Horizon 2020

PROTECT

State-of-the-art with regard to mycotoxin and microbial risk assessment in dairy products with special attention to potential climate change effects

Deliverable number: D3.1

Version 1.0

This project has received funding from the European Union's Horizon 2020 research and innovation programme under **813329-PROTECT-H2020-MSCA-ITN-2018.**

Project Acronym:	PROTECT
Project Full Title:	Predictive Modelling Tools to evaluate the Effects of Climate change on food safety
Call:	H2020 MSCA ITN 2018
Topic:	MSCA-ITN-2018
Type of Action:	MSCA-ITN-ETN -European Training Network
Grant Number:	813329
Project URL:	www.protect-itn.eu

Editor:	Jeanne-Marie Membré, Oniris
Deliverable nature:	Report (R)
Dissemination level:	Public (PU)
Contractual Delivery Date:	30 April 2020
Actual Delivery Date :	30 April 2020
Number of pages:	55
Keywords:	Risk assessment, dairy, mycotoxin, microbial, climate change
Authors:	Rhea Sanjiv Chhaya, University College Dublin Rodney Feliciano, Oniris Jeanne-Marie Membré, Oniris Enda Cummins, University College Dublin
Peer review:	Eleanor Mathews - University College Dublin

Table of Contents

List of Figures

List of Tables

1 Abstract

Climate change manifests itself in many different ways including rising global temperatures, intensification and increased frequencies of extreme events and alterations in precipitation patterns. Environmental factors have an impact on plants, pathogens and animals and therefore climate change is expected to impact food safety. One of the European Union's major industries is the dairy industry. Climate change is expected to have a potential impact on it by affecting milk safety and quality. This document reviews the biological hazards and mycotoxins occurring in the dairy industry and state of the art risk assessments related to these hazards. The impact of extant processes and conditions on the microbial count and microbial hazards occurring along the dairy supply chain are detailed. Seasonal patterns are displayed by mycotoxins and microorganisms, with winter and summer favouring, respectively, the occurrence of mycotoxins and biological hazards in the dairy supply chain. As environmental factors may cause hazards, it is postulated that climate change will have an impact along the dairy supply chain. Based on the literature reviewed, very few studies have incorporated climate change as a variable into risk assessments related to the dairy industry, and full models assessing the mycotoxin exposure from the farm to the fork are not yet available. The need to conduct climate responsive quantitative risk assessments is underscored. The step towards such risk assessments is through the incorporation of climate conditions or events as variables. In addition, the monitoring of climate conditions is needed in order to verify if the current climate conditions reflect the trajectory of climate change and its effects on the dairy supply chain. The report also summarises the potential risk mitigation strategies that should be adapted in the current food safety management systems given the current and projected effects of climate change.

2 Introduction

Europe is a major contributor to the Global Dairy Industry. In 2018, it had a net trade of 1 million tonnes of fresh dairy products, 0.8 million tonnes of cheese exported at 3000 euros/tonne and 0.157 million tonnes of butter at 4000 euros exported (EC 2019). The European dairy industry produced 167 million tonnes of raw milk in 2018 alone. Pressures such as climate change and population growth are expected to create a significant impact on the dairy industry either directly or indirectly. Climate change has been associated with increasing temperatures, changes in precipitation patterns and increased carbon dioxide levels. The EU dairy industry may be significantly impacted by climate change which could potentially result in a poor yield of milk, low milk quality, damage to animal health, and an increase in potential illnesses in humans (related to consumption of contaminated milk and milk products) and economic losses. Mitigation steps could be implemented with the proper food safety management systems currently in place. Therefore, this report seeks to explore the following topics 1) To present the possible effects of climate change in the dairy supply chain. 2) To identify the current biological and chemical hazards affected by climate change in the dairy supply chain. 3) To highlight the role of food safety management in assuring food safety. 4) To underline the role of Feed Chain Risk Assessment and Quantitative Microbial Risk Assessment. 5) To present the possible mitigation strategies in relation to the effects of climate change in the dairy supply chain.

2.1 Dairy Supply Chain

The dairy industry comprises of multiple products including milk, cheese, yoghurt, ice cream and butter. Dairy production is a major activity in Europe. An estimated 168 million tonnes of milk was produced in the year 2019, and it is projected that the figures will be around 179 million tonnes by 2030 (EC 2019). The main producers of milk and milk products are Germany, France, Poland, Netherlands, Italy and Spain. The European Union (EU)'s production of cheese in the year 2019 was approximately 10.8 million tonnes and is expected to grow to 11.5 million tonnes in 2030 (EC 2019). The predicted per capita consumption of cheese is expected to increase to 20.2 kg. **Figure 1** shows the percentage division of milk and milk produced by Europe as of January 2020. The European Union milk industry recorded 22.6 million dairy cows as of 2019, with a milk yield of 7325 kg/cow and since 2005, the fat content of the milk has been fairly consistent at 4%. Globally, the European Union is a major supplier for dairy and dairy products and is projected to grow its exports by 44% by 2030. However, an exhaustive list of factors may affect the production of milk and milk products such as consumer behaviour, consumer income, population growth and climate change.

The dairy supply chain encompasses a farm to fork continuum. It is comprised of sequential processes that are performed in various locations. An overview of the dairy supply chain processes is presented in **Figure 2**. These processes are located at the farm level (from the production of feed to hold-on of raw milk), at dairy manufacturing facility (deposit of raw milk in bulk tanks, processing and its packaging), at distribution points and consumer locations.

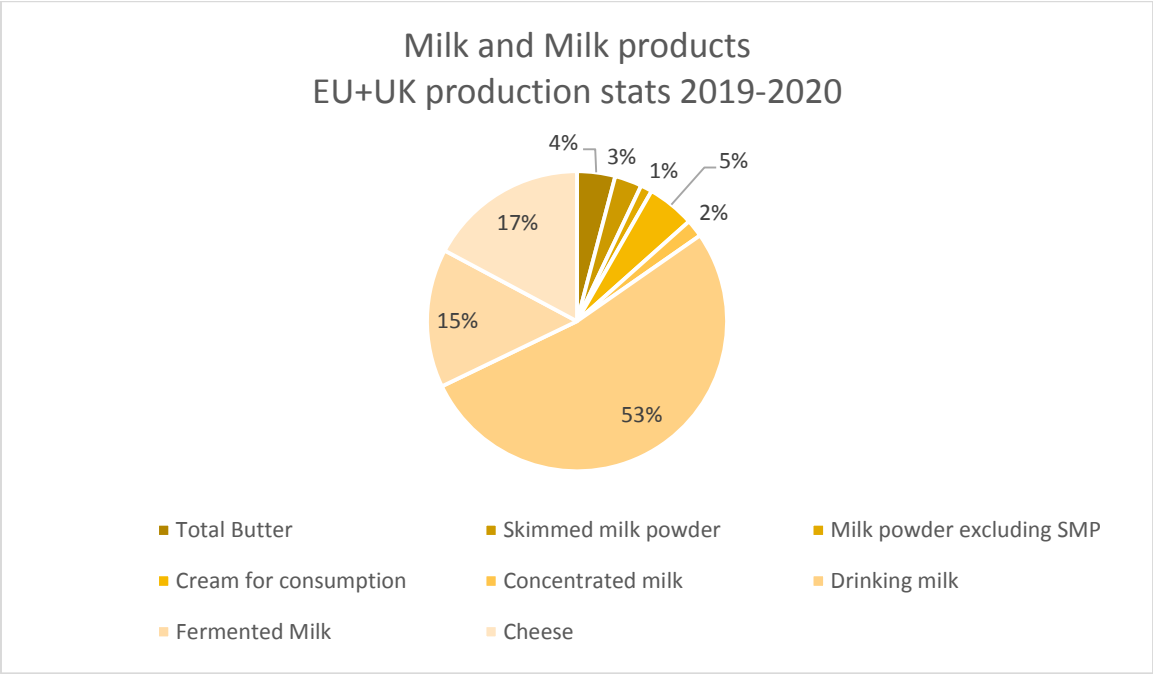

Figure 1: Distribution of dairy products produced in EU & UK

Adapted from EU (2019)

2.1.1 Farm level: from the production of feed, transport and milking facility

Feeding practices are subject to climatic conditions, feed availability and quality, and farmer preferences. When fresh grass is plentiful and it can provide the amount of energy required for healthy milk production, farmers allow cattle to graze freely. During droughts or winter when fresh grass may be scarce, cattle are fed industrially manufactured compound feed comprised of grains and silage. Silage generally makes up 50-80% of cattle feed (Tangni *et al*. 2013). Ensiling is a process to store forage in a manner such that the formation of mould and clostridia is inhibited.

The milking procedure at the farm level is performed manually in cages or through the use of automatic milk equipment at a milking parlor. Among the considerations taken into account in choosing the milking procedure is the type and scale of farm. Raw milk is collected and can be used on the farm or sold to the industry. For large scale operations the automatic milking machine transfers the milk in refrigerated bulk milk tanks or milk cans prior to collection and it is then transported to the dairy manufacturing facility. These tanks are kept under sanitary conditions and are monitored continuously. Milk collectors may refuse to collect milk if it appears to be contaminated or to have exceeded temperatures of 7˚C. After collecting the raw milks from the farm, it is transported in bulk in chilled tanker trucks kept at temperatures below 4˚C.

2.1.2 Raw milk: from reception to the dairy manufacturing facility, processing and its packaging prior to distribution

Transported raw milk from the farm is pumped from the tanker truck to raw milk silos tanks (Kable *et al.* 2016) and can be kept up to 4 days in storage. Raw milk samples are also obtained during this period as part of quality management systems in order to perform quality assurance tests to determine whether the extant quality specifications are met (Murphy *et al.* 2016). Among the tests performed at this stage are microbial quality tests to see whether the incoming raw milk meets the microbial specifications set by the dairy manufacturing facility (ICMSF 2011).

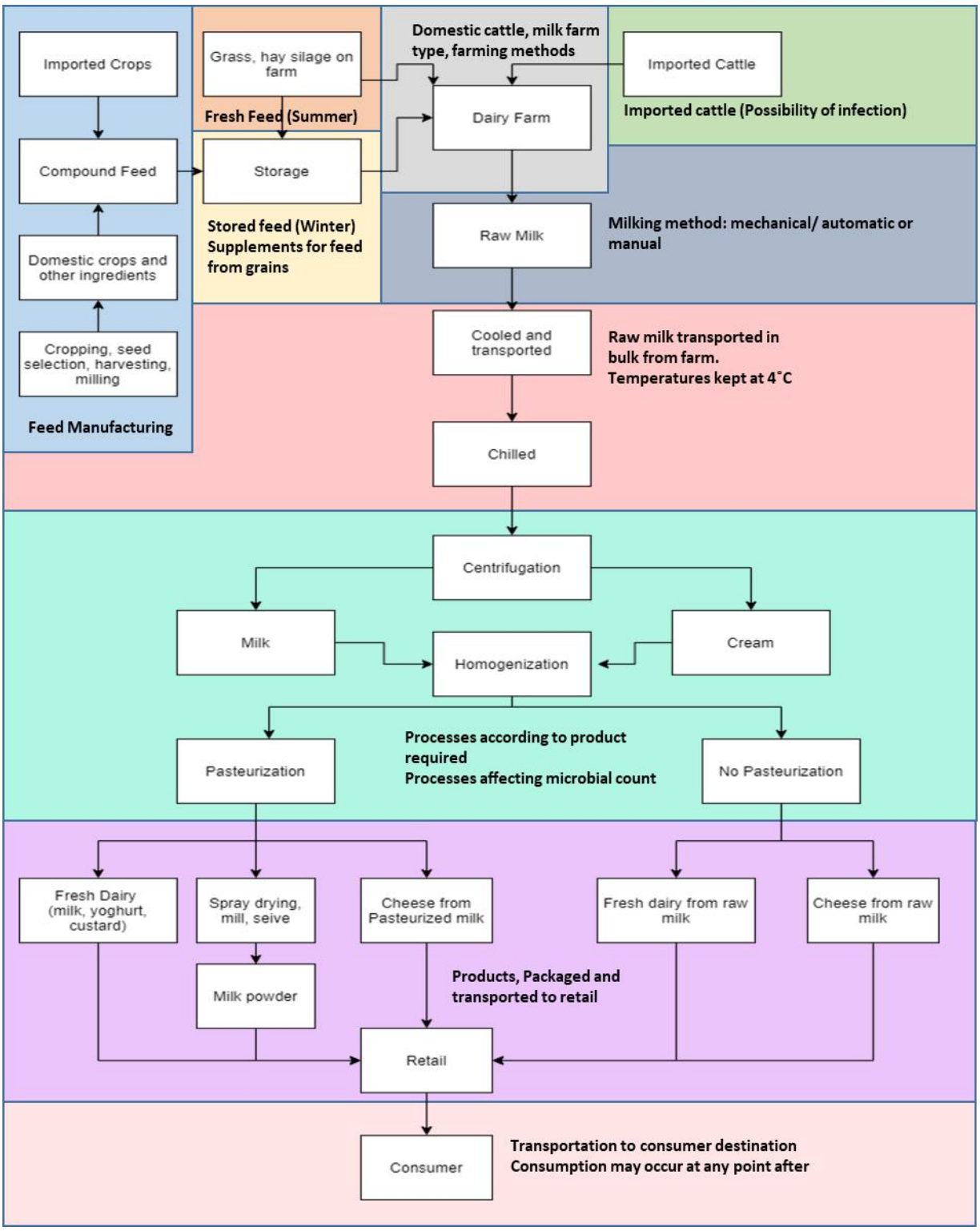

Figure 2: Farm to fork process in the dairy supply chain.

Adapted from van Asselt *et al.* (2017)

Prior to processing raw milk it is firstly pretreated through filtration and then undergoes centrifugation (ICMSF 2005). This step separates the two major milk components, that is cream and skimmed milk. Dependent upon the dairy processing line, as in the case of liquid milk, some of these separated components are combined. The recombined milk may then be homogenised dependent upon the quality of milk required. Most often than not, milk is then subjected to thermal processing treatments. However, given that artisanal dairy products preferentially opt for the use of raw milk, some of it processed into other products without the application of heat treatment.

Fermented dairy products after pasteurisation (or not) undergo several processes that are specific for cheeses and lactic acid fermentation for yoghurts. These steps may include; the addition of other substances such as rennet for cheese block formation, which is subsequently ripened or, for yoghurts the addition of starter cultures. Fruits, juices, pesto, etc. are added to dairy products to create variations amongst dairy products. After these main processing steps that aim to convert raw milk into a specific dairy product, the products are packaged into secondary and tertiary packages ready for distribution points. The final product is then stored under appropriate conditions (to prevent damage during transport, inhibit growth of microbes or mould), and transported to retail. Commonly, dairy products are stored at chilled conditions (Bishop and Smukowski 2006).

2.1.3 Distribution points and consumer locations

At retail, the dairy products are stored until its sell-by-date period before which a consumer may purchase the dairy product. The dairy product is then transported and stored in the consumer's kitchen and may undergo variable consumer practices. Temperature abuse during handling before a product reaches a domestic refrigerator may occur.

External factors may have an impact on the quality of the dairy product delivered. Improper storage conditions and unhygienic practices at the consumer level might build upon the extant microbial and biological hazards that are introduced during the earlier part of the dairy supply chain making the products unsafe to consume. Another growing concern which may have an impact throughout the dairy supply chain is climate change.

2.2 Climate Change and Dairy Industry

According to the Intergovernmental Panel for Climate Change (IPCC)'s special report (Hoegh-Guldberg, Jacob, Taylor, Bindi, Brown, Camilloni, Diedhiou, Djalante *et al*. 2018) released in 2018, the global mean surface temperatures (GMST) have risen by 0.87˚C in the years 2006-2015 compared to the baseline temperatures in 1850-1900. Southern Europe, Central Europe and the Mediterranean regions have had the strongest hot temperature extremes as a result of climate change. The occurrence of cold temperature extremes is likely to reduce overall but intensify in the Northern latitudes of Europe. The northern hemisphere has experienced an increase in precipitation. The increase of 2˚C in global mean temperatures is associated with increased winter precipitation in central and northern Europe and decreased summer rainfall in central and southern Europe. Increases in global mean temperatures in the future could result in increased incidences of drought in the Mediterranean region (Southern Europe). Global warming is also expected to bring with it increased incidences of floods in the north eastern parts of Europe.

Environmental factors have an impact on plants, pathogens and animals and thus climate change is expected to impact food security. Climate variables have been linked to crop phenology and physiology, as well as changes in sowing times. Climate change and global warming is expected to make some countries in Europe have an increased share of crops such as maize and wheat by 2040 (Elsgaard *et al.* 2012) which are currently limited in some parts of Europe. Projections show maize crops extending to as far as Denmark while decreasing in the tropical regions. The downside of climate change is an increased risk of contamination within the food chain as well as increased discomfort and stress in animals induced by temperature rises (Miraglia *et al.* 2009). Crops, both pre-harvest and post-harvest may be inflicted with fungal diseases, and these crops could be fed to animals causing illness, affecting reproduction and the quality of animal products (Stoev 2015; Knutsen *et al.* 2017, 2018; Wang *et al.* 2019). Extreme climatic events have also been associated with food hazards (Marvin *et al.* 2013): for example, droughts and heatwaves

are directly related to the outbreak of toxigenic fungi and increase in cases of salmonella (Akil *et al.* 2014), floods are associated with increased contamination of agricultural soil and water.

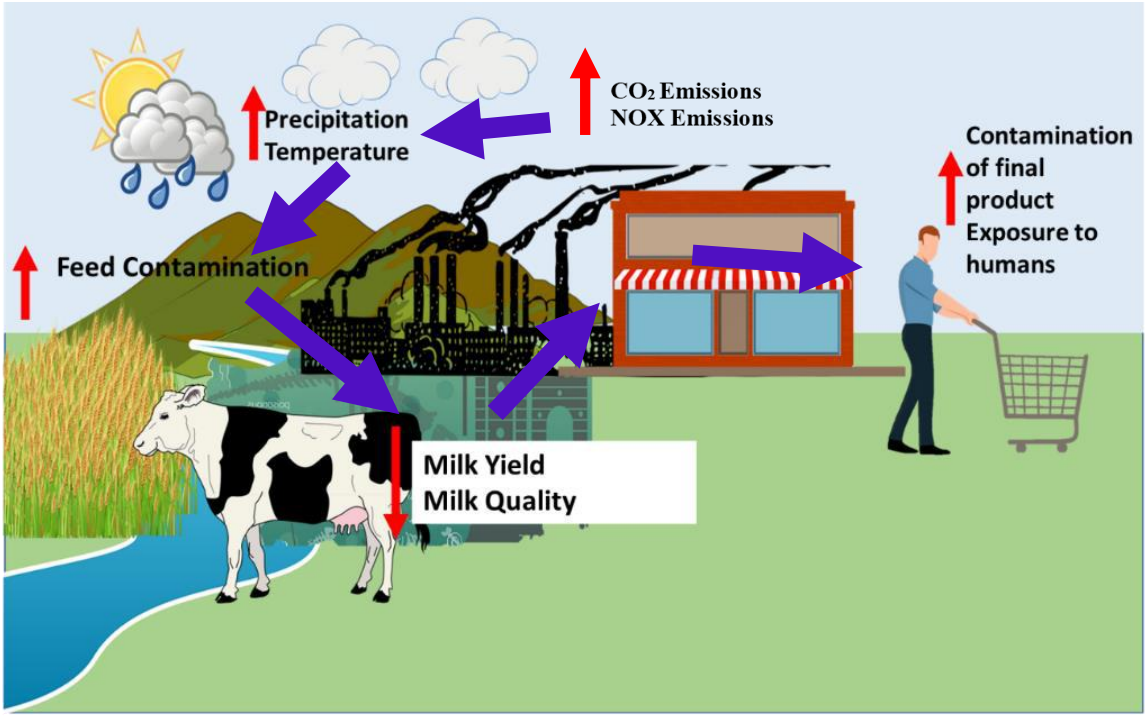

Figure 3: Climate change and Dairy Production

Figure 3 represents the ecological relationship existing in the biosphere with particular emphasis on the dairy supply chain system and external factors. Increases in precipitation and temperature are attributed to anthropogenic activities, which in turn increase the incidence of hazards along the dairy production chain. Humans may be exposed to these hazards by consuming contaminated products which may cause them to fall ill. Climate change is expected to influence the food safety aspect of dairy products through its direct impact on the microbial ecology of food and occurrence of hazards along the food supply chain. It is also expected to have an indirect influence towards farming practices, which may include altering current farm practices, possible mitigation responses towards changes in climatic conditions and extreme meteorological events (e.g. rain, flooding or droughts). Extreme weather events, such as heat waves and droughts are expected to impact the physiological status of the livestock (Miraglia *et al.* 2009; van der Spiegel *et al.* 2012) by causing heat stress or contaminating the feed. Consequences of contaminated feed are discussed in the following section, however, to summarise, contaminated feed has been linked to low milk yield, feed refusal, impact on reproductive death and in extreme cases death of the livestock (Bryden 2012; Alshannaq and Yu 2017; Knutsen *et al.* 2017; Wang *et al.* 2019). Farm management practices are expected to be affected such as an increase in intensive dairy farming methods with climate controlled barns to avoid heat stress and changes in cropping patterns.

