shelf-life of only about a week would be considered as safe[112].

Despite of the pasteurisation process step in manufacturing Gorgonzola, the bacteria is often found in the cheese due to post-pasteurisation contamination. Post-pasteurisation contamination most likely occurs with cutting the cheese[113], which brings the microbiota present on the rind into the core of the cheese[114]. Albeit the Consorzio per la tutela del formaggio Gorgonzola emphasises the importance to mention that the rind is not edible, a preventive measure regarding labelling of the product is left out[115].

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[106] Consorzio per la tutela del formaggio Gorgonzola. 1993. *Application for registration.*
Consorzio per la tutela del formaggio Gorgonzola. 2014. *Amendment application in accordance of article 9 'Gorgonzola' - EU-nr.: IT-PDO-0217-01214 — 18.3.2014.*

[107] Agence nationale de securité sanitaire de l'alimentation, de l'environment et du travail (French competent authority). 2011. *Characteristics et sources of Listeria monocytogenes.*

[108] Office of research compliance for Montana University. N.d. *Pathogen safety data sheet – Listeria monocytogenes.*

[109] European Food Safety Authority and European Centre for Disease Prevention and Control. 2016. *The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2015.*

[110] European Commission. N.d. *RASFF portal*. Retrieved on 18-12-2017 from https://webgate.ec.europa.eu/rasff-window/portal/

[111] European Commission for the European Union. 2005. *Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs*. Category 1.2 of Chapter I in Annex I.

[112] E. Dalzini, E. Cosciani-Cunico, P. Monastero, V. Bernini, E. Neviani, A. Bellio, L. Decastelli, M. Losio, P. Daminelli, G. Varisco. 2017. *Listeria monocytogenes in Gorgonzola cheese: Study of the behaviour throughout the process and growth prediction during shelf life*.

[113] V. Bernini. E. Dalzini, C. Lazzi, B. Bottari, M. Gatti, E. Neviani. 2016. *Cutting procedures might be responsible for Listeria monocytogenes contamination of foods: The case of Gorgonzola cheese*.

[114] C. Fontana, F. Cappa, A. Rebecchi, P.S. Cocconcelli. 2010. *Surface microbiota analysis of Taleggio, Gorgonzola, Casera, Scimudin and Formaggio di Fossa Italian cheeses*.

[115] Consorzio per la tutela del formaggio Gorgonzola. 2002. *Amendment application in accordance of article 9 'Gorgonzola' - EC No: IT/PDO/117/0010/12.4.2002.*

The fermentation process proteolysis occurs in Gorgonzola, as it occurs in Casu Marzu, which poses biochemical hazards. Due to proteolytic activity by enzymes of human indigenous enzymes, the protein β-casein is hydrolysed into the smaller peptide β-Casomorphin-7[116]. Studies found correlation between the intake of the peptide and diabetes type I[117]. Besides, the consumption has been related to the Cardio Vascular Diseases[118]. However, according to EFSA the evidence of the link between the consumption of β-Casomorphin-7 and the health issues discussed above is too weak[119].

Another biochemical hazard comes as a result of lipolysis due to the enzymes of Penicillium roqueforti, what fragmentises glycerides into free fatty acids[120]. High exposure of free fatty acids (named FFA hereinafter), starting from 550 µM, have been found making cells insulin resistant. This results in no uptake of glucose by the cells in the body with in the end diabetes type I[121]. During the ripening of Gorgonzola the amount of FFA increases continuously[122]. Gorgonzola, which has ripened for 86 days, would meet the dose-response with the consumption of 57,2 gram thereof (for the calculation is referred to *Annex II* of this report, important to note: many variables in this calculation are uncertain in reality). Therefore, FFA considerably poses a health risk for consumers of Gorgonzola .

Another biochemical hazard in gorgonzola are mycotoxins. Penicillium roqueforti has the capability to produce mycotoxins. Specifically, Roquefortine C and Mycophenolic acid have been found to be produced by the mould. The first toxin mentioned is a neurotoxin and can cause paralysis. The second toxin has acute toxicity and is mutagenic. Despite of the serious hazards for health these toxins can bring, these are not very likely to pose a great risk because of the relatively low exposure. For instance, for Roquefortine C the lowest dose-response starts from 15 mg/kg bodyweight and the toxin is found to be present for 12 mg/kg cheese at its highest amount[123].

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[116] I. De Noni, S. Cattaneo. 2010. *Occurrence of b-casomorphins 5 and 7 in commercial dairy products and in their digests following in vitro simulated gastro-intestinal digestion*.

[117] R.B. Elliott,D.P. Harris, J.P.Hill, N.J. Bibby, H.E. Wasmuth. 1999. *Type I (insulin-dependent) diabetes mellitus and cow milk: casein variant consumption.*

[118] C. N. S. McLachlan. 2001. *β-casein A1, ischaemic heart disease mortality, and other illnesses.*

[119] European Food Safety Authority. 2009. *Scientific report - Review of the potential health impact of β-casomorphins and related peptides.*

[120] G. Contarini, P.M. Toppino. 1995. *Lipolysis in Gorgonzola Cheese during Ripening*.

[121] G. Boden, X. Chen, J. Ruiz, J.V. White, L. Rossetti. 1994. *Mechanisms of fatty acid-induced inhibition of glucose uptake.*

[122] M. Gobbetti, R. Burzigotti, E. Smacchi, A. Corsetti and M. De Angelis. 1997. *Microbiology and Biochemistry of Gorgonzola Cheese During Ripening*.

[123] L. Vallone, A. Giardini, G. Soncini. 2014. *Secondary metabolites from Penicillium roqueforti, a starter for the production of Gorgonzola cheese*.

4.3.3. Oysters

Oysters can act as an opponent in the comparison with Casu Marzu as resemblances in eating the product alive and traceability are found. Many Sardinians have the believe that when the larvae in the cheese are not alive anymore, also the cheese has begun its putrefaction. For Sardinians, the living larvae function as a parameter for an edible Casu Marzu[124]. This believe results in eating the cheese when the larvae within are still alive. Besides being alive, another similarity can be found between oysters and in one of the raw materials of Casu Marzu. Nowadays, many oysters are still harvested at non-controlled water areas, where it is hard to monitor the living circumstances of the product. Confirmation hereof can be found in Regulation (EC) No 853/2004 whereas 'production areas' of bivalve molluscs is defined as any sea, estuarine or lagoon area, containing either natural beds of bivalve molluscs or sites used for the cultivation of bivalve molluscs and from which live bivalve molluscs are taken[125]. This definition suggests that oysters can be harvested from controlled as well as from uncontrolled areas. In this way traceability is hard to complete and therefore the obligation under article 18 of GFL can hardly be fulfilled. The traceability of the *Piophila casei* is of great concern regarding health issues for the cheese, as it plays a big role in the hazards of the consumption of oysters.

One of the main biological hazards in the consumption of oysters is norovirus. Norovirus is remarked as highly infectious, where the illness rate can be 10% but can hit 70% as well. The incubation time is between 10 and 50 hours with a median of 24 hours, however the infectivity of the virus can remain for 25 years[126]. Symptoms of an infection with norovirus are stomach cramps, non-bloody diarrhoea, abdominal pain, low-grade fever and headaches, but in the majority of the cases is vomiting the main symptom. Small amounts of intake can pose these symptoms, 1-10 particles of the virus is enough. Not many long-term effects are ascribed to the virus, nor many cases of fatality. Nevertheless, dehydration has been fatal to elderly patients as a result of diarrhoea due to a norovirus infection[127].