High temperatures induce heat stress in animals and affect feed availability. Thermal stress in animals affects the body temperature, respiration rate, milk yield, feeding and drinking behaviour. Heat stress risk for different climate projections, and its impact on dairy production, was modelled for two naturally ventilated barns located in different regions in Europe (Hempel *et al.* 2019). Cattle located in Southern Europe are expected to experience higher heat stress events as compared to central Europe. A predicted decrease in average European milk yield by 2.8% is expected under a worst-case climate change scenario. Another effect of heat stress in cows is the reduction in blood

glucose levels which will ultimately lead to an increase heat associated deaths (Nardone *et al.* 2010; Das *et al.* 2016).

Associated changes in the physicochemical properties of raw milk obtained from heat stressed lactating cows were also shown to be expected (Bouraoui *et al.* 2002; West 2003; Wheelock *et al.* 2010; Santana *et al.* 2017). An example of this is the decrease in milk protein content, lower α_S-casein, κ-casein, β-casein (Bernabucci *et al.* 2002), fatty acid profile (Liu *et al.* 2017), fat to protein ratio and lower casein content of milk (Ozcan *et al.* 2015; Liu *et al.* 2017; Kekana *et al.* 2018; Cai yun *et al.* 2019) were among these alterations. Milk fat content is also lowered as a result of heat stress and poor feed quality induced by adverse weather conditions (De Rensis and Scaramuzzi 2003; Renna *et al.* 2010). Lambertz *et al.* (2014) also found a decrease in milk fat and protein content as a consequence of heat stress.

The implications of these changes in milk quality will also affect the techno-functional and biofunctional properties of milk. For the technofunctional properties, it was shown that lower casein content in milk affects cheese block formation, negatively impacting the cheese making process (Bernabucci *et al.* 2002). The biofunctional properties of casein and other milk proteins in milk that were shown to have antihypertensive and antihyperlipidemic activities will be affected by the climate change induced heat stress effects in lactating cows (Tidona *et al.* 2009; Broyard and Gaucheron 2015; Banno *et al.* 2019; Nagaoka 2019).

Farms are also expected to be impacted by increases in pests incidences, as pest species migrate pole-wards for more favourable climates (Elsgaard *et al.* 2012; Delcour *et al.* 2015). The efficacy of pesticides, fungicides and fertilisers has been predicted to reduce as a consequence of warming temperatures, high volatilization rates and slower uptake (Delcour *et al.* 2015). Thereby requiring a change in application rates. Sowing times of crops are expected to be earlier, as a result of warmer winters and change in crop physiology (van Asselt *et al.* 2012; Peltonen-Sainio *et al.* 2018; Madege *et al.* 2019). These factors are a result of climate change, and affect mycotoxin production thereby, climate change has an indirect effect on the dairy supply chain.

While these are the direct impacts of climate change on the animal itself, climate change also impacts the safety of the milk product. Changes in ambient temperatures and relative humidity can increase pest incidence and may impact the quality of the feed and the final dairy product by contaminating it with hazards. Exposure to these hazards could affect animal health and productivity. Consumers of milk could get exposed to contaminants which could carryover in the milk products from the infected animal. The next section lists the potential hazards occurring in the dairy supply chain. It also summarises the effects of climate change on the hazards.

3 Potential hazards in the Dairy Supply Chain

Maintaining food safety is crucial to the food industry to prevent any harm or even death to consumers. It is estimated that there are several million foodborne illnesses every year with many deaths resulting. In 2010, the WHO estimated 600 million cases of foodborne illnesses with 420,000 deaths as a result (WHO, 2015). Contaminants or hazards in food are substances which could potentially harm human or animal health. They can be classified as biological, physical or chemical hazards. While most hazards can be removed during the processing steps, such as pasteurisation, it is necessary to eliminate or reduce contaminants at the source. Risk assessments and HACCP practices can also help to maintain safe milk. Biological hazards and mycotoxins occurring along the dairy supply chain have been displayed in **Figure 4**.

3.1 Biological hazards in raw milk: an overview

The microorganisms in raw milk are known to be influenced by the cow udder and health, environment, equipment surfaces, climate conditions and the persons handling milk (ICMSF 2005, 2011). As such it was pointed out by previous research that raw milk microbiology is not only unique to where it is sourced from but also it is unique to the animal husbandry conditions it is subjected to (Mallet *et al.* 2012; Montel *et al.* 2014). Moreover, the contribution of these factors on the microbial contamination of raw milk will be a burden of significance across the dairy supply chain. These microorganisms may increase and produce metabolites that contribute, not only to the increased microbial load, but also the presence of proteolytic, lipolytic enzymes that will ultimately alter the quality of raw milk and possibly even the end products to be derived from it. Therefore, the impact of conditions during the handling of raw milk and the stringency of control measures that are s*et al*ong the dairy supply chain will be significant in achieving microbial food safety and quality of dairy end products. These claims are supported by cases of foodborne disease outbreaks linked with the consumption of milk and dairy products that were subjected to abuse conditions along the dairy supply chain (Asao *et al.* 2003; Olivier *et al.* 2005).

3.1.1 Raw milk microbiology

The conditions on the farm and the animal husbandry practices influence the microorganisms present in milk. The microorganisms present in raw milk can be traced from the dairy environment and fecal contamination (Olivier *et al.* 2005). These include zoonotic pathogens such as *Mycobacterium avium* and *Brucella* spp., those belonging to *Enterobacteriaceae* such as *Escherichia coli, Yersinia* spp., and *Salmonella* spp. from fecal contamination (ICMSF 2005). Others include *Bacillus* spp., *Clostridium perfringens, Clostridium butyricum and Clostridium tyrobutyricum, Flavobacterium* spp., *Sphingomonas* spp., *and Tumebacillus* spp. which were found in silages, farm soil and cow beddings (ICMSF 2005; Doyle *et al.* 2017). On the other hand, yeast and lactic acid bacteria (i.e. *Lactococcus lactis, Lactobacillus parabuchneri* and *Pediococcus pentosaceus*) are traced back from grasslands and silage which is important for its techno-functional role in fermented products such as cheese and yoghurt (Montel *et al.* 2014). These microorganisms are then inoculated to raw milk to udder surfaces and milking equipment among others. Moreover, some of these microorganisms, together with other psychrophiles such as *Pseudomonas* spp., *Acinetobacter* spp., *Serratia* spp., *Streptococcus* spp. are able to produce biofilms in equipment surfaces that contribute to their spread in raw milk (Yuan *et al.* 2019). In order to reduce contamination of microorganisms in milk surface cleaning of udders prior to milking, cleaning of milking equipment and a separate location of milking parlors at a different area in the farm are being done (ICMSF 2005; Pantoja *et al.* 2011).

Pathogenic microorganisms in milk such as *Staphylococcus aureus, Listeria monoctyogenes, Escherichia coli* together with *Clostridium* spp. *Streptococcus* spp. (*S. agalactiae* and *S. dysgalactiae,* and *S. uberis*) are linked with mastitis in cows (ICMSF 2005; Condoleo *et al.* 2017; Grispoldi *et al.* 2019). Furthermore, mastitis in lactating cows by microbial infection is also influenced by milking practices such as automatic milking equipment and heat stress due to climate conditions (Hovinen and Pyörälä 2011). In addition, the presence of antibiotic resistant strains of these mastitis promoting microorganisms can also be found in milk due to the use of antibiotics in cows (Jamali *et al.* 2013; Gundogan and Avci 2014; Kevenk and Terzi Gulel 2016). These microorganisms and their forms are to be found in raw milk due to the practices and conditions implemented at the farm level.

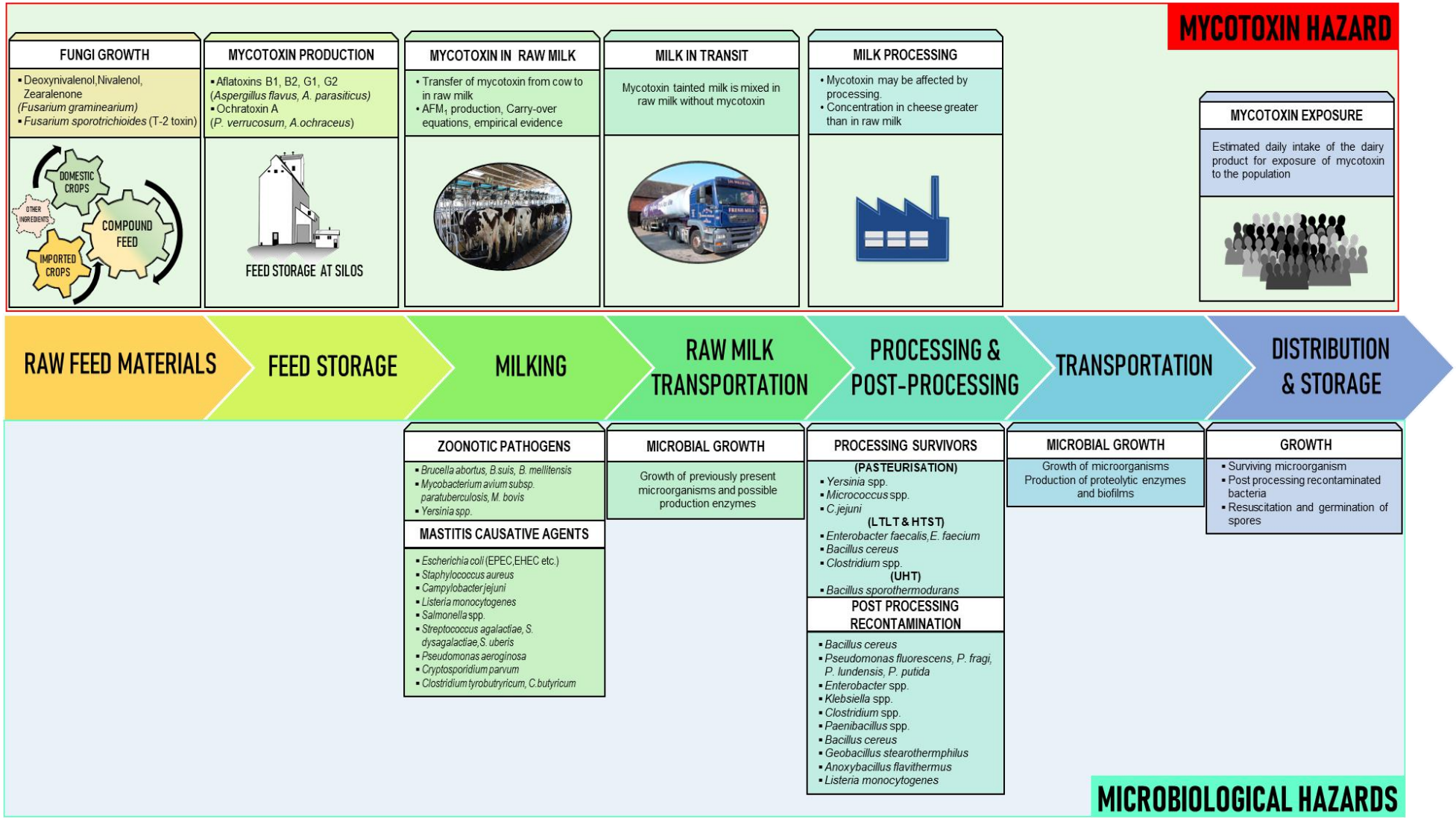

Figure 4: Mycotoxin and microbial hazard occurrence along the dairy supply chain

Adapted from ICMSF (2005).

Raw milk obtained from cows is immediately cooled to lower the temperature to < 6 °C. These conditions are maintained during transportation. Quality controls that are being practiced during transit include; the cleaning of surfaces as well as the monitoring of conditions to ensure reduced microbial growth and production of metabolites. However, psychrophiles were still been found to produce lipolytic and proteolytic enzymes that may alter the properties of raw milk by producing spoilage features such as bitterness (*Pseudomonas* spp.), ropiness (*B. subtilis*), sweet curdling (*B. cereus*), red discoloration (*Serratia* spp.) and purple (*Chromobacterium* spp.) discoloration in raw milk and even in processed milk (ICMSF 2005; Burgess *et al.* 2010). Therefore, the impacts of the quality controls will shape the products to be derived from raw milk and the effectivity of the subsequent process.

3.1.2 Dairy Processing and post processing microbiology

The microbiological hazards in raw milk may change during product transport and storage prior to reaching the dairy manufacturing facility. These changes may result in higher levels of microbes or the production of metabolites (i.e. enzymes, biofilms and toxins) if temperatures abuse occurs over a prolonged period. Therefore, food safety managers along the dairy supply chain need to implement food safety controls that are validated and verified. The ICMSF (2005) have outlined different controls for different dairy products that include, assuring lower microbial contamination at the farm level, protection of transportation chain conditions, application of a series of pre-processing and thermal treatments in order to bring the microorganisms at acceptable levels.

Thermal processing is still the widely applied processing treatment being used in reducing the levels of microorganisms in raw milk. Auxiliary steps to remove physical hazards and some of the microorganisms prior to the main processing treatments are usually performed. These include filtration of milk and thermization (57-70°C)(ICMSF 2005; Ramírez *et al.* 2006). These are then followed by a separation process that removes cream from skimmed milk. Both of these are separately subject to pasteurisation treatments at their subsequent processing lines. For dairy milk the thermal processing regimes vary, for Ultra High Temperature processed milks (135-150 °C thermal treatment, 3-5 seconds duration at different cycles) and less in the case of pasteurised milks (62-65 °C for 30-32 minutes), High Temperature Short Time processed milks (71-78 °C, 15s) (ICMSF 2011). For an extended shelf life skimmed milk is heat treated or passed through ultrafiltration while the cream is pasteurised. Both of these two are later combined (ICMSF 2005). The required log reduction value for pasteurised milk is a 5 log reduction of vegetative bacteria and a 9 log reduction of thermophilic spores for commercially sterile milk (ICMSF 2005; Deeth 2017). Alternative novel non-thermal processing technologies have been shown to inactivate pathogenic microorganisms in milk and were shown to have a potential to be used instead or in conjunction with the current processing treatments. These include the use of atmospheric plasma sonication, high pressure processing and membrane separation technologies (Brans *et al.* 2004; Evelyn and Silva 2015; Gabriel 2015; Coutinho *et al.* 2018; Alirezalu *et al.* 2020).

However, dairy processing lines are not without their own complexities as these series of unit operations may be reservoirs for spoilage and pathogenic microorganisms. Cross contamination might occur through the formation of biofilms on the contact surfaces of dairy manufacturing equipment (e.g. heat exchangers, bulk milk tanks, evaporators, membrane filters) and the recovery mechanisms along the process line (Flint *et al.* 2020). An example of these are the harbouring of *Streptococcus thermophilus, Bacillus lichenformis, Geobacillus stearothermophilus, Bacillus thermodurans* and other thermophiles in heat exchangers (Jindal *et al.* 2016; Flint *et al.* 2020).

In relation to recovery mechanisms in dairy processing lines there have been a number of documented hazards. An example of a recovery mechanism includes insufficiently dried milk which can be re-circulated again in bulk milk tanks. Another example is in infant milk formula

manufacturing where some of the dried powder can be carried together with drying air which are recovered through separation of these powder through cyclones and air filters. The former mechanism was linked to the staphylococcal toxin foodborne disease outbreak in Japan. The latter mechanism, air filters have been documented to be a reservoir of *Cronobacter sakazakii* in powdered infant milk formula (Soejima *et al.* 2007; Jacobs *et al.* 2011).

The unit operations in which post processing recontamination might occur include filling, cooling of pasteurised milk and filling of milks or primary packaging of solid and liquid dairy products. Therefore, the microbial hazards that might be present in these unit operations may be re-introduced from contaminated surfaces and those thermoduric, spore-forming bacteria that have survived the processing treatments might be able to germinate in favorable conditions. Among the spores that are known to survive thermal treatment include *Bacillus* spp. (*B. cereus, B lichenformis* and *B.thermodurans*), *Clostridium* spp., *G. stearothermophilus, Anoxybacillus flavithermus, Paenibacillus* spp. (Burgess *et al.* 2010; Porcellato *et al.* 2018; Eijlander *et al.* 2019). Therefore, the presence of these microorganisms have been detected in different dairy products (van Asselt *et al.* 2017).

3.1.3 Distribution and consumption of dairy products

The impact of these surviving microorganisms and post processing contamination can be seen during distribution and consumption of dairy products. Pujol *et al*., (2015) have shown that spore forming microorganisms are able to cause spoilage of UHT milks and results to the failure and rejection of these products. Similarly, Kakagianni and Koutsoumanis, (2018) have shown that spore forming bacteria remains a challenge in other dairy milk products and is directly influenced by the distribution conditions, and even the season in which the raw milk is produced (Montebello *et al.* 2018; Porcellato *et al.* 2018). In relation to these, refrigeration conditions at the domestic level further contribute to the shelf life of dairy products (Koutsoumanis *et al.* 2010; Rodriguez-Martinez *et al.* 2020). Thus, it was pointed out that indeed product properties should be revisited in lieu of the distribution and domestic conditions (Membré *et al.* 2008).

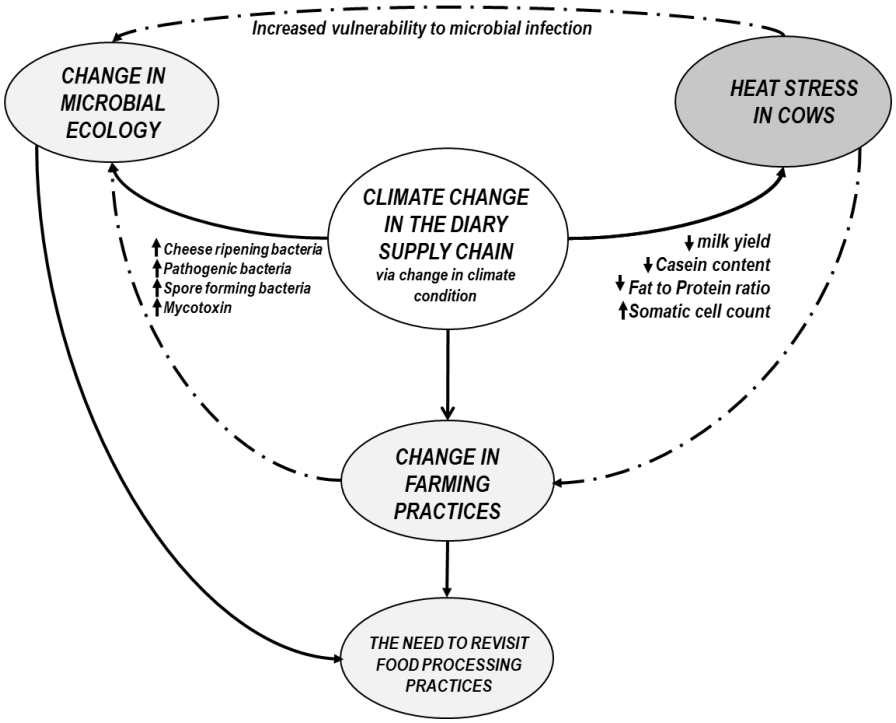

Figure 5: Effect of Climate Change on Dairy Production Chain

Adapted from Feliciano *et al*., (2020)

3.1.4 Microorganisms and climate change

The relationship of climate and microorganisms in raw milk is presented in **Figure 5** (Feliciano *et al.* 2020). The microbial load of raw milk and other dairy products is expected to increase with the projected rise in global mean temperature which will enable faster growth and changes in microbial ecology of raw and processed milk products (van der Spiegel *et al.* 2012; Li *et al.* 2018). Several researchers have already shown that seasons and climate influence the microbial ecology and diversity of raw milk (Hantsis-Zacharov and Halpern 2007; Marchand *et al.* 2009; Mallet *et al.* 2012; Vithanage *et al.* 2016; Metzger *et al.* 2018). The summer season was found to have the most diverse microorganisms followed by spring and autumn, with the least microbially diverse milks obtained during winter (Li *et al.* 2018; Metzger *et al.* 2018). On the other hand, Montebello, Spiteri, & Valdramidis, (2018) found that most of the spore forming bacteria in raw milk from Maltese cows were present in the same numbers for both winter and summer. During spring it was found by Metzger *et al*., (2018), that the predominant bacteria in milk includes *Corynebacterium, Aerococcacea, Knoellia, Enhydorbacter, Acinetobacter*. While, Hantsis-Zacharov & Halpern, (2007) reported that the microbial ecology of raw milk in Israel for spring and winter are quite similar with evidence of *Gammaproteobacteria* (includes *Pseudomonas, Acinetobacter*), *Bacillus, Enterococcus, Leuconostoc, Staphylococcus, Lactobacillus, Actinobacteria, Flavobacteria*. During winter, milk samples collected in Normandy France were reported by Mallet *et al*., (2012) to be composed of gram negative and presumptive lactococci. Porcellato *et al*., (2018) also found *Pseudomonas* and *Lactobacillus* in milks from Norway. On the other hand, during the same season it was reported by Vithanage *et al*., (2016) that *Pseudomonas, Acinetobacter Psychrobacter* and *Bacillus* were higher.

The other effect of climate change is with the increased occurrence of mastitis in lactating cows due to heat stress. It was reported that milk obtained from cows with mastitis has an increased presence of microbes such as *Listeria monocytogenes* and *Staphylococcus aureus* (Akineden *et al.* 2001; Metzger *et al.* 2018)**.** Ultimately, these mastitis causative microorganisms are passed onto raw milk including those obtained from cows that are not presenting symptoms of mastitis as in the case of subclinical form of mastitis (Tong *et al.* 2019).

3.2 Mycotoxins

3.2.1 Overview

Mycotoxins are a globally recognised threat. Mycotoxins are toxins produced by toxigenic fungi. They became recognised after the death of 100,000 turkeys in 1960 near London, England. It came to be known as the "Turkey X disease" and the substance found in the feed was subsequently named Mycotoxin (Pitt 2013). These hazards can be introduced at the start of the dairy production chain when feed is contaminated by a fungus (Coffey and Cummins 2008; Frazzoli *et al.* 2017). There are several factors which impact the growth of the fungus and its production of toxins. These factors include physical stresses such as humidity and temperature, chemical stresses such as pesticides and fungicides as well as mechanical damage and damage done by insects and pests. Biological factors such as plant variety and type of fungi also affect the type of mycotoxin produced (Bryden 2012). Mycotoxins are harmful to humans and animals alike at low concentrations. Some of them are known carcinogens and may cause death, others are known immunosuppressants and affect the reproduction in animals. The most commonly occurring mycotoxins and the food commodities they occur in as well as their toxicity and characteristics are given in **Table 1**.

Aflatoxins B_1, B_2, G_1 and G_2 are the most commonly occurring mycotoxins studied in relation to the dairy industry. They are mainly produced by *Aspergillus flavus* and *Aspergillus parasiticus*. Aflatoxin B_1 is a known carcinogen associated with liver cancer and is studied for its

carryover into milk by bio-conversion. The International Agency for Research on Cancer categorises Aflatoxin B_1 as a known carcinogen to human beings (IARC Group 1). Aflatoxins have been known to occur in a wide range of foodstuff including cereals, nuts, seeds and spices. Aflatoxin is a known carcinogen and has a synergistic effect with hepatitis B antigen. AFB_1 is a strictly regulated mycotoxin with the EU establishing the maximum limit at 0.005 mg/kg in cattle feed and the FDA establishing limits for the same at 0.02 mg/kg. Aflatoxin M_1 is a bio transformed mycotoxin and a derivative of Aflatoxin B_1. The conversion takes place in ruminants which are fed feed contaminated with aflatoxin B_1. Aflatoxin M_1 has a high affinity for casein and therefore it can be concentrated in cheese produced from contaminated milk. Exposure to aflatoxin has also been correlated to growth impairment and stunting in children in studies in Kenya. Aflatoxins production typically takes place in hot, semi-arid conditions. Ochratoxin (OTA) is a mycotoxin more commonly found in wine and coffee, however, its occurrence in infant formula and cattle feed has been recorded (Ul Hassan *et al.* 2018; Elaridi *et al.* 2019; Viegas *et al.* 2020). Ochratoxin is produced by *Aspergillus ochraceus, Aspergillus carbonarius, Penicillium verrucosum.* OTA is a suspected carcinogen and has been suspected to cause kidney failure in the Balkan region. OTA is mostly studied in relation to wine and coffee (Passamani *et al.* 2017; Oliveira *et al.* 2019a), and currently there are climate change models concerning this subject. Fumonisins commonly occur in cereal crops and are produced by *Fusarium* fungi. They are classified as potential carcinogens by IARC (Group 2B) and are associated with liver and kidney damage. The most commonly occurring fumonisins are FB_1 and FB_2. Occurrence of fumonisins is affected by climate change. They are hydrophilic in nature and may not be found in large concentrations of milk. Zearalenone (ZEA) are produced by *Fusarium* fungi and are known to affect the reproductive systems in animals. ZEA can be partially eliminated at high temperatures and is most commonly found in cereals along with DON and other modified forms of ZEA such as α-zearalenone and β-zearalenone. Deoxynivalenol (DON) is produced by *Fusarium* fungal strains growing on cereal crops such as maize, wheat, barley, oats etc. It is known as vomitoxin and can cause vomiting and feed refusal in animals. This mycotoxin co-occurs with ZEA (Korn *et al.* 2011; Pleadin *et al.* 2017) and affects the reproductive system of animals and human beings.

Exposure to mycotoxins is possible indirectly via products of animal origin. Milk and dairy products are widely consumed among all age groups and therefore exposure to mycotoxins could occur through this route. Milk may be contaminated with mycotoxins due to contaminated feed. Exposure to mycotoxins in feed to cows leads to decreased yield in milk and decreased feed consumption. McKay *et al*. (2018) studied the effects of feeding dairy cows feed containing high *Fusarium* mycotoxin and low *Fusarium* mycotoxin matter. Feed contaminated with high amounts of *Fusarium* mycotoxins (Fumonisins, DON and Zearalenone) were fed for a period of 28 days which led to a decrease in feed intake by the cows as a consequence of which milk production was 0.74 kg/cow/day less. Fumonisins, due to their hydrophilic nature, are not typically present in great amounts in milk, therefore, humans are not exposed to this particular mycotoxin via milk. However, it has considerable effects on livestock and can result in poor animal health, resulting in significant economic losses. Mycotoxin contaminated feed can cause long term effects on the physiology of livestock. Another study carried out on Japanese black cattle examined the effects of high levels of Zearalenone and Sterigmatocystin contaminated feed. Sterigmatocystin is another mycotoxin produced by *Fusarium spp* and *Aspergillus spp*. The contaminated feed caused alterations in the systemic metabolic processes which were not rectified after two weeks of the experiment.

Table 1: Mycotoxin Toxicity and Food Occurrence

Mycotoxin	Fungi	Toxicity	Symptoms	Characteristics	Commodity
Aflatoxin B_1, B_2, G_1,G_2	*Aspergillus flavus, Aspergillus parasiticus*	IARC Group 1 classification: Carcinogenic (AFB1), acute hepatatoxic, immunosuppression	Vomiting, abdominal pain, coma, cancer, death	Heat stability, Synergistic with Hep B (AFB_1)	Maize, nuts, rice, wheat
Aflatoxin M_1	*Metabolite of AFB1*	IARC Group 2B Classification		Affinity to casein, hydroxylated form of Aflatoxin B_1	Milk
Ochratoxin A	*Aspergillus ochraceus, Aspergillus carbonarius, Penicillum verrucosum*	IARC Group 2B Possibly carcinogenic, nephrotoxic, hepatoxic, immunotoxic, teratogenic	Affects productivity in animals, body weight gain	Heat stability, fat soluble	Cereals, coffee, wine, Infant Formula
Fumonisins	*Fusarium verticillioides, Fusarium proliferatum*	IARC Group 2B Possibly Carcinogenic, hepatoxic	Kidney and liver damage	Dissolved by organic solvents, hydrophilic	Maize
Zearalenone	*Fusarium graminearum, Fusarium culmorum*	Group 3 carcinogen, Estrogenic activity	Infertility in pigs, mice, rats, cattle, reduced milk production,	Partially eliminated at high temperatures	Maize, wheat
Deoxynivalenol	*Fusarium graminearum, Fusarium culmorum, Fusarium sporotrichioides, Fusarium roseum, Fusarium tricinctum, Fusarium acuminatum*	IARC Group 3 carcinogen classification, Gastrointestinal haemorrhaging, immunodepressants	Slow growth and low milk production in cattle, known as vomitoxin for humans, abdominal pain, headache, dizziness, and fever		Maize, wheat

Source: Adapted from Bryden (2009) and J. Pitt (2013) and Chhaya and Cummins (2020)

3.2.2 Impact of climate change on mycotoxin contamination

Mycotoxin production is dependent on environmental factors such as temperature, relative humidity, rainfall, and water activity. These factors along with the plant variety and composition influence the colonization of the toxigenic fungi on the crop. Fungal growth and toxin synthesis also have a complex relationship with carbon dioxide emissions. Climatic conditions in Europe are increasingly becoming favourable to the host aflatoxin producing fungi. Though uncommon, recent changes in weather conditions characterised by a hot and dry climate have caused aflatoxin outbreaks in southern Europe. With the prevalence of climate change, geographic expansion of aflatoxin is expected. The geographic occurrence of mycotoxins is given in **Table 2**:

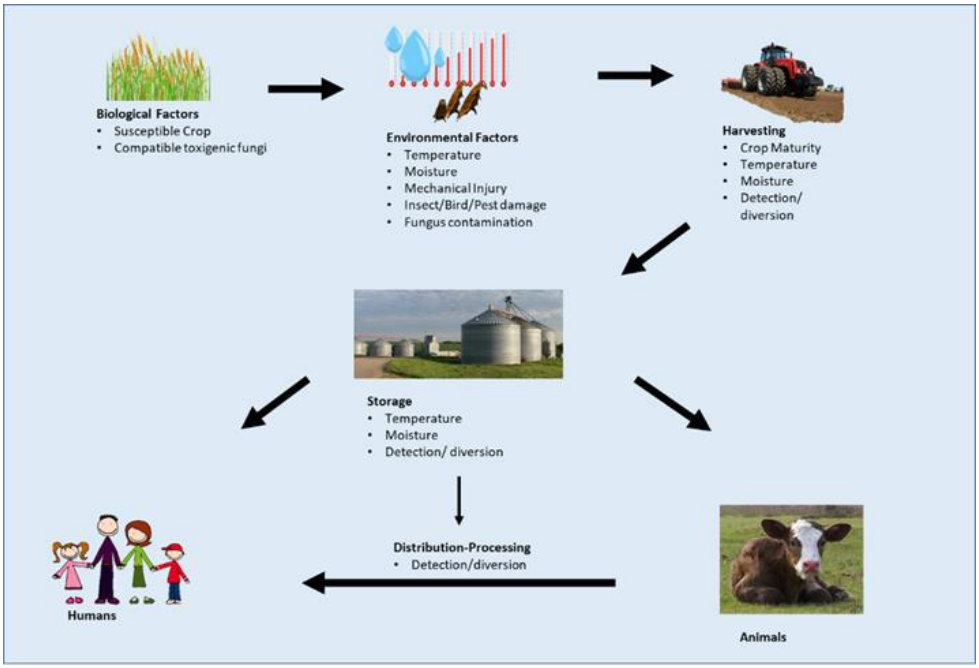

Figure 6: Factors influencing mycotoxin contamination

Adapted from Bryden (2009)

Table 2: Geographic distribution of mycotoxins*

Mycotoxin	Climate Type	Geographic occurrence
Aflatoxin	Temperate, tropical, and sub-tropical	Southern Asia, Africa
Ochratoxin (OTA)	Cool- temperate to tropical regions	North and South America, North and Western Europe, Africa, South Asia
Trichothenes (DON, NIV, T-2, HT-2, DAS)	Northern temperate regions	Europe, America, Asia
Zearalenone (ZEA)	Northern temperate regions	Europe, America, Asia
FB1, FB2, FB3	Hot- temperate regions	Europe, Africa

*Adapted from (Smith *et al.* 2016)

In-vitro Studies

Lab studies on the effects of climate change have shown that factors including: temperature, water activity and carbon dioxide levels play an important role in the synthesis of mycotoxins. The substrate on which the tests are carried out vary in each case, and an on-field replication is required to understand the interactions with these factors and the fungi. Apart from this, factors such as interaction between microbiota, and competing fungi also need to be studied for accurate replication. In-vitro data can, however, be used in making estimations for mycotoxin occurrence and forms the basis of prediction models. Medina *et al.* (2015) examined the three-way effect of carbon dioxide, water activity and temperature on growth of *A. flavus* and aflatoxin B1 production on a conducive medium. While individually only water activity had a significant effect on the growth of *A. flavus*, for the synthesis of aflatoxin B1, carbon dioxide and water activity had an effect for different temperatures. Temperatures of 34˚C were found to be favourable for the production of aflatoxin and temperatures greater than 34˚C reduced the production and carbon dioxide levels played an important role in regulating the biosynthetic pathway. Camardo Leggieri *et al.* (2019) studied the effect of temperature on the growth and interaction of *A. flavus* and *F. verticilliodes*. The study was done for the temperature range of 10-40˚C. The authors also examined the production of aflatoxin and fumonisin. Due to the difference in optimum growth temperatures of both the fungi, the fungi displayed a reduction in growth in the other fungus' optimum temperature, and aspergillus flavus had a stronger impact. The co-occurrence of these fungi and varying temperature affected the production of AFB_1 and FBs. Ochratoxin production on grape juice and coffee with interacting climactic factors has been observed. Ochratoxin occurs commonly in grape juice and coffee infected with moulds and if found in green coffee beans can remain in roasted coffee in concentrations greater than allowed limits. Oliveira *et al.* (2019b) investigated the effect of water activity and temperature to find the optimum growth for ochratoxin producing aspergillus strains: *A. carbonarious* and *A. ochraceus*. Temperature range 25 to 32˚C and water activity range 0.935 to 0.965 was optimum for *A. carbonarious* whereas temperature range: 21 to 30 and 0.94 to 0.99 was optimum for the growth of *A ochraceus*. The study then utilised existing predictive models to predict OTA production. These in vitro studies illustrate that in general interacting effects of temperature change, carbon dioxide and water activity, which are often credited to climate change, can have a profound impact on mycotoxin production. In-vitro studies are necessary to better understand the complex interactions of crop-pathogen and environment interaction.

Seasonality

Mycotoxins occurrence is seasonal (Asi *et al.* 2012; Bryden 2012; Guo *et al.* 2016; Kanwal *et al.* 2018). Poor storage practices and climatic conditions impact the contamination of feed in storage. Studies have established the need to follow good agricultural practices while handling crops destined for animal feed (Coffey and Cummins 2008; Neme and Mohammed 2017; Mutegi *et al.* 2018) . Climatic factors such as temperature and humidity affect the growth of toxigenic fungi and the production of toxins (Bryden 2012; van der Fels-Klerx *et al.* 2012; Sad and Sad 2014;

Hietaniemi *et al.* 2016; Vita *et al.* 2016; Zhang *et al.* 2018). It has also been postulated that feeding practices affect the level of contamination in milk. If there is a lack of fresh feed available, the cattle is fed stored feed. Storage conditions are often not maintained properly and can lead to contamination of the feed by toxigenic fungi.

A study conducted in the Punjab area of Pakistan examined the seasonal patterns of aflatoxin M_1 occurrence in milk (Asi *et al.* 2012). Milk from buffalo, cow, goat, sheep, and camel were studied and it was found that aflatoxin M_1 levels detected were significantly higher in the winter compared to the summer. The study also found that buffalo and cow milk had higher levels of contamination than the other species. The authors postulated that while cattle are fed stored feed, the other animals are still allowed to feed on wild pastures. Another study conducted in China (Guo *et al.* 2016) examined the occurrence of aflatoxin M_1 for four seasons, i.e. summer, winter, spring and autumn and found the highest incidence of aflatoxin M_1 was in winter followed by autumn, summer and then spring, with winter being significantly higher than the other seasons. A study conducted in Iran (Bahrami *et al.* 2016) found the contamination of aflatoxins (AFB_1,AFB_2,AFG_1,AFG_2) in winter to be significantly higher. However, another study conducted in Iran could not find any statistically significant differences for the seasonal occurrence of AFM_1 in milk (Tajkarimi *et al.* 2007), indicating that storage conditions are important in maintaining the quality of the feed.

A study in South Italy evaluating the occurrence of AFM_1 in buffalo and cow's milk for 2 years (2015-2016) found the occurrence of AFM_1 to be higher in cooler seasons, particularly fall, than in warmer seasons (De Roma *et al.* 2017). Cattle in this region were also fed fresh grass and forage during the warmer season, and stored feed during winters. However, only one milk sample exceeded the European maximum limit, which could be an indicative of stricter measures or the socio-economic status of the country. Recently, Leggieri *et al.* (2020) studied the seasonal variability of mycotoxins produced on maize in a region in North Italy and showed significant impact of rainfall on accumulation of mycotoxins during the growing season of the crop, AFB_1 preferring drier conditions and Fusarium species preferring wetter conditions. Another study conducted in Macedonia concluded similar seasonal patterns with occurrence of AFM_1 in raw milk during winter being significantly higher than summer occurrence (Dimitrieska-Stojković *et al.* 2016). Seasonality in exposure to OTA was studied in human serum samples in Turkey (Erkekoğlu *et al.* 2010). The study found higher levels of OTA in the samples in summer as compared to winter. Daily intake levels were back calculated and a significant difference was found in the summer intake levels versus the winter intake levels, where 0.182 ng/kg b.w./day and 0.408 ng/kg b.w./day were winter and summer mean intake values respectively.

Mycotoxin occurrence is also affected by moisture. Precipitation patterns affecting aflatoxin contamination in maize kernels post-harvest were studied in Kenya (Obonyo and Salano 2018). Aflatoxin contamination levels measured after a short rainy season were high compared to contamination levels after a long rainy season. van der Fels-Klerx *et al.* (2012) examined the relationship between climatic factors and incidences of mycotoxin on cereals growing in North Western Europe. The data analyses carried out was based on monitoring data collected from 1999-2009 in that region. The occurrence of DON in maize, wheat, oats, and barley had a high positive correlation with temperature, while the effects of rainfall varied. Zearalenone occurrence in maize had positive correlations with humidity and a negative correlation with its occurrence in oats and rainfall.

Predictive Models

Predictive model studies incorporate climate change scenarios on a local scale and factors related to the plant and the pathogen. The climate change scenarios must be downscaled to the local temperature and precipitation patterns for better predictions. Predicting mycotoxin contamination

can help mitigate risks. The information obtained from these models can be used to decide harvest cycles, sowing times, crop rotation and soil cultivation to better manage mycotoxins.

Battilani *et al.* (2013) predicted under different climate change scenarios as per the IPCC, that the growth of aflatoxins would move northwards as far as the south of UK because conditions would be suitable to produce harmful mycotoxins. The model known as AFLA-Maize predicted the daily growth of *A. flavus* and aflatoxin contamination on maize. This model was based on in-vitro data as opposed to field data. The data obtained from an Italian outbreak was used to calibrate the study and found 73% of the predictions were correct. Battilani, Toscano, Fels-Klerx H.J, *et al.* (2016) used this model to predict the pathogen growth under two climate change scenarios for Europe. The two scenarios were +2 C and +5 C climate change scenarios. They simulated 100 years of daily weather data including, minimum and maximum temperature, rainfall, and solar radiation for different parts of Europe and used this data in the AFLA-maize model. The output were aflatoxin hazard indices for the different parts of Europe included in the simulation. Similarly, they developed another model to simulate climate change scenarios for the case of aflatoxin contamination of wheat in Europe. The model predicted that aflatoxin spread is likely to extend to 60˚N latitude from its current geographic limit at 45˚N. The regions predicted to be of highest concern are Eastern Europe, Balkans, and Mediterranean regions. However, there was no change in the effect of climate change on wheat based on this model.