The oyster is a great vector of norovirus and with that causes many cases of food poisoning in consumers. Oysters have the ability to accumulate virus particles, which can remain viable for

[124] Oral source retrieved on 29-09-2017. Professor Nicoletta Mangia for Department of Microbiology of University of Sassari and Professor Andrea Lentini for Department of Entomology of University of Sassari.
[125] European Parliament and Council for the European Union. 2004. *Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin*. Paragraph 2.5 of Annex I.
[126] P.F.M. Teunis, C.L. Moe, P. Liu, S.E. Miller, L. Lindesmith, R.S. Baric, J. Le Pendu, R.L. Calderon. 2008. *Norwalk virus: How infectious is it?*
[127] Institute of Environmental Science and Research for New Zealand Food Safety Authority. 2010. *Data sheet – Human norovirus*.

a long time. This makes the amount of particles of the virus per food product higher, resulting in a higher probability for falling ill after consuming it. The virus is related to faeces, so the bigger the amount of faeces, the higher the probability of norovirus. *Eschicheria coli* (named *E.coli* hereinafter) is also an indicator for the presence of faeces and therefore often used as measurement parameter for faecal contamination. For example in Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs is described that *E.coli* has to be tested in in live bivalve molluscs[128]. However, some cases in Ireland have posed a regulatory defect here. Although *E.coli* and norovirus are both linked to the presence of faeces, it has proven that many consumers were food poisoned with the norovirus after eating oysters, which did comply to the limit of 230 MPN/100g for *E.coli*[129]. This limit for *E.coli* turned out being not sufficient for diminishing the risk on food poisoning with the norovirus. The EFSA therefore recommends to limit the production of oysters destined for human consumption to only controlled production areas, where the faeces contamination is expected to be low[130].

A biochemical hazard identified in oysters is tetrodotoxin, which is mainly produced by the bacteria *Vibrio*. A well-known example of food poisoning with tetrodotoxin is consuming puffer fish from *Tetraodontidae* family, what still causes yearly fatalities despite of all Japanese regulatory restrictions. Tetrodotoxin is a neurotoxin, which blocks receivers for signals from the nervous system resulting in paralysis. Fatalities can follow this paralysis due to respiratory failure and cardiac rest[131].

Although no minimal lethal dose is stated yet, there are cases reported of acute poisoning occurring after ingesting 4-42 µg per kg bodyweight of the consumer. Besides, no antidote is designed yet in order to cure a tetrodotoxin intoxication. Therefore tetrodotoxin is considered a serious health hazard. Bacteria, producing this toxin, can be found in the sea and therefore is this toxin a risk in oysters as well[132]. Albeit the pufferfish is not the only cause and oysters

[128] European Commission for the European Union. 2005. *Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs*. Category 1.24 of Chapter I in Annex I.
[129] B. Doré, S. Keaveney, J. Flannery, P. Rajko-Nenow. 2010. *Management of health risks associated with oysters harvested from a norovirus contaminated area, Ireland, February–March 2010*.
[130] European Food Safety Authority Panel on Biological Hazards. 2012. *Scientific Opinion on Norovirus (NoV) in oysters: methods, limits and control options*.
[131] J. Lago, L.P. Rodríguez, L. Blanco, J.M. Vieites, A.G. Cabado. 2015. *Tetrodotoxin, an Extremely Potent Marine Neurotoxin: Distribution, Toxicity, Origin and Therapeutical Uses*.
[132] European Food Safety Authority Panel on Contaminants in the Food Chain. 2017. *Risks for public health related to the presence of tetrodotoxin (TTX) and TTX analogues in marine bivalves and gastropods*.

harvested in European waters can pose the same risk, legislation on the specific toxin is still missing[133].

Another food hazard in this class, is the risk on an allergic response of the human body after consuming oysters. As in case of the allergic reaction after consuming insects, can the protein trypomyosin also be responsible for the allergic reaction after consuming molluscs, which includes oysters. In reported cases, eating oysters have led to anaphylaxis[134]. Anaphylaxis can be expressed as in vomiting, low blood pressure, fast heartbeat, dizziness, troubled breathing and even swelling, which can result in oxygen deficiency due to a swollen throat. In contrary with tetrodotoxin, anaphylaxis as result of allergic reaction can be treated with epinephrine provided that treatment is given urgently[135].

In the past few years, the concern of microplastics has been stepping in regarding the consumption of oysters. Since the second half of 20th century, extensive grow of the applications of plastics has been occurring. Plastics cannot be ruled out in nowadays' society. Recently, consequences of the presence of plastics are getting visible. Plastics are for a big part used in the food industry as food contact material, for example. However, due to misuse of plastic by humans, it seems that plastic is turning into a part of the foodstuff itself. It is not deliberately put as an ingredient in the product, so particles of plastic in food are considered as contamination. The size of microplastics ranges from 0.1 to 5000 µm and the size of nanoplastics from 1 to 100 nm. Very limited data is available on nanoplastics, therefore this paragraph will mainly focus on microplastics. Microplastics are a result of fragmentation of plastic[136].

Although EU legislation is available on the migration of plastic particles from food contact material into foodstuffs[137], no legislation is yet put in place for indirect contamination. Indirect contamination due to anthropogenic debris of plastic materials has been detected in different kind of food products, as in honey[138], salt[139] and seafood[140]. Health concern towards

[133] European Parliament and Council for the European Union. 2004. *Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin*. Paragraph 2 of Chapter V in Section VII of Annex III.
[134] European Food Safety Authority. 2006. *Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the evaluation of molluscs for labelling purposes*.
[135] J. Tupper, S. Visser. 2010. *Anaphylaxis.*
[136] Panel on contaminants in the food chain for the European Food Safety Authority. 2016. *Statement on Presence of microplastics and nanoplastics in food, with particular focus on seafood.*
[137] European Commission for the European Union. 2011. *Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food*.
[138] G. Liebezeit G, E. Liebezeit. 2013. *Non-pollen particulates in honey and sugar.*
[139] D. Yang, H. Shi, L. Li, J. Li, K. Jabeen, P. Kolandhasamy. 2015. *Microplastic pollution in table salts from China.*

microplastics in oysters has been raised, since the highest amounts were found in the digestive tracts of marine organisms and this will not be removed in oysters before consuming.

Microplastics function as a vector for chemical compounds, such as polycyclic aromatic hydrocarbons (named PAHs hereinafter) and polychlorinated biphenyl (named PCBs hereinafter), after absorption from the sea to marine organisms. The microplastics, however, just count for a small addition to the total exposure of these chemical compounds to humans. A study on mussels, which fall in the same category as oysters, found that microplastics would count for an addition of 0.006% for PCBs and 0.004% for PAHs. Also the BPA intake of an adult is estimated to be approximately 14µg per day appended by the consumption of mussels contaminated with microplastics. Further fragmentation of plastic material releases smaller plastic compounds, like BPA for example. BPA has been detected in the urine of 95% of the adults in the United States[141].

The smallest microplastics are expected to be absorbed by the human body and can possibly penetrate the organs. However, the human body will excrete the particles via blood and splenic filtration system as faeces in the end[142]. As far it is noticeable at the moment, microplastics do relatively pose a low risk to health. Nevertheless, one should be aware of the accumulative capability of oysters in the combination with the low biodegradability of nowadays' used plastic materials. This combination could realise a higher amount of microplastics and with that a higher amount of several chemical contamination of the food product.

4.3.4. Mushrooms

A resemblance between mushrooms with Casu Marzu can be noticed, whereas mushrooms are grown on manure and Casu Marzu contains manure. In the early 19th century, a French farmer tasted a white-brownish vegetable, which had accidently been growing on a stack of horse manure. This vegetable was surprisingly tasty and farmers started to emulate the environmental characteristics of the season, autumn, in which it was growing. Here, the second resemblance with Casu Marzu is noticeable, foodstuffs that accidentally evolved without being produced intentionally.