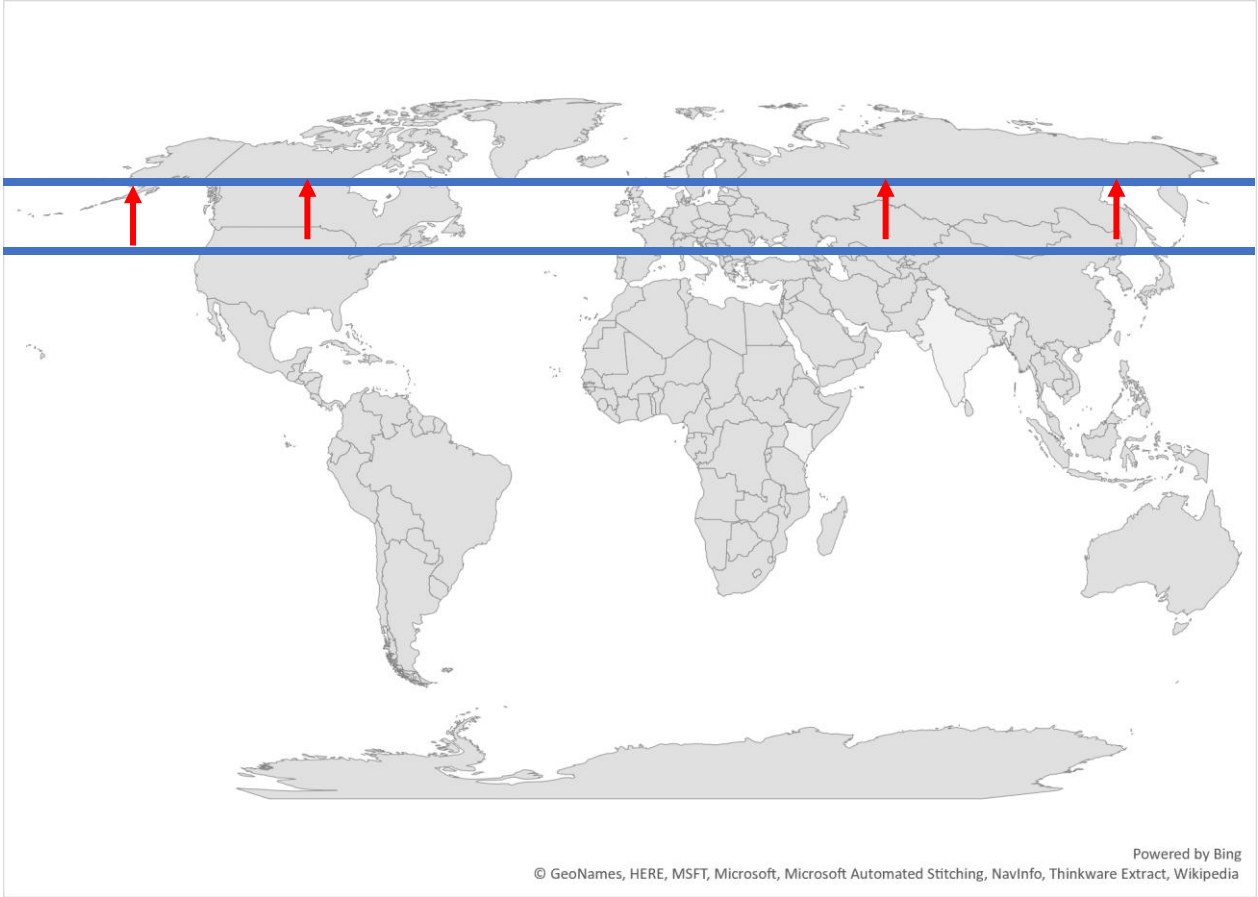

Figure 7: Representation of the 45˚N to 60˚N spread of Aflatoxin.

Adapted from Battilani *et al* (2013) and Medina *et al.* (2017)

Another study by Van der Fels-Klerx *et al.* (2019) modelled the effect of climate change on aflatoxin M1 as a result of carry-over from AFB1 in maize. Different climate change models affecting maize contamination and carry-over models for the conversion of AFB1 to AFM1 were used. It was found that AFM_1 contamination in milk is expected to increase because of climate change (best to worst case scenario) or is expected to be similar. The application of this climate

change: farm to fork model can be useful in carrying out risk assessments.

Another predictive model was used by Madgwick *et al.* (2011) to predict the anthesis date of wheat and the incidence of *Fusarium* ear blight in a climate change scenario. The output from the model suggested that as climate change affects the UK, the flowering dates of wheat are expected to be earlier, and the effects across UK will vary, while the incidence of *Fusarium* ear blight is also expected to increase to a certain extent. Similarly, Hjelkrem *et al.* (2017) predicted the growth cycle of oats based on weather data and correlated weather with DON content. This study also developed models to predict the risk of DON as a result of weather conditions using daily weather data available from Norway. The weather conditions associated with DON contamination in the different stages varied with more dry and warm conditions being associated with DON contamination during the early stages and wet conditions during flowering. The prediction accuracy of the two models developed for DON contamination was greater than 70%. This model was developed for Norway weather conditions and could predict the risk of DON contamination if it were to be extrapolated for climate change scenarios.

Xu *et al.* (2013) developed a logistic model to associate accumulation of DON to climatic conditions and occurrence of Fusarium head blight in Europe. Weather and disease incidence data for the years 2001-2004 was collected from 4 European countries including Hungary, Ireland, Italy and UK. Crop phenology was also studied for this period including anthesis (flowering) period. Several logistic models were developed. DON incidence was the highest in Ireland, followed by UK, then Italy and Hungary. It was found that occurrence of DON increased by 125 times when more than one FHB species was present, and several weather variables had a significant impact on the models. For example, during the anthesis period a variable derived from average relative humidity and average temperature occurred most frequently. Another study quantified the relationship between FHB, environmental factors and occurrence of *Fusarium* mycotoxins based on data collected from Hungary, Ireland and UK (Kriss *et al.* 2012). DON and relative humidity were significantly correlated in this study as well, while other mycotoxins displayed varying relations with moisture related variables. This study was also based on the same data, however it used semi-partial correlations to quantify the associations.

Crop, disease, and climate change models are reliable in predicting disease occurrence to a large extent. These models can be made better by supplementing them with data from in-vitro and on the field studies for which continuous monitoring and research is required. The combined effects of factors other than carbon dioxide, water activity/relative humidity and temperature need to be considered as well to more accurately predict and minimise error.

4 Food Safety Management Overview

Food safety management has been proposed as the key step in ensuring food safety along the food supply chain at the operational level (Gorris 2005). The hierarchy of food safety management and control is commonly presented as a pyramid with stacking blocks of food safety programs to be implemented in a food manufacturing facility (as seen in **Figure 8)**. Food safety control activities include the performance of risk analysis and risk assessment to be performed at the government regulatory level. Thus, the people and the institutions involved with food safety include not only the managers at the manufacturing facility level but also government regulatory agencies. As such, a sort of dichotomy between the actions to be performed can be seen. Food safety managers at the food manufacturing level are involved with establishing and implementing food safety programs while government regulatory agencies are involved with food safety control through the establishment of food safety goals that are in line with a national public health policy. Although coming from different directions in the food safety pyramid the dynamism and compatibility of their works and outputs are needed in order to deliver food safety. As such, the development by

government regulators and use by food manufacturers of food safety metrics are recommended (Gorris 2005).

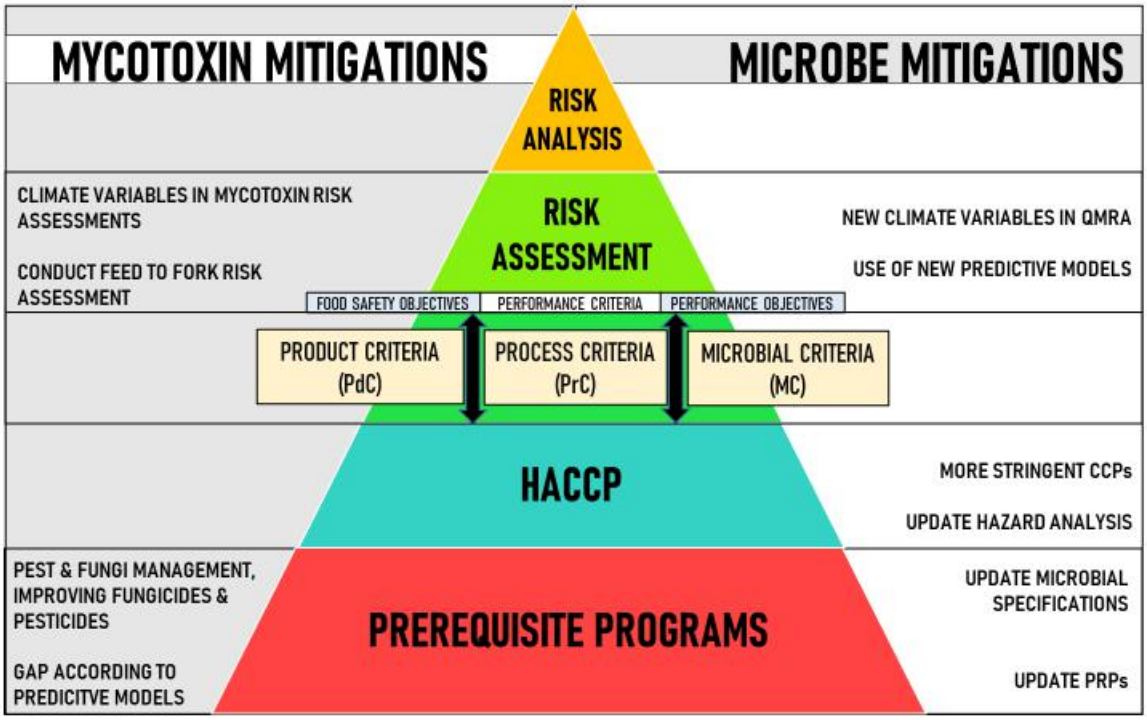

Figure 8: Food Safety Management Systems and climate change mitigation strategies

Adapted from Feliciano *et al*., (2020) and Membré, *(*2014)

The food safety metrics developed by FAO and WHO (2006), include Food Safety Objectives (FSO), Performance Objectives (PO) and Process Criterion (PC). The FSO is an objective based metric to be applied at the last part of the food supply chain prior to consumption. It is derived from an Appropriate Level of Protection determined by the government regulatory bodies. This value should not be exceeded and is achieved through the establishment of controls at the earlier stages of the food supply chain. The advantage of using this food safety metric is the capability to set an equivalence point in food control and the flexibility for food safety risk managers at the factory level to comply with this point given the uniqueness of their current processing setup (Gorris *et al.* 2006). In addition, the latter two metrics are to be used for this reason in order to meet the limit set prior to consumption. The other food safety metrics that are to be implemented in conjunction with these are the Process Criterion (PrC) and Product Criterion (PdC) which are stipulated in a HACCP plan and as such associated with the critical control points. Implementation of these allows to fine tune the control of food safety of final end products.

The transparency and flexibility of using these food safety metrics in a food manufacturing facility cannot be undermined. It enables food safety managers and relevant parties to design a process line that can be adapted to their extant food processing lines and unit operations while being able to comply with the health policy of a country. Therefore, the use of these goals necessitate the existence of established and working food safety programs (ICMSF 2011). It must be highlighted that prerequisite programs and food safety programs must first be working and subject to reviews and regular audit prior to adoption of these metrics.

4.1 Prerequisite Programs

Prerequisite programs are the fundamental programs that deal with proper design of facilities, cleaning procedure and schedules, and manufacturing procedures that are required to be met and established by food manufacturers prior to full scale operations. In detail, there are six types of prerequisite programs to be established namely, premises, receiving and storage, equipment performance, personnel training, sanitation and health and safety recalls (Membré 2014). These prerequisite programs are also known to belong as part of Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP), Good Agricultural Practices (GAP), Good Veterinary Practices (GVP) and Sanitary Standard Operating Procedures (SSOP) which are a set of guidelines to be implemented. In addition, these prerequisite programs may include specifications for accredited suppliers (Kotsanopoulos and Arvanitoyannis 2017).

The relevance of prerequisite programs cannot be undermined as their implementation at the farm level influence the food safety of produce. In fact, in the study by Nada *et al*. (2012) it was shown that implementation of prerequisite programs are more appropriately to be applied at the earlier parts of the food supply chain. Prior to the establishment of HACCP and food safety management systems, auditors usually look for the records and evidence that these programs are in place and subsequently reviewed during the food safety audit. The relevance of these systems can be seen with their relevance in providing guidelines and procedures necessary with the delivery of food safety in large scale food manufacturing operations and in food establishments (Doménech *et al.* 2011).

4.2 Hazard Analysis and Critical Control Points (HACCP)

HACCP was originally a food safety program developed by NASA and Pillsbury for missions in outer space. This food safety program was initially based on three principles where 1) hazards which may be encountered in the production of foods are identified, 2) identification of critical control points along the processing chain where the hazard is to be controlled, and 3) implementation of controls at these points (Ropkins and Beck 2000). Currently, the HACCP procedure is composed of seven steps with the addition of three steps namely, define corrective action, establish record keeping procedures and establishment of verification procedures (Ropkins and Beck 2000; Sperber 2005). The implementation of HACCP has shifted from a product based approach to a process based approach initiated by food safety legislations and therefore allowing the wide-scale application of this method in the food industry (Manning *et al.* 2019). In addition to this, HACCP procedures allow audits to be performed whether the systems and its monitoring indeed works (Kotsanopoulos and Arvanitoyannis 2017). However, the use of HACCPs are not without hurdles, the reported difficulties encountered include in its implementation of the HACCP plans at critical control points, insufficiency in control activities, behavior of the food handler and lack of HACCP knowledge on the part of food processors (Azanza and Zamora-Luna 2005; Cusato *et al.* 2013; Manning *et al.* 2019).

According to Ropkins and Beck (2000), during the hazard analysis step of HACCP quantitative and qualitative risk analysis is to be performed. This is in line with the calls of Buchanan and Whiting, (1998)**,** where the possibility of incorporating ways on how to quantifying the effects of each processing stages in hazards. Thus, the use of quantitative risk analysis methods in the dairy manufacturing industry with established HACCP and food safety programs are starting to gain momentum.

4.3 Risk analysis

The development of risk analysis in the field of food safety can be traced with different events such as the recognition of the hazards related to food, foodborne illnesses during the 90s, independent development of predictive microbiology, widespread use of HACCP, establishment of World Trade Organization and promotion of free trade led to the signing of SPS agreement. As such, in the mid-90s through the request of Codex Alimentarius Commission, the Food and Agricultural Organization and World Health Organization established a working committee that defined the risk analysis procedures. Risk analysis and its components are defined by the Codex Alimentarius as the process composed of three steps, risk assessment, risk communication and risk management (FAO and WHO 2013).

Risk communication refers to the interactive exchange of information and opinions throughout the risk analysis process between risk managers, risk assessors, industry, consumer and academia. Their interaction revolves around the risk, its factors, communication of risk assessment findings, methods performed during the risk assessment and the basis of risk management decisions. Risk management is the process of making a decision on the appropriate prevention and control options to be taken, formulation of policy in consideration of the risk assessment results and other actions related to the protection of the health of consumer and fair trade. Risk assessment refers to a scientifically based four step process: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization. The interaction of these three separate risk analysis activities in the food supply chain was shown by Membré and Guillou (2016). Adaptation of this in the dairy supply chain was presented in **Figure 9**. Therefore, through the performance of risk analysis and its activities, risk managers at the government level are able to formulate policies, mitigation strategies and perform risk management decisions that is science and evidenced based, maintaining transparency of its conception and implementation. In a clear and accessible to the parties involved and the general public. The output of these risk analysis procedures in a food safety pyramid are the food safety metrics and microbiological criteria to be complied at the food manufacturing levels (Gorris 2005).

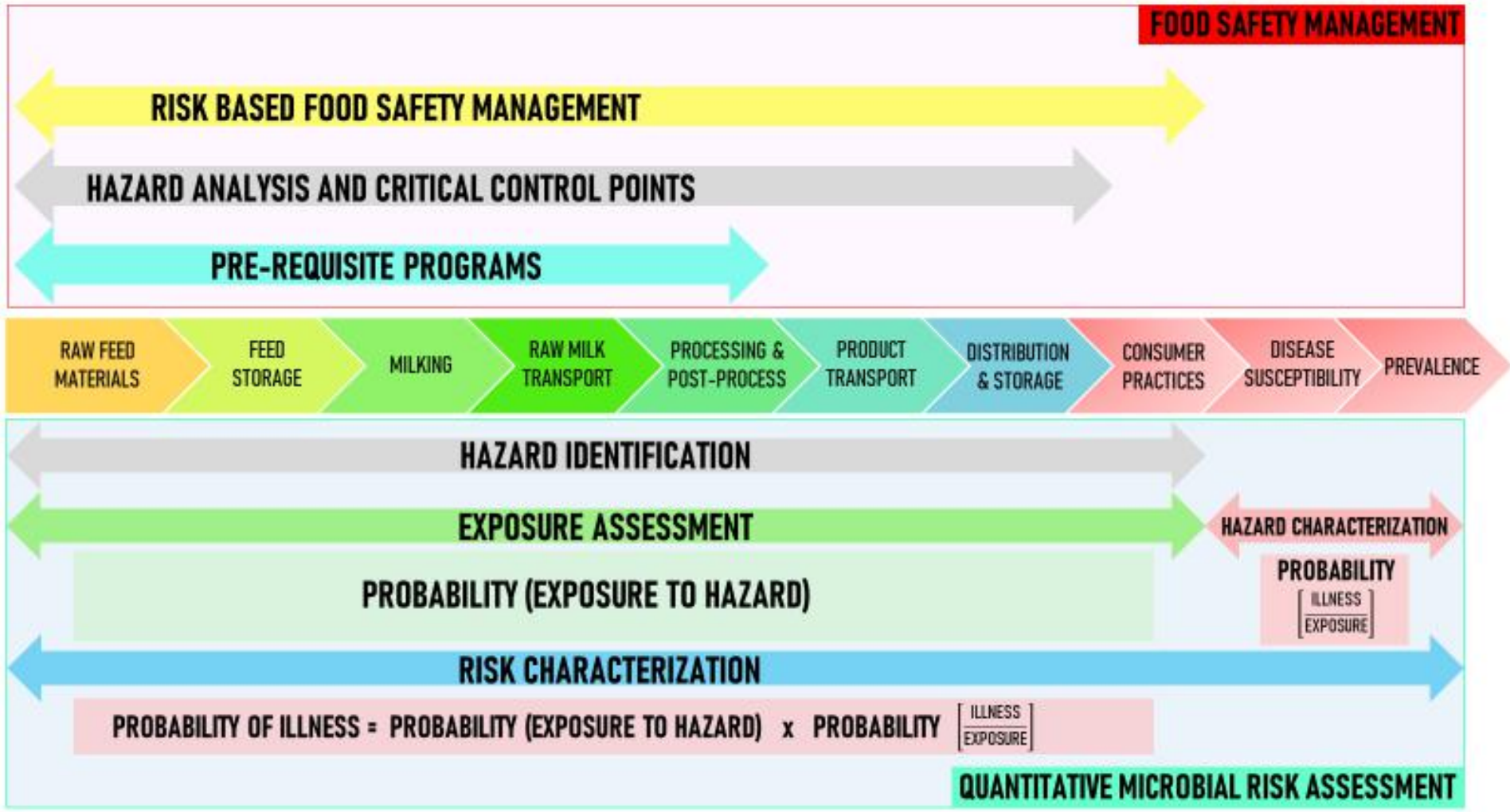

Figure 9: Risk Assessment Process for Dairy Supply Chain

Adapted from Membré and Guillou (2016)

Risk assessments have commonly been used by government authorities to develop regulatory standards, to aid risk management decisions in assessing and taking actions on specific public health issues. In food safety management, these activities involve the review of food safety regulations and establishment of food safety metrics. Given the previously mentioned activities involved with risk assessments, QMRA and FCRA are *sensu stricto* an exposure assessment (Membré 2016). Risk assessments are generally classified into quantitative, qualitative and semi-quantitative type (Dearfield *et al.* 2014).