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[140] C.M. Rochman, A. Tahir, S.L. Williams, D.V. Baxa, R. Lam, J.T. Miller, F.C. Teh, S. Werorilangi, S.J. Teh. 2015. *Anthropogenic debris in seafood: plastic debris and fibers from textiles in fish and bivalves sold for human consumption.*

[141] J. Glenza. 2017. *Sea salt around the world is contaminated with plastic, studies show* from The Guardian.

[142] Panel on contaminants in the food chain for the European Food Safety Authority. 2016. *Statement on Presence of microplastics and nanoplastics in food, with particular focus on seafood.*

In those times the farmers in northern France found out that the caves (see figure 6) were able to resemble the circumstances in autumn; dark, moisty and a constant temperature. The first grower of mushrooms in France is Mr. Chamberry. However, not much later the idea of growing mushrooms was copied by Pierre Kuijpers and The Netherlands became one of the largest producers[143].

Figure 6 Mushroom cultivation in cave (Retrieved on 14-02-2018)

Agaricus bisporus is the most common-consumed mushroom and produced in numbers of 260 million kg in The Netherlands in 2015[144]. The mycelium, the white-yellowish body of the mould, is the mushroom and that part is eaten.

The same biochemical hazard as in Casu Marzu, biogenic amines, also occurs in mushrooms. High amounts of the biogenic amine putrescine is found in mushrooms. As described before, carboxylase positive bacteria are responsible for the metamorphose from amino acids to biogenic amines. Higher storage temperatures result in higher values of biogenic amines, as study shows values of putrescine in sliced mushrooms 5050 mg/kg stored at 20°C and 1630 mg/kg at 6°C[145]. Putrescine poses a considerable risk here, since the exposure is quite high, as values are even higher as values found in Casu Marzu.

Putrescine is not only a risk itself, it is also a predecessor of another biochemical hazard in mushrooms, named nicotine. Due to alkaloid biosynthesis, which occurs in plants, metabolises putrescine further in nicotine[146]. When looking to legislation, the lowest limit is set on some specific foodstuffs at 0.3 mg/kg[147]. However this limit does not apply for mushrooms, despite the numbers found in researches.

Another biochemical hazard is the mycotoxin Agaritine, which has been found in mushrooms in concentrations up to 400 mg/kg. This toxin can be further metabolised into N'-Acetyl-4-(hydroxymethyl)phenylhydrazine (named AMPH hereinafter). Toxicological experiments

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[143] Keuringsdienst van waarde for the Public Dutch Broadcasting. Broadcasted on 11-05-2017. *Champignon.*
[144] Wageningen University and Research. N.d. *Dashboard groenten en fruit – Productie van champignons in Nederland*. Information retrieved on 22-12-2017 from https://www3.lei.wur.nl/MarketIntelligenceAGF/champignons.html#16552
[145] P. Kalač, Martin Křížek. 1996. *Formation of biogenic amines in four edible mushroom species stored under different conditions*.
[146] B.K. Schindler, S. Bruns, G. Lach. 2015. *Biogenic amines – A possible source for nicotine in mushrooms? A discussion of published literature data*.
[147] European Parliament and Council. 2005. *Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. Annex III.*

have shown tumour forming in mice exposed to AMPH. Specifically, 48% of male mice developed tumours in the lungs after daily exposure of 625 mg AMPH[148]. Nevertheless, this toxin is not mentioned in the list of maximum levels set for mycotoxins in Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs[149]. Due to the dose-response and the maximum exposure, this would not pose a high risk for humans.

In the class of chemical hazards, some results showed levels of the heavy metal arsenic in mushrooms. Highest number was found in raw mushrooms, 185µg/kg, and the lowest in boiled mushrooms, 86.2 µg/kg[150]. However, no information on handling mushrooms is provided, so it is not stated that mushrooms should be cooked. Albeit legislation does not state a limit on arsenic specifically for mushrooms, the level of arsenic found in the study is close to the limit set for milled rice. Furthermore, the level is exceeding the limit set for rice destined for the production of food for infants and young children[151]. Consuming raw mushrooms can therefore be considered significant risk due to arsenic content.

Biogenic amines and the (lack of) traceability of *Piophila casei* pose risks with the consumption of Casu Marzu. However, since the extremely strong sensory attributes of the cheese, the intake of the product is relatively low and with that the exposure to these hazards, resulting in probably low risks. Furthermore, risks coming from the hazards described in *4.2 Health hazards of Casu Marzu*, can be diminished by taking measures concerning hygiene and traceability. In the current situation, the traceability cannot be guaranteed. For this matter, the FBO is not able to fulfil his obligation under article 18. In the comparison study can be noticed that other food products, commonly considered safe in EU, can pose serious risks to human health. In some cases, these products even breach normative EU-food law.

[148] B. Toth. 1979 *Hepatocarcinogenesis by hydrazine mycotoxins of edible mushrooms.*
[149] Commission for the European Union. 2006. *Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs.* Section 2 of Annex.
[150] T. Llorente-Mirandes, M. Llorens-Muñoz, V. Funes-Collado, À. Sahuquillo, J.F. López-Sánchez. 2016. *Assessment of arsenic bioaccessibility in raw and cooked edible mushrooms by a PBET method*.
[151] Commission for the European Union. 2006. *Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs*. Section 3 of Annex.

5. Unfit for human consumption

In this chapter, the second characterisation of unsafe, unfit for human consumption will be discussed and the definition thereof will be explained. In order to give a better understanding of the meaning of unfitness, explanation will be specified on both causes of food becoming unacceptable. Furthermore, the meaning of unfit for human consumption will be elaborated with the help of cases of extraneous contamination and cases of putrefaction, deterioration or decay. After that, this chapter will elaborate on the definition of the interest of the consumer and nowadays' food perception of the consumer.

5.1. Unfit for human consumption

The second class, which is part of the definition unsafe, is unfit for human consumption. The following is said on unfit for human consumption in article 14: 'In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.'

Where the frontiers of injuriousness seems to be determined by limits laid down in provisions, unfitness seems to encompass the overall rest of unacceptable foodstuffs, which falls outside the meaning of injuriousness. The unacceptability of the food can be resulting from physical contamination or from putrefaction, deterioration or decay. The Commission explains in its memorandum in the proposal of GFL that foodstuffs can be not injurious per se, but can still be unacceptable to be consumed by humans. This unacceptability can result in injuriousness to health in the end. Because of obviously unacceptable character of the food product, it is unnecessary to prove the actual injuriousness[152]. Therefore it falls under the definition of unfit for human consumption as well as under the definition of unsafe.

In the category of extraneous contamination one can think of the example of a hair in soup, which was not expected to be part of the product to be consumed by humans. The hair would not explicitly pose a risk for human health. However it is an object, which is not reasonably expected to be ingested by humans as food is deemed to be[153].

Although this explanation seems clear and obvious, the Divisional Court of the Queen's Bench Division in Great Britain once stressed the importance of certain modicum of common

[152] European Commission for the European Union. 2000. *Proposal for a Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food*.
[153] European Parliament and Council for the European Union. 2002. Regulation (EC) No 178/2002

sense. The court stated that one can know that some extraneous matters are not to be consumed by humans. It elaborated further that a food product cannot be called unsound just because of the presence of extraneous matter, which had no effect on the general composition of food[154]. The same reasoning can be found in Regulation (EU) No 1935/2004 on food contact materials, where the general requirements are laid down in article 3. This article says that food contact materials shall not have a deviating effect on the composition of a food product[155]. To the extent of the Divisional Court's statement, it is for this reasoning that chocolate surprise egg is allowed to be placed on the market. One knows that the surprise inside the chocolate egg is not to be ingested by humans and therefore shall not be eaten. However, such big objects can easily be avoided during consumption, because the consumer is able to observe the object.

There are a lot of cases were extraneous contamination cannot be detected by the blind eye of the consumer and therefore cannot be avoided during consumption of the contaminated food product. In *chapter 4. Injurious to health* the chemical hazard of microplastics is discussed as posing a risk in oysters. Although the microplastics nowadays would not be injurious to health, due to the small quantities, it can be seen as extraneous matter, which cannot be detected by the blind eye of the consumer. Therefore it would fall in the first category of unfit for human consumption and still be unsafe food.