The quantitative type of risk assessments include quantitative microbial risk assessment, quantitative chemical risk assessment, Bayesian risk assessment methods and feed chain risk assessment (Coffey and Cummins 2008; Coffey *et al.* 2009). The qualitative forms risk assessment includes risk profiling. Semi quantitative risk assessments include risk ranking. Although the strict classification of these examples of risk assessments may not be limited to these such as in the case of risk ranking where it can take the form of either quantitative or semi-quantitative types (Van der Fels-Klerx *et al.* 2018). Efforts to quantify risk ranking assessments through use of quantitative tools have been proposed by the European Food Safety Authority (EFSA 2015). Therefore risk assessments that are applied in the food supply chain vary according to the goals to be achieved, questions to be answered and the availability of data to be used in the assessment (Dearfield *et al.* 2014).

5 Quantifying risks in the Dairy Supply Chain

5.1 Quantitative Microbial Risk Assessment

5.1.1 Steps in QMRA

There are four steps in developing a QMRA as previously shown by Membré and Boué, (2018). An adaptation of these steps is presented in **Figure 10**. These steps were initially developed as an adaptation to be implemented at an industry level. The objective is to compare the efficiency of the process steps in mitigating risks by predicting the effects of operational settings on the output of the model.

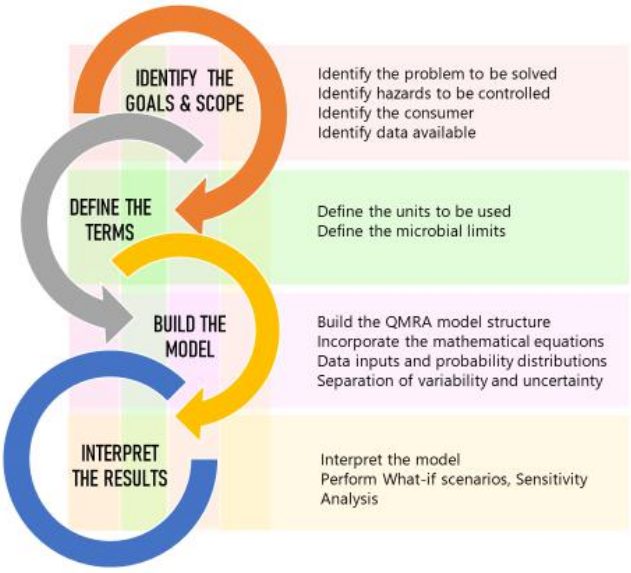

Figure 10 Steps in a QMRA

Adapted from Membré and Boué, (2018)

Step 1: Identify the goals and scope of the quantitative risk assessment

The goal of this step is to state the goal clearly. The risk managers and assessors must first agree upon the problem or questions to be explicitly answered by the risk assessment. This allows for both parties to clarify the relevant hazard which is to be considered and also for the model to be used in addressing the hazard. In addition, this will also allow them to explore different inputs in the model at a later stage. Recognizing the hazard to be considered, a systematised method was developed by Van Gerwen *et al*., (1997). This method allows risk managers to objectively select the relevant microorganism to be monitored in the supply chain. An advantage of this method is the selection of the relevant microorganism among a series of microorganisms initially present at the start of the supply chain. Risk managers and assessors at the manufacturing facilities have the ability to choose not only between a pathogenic and spoilage microorganism but also, the current microorganisms of concern or those that may be a potential concern in the future. For example, the most resistant one can be selected from a series of microorganisms that are usually found in the food. The justification for selection may be because it can survive multiple processes and may also be able to resuscitate again if the conditions of the food product in the later stages of the process are suitable. Justification for selection may also be in relation forecasting changes with conditions in the supply chain with which the product is to be distributed or marketed. Insights like these might be relevant in the future given that the forecasted effects of climate change will also affect different food supply chains in different countries. Relative to the goals to be identified are the target consumer of the product. As was previously established, vulnerability groups (e.g. elderly, young, immunocompromised) exist and as such must be considered given their susceptibility to the hazard and their respective consumer patterns which may include serving size.

The scope where the QMRA will start and end must also be considered. This is dependent upon the food manufacturers, their data and their domain. The scope of extant risk assessments on dairy products usually range from farm to the distribution of products. However, dependent upon the data available some were also able to include the consumer domain and as such were given a stand-alone module in the QMRA model (Koutsoumanis *et al.* 2010; Rodriguez-Martinez *et al.* 2020).

Step 2: Define terms to be used in the model

This step aims to clarify and agree upon the input and output units in the model. This is true for data to be input in the model that may have been retrieved from different sources and periods. An example of this in risk assessment is a toxin producing bacteria, which, depending on the available data, can be expressed as a bacterial concentration or a concentration of the toxin. (Heidinger, Winter and Cullor, 2009; Weldeabezgi *et al*., 2019). In addition, other cases in which the units in small scale manufacturing environment currently in the process of adapting to the ones used in government regulations. Therefore, this stage will allow the conversion of data available into units if needed.

Furthermore, it was pointed out that iterations during stochastic process need to be clearly defined before performing these mathematical operations. Iterations can be defined in the context of the data it was taken from and the appropriate representation given to it. Therefore, clarifying the terms to be used in the model must therefore be useful in understanding the results later on.

Step 3: Model building: Model structure, incorporation of mathematical equations and inputs

Build the QMRA model structure

The next step is to determine the process line or steps along the supply chain. This line will therefore be the main structure of the model with the subsequent sections or “modules” to be

defined with respective models. These sections can be appropriately termed as “modules” where it represents a specific unit operation or equipment in the processing line or stage in the dairy supply chain wherein the state of the food has an impact on the concentration of microbial hazard. A way in which a process line or dairy supply chain can be structured for risk assessment is through the use of the modular process risk model structure (MRPM) developed by Nauta, (2001). The use of this structure allows risk managers to simplify the process line and categorise each process into six steps; growth of microorganism in food matrix, microbial inactivation, partitioning during filling or other unit operation, recontamination and growth/resuscitation of microorganism until final storage. This simplification is true especially in the dairy industry where recovery mechanisms of milk retentions is commonly performed in industrial process lines such in the case of powdered milk (Soejima *et al.* 2007).

Incorporating the mathematical equations to be used in the model

Following the establishment of the QMRA model structure is the incorporation of mathematical equations and inputs in the subsequent modules of the QMRA model. These mathematical equations can be classified into four types namely, probability functions, mass and heat transfer models, predictive microbiology growth or inactivation models (primary and secondary) and dose response models. In addition to these, new equations were recently used in risk assessment models such as consumption patterns, climate variables, toxin production of microorganisms, recontamination equations for air and biofilm (Heidinger *et al.* 2009a; Castro-Ibáñez *et al.* 2015; Pujol *et al.* 2015a; Campagnollo *et al.* 2018).

In this part of the QMRA model, predictive microbiology comes into the fore. The mathematical models and tools that were developed separately in the said field give the risk assessors the capacity to predict the growth of microorganism through time, with the influence of intrinsic food properties and extrinsic processing variables. The predictive microbiology equations that can be used in the QMRA model are the ones commonly used for microbial growth and inactivation models (Van Gerwen and Zwietering 1998; Geeraerd *et al.* 2000). Furthermore, the use of secondary models whether it is growth or inactivation models allow the risk assessors to customise the growth predictions with the extant product criteria. For risk assessments dealing with toxin producing microorganisms, the use of toxin production models were have been previously shown (Asao *et al.* 2003; Soejima *et al.* 2007).

Data inputs and probability distributions

The data to be inputted in a QMRA model can come in the form of settings or variables. Settings are management options chosen as a way to control risk. Examples of settings are process criteria (PrC) and product criteria (PdC). As such, these types of inputs can be drawn from extant HACCP plans currently implemented where these two are stipulated. Variables are those uncontrollable inputs that cannot be associated with management. These kinds of inputs are defined as a deterministic value or range of values described by a probability distribution. For the former it is inputted in the QMRA model as a single value while for the latter it is inputted as statistics (e.g. mean and standard deviation) and a specific probability distribution (e.g. normal) describing the dataset with which the statistics are taken from. Through the latter input the variability is taken into account by the QMRA model. During this part of the QMRA it is important to separate variability and uncertainty. The former is defined by Haas *et al.* (2014) as real and identifiable differences between individuals within a population, and it does not disappear with additional data. Variabilities in a QMRA can be grouped into: pathogen (e.g. strain variations in pathogenicity, variation in resistance to a treatment), food product (e.g. pH, Aw) or consumer associated (e.g. susceptibility to disease, consumption pattern, behavior) (Membré and Guillou 2016). Uncertainty refers to a lack of data to characterise the input and the model.

Incorporation of these two in the model is through the use of two dimension Monte Carlo analysis (Pouillot and Delignette-Muller 2010; Cummins 2016). Methodologies using these two have been previously shown, depending on the availability of data (Membré and Boué 2017). The first case is if there is a lot of data and limited knowledge about the mechanism. In that situation, the approach is to fit data into probability distribution or perform bootstrap. The second case, if there is limited data and a lot of information about mechanism, then the course of action is to select the appropriate probability distribution. The third case, where there is both limited data and knowledge on mechanism the use of a simple distribution is the course of action. The fourth case where there is no data available, the course of action is to do expert elicitation.

Fitting the data into a probability distribution, according to Jarvis (2008), allows us to describe into mathematical terms the spatial dispersion of the population, to estimate the variance of the population and, to compare the temporal and spatial changes in density. Another example for the first case is to use bootstrapping. Recently researchers have tried to do meta-analysis in published data such as thermal inactivation of microorganisms. This in recognition of the issue where differences in values of inactivation kinetic parameters exist for different products. As such the approach of conducting a meta-analysis of this data prior to incorporation in a QMRA model has been previously proposed (den Besten and Zwietering 2012; Guillou and Membré 2019).

Step 4: Interpretation of model output

The first output of a QMRA is a concentration of microorganisms and its probability distribution. This fact highlights that the QMRA steps previously mentioned covers the exposure assessment part of the risk assessment. The microbial outputs produced are further processed separately under a consumer or distribution module in a QMRA. These modules are part of the risk characterization part of the QMRA (Carrasco *et al.* 2010). These modules are usually done in order to determine the prevalence of the microbial contamination level in a batch for packaged products. The other module used is in association with identifying the probability of illness in a population (or a specific member of that population) due to the consumption of food product. In these modules the respective outputs are not given as a single value but also in tandem with their probability of occurrence (Membré and Boué 2017).

The results from the QMRA model are not easily interpreted especially by those belonging to another discipline not directly involved with food microbiology but involved in policymaking and as such need to make decisions based on a QMRA. Therefore, the use of visualizations of the model outputs and risk characterization have been suggested. These include ‘what if’ scenarios and 2D plots of iso-risk curves (Membré and Boué 2017).

5.1.2 Insights from QMRA of dairy products

QMRA has been used in determining the safety and the risks posed by microbial hazards present in dairy products on consumers. This is presented in **Table 3**. The microbial hazards commonly studied were pathogenic microorganisms such as *E.coli*, *L. monocytogenes*, *M. avis* and bacteria that cause foodborne intoxication by their microbial toxins such as *B. cereus* and *S. aureus*. The former group of microorganisms were based on their acceptable levels and the relative susceptibility of different consumers at these levels prior to consumption. While for toxin producing pathogens, aside from their acceptable levels, the determination of the toxin concentrations at the time of consumption are also performed (Heidinger *et al.* 2009b; Barker and Goméz-Tomé 2013). This principle of quantifying the toxin produced lies with their mechanism in foodborne intoxication. Additionally, QMRA was also shown to quantify the effects food processes to the spoilage of microorganisms. Pujol *et al*., (2015) have shown that for food spoilage, the use of sterility failure rates can be used as the link between product acceptability and line performance.

Also, it can be an alternative measure or endpoint wherein the product is not fit for human consumption when it comes to microbial food spoilage.

QMRA in dairy products was mostly performed for milk and cheese which were either pasteurised or unpasteurised. Raw milk is currently seeing a boom in popularity of because of the consumer demand for fresh and clean labelled dairy products (Claeys *et al.* 2013). However, as shown by researchers maintaining the microbial food safety of raw milk is difficult and subject to the initial microbial load introduced at the farm level and its fluctuations given the subsequent conditions during storage of raw milk at marketing and consumer phase. In the study by Latorre *et al*., (2011) they found that inspection of raw milk prior to selling together with the maintenance of cold chain from raw milk collection, selling phase and consumer are crucial points for preventing the growth of *L. monocytogenes* at unacceptable levels. These findings are also similar for other risk assessments on raw milk (Grace *et al.* 2008; Giacometti *et al.* 2012). On the other hand in the study conducted by Perrin *et al*., (2015) they have explored scenarios on how to reduce microbial contamination of raw milk and in soft cheese through the use of QMRA, and quantification of these impacts on intervention strategies. Insights like these reinforce the established principles of food safety and allow the quantification of its impact towards the growth of pathogenic microorganisms. For pasteurised milks, the findings are similar where the implementation of pasteurisation and control points along the dairy supply chain remain key to reducing microbial contamination in packaged milks (Clough *et al.* 2009; Serraino *et al.* 2014).

Another dairy product with several risk assessments performed were cheeses which were made by either raw or pasteurised milk. The use of raw milk in cheeses is still being done especially in traditional and artisanal cheeses. The raw milk microflora are known to confer distinct organoleptic properties such as flavour profile (Montel *et al.* 2014). However, occurrences of foodborne disease outbreaks and food recalls were linked with raw cheeses, giving the need to establish controls along the supply chain (van Asselt *et al.* 2017). For cheeses made with unpasteurised milks, the impact of raw milk microbial quality on food safety quality is increased throughout the manufacturing stages of cheese. Similar to raw milks, the food safety of cheeses must be maintained throughout the supply chain as the impacts will be additive causing an increase in foodborne illness due to lack of controls that will decrease the microbial growth (Tenenhaus-Aziza *et al.* 2014; Perrin *et al.* 2015).

5.1.3 Incorporating climate variables in a QMRA

The dairy supply chain is vulnerable to the effects of climate change at each step. This is evident from conditions induced by the influence of climate on raw milk when transporting, processing and until final distribution to consumers. However, incorporation the of climate change effects as a variable and quantification of its effects on the microbial hazards in dairy products through use of a QMRA is yet to be realised. Nevertheless, this incorporation is currently being explored in the fresh produce sector (Strawn *et al.* 2013; Pang *et al.* 2017, 2018; Miranda and Schaffner 2018). These climate variables may include changes in average temperature, relative humidity, average precipitation and sunlight among others which are also associated with different seasons (Castro-Ibáñez *et al.* 2015; Pang *et al.* 2017). Approaches on how these climate change effects can be incorporated in a QMRA model as inputs were seen in these previous researches. Two methods on how can this be done were shown by these researches, direct incorporation of climate data with probability distribution (Danyluk and Schaffner 2011; Allende *et al.* 2017) and dimension reduction of extant environmental variables (Pang *et al.* 2017, 2018).

Table 3 Overview of quantitative risk assessments in dairy products*

Paper	Country	Microbial hazard	Product	Scope	Modules or parts of the QMRA model
			Milk		
Giacometti *et al*., (2012)	Italy	*E. coli* O157:H7 *C. jejuni*	Raw milk	Farm to consumption	Prevalence in herds Time and Temperature history Consumption
Latorre *et al*., (2011)	USA	*L. monocytogenes*	Raw milk	Farm to consumption	Buk milk tank contamination, time temperature distribution, consumption
Clough *et al*., (2009)	UK	*E.coli* O157	Pasteurised milk	Farm to packaged milk	On farm, transport raw milk, raw milk holding time, processing, prevalence in package
Serraino *et al*.,(2014)	Italy	*M.avium* subsp. *paratubercolosis*	Pasteurised milk	Farm to packaged milk	Pathogen in raw milk, transport of raw milk, silo concentration, pasteurisation, prevalence in package
Pujol *et al*., (2015)	France	*G. stearothermophilus* *C. botulinum* *B. cereus*	UHT milk	Raw milk to packaged milk	Raw material mixing and storage, packaging sterilization, UHT treatment, process line sanitization UHT treated product storage, sterilized packaging storage, aseptic filling, short holding of filled product sealing and storage
Heidinger *et al*., (2009)	USA	*S. aureus toxin*	Raw milk	Raw milk to consumption	*S. aureus* growth (Variable & Static growth), long term consumer storage, Staphylococcal toxin production
(Barker and Goméz-Tomé 2013)	UK	*S. aureus toxin*	Pasteurised milk	Raw milk to packaged milk	*S. aureus* in pooled milk, population & toxin production, pasteurisation of raw milk, cooling and farm storage, packaged milk
			Cheese		
Perrin *et al*.,(2015)	France	*E. coli* O157:H7	Soft cheese made from raw milk	Farm to consumption	Farm, cheese production, consumption
Bemrah *et al*., (1998)	France	*L. monocytogenes*	Soft cheese made from raw milk	Raw milk to consumption	Milk production, cheese processing, consumption
Lindqvist *et al*., (2002)	Sweden	*S. aureus*	Unripened cheese from raw milk	Cheese to consumer	Producer, consumer
Tenenhaus-Aziza *et al*., (2014)	France	*L. monocytogenes*	Soft cheese made from pasteurised milk	Pasteurised milk to distribution of cheese	Contamination at cheese making, (smearing, ripening, recontamination during ripening) growth in environment, hygienic operations, sampling
Campagnollo *et al*., (2018)	Italy	*L. monocytogenes*	Semi-hard cheese from raw milk and soft cheese from pasteurised milk	Raw milk to consumption	Contamination at cheese making, ripening, retailing shelf-life, consumption
Tiwari *et al*., (2015)	Ireland	*L. monocytogenes*	Cheese from raw milk and pasteurised milk	Farm to consumption	Contamination at farm level, cheese making & recontamination, ripening, storage, consumption
Condoleo *et al*., (2017)	Italy	*L. monocytogenes*	Soft cheese from raw sheep milk	Farm to consumption	Farm, cheese processing, consumption
Sanaa *et al*., (2004)	France	*L. monocytogenes*	Soft cheese from raw milk	Raw milk to consumption	Initial level and concentration in raw milk, Concentration in cheese, time temperature of cheese, Consumption

*Adapted from Feliciano *et al*., (2020)

5.2 Mycotoxin Risk Assessment

Strict regulations are imposed on the levels of many mycotoxins, while some just have guidance values (as given in Table 4). Each country sets the limits or guidance according to risk analysis carried out. These decisions are based on, but not entirely dependent on, scientific evidence given by risk assessments. Where a probability of an adverse health effect because of a hazard exists, the process of risk analysis is carried out to decide if any actions for the same need to be taken.

Table 4: Maximum residue levels in raw milk and cattle feed

Country	Mycotoxin	Raw Milk (µg/kg) and dairy products	Cattle Feed (mg/kg)
EU	AFB1		0.005
	AFM1	0.05	
	OTA		0.25
	DON		8-12
	Zearalenone		0.5
	FB1+FB2		60
	T2& HT-2		Not present
USA (FDA)	Aflatoxin		0.02
	AFM1	0.5	
	DON		5
	FB1+FB2+FB3		30
Australia (FSANZ)	AFM1	0.05	
Iran	AFM1	0.05	
India	AFM1	0.5	

5.2.1 Occurrence

Mycotoxins occur across the world in many different food products and feedstuff. The presence of mycotoxins in the feed and foodstuff is continuously monitored to support risk assessments. The prevalence of mycotoxins depends on many factors and as a consequence levels vary annually. Milk and milk products are mainly monitored for aflatoxin M1. Most of the studies conducted look at milk and cattle feed samples for aflatoxins. Cattle feed samples may be contaminated with mycotoxins and are typically analysed for multiple mycotoxins (dos Anjos *et al.* 2016; Yan *et al.* 2018). The bioconversion of aflatoxin B1 to aflatoxin M1 can be up to 6%. A study in Nairobi, Kenya found a total of 83/84 samples of milk contaminated with AFM1, with 64% samples exceeding the EU regulatory limits of 0.05 ug/kg (Kuboka *et al.* 2019). A survey of the farms sampled found that the farmers were not aware of the carry-over of aflatoxin into the milk. No concrete source for the contamination was traced as sampling of the feed was not done, therefore the reason of contamination remained ambiguous. A study carried out in Kosovo in 2009-2010 investigated 895 milk samples from different parts of the country. An overall incidence rate of 2.8% was observed over the two years in excess of the limit of detection, however none of the samples contained concentrations in excess of the EU limit (Rama *et al.* 2016). Rise in the occurrence of aflatoxin is expected due to climate change. An Irish study (Mcelhinney *et al.* 2016) investigated the occurrence of multiple mycotoxins in baled and pit silages on farms for two years. None of the major regulated mycotoxins were present in these samples. The mycotoxins present were in relatively low concentrations. While ZEA was found in low concentrations in very few samples. This could be since Irish weather is not conducive to foster aflatoxin production. In Galicia, Spain (Dagnac *et al.* 2016) maize silage from 19 dairy farms was analysed for the presence

of multiple mycotoxins. 148 samples were collected from which 62% mycotoxins were found to be contaminated. In Italy (Armorini *et al.* 2016), milk was tested for the presence of Aflatoxin M_1, while 11/22 organic milk samples and 24 out of 36 conventional milk samples were found to be contaminated with AFM_1following an aflatoxin outbreak, none of the samples exceeded the EU maximum limits. The occurrence data obtained from studies can be used to quantify exposure. **Table 5** shows a few studies investigating the occurrence of some mycotoxins in milk, milk products and cattle feed.