Another example of extraneous contamination, which is hardly detectable by the blind eye of consumers, is the example of textile dyes in fish. Dyes can follow their way through laundry machines, proceed through filtration systems and end up in the sea. This was observed in Belgium, where eel is found contaminated with several dyes, used for colouring textiles for example. Some of the compounds in the dyes are experienced toxic and some are not. For the dyes not found injurious to health, the product is considered unfit, as these dyes are not naturally present in the fish species and are seen as contamination of extraneous matter[156].

More approaching to the case of Casu Marzu, is the case of insect infestation of cashews in India, in which approximately 20% of the harvest of cashews is lost due to this issue. The kernel is infested by the insect *Trogoderma granarium* and specifically at the stage of larvae. This insect is of great concern, since it is widely spread by shipment in international trade.

[154] The British Medical Journal. 1956. *Food unfit for human consumption – J. Miller Ltd. v. Battersea Borough Council.*
[155] European Parliament and Council for the European Union. 2004. *Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC*. Paragraph 1 (b) of article 3.
[156] C. Belpaire, T. Reyns, C. Geeraerts, J. Van Loco. 2015. *Toxic textile dyes accumulate in wild European eel Anguilla Anguilla*.

Although resemblance with Casu Marzu can be noticed here, the insect ingesting the cashews is not from the same family nor from the same order as the *Piophila casei* in Casu Marzu. Furthermore, this insect leaves holes with nothing in the cashew kernel, while the larvae of *Piophila casei* leaves a cheese mass with velvety texture. No consumer expects just holes in their product when buying cashews. Despite the fact that it has not shown that the insect leave any toxic substances in the product after infesting, it is not wanted to be ingested by insects first and leave less cashew kernel for the consumer[157]. The cashew kernels with holes would therefore be unacceptable according to its intended use and thus unfit for human consumption. Besides, it is more likely that the food product, being infested by the insect, becomes increasingly vulnerable for other diseases like moulds. When purchasing a Casu Marzu, one demands particularly a cheese infested by larvae of *Piophila casei*, because of the characteristics the insect causes in the cheese.

The second category of unfitness is due to putrefaction, decay or deterioration. High amounts of moulds or bacteria can be seen as falling in this category of unfitness. It does not have to harm human health, but it is likely to develop harmful substances. One can think of tomatoes, on which mould has grown. The mould itself is not found injurious to health, and there is not a legal limit set on mould, but the probability of mould producing mycotoxins throughout the food product is an issue for health. In this case, it would be redundant to test for mycotoxins at the point it left the supervision of the FBO, since the moulds would not have come so far in developing the toxins. Nevertheless, the development and the spreading of the toxins would occur during shelf-life, which then the FBO cannot guarantee the safety of the product anymore.

Cases of fraud in selling frozen fish as fresh can act as an example of food unfit for human consumption in the latter category. Deviation of the original composition of the food product can occur due to extraneous contamination, but also due to decay. Fish can be frosted easily to maintain shelf-life. Nevertheless, freezing causes mechanical and physiological damages to the food product of animal origin. Freezing augment the level of denaturation of proteins due to the mechanical damage of the cellular membranes, caused by the ice crystals[158]. This mechanical damage not only causes a movement in protein, but also in water, which results in

[157] V. Sharma. 2011. *Deterioration of cashewnuts in Kerala state of India due to insect infestation along with the fungal incidence*.
[158] V. Tironi, A. Lebail, M. de Lamballerie. 2007. *Effects of Pressure-Shift Freezing and Pressure-Assisted Thawing on Sea Bass (Dicentrarchus labrax) Quality*.

drip loss[159]. The average consumer is not always capable of judging the food product and determining whether it has been frozen or not. Therefore the consumer shall be informed sufficiently as prescribed in Regulation (EU) No 1169/2011. In 10 article thereof is written that additional mandatory particulars for the labelling of specific types of food products exists in annex III. It is described that the date of freezing shall be named on the label of frozen fish[160]. Although freezing is an excellent opportunity for extending the shelf-life of fish products and is not injurious to health, can still be unacceptable and thus unfit. Selling frozen fish under the name of fresh fish or without mentioning the product has been frozen would not be in accordance with the regulation mentioned above. The frozen fish does not meet the consumer's expectation of purchasing fresh fish. The purchased product has undergone several mechanical and physiological changes in the product's structure as is not the same as fresh fish anymore. For this reason this kind of fraud could be considered as placing on the market of food unfit for human consumption and thus unsafe food.

Decay of a food product can also be characterised by the high values of bacteria present in the food product[161]. A clear example can be set with the food product smoked salmon, a ready-to-eat food product, of which its intended use excludes preheating. Because the product is not intended to be heated prior to consumption, bacterial count during the shelf-life of the product is very much related to the sensory attributes of the product. A study showed the negative relation between bacterial count and sensory scores, the higher the bacterial count, the lower the scores for the sensory attributes of the product. Although, not all the bacteria have to pose a health risk, trained sensory analysists perceived the smoked salmon with a bacterial count higher than 1.000.000 cfu/g as unfit for human consumption. This judgement resulted from the salmon developing an off-odour and a change in dark violet colour[162].

The Berger case is also remarkable for the clear statement that unfitness falls under the definition of unsafe. The meat products being not injurious to health, as in not exceeding food safety criterion, did not preclude the competent authority to inform the public on high

[159] M.V. Burgaard. 2010. *Effect of frozen storage temperature on quality-related changes in fish muscle - Changes in physical, chemical and biochemical quality indicators during short- and longterm storage*.
[160] European Parliament and Council. 2011. *Regulation (EU) No 1169/2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004*.
[161] Standing Committee on the Food Chain and Animal Health. 2010. *Guidance on the implementation of articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002*.
[162] U. Lyhs, J. Lahtinen, M. Fredriksson-Ahomaa, E. Hyytiä-Trees, K. Elfing, H. Korkeala. 2001. *Microbiological quality and shelf-life of vacuum-packaged 'gravad' rainbow trout stored at 3 and 8°C.*

numbers of bacteria found in these products. These high numbers weighted for the Court enough to stress the responsibility of the national competent authority to take actions in order to enforce food law over the obligation to inform the public on health risks. These actions includes informing the public on food and feed safety and risk. For that reason, the Court found that the national competent authority was in its right to act in accordance with national law implemented to enforce food law. This judgement shows that values of bacteria, which are significantly deviating from what is in average, can still fall under the definition of unsafe although there is no potential injuriousness involved[163].

In the beginning of 2017, inappropriate food handling was detected concerning meat in Brazil. Samples of the meat taken were showing high values of bacteria, which were not compliant to the standards of other importing countries. Some of the meat products were repacked and sold again as new[164]. Nevertheless, due to corruption, the FBOs were still granted the right to place their products on the market and export it. Directorate General Sante urgently requested the Brazilian government to put a halt on all meat exports towards the EU, making a long-term ban unnecessary[165]. The biggest concern for the European Commission is not specifically, the high bacterial count, but the failing controlling system for food practices[166]. This concern led to a preliminary ruling that meat from Brazil is unfit for human consumption due to unsound practices regarding the national competent authority and meat imports are rejected at the border[167].

In a study conducted by Daniela Polsinski (2017), Member States explained in which way national law was further elaborated in light of the concept of unfit for human consumption. Polsinski found that the Dutch Act on Food Hygiene contains elements of the concept of unfit for human consumption[168]. This Act refers frequently to the hygiene package of EU food law. Noteworthy, it says in article 3 that the competent authority has the competence to prohibit placing on the market of food products, which do not comply with Regulation (EC) No

[163] Court (Fourth Chamber) for the European Union. 2013. Case C-636/11 Karl Berger v Freistaat Bayern.
[164] Nederlandse Voedsel- en Warenautoriteit (Dutch Food Safety Authority). 22 March 2017. *Vlees uit Brazilië (Meat from Brazil).*
[165] Euractiv. 30 March 2017. EU health chief says Brazil meat scandal 'is not closed'. Information retrieved on 02-01-2018 from https://www.euractiv.com/section/agriculture-food/news/eu-health-chief-says-brazil-meat-scandal-is-not-closed/.
[166] European Commission. 2017. *Final report of an audit carried out in Brazil from 02 May 2017 to 12 May 2017 in order to evaluate the operation of controls over the production of beef, horse and poultry meat, and products derived therefrom intended for export to the European Union*.
[167] European Commission. N.d. *RASFF portal*. Information retrieved on 12-01-2018 from https://webgate.ec.europa.eu/rasff-window/portal/?event=searchResultList.
[168] Daniela Polsinski. 2017. *Thesis report for the Wageningen University & Research – Unfit for consumption – Application and Interpretation of the concept 'unfit for human consumption' according to Article 14 (2)(b) Regulation (EC) No 178/2002 in the European Union*.

852/2004 and 853/2004[169]. Although much content of the hygiene package exists of generic law and thus it is toughly measured to determine injuriousness, resemblance between article 3 of Dutch Act on Food Hygiene and article 14.1. of GFL can be found. This resemblance shows the link between unfitness and hygiene requirements. Taking a closer look at the first regulation in the hygiene package, Regulation (EC) No 852/2004, elements of unfit for human consumption can be detected. In article 2 thereof it is written that hygiene is necessary to take control over hazards and to ensure the fitness of foodstuffs for human consumption. This regulation stresses the importance of practising HACCP-principle, Hazard Analysis Critical Control Points-principle, in food premises. This principle is based on the believe that food risks can be diminished significantly by the recognition of the potential hazards and participation on these. In addition, the regulation sets generic rules for rendering a hygienic environment for processing foodstuffs. In relation to the case of Casu Marzu, the current production process would be in controversy with article 15 of Regulation (EC) No 852/2004. This article explains that food premises should be closed and where open access occurs, measures should be taken in order to avoid insects coming from outside in the food premise.

Another example of unfit for human consumption in light of hygienic design of premises is the Kebab meat producer. Last year, a British FBO from Turkeys origin was prosecuted for unsound food processing. The manufacturer of kebab meat, placed on the market in the United Kingdom, had used a cement mixer for the purpose of mixing meat. That was not the only violation of food law, he was accused of reworking chicken meat in his product, which had passed the use-by date or did not have a use-by date. Additionally, the country of origin was not the same as he stated on the label of his products. The FBO was fined with £53.760,00 and was jailed for four months, since magistrates in the United Kingdom deemed the products, which this FBO has been placing on the market, unfit for human consumption[170].

5.2.Interest of the consumer

In the last century, the recognition of the importance of consumers' interest has been raising[171]. In 1975, the European Economic Community implemented a policy for consumer

[169] Minister van Volksgezondheid, Welzijn en Sport, Ministers van Landbouw, Natuur en Voedselkwaliteit, en van Economische Zaken (Minister of Public health, Welfare and Sports, Minister of Agriculture, Nature and Food quality and Economic Affairs) for the Netherlands. 2016. *Warenwetbesluit Hygiëne van Levensmiddelen*. Artikel 3.

[170] D. O'Mahony (for the Eveningstandard.). 2017. *Jailed: kebab shop owner who used cement mixer to make doner meat*. Information retrieved on 23-12-2017 from https://www.standard.co.uk/news/crime/jailed-kebab-shop-owner-who-used-cement-mixer-to-make-doner-meat-a3646701.html.

[171] F.J. Schlink. 1934. *Safeguarding the Consumer's Interest-An Essential Element in National Recovery*.

protection and information[172]. In the GFL, the definition 'consumers' interest' is present at three places, which stresses the importance of this definition in food law. Consumers' interest is discussed in article 1, the aim and scope of GFL, where it says that the regulation pursues a high level of protection of human health and consumers' interest in relation to food. Further, in the general objectives as described in article 5, it highlights again that food law shall aim at a high level of protection of consumers' interest. Consequently, the definition is given its own article, in names of article 8, elaborating on how the protection of consumers' interest should be achieved. This achievement is based on the prevention of fraudulent or deceptive practices, the adulteration of food and any other practices, which may mislead the consumer[173]. These articles are stemming from article 12 of TFEU, which points out that the Commission should take consumer protection into account when implementing policies and activities. Article 4 of TFEU states that the EU has shared competence in the field of consumer protection, which justifies the persuasion of protection of consumers' interest[174].

Consumers' interest is rather hard to define, since it concerns different individuals tended to be seen as one group. Different individuals have different views on what is important for them, giving all differentiating meanings to the definition 'consumers' interest'. Consumers' interest forms preferences regarding economic, political and social benefits from all individuals. With putting in place this definition, one generalises an enormous group of society. Consumers' interest, together with owner interest and labour interest is part of the public interest. In law-making, 3 philosophical conflicts can occur, being freedom, equity and efficiency. Especially the first conflict, freedom, can be noticed in the protection of consumers' interest. In decision-making, there will always be a group of citizens not being satisfied with the decision made. Also in the conflict in freedom, serving the common erodes individuals' freedom and serving individuals to its best will not fully contribute to the collective good. In order to slightly tackle this conflict, law is often made with having utilitarianism in mind. Utilitarianism believes that law must result in the greatest good for the greatest number of individuals[175].

[172] Council for the European Economic Community. 1975. *Council Resolution on a preliminary programme of the European Economic Community for a consumer protection and information policy*.
[173] European Parliament and Council for the European Union. 2002. *Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*. Article 1, article 5 and article 8.
[174] European Union for the European Union. 2012. *Treaty on the Functioning of the European Union*. Article 4 and article 12.
[175] J.D. Forbes. 1987. *The consumer interest.* Chapter 1 and chapter 6.

Keeping this in mind, one can notice clearly, with the help of article 8 in GFL, that the government is there to serve citizens as being consumers. This can be seen as an externality response to recover a failure of the internal market, being the fact that liberal market working will not result in achieving safe food immediately. Such a philosophical conflict can be noticed in food law and perhaps in the case of Casu Marzu as well. In order to encourage the right to safe food, food law is put in place, which sets rules on food products[176]. The more rules, and specifically normative rules, are set, the more food is standardised. This encouragement of food safety may be trumping the food diversity[177]. Food diversity can be seen as an extension in the freedom of choice of the consumer. Food safety and food diversity are in negative relationship, but are both in the interest of the consumer. It is the art in law-making to find the balance between the two in order to guarantee consumers' interest to its best.

However, consumers' interest can strongly influence the food industry in its decision-making. For instance, in the food safety issue of high salt intakes, the intake is tended to be reduced with the help of corporate salt reduction in ready-to-eat food products. At EU-level, no normative requirements on the salt content is set. Nevertheless, the FBO feels pressure to act in order to satisfy consumers' interest, which has been adjusted by information given by the government. In European Salt Reduction Framework, one of the key-activities in the campaign is to raise public awareness on the risk of high salt intake. This has an indirect effect on the handling of food safety issues in the food industry. Consumers, having more knowledge on the matter and being better informed, become more critical towards food products. This results in a shift in the demand of consumers[178].