5.2.2 Exposure Assessment

Exposure assessments carried out assesses the consumption of the hazard via food. Exposure is calculated using the consumption and occurrence data available. Coffey and Cummins (2008) carried out an exposure assessment from feed to fork. A feed chain risk assessment is undertaken when all the processes involved from the production of the feed to the consumption of the food product are considered. Coffey *et al.* (2009) carried out a stochastic feed chain risk assessment related to bovine feed for Ireland. Stochastic calculations utilise probabilistic values to obtain the range of population likely to be exposed to the hazard. The study calculated mean mycotoxin occurrence levels by simulating data found in the scientific literature. The calculated levels were below the guideline levels established by the European Union. The exposure assessment was carried out using total exposure for male and female was calculated by summing up exposure levels in each dairy product as follows:

$$Total\ Exposure = \sum(CM_x/1000) \times P/M \quad (1)$$

Where *CMx* is the concentration of mycotoxin in milk (μg/kg), *P* is the milk product consumption value and *M* is the body mass of the individual. The exposure assessment carried out found all the exposure levels to be below the limit placed by European Union and the simulated values from these were well below tolerable daily intake values and therefore were not considered a threat in Ireland. Maize is not grown in Ireland and is imported for feed and the possibility of contamination via imported feed mixed with domestic feed exists. Weather conditions are not optimum for production of aflatoxin B1. However, with climate change, much of the imported maize is likely to be contaminated as more and more maize growing countries are predicted to be afflicted with aflatoxins (Battilani, Toscano, Van Der Fels-Klerx, *et al.* 2016).

Deterministic calculations rely on fixed values as opposed to probabilistic. This gives a single value, whereas probabilistic calculations give a range of values, considering all possible combinations. Bahrami *et al.* (2016) carried out a deterministic calculation for the exposure to AFM_1 from milk and other traditional Iranian dairy products. The values obtained were calculated using estimated daily intake which utilised mean concentration of AFM_1 [toxin] and mean milk consumption and body weight [bw] data of the individual.

$$EDI = \frac{[toxin]\times[milk\ consumption]}{[bw]} \quad (2)$$

Where :
EDI = Estimated daily Intake

Table 5: Mycotoxin occurrence globally in dairy products and dairy feed*

Country	Mycotoxin	Test[1]	Product	Limit[2]	Min[3]	Mean[4]	Max[5]	LOD[6]	LOQ[6]	Sample number	Detection range	Above limits	Papers
Mexico	AFM1	ELISA	Domestic Milk	0.5	0.1	0.72	1.27	5 ng/kg		84	<80	33	(Quevedo-Garza *et al.* 2018)
			Imported Milk		0.1		0.6						
Kosovo	AFM1	ELISA	Raw milk	50 ng/l (EU)	5.2	5.19	26.6			656, 170		19,4	(Rama *et al.* 2016)
			UHT		7.2	5.1	9.9			39, 30		1,1	
Kenya	AFM1	ELISA	Milk	50 ng/kg (EU)	15.4 ng/kg	290.3±663.4 ng/kg	4563 ng/kg	5 ng/kg		96	96	64	(Kuboka *et al.* 2019)
Italy	AFM1	HPLC-FD	Organic	0.05 ug/kg	0.009	0.017	0.026	0.008 ng/mL	0.025 ng/mL	22	11	0	(Armorini *et al.* 2016)
			Conventional		0.009	0.016	0.026			36	24	0	
Lebanon	AFM1	ELISA	Baby formulae	25 ng/kg	ND	20.1±1.3 NG/KG	48.1	5 ng/L		84	74	13	(Elaridi *et al.* 2019)
	OTA			0.5 ug/ng	ND	0.37±0.1 ug/kg	0.96 ug/kg			84	80	14	
Serbia	AFM1	ELISA	Heat treated cow's milk	0.25 ug/kg, 0.05 ug/kg	<0.005 ug/kg	0.035±0.029 ug/kg	0.28 ug/kg	0.005 ug/kg		1233	1117	14, 214	(Milićević *et al.* 2017)
			infant formula		<0.005 ug/kg	0.011±0.0025 ug/kg	0.017 ug/kg			349	23	1,1	
			milk powder		<0.005 ug/kg	0.018±0.01	0.0035 ug/kg			94	25	0,0	
			dairy drink		<0.005 ug/kg	0.034±0.04 ug/kg	0.147 ug/kg			58	13	0,3	
Serbia	AFM1		Silage	20 ug/kg	3.5	13.4 ug/kg	44 ug/kg		5 ug/kg	48	36	7	(Glamočić *et al.* 2019)
	OTA			250 ug/kg	2.6	10.4 ug/kg	34.3 ug/kg		2 ug/kg	48	41	0	
	Zea			4000 ug/kg	40.5	138 ug/kg	538 ug/kg		25 ug/kg	48	48	0	
Pakistan	AFM1	ELISA	Raw milk	0.50 ug/L (USA)		0.64±0.053		0.1 ug/L	0.25 ug/L	960		672	(Akbar *et al.* 2019)
Belgium	NIV	LC-MS/MS	Maize	No established limit		748.7	6776.3			257	255	0	(Vandicke *et al.* 2019)
	DON			2000 ug/kg		396.4	5322.4			257	223	6	

[1] ELISA Enzyme linked immunoabsorbent assay, HPLC-FD High performance liquid chromatography fluorescence detection, LC-MS/MS Liquid chromatography mass spectroscopy are the tests used to detect mycotoxins

[2] Maximum permissible limits of mycotoxin in commodity with units given and regulatory body in brackets if given or country of origin is the country establishing limits

[3] Minimum reported value according to paper

[4] Mean reported value with range or standard deviation

[5] Maximum reported value

[6] LOD and LOQ if given limits of detection and quantification of the test

Country	Mycotoxin	Test[1]	Product	Limit[2]	Min[3]	Mean[4]	Max[5]	LOD[6]	LOQ[6]	Sample number	Detection range	Above limits	Papers
	ZEN			500 ug/kg		159.7	2791.6			257	128	20	
	FUM			20000 ug/kg		131.8	6293.5			257	73	0	
	T2			250 ug/kg		2.1	121.6			257	8	0	
Malaysia	AFM1	HPLC-FD	Cow's milk	0.5 ug/kg (Malaysia Regulations)	0.020 ug/kg		0.142 ug/kg	0.013 ug/L	0.039 ug/L	102	4	0	(Shuib *et al*. 2017)
Iran	AFM1	ELISA	Commercial pasteurised milk	50 ng/L	11.7 ng/l	65.8 ng/L	106.6 ng/l	5 ng/L		76		46	(Mohammadi *et al.* 2016)
Iran	AFM1	ELISA	Cow's milk	50 ng/L (Iran MPL)	<LOD	61±8 ng/L	240	5 ng/L		60	59	24	(Hajmohammadi *et al.* 2020)
Iran	AFM1	ELISA, HPLC	Raw milk	50 ng/L	6.1 ng/L	59.3±6.2 ng/L	188.2			64	54	23	(Bahrami *et al*. 2016)
			Yoghurt	50 ng/L	6.3 ng/kg	15.1±1.7 ng/kg	21.3 ng/kg			42	10	0	
			Doogh	50 ng/L	7	9.0±0.9ng/kg	12.1			44	6	0	
			Kashk	250 ng/kg	51.7	62.1±2.2 ng/kg	80			40	14	0	
			Tarkhineh	NA	8.2	11.0±1.2 ng/kg	16.6			20	7	NA	
India	AFM1	ELISA	Raw milk	500 ng/l (FSSAI MPL)	9	960±610	4185	5 ng/l		116	60	47	(Patyal *et al*. 2020)
			Pasteurised milk		6	850±590	2330	40 ng/l	100 ng/l	80	41	28	
			UHT milk		9	810±490	2585			34	47	35	
South Korea	DON	HPLC	Cattle Feedstuff	2 mg/kg (EU: complementary and complete feedstuffs for calves)		646.3, s.d 452.58ug/kg		1-10 ug/kg	3-35 ug/kg	174	170	0	(Park *et al.* 2018)
Ireland	Zea	UHPLCMS/MS	Baled Silage Year 1, Pit Silage Year 1, Baled Silage Year 1, Pit Silage Year 2						20	300	0,0,1,2		(McElhinney *et al.* 2016)
England	DON	UPLC-MS	Maize Silage		0	603	7111	10		29	26		(Cogan *et al.* 2017)
	ZEA				0	209	3901	10					
	FB1				0	10.4	107	1					
	FB2				0	2.5	24	1					
	T2				0	-	0	1					
	HT2				0	-	0	1					
Croatia	AFM1	ELISA	Raw cow's milk	50 ng/kg	0.93 ng/kg		85.4 ng/kg	22.2 ng/kg	34.2 ng/kg			12	(Bilandžić *et al.* 2017)

*Adapted from Chhaya and Cummins (2020)

Udovicki *et al.* (2019) carried out an exposure assessment which used the consumption data of 500 students and calculated the Estimated Daily intake (EDI) from the data and occurrence values of AFM_1 in milk and yoghurt. 500 students from Serbia and Greece were interviewed to obtain consumption data and occurrence values were taken from published literature. The study carried out stochastic calculations and obtained estimated daily intake values of AFM1 for students in Serbia (1.238-2.674 ng/kg bw/ day) and 0.350- 0.499 ng/kg bw/day for Greece. Serraino *et al.* (2019) calculated the exposure to aflatoxin M_1 based on a consumption survey carried out by summarizing the calculations for age group and getting the mean and 95^{th} percentile values for the groups. The total number of consumers was 3322 and 31702 milk samples were used for calculating the occurrence values. Estimated daily intake was calculated using AFM_1 occurrence values. The results varied for large portion consumers between 0.35 to 1.16 ng/kg bw/day for toddlers, 0.04 to 0.13 ng/kg bw/day for adults and 0.49 to 1.62 ng/kg bw/day for infants. The EDI's obtained were then used to characterise risk using Hazard Index and Risk of Hepatocellular cancer.

An alternative in assessing the exposure to mycotoxins is to carry out biomonitoring studies. Biomonitoring studies analyse biomarkers which indicate the exposure to mycotoxins. Urinary biomarkers were used to quantify the exposure to ZEN and its modified forms in German population (Ali and Degen 2018). The ZEN values observed in the study varied between 0.04 to 0.28 ng/mL. However, exposure to mycotoxins other than food sources can occur. It is possible for work-place exposure to occur and therefore carrying out an exposure assessment via a dietary intake parallelly might help to understand the exposure difference. A study in Malaysia carried out an exposure to aflatoxin M_1 through urine biomarker and dietary intake (Sulaiman *et al.* 2018) to make an association between both methods of study. The study found weak associations between urinary AFM_1 concentrations and consumption of eggs and dairy products. No association between cereal products (rice) was found. Stronger associations were found between urinary biomarker and the socio-demographic factors. Another study carried out in Portugal (Viegas *et al.* 2018), studied the exposure to mycotoxins from the work-place. A group of workers from a fresh dough Portuguese company, who had maximum contact with the dough were part of the study group. The control group had a lower exposure to DON levels, which was found in dust samples in the workplace suggesting the likelihood of exposure through means other than food.

5.2.3 Risk Characterization

Risk characterisation is done to estimate the probability of occurrence and severity of adverse health impacts on a given population. Udovicki *et al.* (2019) utilised 3 risk characterisation methods for aflatoxin M_1 in yoghurt and milk. EDI values obtained from the study were used to calculate the risk of hepatocellular carcinoma incidence per year due to aflatoxin, the hazard index and margin of exposure.

HCC Risk

Hepatocellular cancer (*HCC*) risk has been previously used by studies where the risk of aflatoxin related cancer was present (Liu and Wu 2010; Serraino *et al.* 2019). The risk of hepatocellular cancer is increased if an individual has a hepatitis B antigen and therefore the carcinogenic potency of aflatoxin varies (JECFA). They found the potency of liver cancer from exposure to aflatoxin to be 0.01 cancers/year/100000 people/ 1ng of aflatoxin/bw in people without hep B antigen, and 0.3 for those with hep b antigen. Using potency estimates, the probability of cancer (*P*) is calculated following which the risk of HCC is obtained.

$$HCC\ Risk = EDI\ \times P(cancer) \tag{3}$$

Liu and Wu (2010) quantified the annual HCC cases due to aflatoxin related to each region using this method. Africa was at the highest risk according to the study followed by south east asia. While Europe had the lowest risk. Climate conditions and monitoring and control of contaminants in the areas studied vary significantly. Serraino *et al.* (2019)'s study investigated the exposure to AFM_1 in Italy for different age groups consuming milk. The incidence of HCC cases for infants was higher: 0.0038 to 0.0078, followed by toddlers: 0.0032 to 0.0067, and adults 0.0004 to 0.0008 per 100,000 people. Infants had a relatively higher intake of milk as compared to the other two age groups concluding that the risk of HCC was low. However, this study only considered the risk due to milk and did not consider other food commodities. Udovicki *et al.* (2019) found the risk of HCC in Serbian students was relatively higher than Greek students: 0.0036-0.0047 to 0.0007-0.0009 HCC cases/year/100000 people. The author's assumed that Greece, being a part of EU, would not have significant increases in AFM_1 concentrations reported in literature, whereas the prevalence for AFM_1 in Serbia was taken as 85.7% with a mean value of 0.09 μg/kg and a range of 0.003 to 0.319

Margin of Exposure

Margin of exposure (MoE) is calculated by dividing the estimated daily intake by the benchmark dose. A benchmark dose is the dose at which there is a low but measurable response. MOE values greater than 10000 indicate that the risk is of low concern to the population. For the study, Udovicki *et al.* (2019) used the dose response of 50 ug/kg. Mean MoE values calculated for Serbia (213.2-460.4) were lower as compared to Greece (1142.3-1628.6). However, both values indicated exposure to AFM_1 was concerning.

Hazard Index

Hazard index is calculated by dividing the EDI by (TD_{50}/5000). Here TD_{50} is the daily dose rate at which 50% of test animals get tumour who did not have any tumours at zero dose rate. 5000 is the uncertainty factor which is equal to the risk level of 1:100000. A HI higher than 1 means there is a risk of to the population. Udovicki *et al.* (2019)'s research showed, most of the HI values were greater than 1, indicating there was a risk to the population. In Italy, Serraino *et al.* (2019) found that the ge group above 3 were not at risk as the HI values were <1, while those below 3, i.e. toddlers and infants were at risk since the HI values were >1.

5.2.4 Risk Assessment and Climate Change

A study carried out in the Philippines (Salvacion *et al.* 2015), assessed the risk of aflatoxins and fumonisins under a climate change scenario using fuzzy logic methodology. It found that the risk of aflatoxin for Philippines was going to reduce in a climate change scenario. For the baseline scenario, aflatoxin contamination was categorised as high risk during the first and second cropping season. However, under a climate change scenario for the Philippines, the risk of aflatoxin was categorised as medium for both the cropping seasons. Fumonisins were not affected by the cropping season or climatic conditions, according to this study.

Feed to fork models incorporating climate change models have not been fully explored in the dairy industry. However recently, a feed to food model was developed by Van der Fels-Klerx *et al.* (2019). Although, a risk assessment was not carried out and instead this model was used to assess the effects of climate change on Aflatoxin M_1 contamination in raw cow's milk as a result of carry-over from AFB1 in maize. A similar approach could be used to carry out a full feed to fork risk assessment, with feed contamination rates, carry over models and climate change-crop contamination models for other mycotoxins as well.

6 Mitigation strategies along the dairy supply chain

6.1 Feed Processing

The risk assessment carried out by (Coffey *et al.* 2009) found that exposure to mycotoxins was highly sensitive to concentrations in the feed and therefore levels needed to be eliminated, reduced or avoided in the feed itself. Contamination of the feed with mycotoxins is due to the interaction between environment factors such as water activity, temperature and carbon dioxide, the fungus and the crop, and therefore climate change is expected to impact mycotoxin production. Prevention of fungal contamination in the crop is the first step to mitigating the overall mycotoxin contamination. The best way to go about this is to employ Good Agricultural Practices and to carry out agricultural activities supported by crop-disease models calibrated to future weather conditions. Appropriate steps can then be taken to minimise the risk such as changing the time of sowing, which crop to grow, fungicide and insecticide application time and rate, soil tilling, irrigation practices to reduce drought and to breed genetically modified plants which are resistant to fungal attack. Feed processes which have an effect on the level of mycotoxins in the feed include mechanical sorting and milling. The process of mechanical sorting can help in initially removing any visibly infected crop. However, despite not being visible, there is a possibility of the crop being infected. Milling processes do not eliminate mycotoxins but distribute them into different fractions. Burger *et al.* (2013) investigated the effects of milling on the distribution of Fumonisins, DON and ZEA in an experiment. It was found that the mycotoxins were more concentrated in the fraction meant for animal feed. The product from that fraction is known as the hominy feed. The hominy feed fraction consists of the parts of the crop contaminated with mycotoxins. However, the commercial milling fractions examined had inconsistent distributions. This could be due to different milling conditions and processes compared to the experimental set up. Aprodu and Banu (2015) studied the co-occurrence of fumonisins and T-2 in maize fractions for commercial milling conditions. The hominy feed had the highest concentration of fumonisins and T-2.

6.2 Dairy Farming stage

The dairy farming stage considered encompasses agricultural farming practices, milking practices, raw milk pooling and hold-on in pooling tanks prior to transportation to dairy processors (Barker and Goméz-Tomé 2013). The effects of climate change previously mentioned are changes with the microbial ecology, load of raw milk and decline in raw milk supply or feed for cows. Thus, the mitigation strategy for the former is introduction of hygienic procedures or pretreatment steps and more stringent veterinary health maintenance. For the latter, sourcing of raw feed and raw milk materials during a decline in raw milk supply might be an option. Incorporating both of these strategies, will be dealt with at the first level of food safety management through the revision of the current prerequisite programs GAP, GHP and even Good Veterinary Practice (**Figure 8)**.

For the first possible effect of climate change, a concrete example of the proposed mitigation strategy is by implementing or revisiting the procedures for cleaning the udder of cow, milking equipment and surfaces prior to milking (Bava *et al.* 2009; Zucali *et al.* 2011). If already being done, the use of alternative cleaning technologies such as use of probiotics or other disinfectants might be considered (Garvey *et al.* 2017; Yu *et al.* 2017). Establishment of these new cleaning procedures aims to contribute in meeting the microbiological specifications of a dairy manufacturer and cushioning the possible effects of climate change. Incorporating these changes will necessitate the updating of current GAP and GHP implemented at the farm level. New source of raw materials might be needed for both cow feed and raw milk sources due to difficulty in obtaining these during occurrences of extreme weather events such as drought or floods (van der Spiegel *et al.* 2012). However, this option might come at a cost given the possible changes with the microbial properties of raw material (Mallet *et al.* 2012).

6.3 Transportation of Raw milk

Milk transportation includes transportation along the entire chain up until the raw bulk milk enters the processing line and until the component separation prior to thermal processing. An option recommended in this part of the dairy supply chain is the establishment assurance systems, proactive monitoring systems of the transport conditions (Jacxsens *et al.* 2010; Marvin *et al.* 2013). Establishment and inclusion of these monitoring systems in prerequisite programs must be validated and verified from time to time to allow food manufacturers gather real-time data that may be used not only in present monitoring but the future progression of climate change effects.