The Berger case shows that information from authorities can have a detrimental impact on the food industry. The national competent authorities have informed the public on the potential risk that the meat products of the premise could have. This action was justified under article 17 paragraph 2 of GFL. However, after this action of informing the public, consumers massively prorogued with purchasing any product of the respective manufacturer. In the eyes

[176] M.M. Arpaia. 2017. *The Right to Safe Food: A Short Path to the Roots of the International Legal Protection of Food Safety*.
[177] K.P. Purnhagen. 2013. *Beyond Threats to Health: May Consumers' Interests in Safety Trump Fundamental Freedoms in Information on Foodstuffs? Reflections on Karl Berger v Freistaat Bayern*.
[178] Y. Hoffmans. 2016. *Paper for Food Law, Management and Economics - European Salt Reduction Framework*. Chapter 5.

of the complainant, the activity of informing the public was disproportionate and gave him reason to bring the case before court[179].

According to article 169 of the TFEU, the right to information, education and to organise themselves shall be promoted in order to safeguard the interests of the consumers[180]. The believe of the EU to ascribe the right to make informed choices to the consumers is noticeable in Regulation (EU) No 1169/2011 on the provision of food information to consumers. In article 1 thereof is stated that the regulation shall assure a high level of consumer protection in relation to food information and that it shall guarantee the right of the consumers to be informed[181]. Nevertheless, informing the consumer can have two sides; education of the consumer and shaping of the consumer. In the first meaning, one provides information to the consumer and with that the consumer gains knowledge in order to make informed choices. On the other side, by giving information, the consumer is shaped. With every information given, the consumer is led in a particular way[182]. With this regulation is particularly aimed at making consumers able to make informed choices, but is leading the consumer to the believe that, what is obliged by this regulation to provide, is important to know.

Considering consumers' perception matters for the protection of consumers' interest. How a food product is perceived by the consumer partly influences the determination of unfitness. The way food product is perceived by the consumer decides that mould makes tomatoes unfit, but makes cheese a special food product. In case a product is eaten for several years by the environment, consumers perceive a certain level of safety with regards to that food product[183].

To the extent of the case of Casu Marzu, consumers may think that the product is unsafe because of the living larvae in it. However, consumers do not consider dried sausage or other cheeses as unsafe, which contain the same considerably unsafe components as regarding to biogenic amines[184]. In the search for the perception of eating insects, rejection can be caused

[179] V.R. Fuentes. 2013. *The Berger Case: Food Risk and Public Information. Professional Secrecy and Reputation. Judgement of the Court of Justice (Fourth Chamber) of 11 April 2013*.
[180] European Union for the European Union. 2012. *Treaty on the Functioning of the European Union*. Article 169.
[181] European Parliament and Council for the European Union. 2011. *Regulation (EU) No 1169/2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.* Article 1.
[182] S. Tommasi. 2017. *Food Diversity and Consumer Protection*.
[183] S. Sijtsema, A. Linnemann, T. van Gaasbeek, H. Dagevos, W. Jongen. 2002. *Variables Influencing Food Perception Reviewed for Consumer-Oriented Product Development*.
[184] S. Bover-Cid, M. Hugas, M. Izquierdo-Pulido, M. C. Vidal-Carou. 2001. *Amino acid-decarboxylase activity of bacteria isolated from fermented pork sausages*.

in three ways; distaste, danger, disgust. Casu Marzu may trigger all three of them. Relevantly, danger relates to the fact that consumers are afraid of eating, because they believe it can have negative results on their health. Insects in food are often associated with the putrefaction of a food product and can support the rejection of the product due to danger. To this extend, the consumers perceived a higher feeling of safety and comfort when they know in advance that the insects were reared deliberately for the function of being food[185].

Unfit for human consumption is the second description of unsafe and can be caused by contamination with extraneous matter or through putrefaction etc. Many cases have shown food to be unfit, because it was not expected that the food product would turn out to be as it had and did therefore not comply to consumers' expectations. However, with Casu Marzu the larvae and the strong sensory attributes are expected by the consumers and can be considered fit. Consumers' interest seems to be at the centre of the two objectives of the GFL, being free movement of foodstuffs and protection of health of consumers, in this light Casu Marzu is an interesting case for risk managers. Consumers' perception influences consumers' interest. Casu Marzu can be found fit by consumers, whose environment has been consuming it for years, but unfit for consumers who never consumed insects. Controlled production of the insects, used in Casu Marzu, for the purpose of a food product, can lead to more perceived safety with consumers.

[185] S. Balzan, L. Fasolato, S. Maniero, E. Novelli, 2016. *Edible insects and young adults in a north-east Italian city an exploratory study*.

6. Conclusions

Casu Marzu is a cheese made of sheep milk originating from Sardinia, with the special ingredient larvae. The cheese is often eaten during special occasions and festivities, where people are gathering together for the celebration. The geographical characteristics of the island, as surrounded by the sea and herbal plants, influences the sensory attributes of the end-product. In the months September, October and November no new cheese making is involved, because of the lactation periods of the sheep. With producing Casu Marzu, another parameter has to be taken into account, the living circumstances of the *Piophila casei.* These are optimal when the temperature is 25°C and relative humidity is 60% and the insect can survive temperatures up to 50°C. *Piophila casei* fly is attracted by dairy products. In order to get a homogeneous ingested Casu Marzu, 40.000 eggs of *Piophila casei* are required.

Casu Marzu cannot be placed on the market due to safety reasons. According to article 5 of Legge 283 del 30 aprile 1962 of Italian law, it is forbidden to market a food product, which has been infested by intruders. Here, the natural way of the *Piophila casei* fly towards the cheese can be seen as an infestation by intruders. This same step in the production process is not in line with the FBO's obligation of traceability in article 18 of GFL and with the requirements laid down in Regulation 852/2004. Here, one can notice the desire to avoid insects in food processing. Nevertheless, the recognition of edible insects as more sustainable protein source has come to a shift of insects as contamination to insects as food and feed. In recital 8 of Regulation (EU) No 2015/2283 is specifically described that insects should be taken into account in product categories of novel food. In this case, the EU has shared competence, therefore FBOs in Italy have to comply with Italian law and EU-law.

In article 14 of GFL is stated that food cannot be placed on the market if unsafe. Unsafe is defined as injurious to health and unfit for human consumption. Food can be found injurious to health in three ways; having probable cumulative toxic effects, having any adverse effect on health for specific categories of consumer due to sensitivities and having any adverse effect on health including those on subsequent generations.

Risks can be defined as the probability of a hazard occurring. Hazards identified in this report are classified under the names biological hazards, biochemical hazards, chemical hazards and physical hazards. The biological hazard of high values of pathogenic bacteria would not pose a high risk in Casu Marzu, since it has shown that lactic acid bacteria decreases the amount of pathogenic bacteria during maturation of the cheese. However, the maturing process poses a biochemical risk called biogenic amines.

Especially tyramine, histamine and probably NDMA form risks in Casu Marzu. Tyramine causes headaches, high blood pressure and hypertension and NDMA is found carcinogenic. Nevertheless, further research on the metabolism on the conversion from putrescine and cadaverine to NDMA has to be conducted. When looking to a limit set for histamine, in fishery products, Casu Marzu would be incompliant. Important to note here is that Casu Marzu is not expected to be consumed in the same amounts as fishery products are. Histamine can cause nausea, sweating, headaches, hypo- and hypertension. Additionally, traceability cannot be guaranteed with the natural supply of the last ingredient of Casu Marzu, the eggs of *Piophila casei.* The fly can function as a vector of any transmittable diseases, without monitoring. Therefore, the obligation of the FBO under article 18 of GFL cannot be fulfilled. Casu Marzu should be labelled that it contains the allergens milk and insects.

In order to obtain a more relativized view on risks to health due to food and to put the risks more in perspective, a comparison study is conducted. The food products used in the comparison study to compare with the hazards of Casu Marzu are insects, Gorgonzola, oysters and mushrooms.

Insects can act as a vector for micro-organisms, but they cannot replicate them due to phylogenetically differences. The chemical hazard, cadmium, can be accumulated in insects. Especially in larvae, which excrete high concentration of cadmium in the faeces. This would particularly be a health issue with regards to Casu Marzu. Nevertheless, in this issue the substrate is of great importance and it is unlikely that the cheese mass contains high levels of cadmium. To this extend, cadmium is not considered as risk in Casu Marzu. Good housing conditions diminishes many risks in insects. Insects and insect products should be labelled with the allergen information regarding insects.

On the contrary of Casu Marzu, the biological hazard of pathogenic bacteria is often available in Gorgonzola. Therefore, a high risk of Listeriosis is present when consuming Gorgonzola. Furthermore, Gorgonzola contains high amount of free fatty acids, which can cause insulin resistance and can result in diabetes type I.

In oysters, some serious concerns for health can be defined. The risk of contamination with norovirus is high in consuming oysters. The norovirus is highly infectious, detection methods are complicated and recent cases have shown a failure in law. Another serious risk in relation with the consumption of oysters, is the biochemical hazard of tetrodotoxin, which can cause paralysis already in low doses. This can be considered as a high risk, since no antidote is discovered yet. Oysters should be labelled that it contains an allergen.

As identified as biochemical hazards in Casu Marzu, biogenic amines are also found present in mushrooms. Putrescine is found with higher values in mushrooms than in Casu Marzu. Besides, a further transformation of this amine occurs in mushrooms, which results in nicotine. Another important issue for health in mushrooms to consider, is the chemical hazard arsenic. Levels of arsenic found in raw mushrooms are approaching the legal limit for arsenic in milled rice for adults and are exceeding the limit for rice products for infants. This can be considered a high risk of consuming raw mushrooms.

One can notice from the comparison study that Casu Marzu can pose risks, but that other products, widely marketed within the EU, can pose risks as well. The major risk in larvae, is unlikely to occur in the case of Casu Marzu. Besides, some hazards identified in Gorgonzola, oysters and mushrooms can easily pose a risk for its consumers, since dose-response or the legal limit is approached.

The second part of unsafe is described in GFL as unfit for human consumption. Whether a product is unfit for human consumption or not is harder to measure than the injuriousness of a product. The meaning of unfit for human consumption in GFL seems to be capturing the overall rest that cannot fall under the definition of injurious to health. The unacceptability of the food can result from contamination with extraneous matter or from putrefaction, deterioration or decay. Many cases, showing the meaning of the different kinds of unacceptability, are mentioned in this report. In all these cases, one can detect that the product is found unfit, because it was not expected to be, as it was found to be. In the case of Casu Marzu, one is aware that larvae are still inside and have ingested the cheese, that is what consumers expect when consuming the particular cheese. The perception of the consumer matters in the protection of the consumer's interest, as aimed at with the GFL. Consumers would perceive a higher feeling of safety, when they know the larvae are reared specifically for the purpose of being food.

7. Discussion

In the current situation, placing on the market of Casu Marzu would not only breach Italian food law, but also hygienic requirements on the food premises as described in Regulation (EC) No 852/2004 and article 18 of GFL. Nevertheless, I see possibilities in the future for a safe Casu Marzu with the implementation of Regulation (EU) No 2015/2283. Since 2018, insects are considered as novel food. This would make marketing of larvae possible throughout the EU. Rearing the larvae under monitored conditions for the purpose of using it as raw material in Casu Marzu would be a solution to consider. FBOs can be supplied with reared larvae of *Piophila casei* and with using these larvae, one does not breach the article 18 of GFL and Regulation (EC) No 852/2004 anymore. Manufacturing Casu Marzu with reared larvae would not only contribute to conforming with EU-food law, but would also contribute to higher safety perception of consumers towards Casu Marzu. However, Italian law stresses the prohibition of food products, which are infested by an insect, larvae will still infest the cheese mass with Casu Marzu. To this extend, Italian decision-makers would have to maintain a more open policy regarding insects as food in order to keep up with scientific developments.

When the product is legalised, FBOs are able to standardise the production process and the hygienic design in premises more easily. FBOs can consider pasteurisation of milk prior to the cheese production. This production step decreases the number of micro-organisms, also of decarboxylase positive bacteria. This results in less decarboxylase activity occurring during maturation of the cheese and less proteins are metabolised into biogenic amines. The biochemical risks in Casu Marzu, named tyramine, histamine and probably NDMA, would be diminished massively.

From my point of view, the illegibility is the biggest risk in this case. The demand of Casu Marzu is present, despite its illegibility. Therefore, there is still a supply from producers, who are not approved FBOs. These producers all have their own manner of producing Casu Marzu differentiating from the other. Approved FBOs are not able to produce the product, since they will be incompliant and they face the risk of forfeiting the approval. However, the illegibility causes the presence of not standardised and not monitored food products. That can pose greater risks than Casu Marzu actually can when legalised. Legalising the marketing of the product and regulating food risks found in Casu Marzu, can help towards a safer Casu Marzu. With setting food safety criteria and process hygiene criteria, the FBOs do not only have to

comply, but also function as a guidance in good manufacturing practices. In this way allowing Casu Marzu to be marketed, enriches the food safety.

Furthermore, I would like to stress here, a lot of uncertainties are present and variables are missing in this report. Clear examples hereof are:

- Missing numbers of pathogenic bacteria in Casu Marzu;
- Uncertainty on the metabolism on the conversion from putrescine and cadaverine;
- Uncertainty on the specific decarboxylase activity of the larvae of *Piophila casei*;
- Uncertainty on the capability of the larvae of *Piophila casei* to cause myasis;
- Uncertainty on the metabolism on the absorption and maintenance of free fatty acids in blood etc.

Further assessments should be made in order to establish information more confidently.

Additionally, I would like to mention, that I take the worst-case scenarios into my considerations. For example, the uptake of free fatty acids in blood is set on 100%, since the actual uptake of this acid in blood is unknown.

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So, I was decided on the topic being the legal safety of Casu Marzu. With a couple of alternatives on the side, I went for an exploratory meeting to Kai Purnhagen. I told him about my vision regarding individual work and the ideas for my thesis topic and awaited his judgement. To my experience, this turned out to be positive and we agreed on the topic and on me conducting the thesis under his supervision. I am very grateful with his acceptance of the creative and liberal mind of students and with his confidence. I would like to utterly thank Kai Purnhagen for the help, support and feedback during the thesis period. Besides, I want to express my grace for his patience and for him reminding me on my learning objective to focus on doctrinal research. I praise myself lucky wit having a supervisor as Kai Purnhagen.