6.4 Dairy Processing and post processing

The dairy processing stage for the different dairy products shows the different unit operations until its packaging prior to distribution. These respective unit operations are usually operated in the same facility. As such the possible mitigation strategies might be through changes with the current food safety programs and prerequisite programs *in lieu* of the projected effects of climate change (**Figure 8)**. Mitigation strategies proposed are the establishment of stringent processing regimes and introduction of pre-treatment processes.

The option to implement stringent processing regimes may come as an increase in the required log reduction value, after expert reviews, because these values are already very stringent (for pasteurised milk 5 log reduction of vegetative bacteria; 9 log reduction of thermophilic spores for commercially sterile milk) (Roberts *et al.* 2005; Deeth 2017). Another option is to introduce non-thermal processing technologies as a hybrid with thermal treatments in order to decrease microbial burden incurred by climate change effects. Notwithstanding the fact that the initial inactivation resistance of the microorganisms to these technologies, is suggested to be taken into consideration in its inactivation kinetics (Gabriel 2015; Feliciano *et al.* 2019).

The post-processing part is a significant source of recontamination in milk and other dairy products mentioned (Kure *et al.* 2004; D'amico 2014; Pujol *et al.* 2015b). Currently, food safety programs and routine environmental testing is used to monitor the possible sources of post processing contamination. Revisiting the currently implemented systems might be needed depending on the projected vulnerability of the facility to the effects of climate change and extreme weather events. As such, it was recommended that effective implementation of food safety programs is needed into order to avoid inoculation of moulds producing mycotoxin during cheese ripening stage Dagnas & Membré, (2013). The inclusion of the post processing stage in a QMRA model were also shown to be helpful in identifying the contribution of the recontamination at this stage in the microbial food safety of different dairy products (Tenenhaus-Aziza *et al.* 2014; Pujol *et al.* 2015a).

6.5 Distribution and consumption of dairy products

The last part of the dairy supply chain is the distribution of products from the food manufacturing environment. As such, with the projected climate change effects the optimum conditions during the distribution until retailing might be harder to maintain. Climate conditions and temperature during the distribution, retailing and consumption of the shelf-life of dairy products were recently shown to impact the microbial food safety of evaporated milk and pasteurised milk (Schaffner *et al.* 2003; Kakagianni and Koutsoumanis 2018). This is true for the presented dairy products where most of the current storage conditions require a low temperature during storage. The

mitigation strategy proposed during this part is the use of predictive microbiology models and its incorporation in QMRA model.

The development or use of predictive microbiology models allows the estimation of the growth rate of spoilage microorganism in dairy products as influenced by the intrinsic food properties and extrinsic properties such as temperature. This will allow risk managers to estimate the final concentration of microorganism in a particular food product until consumption. As such this will allow manufacturers to estimate the shelf-life of dairy products (Tiwari *et al.* 2015; Kakagianni and Koutsoumanis 2018). Several ways on how climate variables during distribution can be incorporated in a QMRA model were previously mentioned.

Several studies have also pointed out the importance of consumer practices and refrigerators in impacting the shelf life of dairy products and used this data in estimating the shelf life of dairy products (Roccato *et al.* 2017; Rodriguez-Martinez *et al.* 2020). It is suggested that incorporation of this data in a separate module dedicated to consumer handling in a QMRA model would improve risk estimates, and better estimate the shelf-life of dairy products during hot weather or extreme weather events. Implications of these might necessitate changes with product formulation, changes along the manufacture of foods or changes in shelf-life of the product.

7 Conclusion

Projected climate change effects are expected to increase the potential risk of contamination from microbiological and chemical hazards in the dairy industry. Monitoring these effects with the incorporation of climate change models is necessary to formulate mitigation plans. Feed chain risk assessments combining mycotoxin producing models with climate data can help plan and regulate exposure to mycotoxins along the chain. Environmental factors affecting the production of mycotoxins are expected to change in Europe, favouring the production of mycotoxins. Currently, very few mycotoxins are regulated and studied in relation to the dairy supply chain. To date, a complete feed to fork risk assessment model incorporating climate change factors has not been created, therefore creating one may be beneficial in the long run to estimate the likely climate change influences on safety and quality of dairy products. Similarly, microbiological hazards in the dairy supply chain are expected to increase as a result of climate change. The use of QMRAs in conjunction with climate change models will help risk managers and producers take necessary measures to maintain the safety and quality of dairy products.

Bibliography

Akbar, N., Nasir, M., Naeem, N., Ahmad, M.U.D., Iqbal, S., Rashid, A., Imran, M., Gondal, T.A., Atif, M., Salehi, B., Sharifi-Rad, J., Martorell, M., Cho, W.C. (2019) ‘Occurrence and seasonal variations of aflatoxin M1 in milk from Punjab, Pakistan’, *Toxins*, 11(10), 1–16.

Akil, L., Anwar Ahmad, H., Reddy, R.S. (2014) ‘Effects of climate change on Salmonella infections’, *Foodborne Pathogens and Disease*, 11(12), 974–980.

Akineden, Ö., Annemüller, C., Hassan, A.A., Lämmler, C., Wolter, W., Zschöck, M. (2001) ‘Toxin genes and other characteristics of Staphylococcus aureus isolates from milk of cows with mastitis’, *Clinical and Diagnostic Laboratory Immunology*, 8(5), 959–964.

Ali, N., Degen, G.H. (2018) ‘Urinary biomarkers of exposure to the mycoestrogen zearalenone and its modified forms in German adults’, *Archives of Toxicology*, 92(8), 2691–2700, available: http://dx.doi.org/10.1007/s00204-018-2261-5.

Alirezalu, K., Munekata, P.E.S., Parniakov, O., Barba, F.J., Witt, J., Toepfl, S., Wiktor, A., Lorenzo, J.M. (2020) ‘Pulsed electric field and mild heating for milk processing: a review on recent advances’, *Journal of the Science of Food and Agriculture*, 100(1), 16–24.

Allende, A., Castro-Ibáñez, I., Lindqvist, R., Gil, M.I., Uyttendaele, M., Jacxsens, L. (2017) 'Quantitative contamination assessment of Escherichia coli in baby spinach primary production in Spain: Effects of weather conditions and agricultural practices', *International Journal of Food Microbiology*, 257(June), 238–246. http://dx.doi.org/10.1016/j.ijfoodmicro.2017.06.027.

Alshannaq, A., Yu, J.-H. (2017) 'Occurrence, toxicity, and analysis of major mycotoxins in food', *International Journal of Environmental Research and Public Health*, 14(6), 632.

dos Anjos, M.R., Castro, I.M. de, Souza, M. de L.M. de, de Lima, V.V., de Aquino-Neto, F.R., de Aquino-Neto, F.R. (2016) 'Multiresidue method for simultaneous analysis of aflatoxin M1, avermectins, organophosphate pesticides and milbemycin in milk by ultra-performance liquid chromatography coupled to tandem mass spectrometry', *Food Additives & Contaminants: Part A*, 33(6), 995–1002.

Aprodu, I., Banu, I. (2015) 'Co-occurrence of fumonisins and T-2 toxins in milling maize fractions under industrial conditions', *CYTA - Journal of Food*, 13(1), 102–106, available: http://dx.doi.org/10.1080/19476337.2014.917702.

Armorini, S., Altafini, A., Zaghini, A., Roncada, P. (2016) 'Occurrence of aflatoxin M1 in conventional and organic milk offered for sale in Italy', *Mycotoxin Research*, 32(4), 237–246.

Asao, T., Kumeda, Y., Kawai, T., Shibata, T., Oda, H., Haruki, K., Nakazawa, H., Kozaki, S. (2003) 'An extensive outbreak of staphylococcal food poisoning due to low-fat milk in Japan: Estimation of enterotoxin A in the incriminated milk and powdered skim milk', *Epidemiology and Infection*, 130(1), 33–40.

Asi, M.R., Iqbal, S.Z., Ariño, A., Hussain, A. (2012) 'Effect of seasonal variations and lactation times on aflatoxin M 1 contamination in milk of different species from Punjab, Pakistan', *Food Control*, 25(1), 34–38.

van Asselt, E.D., Booij, C.J.H., van der Fels-Klerx, H.J. (2012) 'Modelling mycotoxin formation by Fusarium graminearum in maize in The Netherlands', *Food Additives and Contaminants - Part A Chemistry, Analysis, Control, Exposure and Risk Assessment*, 29(10), 1572–1580.

van Asselt, E.D., van der Fels-Klerx, H.J., Marvin, H.J.P., van Bokhorst-van de Veen, H., Groot, M.N. (2017) 'Overview of Food Safety Hazards in the European Dairy Supply Chain', *Comprehensive Reviews in Food Science and Food Safety*, 16(1), 59–75.

Azanza, M.P. V., Zamora-Luna, M.B. V. (2005) 'Barriers of HACCP team members to guideline adherence', *Food Control*, 16(1), 15–22.

Bahrami, R., Shahbazi, Y., Nikousefat, Z. (2016) 'Aflatoxin M1 in milk and traditional dairy products from west part of Iran: Occurrence and seasonal variation with an emphasis on risk assessment of human exposure', *Food Control*, 62, 250–256, available: http://dx.doi.org/10.1016/j.foodcont.2015.10.039.

Banno, A., Wang, J., Okada, K., Mori, R., Mijiti, M., Nagaoka, S. (2019) 'Identification of a novel cholesterol-lowering dipeptide, phenylalanine-proline (FP), and its down-regulation of intestinal ABCA1 in hypercholesterolemic rats and Caco-2 cells', *Scientific Reports*, 9(1), 1–12.

Barker, G.C., Goméz-Tomé, N. (2013) 'A Risk Assessment Model for Enterotoxigenic Staphylococcus aureus in Pasteurized Milk: A Potential Route to Source-Level Inference', *Risk Analysis*, 33(2), 249–269.

Battilani, P., Camardo Leggieri, M., Rossi, V., Giorni, P. (2013) 'AFLA-maize, a mechanistic model for Aspergillus flavus infection and aflatoxin B1 contamination in maize', *Computers and Electronics in Agriculture*, 94, 38–46, available: http://dx.doi.org/10.1016/j.compag.2013.03.005.

Battilani, P., Toscano, P., Fels-Klerx H.J, van der, Moretti, A., Camardo Leggieri, M., Brera, C., Rortais, A., Goumpertis, T., Robinson, T. (2016) 'Aflatoxin B1 contamination in maize in Europe increases due to climate change', *Scientific Reports*, 6(1), 24328.

Battilani, P., Toscano, P., Van Der Fels-Klerx, H.J., Moretti, A., Camardo Leggieri, M., Brera, C., Rortais, A., Goumperis, T., Robinson, T. (2016) 'Aflatoxin B 1 contamination in maize in

Europe increases due to climate change', *Scientific Reports*, 6(March), 1–8.
Bava, L., Zucali, M., Brasca, M., Zanini, L., Sandrucci, A. (2009) 'Efficiency of cleaning procedure of milking equipment and bacterial quality of milk', *Italian Journal of Animal Science*, 8(SUPPL. 2), 387–389.
Bemrah, N., Sanaa, M., Cassin, M.H., Griffiths, M.W., Cerf, O. (1998) 'Quantitative risk assessment of human listeriosis from consumption of soft cheese made from raw milk', *Preventive Veterinary Medicine*, 37(1–4), 129–145.
Bernabucci, U., Lacetera, N., Ronchi, B., Nardone, A. (2002) 'Effects of the hot season on milk protein fractions in Holstein cows', *Animal Research*, 51(June), 25–33.
den Besten, H.M.W., Zwietering, M.H. (2012) 'Meta-analysis for quantitative microbiological risk assessments and benchmarking data', *Trends in Food Science and Technology*, 25(1), 34–39.
Bilandžić, N., Varenina, I., Solomun Kolanović, B., Božić Luburić, Đ., Varga, I., Želježić, B., Cvetnić, L., Benić, M., Tanković, S., Cvetnić, Ž. (2017) 'Occurrence of aflatoxin M1 in raw cow, goat and sheep milk during spring and autumn in Croatia during 2016', *Toxin Reviews*, 36(4), 290–296, available: https://doi.org/10.1080/15569543.2017.1306785.
Bishop, J.R., Smukowski, M. (2006) 'Storage Temperatures Necessary to Maintain Cheese Safety', *Food Protection Trends*, 26(10), 714–724.
Bouraoui, R., Lahmar, M., Majdoub, A., Djemali, M., Belyea, R. (2002) 'The relationship of temperature-humidity index with milk production of dairy cows in a Mediterranean climate', *Animal Research*, 51(6), 479–491.
Brans, G., Schroën, C.G.P.H., Van Der Sman, R.G.M., Boom, R.M. (2004) 'Membrane fractionation of milk: State of the art and challenges', *Journal of Membrane Science*, 243(1–2), 263–272.
Broyard, C., Gaucheron, F. (2015) 'Modifications of structures and functions of caseins: a scientific and technological challenge', *Dairy Science and Technology*, 95(6), 831–862.
Bryden, W.L. (2012) 'Mycotoxin contamination of the feed supply chain: Implications for animal productivity and feed security', *Animal Feed Science and Technology*, 173(1–2), 134–158, available: http://dx.doi.org/10.1016/j.anifeedsci.2011.12.014.
Buchanan, R.L., Whiting, R.C. (1998) 'Risk assessment: A means for linking HACCP plans and public health', *Journal of Food Protection*, 61(11), 1531–1534.
Burger, H.M., Shephard, G.S., Louw, W., Rheeder, J.P., Gelderblom, W.C.A. (2013) 'The mycotoxin distribution in maize milling fractions under experimental conditions', *International Journal of Food Microbiology*, 165(1), 57–64, available: http://dx.doi.org/10.1016/j.ijfoodmicro.2013.03.028.
Burgess, S.A., Lindsay, D., Flint, S.H. (2010) 'Thermophilic bacilli and their importance in dairy processing', *International Journal of Food Microbiology*, 144(2), 215–225.
Cai yun, F., Su, D., Tian, H., Hu, R., Ran, L., Yang, Y., Su, Y. jing, Cheng, J. bo (2019) 'Milk production and composition and metabolic alterations in the mammary gland of heat-stressed lactating dairy cows', *Journal of Integrative Agriculture*, 18(12), 2844–2853.
Camardo Leggieri, M., Giorni, P., Pietri, A., Battilani, P. (2019) 'Aspergillus flavus and Fusarium verticillioides Interaction: Modeling the Impact on Mycotoxin Production', *Frontiers in Microbiology*, 10(November), 1–10.
Campagnollo, F.B., Gonzales-Barron, U., Pilão Cadavez, V.A., Sant'Ana, A.S., Schaffner, D.W. (2018) 'Quantitative risk assessment of Listeria monocytogenes in traditional Minas cheeses: The cases of artisanal semi-hard and fresh soft cheeses', *Food Control*, 92(May), 370–379.
Carrasco, E., Pérez-Rodríguez, F., Valero, A., García-Gimeno, R.M., Zurera, G. (2010) 'Risk assessment and management of listeria monocytogenes in ready-to-eat lettuce salads', *Comprehensive Reviews in Food Science and Food Safety*, 9(5), 498–512.
Castro-Ibáñez, I., Gil, M.I., Tudela, J.A., Ivanek, R., Allende, A. (2015) 'Assessment of microbial risk factors and impact of meteorological conditions during production of baby spinach in the Southeast of Spain', *Food Microbiology*, 49, 173–181.
Chhaya, R., Cummins, E. (2020) 'A Review of Mycotoxin related Challenges due to Climate

Change in Feed and Dairy Products', *Manuscript in Preparation*.
Claeys, W.L., Cardoen, S., Daube, G., De Block, J., Dewettinck, K., Dierick, K., De Zutter, L., Huyghebaert, A., Imberechts, H., Thiange, P., Vandenplas, Y., Herman, L. (2013) 'Raw or heated cow milk consumption: Review of risks and benefits', *Food Control*, 31(1), 251–262.
Clough, H.E., Clancy, D., French, N.P. (2009) 'Quantifying exposure to Vero-cytotoxigenic Escherichia coli O157 in milk sold as pasteurized: A model-based approach', *International Journal of Food Microbiology*, 131(2–3), 95–105.
Coffey, R., Cummins, E. (2008) 'Feed to food risk assessment, with particular reference to mycotoxins in bovine feed', *International Journal of Risk Assessment and Management*, 8(3), 266–286.
Coffey, R., Cummins, E., Ward, S. (2009) 'Exposure assessment of mycotoxins in dairy milk', *Food Control*, 20(3), 239–249, available: http://dx.doi.org/10.1016/j.foodcont.2008.05.011.
Cogan, T., Hawkey, R., Higgie, E., Lee, M.R.F., Mee, E., Parfitt, D., Raj, J., Roderick, S., Walker, N., Ward, P., Wilkinson, J.M. (2017) 'Silage and total mixed ration hygienic quality on commercial farms: implications for animal production', *Grass and Forage Science*, 72(4), 601–613.
Condoleo, R., Mezher, Z., Marozzi, S., Guzzon, A., Fischetti, R., Senese, M., Sette, S., Bucchini, L. (2017) 'Risk Assessment of Human Listeriosis from Semisoft Cheeses Made from Raw Sheep's Milk in Lazio and Tuscany (Italy)', *Risk Analysis*, 37(4), 661–676.
Coutinho, N.M., Silveira, M.R., Rocha, R.S., Moraes, J., Ferreira, M.V.S., Pimentel, T.C., Freitas, M.Q., Silva, M.C., Raices, R.S.L., Ranadheera, C.S., Borges, F.O., Mathias, S.P., Fernandes, F.A.N., Rodrigues, S., Cruz, A.G. (2018) 'Cold plasma processing of milk and dairy products', *Trends in Food Science and Technology*, 74(October 2017), 56–68.
Cummins, E. (2016) 'Quantifying microbial propagation', in Membré, J.M. and Valdramidis, V.P., eds., *Modeling in Food Microbiology: From Predictive Microbiology to Exposure Assessment*, ISTE Ltd., 17–31.
Cusato, S., Gameiro, A.H., Corassin, C.H., Sant'ana, A.S., Cruz, A.G., Faria, J.D.A.F., De Oliveira, C.A.F. (2013) 'Food safety systems in a small dairy factory: Implementation, major challenges, and assessment of systems' performances', *Foodborne Pathogens and Disease*, 10(1), 6–12.
D'amico, D.J. (2014) 'Microbiological Quality and Safety Issues in Cheesemaking', *Microbiology Spectrum*, 2(1), 1–44.
Dagnac, T., Latorre, A., Fernández Lorenzo, B., Llompart, M. (2016) 'Validation and application of a liquid chromatography-tandem mass spectrometry based method for the assessment of the co-occurrence of mycotoxins in maize silages from dairy farms in NW Spain', *Food Additives & Contaminants: Part A*, 33(12), 1850–1863.
Dagnas, S.P., Membré, J.M. (2013) 'Predicting and preventing mold spoilage of food products', *Journal of Food Protection*, 76(3), 538–551.
Danyluk, M.D., Schaffner, D.W. (2011) 'Quantitative assessment of the microbial risk of leafy greens from farm to consumption: Preliminary framework, data, and risk estimates', *Journal of Food Protection*, 74(5), 700–708.
Das, R., Sailo, L., Verma, N., Bharti, P., Saikia, J., Imtiwati, Kumar, R. (2016) 'Impact of heat stress on health and performance of dairy animals: A review', *Veterinary World*, 9(3), 260–268.
Dearfield, K.L., Hoelzer, K., Kause, J.R. (2014) 'Review of various approaches for assessing public health risks in regulatory decision making: Choosing the right approach for the problem', *Journal of Food Protection*, 77(8), 1428–1440.
Deeth, H. (2017) 'Optimum Thermal Processing for Extended Shelf-Life (ESL) Milk', *Foods*, 6(12), 102.
Delcour, I., Spanoghe, P., Uyttendaele, M. (2015) 'Literature review: Impact of climate change on pesticide use', *Food Research International*, 68, 7–15, available: http://dx.doi.org/10.1016/j.foodres.2014.09.030.
Dimitrieska-Stojković, E., Stojanovska-Dimzoska, B., Ilievska, G., Uzunov, R., Stojković, G., Hajrulai-Musliu, Z., Jankuloski, D. (2016) 'Assessment of aflatoxin contamination in raw milk