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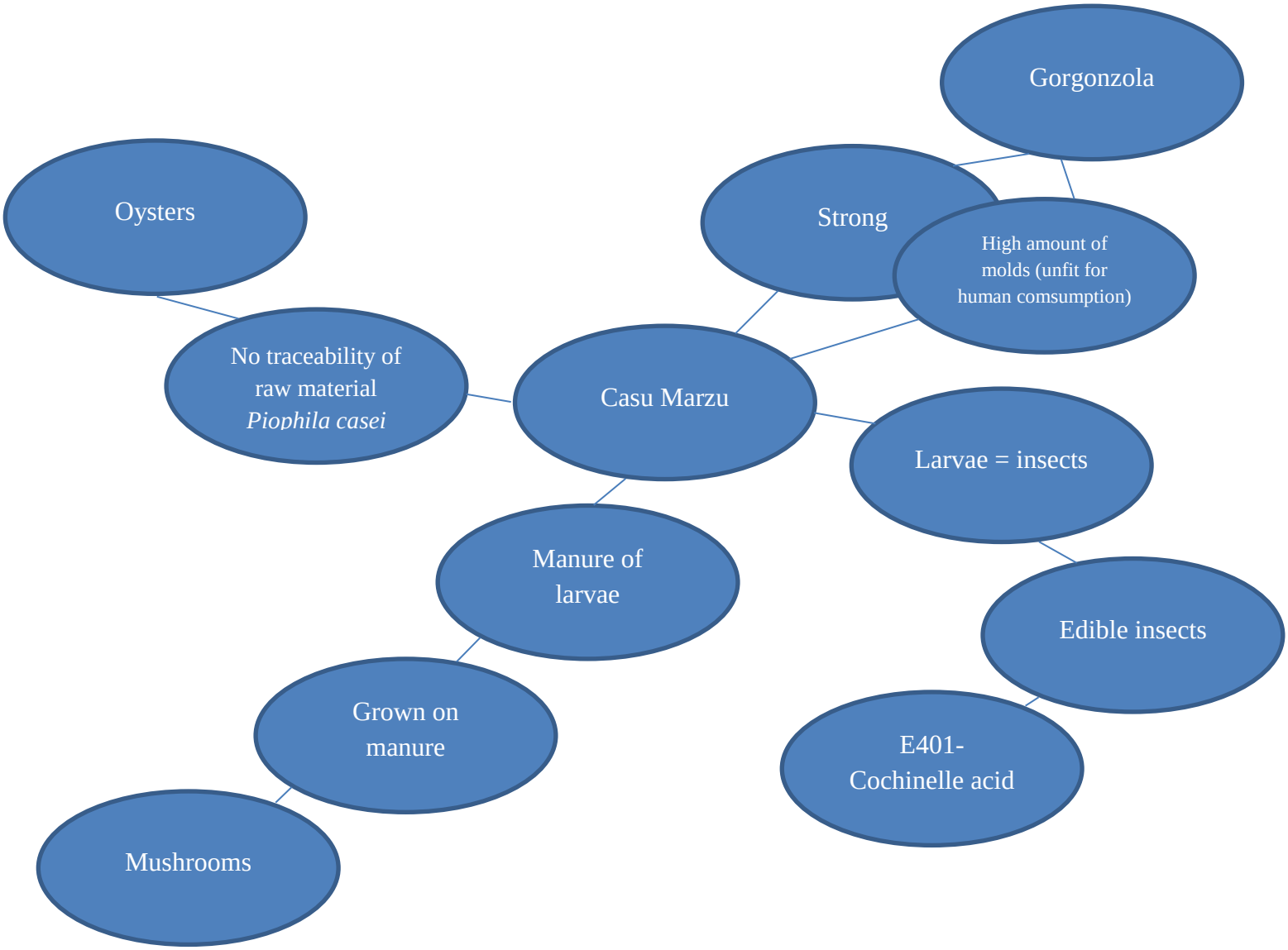
Thank you for reading!

Annex I

Mind map characterisation Casu Marzu

Before starting the comparison study, a mind map is made for the characterisation of Casu Marzu in order to be able to identify foodstuffs to compare the respective food product with.



Annex II

Conversion and calculation FFA dose-response

Important to note here, is that there are uncertain variables used in this calculation. Further investigation is needed, in order to obtain more reliable numbers. This calculation was used to show an example in the comparison study.

Given that:

- Worst case in amount of blood, in the case of women, 4,5 L[186];
- Worst case in uptake of FFA in human blood, 100% (specific data is missing on the relatively uptake of FFA);
- The molecular weight used in the calculation for FFA is the molecular weight of Stearic acid = 284,48 g/mol[187];
- Dose-response of FFA for insulin resistance is 550 μM;
- Gorgonzola contains 12.305 mg/kg FFA after 86 days of maturing.

1 M stearic acid = 284,48 g/L

1 mM stearic acid = 0,28448 g/L

1 μM stearic acid = 0,00028448 g/L

55o μM stearic acid = 0,00028448 g/L * 550 = 0,156464 g/L

Dose-response in human body = dose-response/L * amount of blood in human body
= 0,156464 * 4,5 = 0,704088 g/human body

Amount FFA in Gorgonzola = 12.305 mg/kg
= 12,305 g/kg

Break-even point for FFA in Gorgonzola and dose-response = dose-response/dose
= 0,704088/12,305
= 0,05721966… kg
= 57,21966…≈ 57,2 g Gorgonzola

[186] Information retrieved on 15-02-2018 from https://www.sanquin.nl/bloed-geven/over-bloed/faq-bloed/hoeveel-liter-bloed-heeft-een-mens/

[187] Information retrieved on 15-02-2018 from https://pubchem.ncbi.nlm.nih.gov/compound/stearic_acid#section=Top

Annex III

Health benefits of the consumption of Casu Marzu

During fermentation in cheese-making, proteins and lipids are broken down in smaller particles during fermentation. As well milk indigenous bacteria as exogenous bacteria have the ability to catalyse proteolysis. Proteolysis is the hydrolysing process responsible for fragmenting proteins in smaller compounds, such as peptides and free amino acids. Free amino acids are found to have beneficial outcomes for the human body, such as anti-tumorigenic[188].

Casu Marzu is exposed to a second catabolic transformation of the free amino acids, named decarboxylation, which result in amines. Bacteria with aminoacyl decarboxylase activity, which are present in cheese, split the carboxyl group from the rest of the amino acid.

With the decarboxylation by L-glutamic enzyme, γ-aminobutyric acid (named GABA hereinafter) is produced. GABA was never found in such high quantities as it was found in Casu Marzu. GABA is known for its nutraceutical character[189]. The term nutraceutical is a mash-up of nutrient and pharmaceutical, which stresses the believe in nutrients in food having beneficial effects on human health comparable to medicinal drugs. This believe is relating to the saying: ''Let food be your medicine'' (Hypocrates)[190]. GABA is naturally present in a wide range of mammals, however in very small entities, but is largely produced in Casu Marzu[191]. A lot of white powder containing pills are offered in order to elevate the level of GABA[192],[193],[194]. The beneficial health effect of GABA are relaxing properties, like antianxiety, antidepressant, lowering blood pressure and with that antihypertension. Besides,

[188] M. Mancino, E. Ametller, P. Gascón, V. Almendro. 2011. *The neuronal influence on tumor progression*.
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[192] Information retrieved on 09-11-2017 from https://www.vitaminesperpost.nl/gaba?gclid=EAIaIQobChMIncrKpuex1wIVzZztCh1GbwASEAQYASABEgJVhPD_BwE
[193] https://www.bsnutrition.nl/amino_521/gaba-500mg-now-foods_836.html?variation=545%3D1678&gclid=EAIaIQobChMIncrKpuex1wIVzZztCh1GbwASEAQYAiABEgLBUPD_BwE
[194] Information retrieved on 09-11-2017 from https://xxlnutrition.com/nl/nld/xxl-nutrition/gaba?gclid=EAIaIQobChMIncrKpuex1wIVzZztCh1GbwASEAQYBCABEgLG1fD_BwE

it is functional for regulating the secretion of hormones[195], which includes insulin what in that turn can prevent diabetes[196].

Another beneficial characteristic is that GABA has been found to be anti-tumorigenic, since it can slow down the dose and time response and in that way also prevent cancer from being spread throughout the body[197].

Many other amines are produced in Casu Marzu, of which histamine is one of them. Histamine lowers the blood pressure, which can be seen as a health benefit for a lot of consumers in the EU. Besides, the amine is needed by the human body to fulfil metabolic functions, especially in the nervous system[198].

Also the biogenic amine β-phenylethylamine is found in significantly amounts. This amine is expected to cause a happiness and loving feeling as it releases the hormone endorphine[199]. Hypertension is induced after intake of this amine. An average of 202,7 mg β-phenylethylamine was present in 1 kg Casu Marzu

On a lesser microscopic scale, but on the scale of macronutrients, another benefit on the consumption of Casu Marzu can be described. Casu Marzu is a source of proteins. Proteins are supplied not only through the cheese mass, but also through the presence of larvae in the cheese. Insects can point at additional protein content in the Casu Marzu[200].

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