and feed in Macedonia during 2013', *Food Control*, 59, 201–206.
Doménech, E., Amorós, J.A., Pérez-Gonzalvo, M., Escriche, I. (2011) 'Implementation and effectiveness of the HACCP and pre-requisites in food establishments', *Food Control*, 22(8), 1419–1423.
Doyle, C.J., Gleeson, D., O'Toole, P.W., Cotter, P.D. (2017) 'High-throughput metataxonomic characterization of the raw milk microbiota identifies changes reflecting lactation stage and storage conditions', *International Journal of Food Microbiology*, 255(December 2016), 1–6.
EC (2019) *EU Agricultural Outlook for Markets and Income, 2019-2030.European Commission, DG Agriculture and Rural Development, Brussels.*
EFSA (2015) 'Scientific Opinion on the development of a risk ranking toolbox for the EFSA BIOHAZ Panel', *EFSA Journal*, 13(1), 1–131.
Eijlander, R.T., van Hekezen, R., Bienvenue, A., Girard, V., Hoornstra, E., Johnson, N.B., Meyer, R., Wagendorp, A., Walker, D.C., Wells-Bennik, M.H.J. (2019) 'Spores in dairy – new insights in detection, enumeration and risk assessment', *International Journal of Dairy Technology*, 72(2), 303–315.
Elaridi, J., Dimassi, H., Hassan, H. (2019) 'Aflatoxin M1 and ochratoxin A in baby formulae marketed in Lebanon: Occurrence and safety evaluation', *Food Control*, 106(June).
Elsgaard, L., Børgesen, C.D., Olesen, J.E., Siebert, S., Ewert, F., Peltonen-Sainio, P., Rötter, R.P., Skjelvåg, A.O. (2012) 'Shifts in comparative advantages for maize, oat and wheat cropping under climate change in Europe', *Food Additives and Contaminants - Part A Chemistry, Analysis, Control, Exposure and Risk Assessment*, 29(10), 1514–1526.
Erkekoğlu, P., Sabuncuoğlu, S., Aydin, S., Şahin, G., Giray, B. (2010) 'Determination of seasonal variations in serum ochratoxin A levels in healthy population living in some regions of Turkey by enzyme-linked immunosorbent assay', *Toxicon*, 55(2–3), 507–513.
Evelyn, Silva, F.V.M. (2015) 'High pressure processing of milk: Modeling the inactivation of psychrotrophic Bacillus cereus spores at 38-70 °c', *Journal of Food Engineering*, 165, 141–148.
FAO and WHO (2006) *The Use of Microbiological Risk Assessment Outputs to Develop Practical Risk Management Strategies : Metrics to Improve Food Safety*, Kiel.
FAO and WHO (2013) *Codex Alimentarius Commision Procedural Manual*, Procedural manual, Rome.
Feliciano, R.J., Boué, G., Membré, J.M. (2020) 'Towards a climate change resilient dairy manufacturing industry: challenges of microbial safety management', *Manuscript in Preparation*.
Feliciano, R.J., Estilo, E.E.C., Nakano, H., Gabriel, A.A. (2019) 'Decimal reduction energies of UV-C-irradiated spoilage yeasts in coconut liquid endosperm', *International Journal of Food Microbiology*, 290.
Van der Fels-Klerx, H.J., Van Asselt, E.D., Raley, M., Poulsen, M., Korsgaard, H., Bredsdorff, L., Nauta, M., D'agostino, M., Coles, D., Marvin, H.J.P., Frewer, L.J. (2018) 'Critical review of methods for risk ranking of food-related hazards, based on risks for human health', *Critical Reviews in Food Science and Nutrition*, 58(2), 178–193, available: https://doi.org/10.1080/10408398.2016.1141165.
van der Fels-Klerx, H.J., Klemsdal, S., Hietaniemi, V., Lindblad, M., Ioannou-Kakouri, E., van Asselt, E.D. (2012) 'Mycotoxin contamination of cereal grain commodities in relation to climate in North West Europe', *Food Additives and Contaminants - Part A Chemistry, Analysis, Control, Exposure and Risk Assessment*, 29(10), 1581–1592.
Van der Fels-Klerx, H.J., Vermeulen, L.C., Gavai, A.K., Liu, C. (2019) 'Climate change impacts on aflatoxin B1 in maize and aflatoxin M1 in milk: A case study of maize grown in Eastern Europe and imported to the Netherlands', *PLoS ONE*, 14(6), 1–14.
Flint, S., Bremer, P., Brooks, J., Palmer, J., Sadiq, F.A., Seale, B., Teh, K.H., Wu, S., Md Zain, S.N. (2020) 'Bacterial fouling in dairy processing', *International Dairy Journal*, 101, 104593.
Frazzoli, C., Gherardi, P., Saxena, N., Belluzzi, G., Mantovani, A. (2017) 'The hotspot for (global)

one health in primary food production: Aflatoxin M1 in dairy products', *Frontiers in Public Health*, 4(FEB), 1–11.
Gabriel, A.A. (2015) 'Inactivation of Listeria monocytogenes in Milk by Multifrequency Power Ultrasound', *Journal of Food Processing and Preservation*, 39(6), 846–853.
Garvey, M., Curran, D., Savage, M. (2017) 'Efficacy testing of teat dip solutions used as disinfectants for the dairy industry: Antimicrobial properties', *International Journal of Dairy Technology*, 70(2), 179–187.
Geeraerd, A.H., Herremans, C.H., Van Impe, J.F. (2000) 'Structural model requirements to describe microbial inactivation during a mild heat treatment', *International Journal of Food Microbiology*, 59(3), 185–209.
Van Gerwen, S.J.C., De Wit, J.C., Notermans, S., Zwietering, M.H. (1997) 'An identification procedure for foodborne microbial hazards', *International Journal of Food Microbiology*, 38(1), 1–15.
Van Gerwen, S.J.C., Zwietering, M.H. (1998) 'Growth and inactivation models to be used in quantitative risk assessments', *Journal of Food Protection*, 61(11), 1541–1549.
Giacometti, F., Serraino, A., Bonilauri, P., Ostanello, F., Daminelli, P., Finazzi, G., Losio, M.N., Marchetti, G., Liuzzo, G., Zanoni, R.G., Rosmini, R. (2012) 'Quantitative risk assessment of verocytotoxin-producing Escherichia coli O157 and Campylobacter jejuni related to consumption of raw milk in a province in Northern Italy', *Journal of Food Protection*, 75(11), 2031–2038.
Glamočić, D., Polovinski Horvatović, M., Jajić, I., Krstović, S., Guljaš, D. (2019) 'Occurrence of aflatoxin B1, ochratoxin A and zearalenone in maize silage in the region of Vojvodina, Serbia', *Acta Veterinaria*, 69(1), 106–115.
Gorris, L.G.M. (2005) 'Food safety objective: An integral part of food chain management', *Food Control*, 16(9 SPEC. ISS.), 801–809.
Gorris, L.G.M., Bassett, J., Membré, J.-M. (2006) 'Food safety objectives and related concepts: the roll of the food industry', in Mortajemi, Y. and Adams, M., eds., *Emerging Foodborne Pathogens*, Woodhead Publishing Limited: Cambridge, 153–178.
Grace, D., Omore, A., Randolph, T., Kang'ethe, E., Nasinyama, G.W., Mohammed, H.O. (2008) 'Risk assessment for Escherichia coli O157:H7 in marketed unpasteurized milk in selected East African countries', *Journal of Food Protection*, 71(2), 257–263.
Grispoldi, L., Massetti, L., Sechi, P., Iulietto, M.F., Ceccarelli, M., Karama, M., Popescu, P.A., Pandolfi, F., Cenci-Goga, B.T. (2019) 'Short communication: Characterization of enterotoxin-producing Staphylococcus aureus isolated from mastitic cows', *Journal of Dairy Science*, 102(2), 1059–1065.
Guillou, S., Membré, J.M. (2019) 'Inactivation of Listeria monocytogenes, Staphylococcus aureus, and Salmonella enterica under High Hydrostatic Pressure: A quantitative analysis of existing literature data', *Journal of Food Protection*, 82(10), 1802–1814.
Gundogan, N., Avci, E. (2014) 'Occurrence and antibiotic resistance of Escherichia coli, Staphylococcus aureus and Bacillus cereus in raw milk and dairy products in Turkey', *International Journal of Dairy Technology*, 67(4), 562–569.
Guo, L.Y., Zheng, N., Zhang, Y.D., Du, R.H., Zheng, B.Q., Wang, J.Q. (2016) 'A survey of seasonal variations of aflatoxin M1 in raw milk in Tangshan region of China during 2012-2014', *Food Control*, 69, 30–35.
Haas, C.N., Rose, J.B., Gerba, C.P. (2014) *Quantitative Microbial Risk Assessment*, 2nd ed, John Wiley & Sons, Inc.: New Jersey.
Hajmohammadi, M., Valizadeh, R., Naserian, A., Nourozi, M.E., Rocha, R.S., Oliveira, C.A.F. (2020) 'Composition and occurrence of aflatoxin M1 in cow's milk samples from Razavi Khorasan Province, Iran', *International Journal of Dairy Technology*, 73(1), 40–45.
Hantsis-Zacharov, E., Halpern, M. (2007) 'Culturable psychrotrophic bacterial communities in raw milk and their proteolytic and lipolytic traits', *Applied and Environmental Microbiology*, 73(22), 7162–7168.

Heidinger, J.C., Winter, C.K., Cullor, J.S. (2009a) 'Quantitative microbial risk assessment for Staphylococcus aureus and Staphylococcus enterotoxin a in raw milk', *Journal of Food Protection*, 72(8), 1641–1653.

Heidinger, J.C., Winter, C.K., Cullor, J.S. (2009b) 'Quantitative Microbial Risk Assessment for Staphylococcus aureus and Staphylococcus Enterotoxin A in Raw Milk', *Journal of Food Protection*, 72(8), 1641–1653.

Hempel, S., Menz, C., Pinto, S., Galán, E., Janke, D., Estellés, F., Müschner-Siemens, T., Wang, X., Heinicke, J., Zhang, G., Amon, B., Del Prado, A., Amon, T. (2019) 'Heat stress risk in European dairy cattle husbandry under different climate change scenarios-uncertainties and potential impacts', *Earth System Dynamics*, 10(4), 859–884.

Hietaniemi, V., Rämö, S., Yli-Mattila, T., Jestoi, M., Peltonen, S., Kartio, M., Sieviläinen, E., Koivisto, T., Parikka, P. (2016) 'Updated survey of Fusarium species and toxins in Finnish cereal grains', *Food Additives and Contaminants - Part A Chemistry, Analysis, Control, Exposure and Risk Assessment*, 33(5), 831–848.

Hjelkrem, A.G.R., Torp, T., Brodal, G., Aamot, H.U., Strand, E., Nordskog, B., Dill-Macky, R., Edwards, S.G., Hofgaard, I.S. (2017) 'DON content in oat grains in Norway related to weather conditions at different growth stages', *European Journal of Plant Pathology*, 148(3), 577–594.

Hoegh-Guldberg O., Jacob D., Taylor M., Bindi M., Brown S., Camilloni I., Diedhiou A., Djalante R. *et al*. (Achlatis M. listed as contributing author) (2018) 'Chapter 3: Impacts of 1.5°C global warming on natural and human systems. In: Global Warming of 1.5 °C. An IPCC special report on the impacts of global warming of 1.5 °C above preindustrial levels and related global greenhouse gas emission pathways [...]', *Special Report, Intergovernmental Panel on Climate Change*, (ISBN 978-92-9169-151-7), 175–311.

Hovinen, M., Pyörälä, S. (2011) 'Invited review: Udder health of dairy cows in automatic milking', *Journal of Dairy Science*, 94(2), 547–562.

ICMSF (2005) *Microorganisms in Foods in 6*, Microorganisms in Foods 6, Kluwer Academic: New York.

ICMSF (2011) 'Microorganisms in Foods 8', in *Microorganisms in Foods 8*, Springer Science+Business Media,LLC: New York, 3–11.

Jacobs, C., Braun, P., Hammer, P. (2011) 'Reservoir and routes of transmission of Enterobacter sakazakii (Cronobacter spp.) in a milk powder-producing plant', *Journal of Dairy Science*, 94(8), 3801–3810.

Jacxsens, L., Luning, P.A., van der Vorst, J.G.A.J., Devlieghere, F., Leemans, R., Uyttendaele, M. (2010) 'Simulation modelling and risk assessment as tools to identify the impact of climate change on microbiological food safety - The case study of fresh produce supply chain', *Food Research International*, 43(7), 1925–1935, available: http://dx.doi.org/10.1016/j.foodres.2009.07.009.

Jamali, H., Radmehr, B., Thong, K.L. (2013) 'Prevalence, characterisation, and antimicrobial resistance of Listeria species and Listeria monocytogenes isolates from raw milk in farm bulk tanks', *Food Control*, 34(1), 121–125.

Jarvis, B. (2008) 'Frequency distributions', in *Statistical Aspects of the Microbiological Examination of Foods*, Academic Press Inc.: London, 163–164.

Jindal, S., Anand, S., Huang, K., Goddard, J., Metzger, L., Amamcharla, J. (2016) *Evaluation of Modified Stainless Steel Surfaces Targeted to Reduce Biofilm Formation by Common Milk Sporeformers*, Journal of Dairy Science, Elsevier.

Kable, M.E., Srisengfa, Y., Laird, M., Zaragoza, J., McLeod, J., Heidenreich, J., Marco, M.L. (2016) 'The core and seasonal microbiota of raw bovine milk in tanker trucks and the impact of transfer to a milk processing facility', *mBio*, 7(4), 1–13.

Kakagianni, M., Koutsoumanis, K.P. (2018) 'Mapping the risk of evaporated milk spoilage in the Mediterranean region based on the effect of temperature conditions on Geobacillus stearothermophilus growth', *Food Research International*, 111(April), 104–110.

Kanwal, R., Mehmood, A., Saleem, S., Randhawa, M.A., Ihsan, A., Amir, R.M., Nadeem, M., Sajid,

M.W. (2018) ‘Seasonal impact and daily intake assessment of mycotoxins in flour, bread, and nixtamalized maize’, *Journal of Food Safety*, 38(6).

Kekana, T.W., Nherera-Chokuda, F. V., Muya, M.C., Manyama, K.M., Lehloenya, K.C. (2018) ‘Milk production and blood metabolites of dairy cattle as influenced by thermal-humidity index’, *Tropical Animal Health and Production*, 50(4), 921–924.

Kevenk, T.O., Terzi Gulel, G. (2016) ‘Prevalence, Antimicrobial Resistance and Serotype Distribution of Listeria monocytogenes Isolated from Raw Milk and Dairy Products’, *Journal of Food Safety*, 36(1), 11–18.

Knutsen, H., Alexander, J., Barregård, L., Bignami, M., Brüschweiler, B., Ceccatelli, S., Cottrill, B., Dinovi, M., Edler, L., GraslKraupp, B., Hogstrand, C., Hoogenboom, L. (Ron), Nebbia, C.S., Petersen, A., Rose, M., Roudot, A., Schwerdtle, T., Vleminckx, C., Vollmer, G., Wallace, H., Dall’Asta, C., Dänicke, S., Eriksen, G., Altieri, A., Roldán Torres, R., Oswald, I.P., (CONTAM), E.P. on C. in the F.C. (2017) ‘Risks for animal health related to the presence of zearalenone and its modified forms in feed’, *EFSA Journal*, 15(7).

Knutsen, H.K., Alexander, J., Barregård, L., Bignami, M., Brüschweiler, B., Ceccatelli, S., Cottrill, B., Dinovi, M., Grasl- Kraupp, B., Hogstrand, C., Hoogenboom, L., Nebbia, C.S., Oswald, I.P., Petersen, A., Rose, M., Roudot, A.-C., Schwerdtle, T., Vleminckx, C., Vollmer, G., Wallace, H., Saeger Sarah, D., Eriksen, G.S., Farmer, P., Fremy, J.-M., Gong, Y.Y., Meyer, K., Parent- Massin, D., Egmond Hans, van, Altieri, A., Colombo, P., Horváth, Z., Levorato, S., Edler, L., (CONTAM), E.P. on C. in the F.C. (2018) ‘Risk to human and animal health related to the presence of 4,15- diacetoxyscirpenol in food and feed’, *EFSA Journal*, 16(8).

Korn, U., Müller, T., Ulrich, A., Müller, M.E.H. (2011) ‘Impact of aggressiveness of Fusarium graminearum and F. culmorum isolates on yield parameters and mycotoxin production in wheat’, *Mycotoxin Research*, 27(3), 195–206.

Kotsanopoulos, K. V., Arvanitoyannis, I.S. (2017) ‘The Role of Auditing, Food Safety, and Food Quality Standards in the Food Industry: A Review’, *Comprehensive Reviews in Food Science and Food Safety*, 16(5), 760–775.

Koutsoumanis, K., Pavlis, A., Nychas, G.J.E., Xanthiakos, K. (2010) ‘Probabilistic model for Listeria monocytogenes growth during distribution, retail storage, and domestic storage of pasteurized milk’, *Applied and Environmental Microbiology*, 76(7), 2181–2191.

Kriss, A.B., Paul, P.A., Xu, X., Nicholson, P., Doohan, F.M., Hornok, L., Rietini, A., Edwards, S.G., Madden, L. V. (2012) ‘Quantification of the relationship between the environment and Fusarium head blight, Fusarium pathogen density, and mycotoxins in winter wheat in Europe’, *European Journal of Plant Pathology*, 133(4), 975–993.

Kuboka, M.M., Imungi, J.K., Njue, L., Mutua, F., Grace, D., Lindahl, J.F. (2019) ‘Occurrence of aflatoxin M1 in raw milk traded in peri-urban Nairobi, and the effect of boiling and fermentation’, *Infection Ecology and Epidemiology*, 9(1), 1–9.

Kure, C.F., Skaar, I., Brendehaug, J. (2004) ‘Mould contamination in production of semi-hard cheese’, *International Journal of Food Microbiology*, 93(1), 41–49.

Lambertz, C., Sanker, C., Gauly, M. (2014) ‘Climatic effects on milk production traits and somatic cell score in lactating Holstein-Friesian cows in different housing systems’, *Journal of Dairy Science*, 97(1), 319–329, available: http://dx.doi.org/10.3168/jds.2013-7217.

Latorre, A.A., Pradhan, A.K., Van Kessel, J.A.S., Karns, J.S., Boor, K.J., Rice, D.H., Mangione, K.J., Grohn, Y.T., Schukken, Y.H. (2011) ‘Quantitative risk assessment of listeriosis due to consumption of raw milk’, *Journal of Food Protection*, 74(8), 1268–1281.

Leggieri, M.C., Lanubile, A., Dall’Asta, C., Pietri, A., Battilani, P. (2020) ‘The impact of seasonal weather variation on mycotoxins: Maize crop in 2014 in northern Italy as a case study’, *World Mycotoxin Journal*, 13(1), 25–36.

Li, N., Wang, Y., You, C., Ren, J., Chen, W., Zheng, H., Liu, Z. (2018) ‘Variation in Raw Milk Microbiota Throughout 12 Months and the Impact of Weather Conditions’, *Scientific Reports*, 8(1), 1–10.

Lindqvist, R., Sylvén, S., Vågsholm, I. (2002) ‘Quantitative microbial risk assessment exemplified

by Staphylococcus aureus in unripened cheese made from raw milk', *international journal of food*, 78(1–2), 155–170.
Liu, Y., Wu, F. (2010) 'Global burden of Aflatoxin-induced hepatocellular carcinoma: A risk assessment', *Environmental Health Perspectives*, 118(6), 818–824.
Liu, Z., Ezernieks, V., Wang, J., Wanni Arachchillage, N., Garner, J.B., Wales, W.J., Cocks, B.G., Rochfort, S. (2017) 'Heat Stress in Dairy Cattle Alters Lipid Composition of Milk', *Scientific Reports*, 7(1), 1–10.
Madege, R.R., Landschoot, S., Kimanya, M., Tiisekwa, B., De Meulenaer, B., Bekaert, B., Audenaert, K., Haesaert, G. (2019) 'Early sowing and harvesting as effective measures to reduce stalk borer injury, Fusarium verticillioides incidence and associated fumonisin production in maize', *Tropical Plant Pathology*, 44(2), 151–161.
Madgwick, J.W., West, J.S., White, R.P., Semenov, M.A., Townsend, J.A., Turner, J.A., Fitt, B.D.L. (2011) 'Impacts of climate change on wheat anthesis and fusarium ear blight in the UK', *European Journal of Plant Pathology*, 130(1), 117–131.
Mallet, A., Guéguen, M., Kauffmann, F., Chesneau, C., Sesboué, A., Desmasures, N. (2012) 'Quantitative and qualitative microbial analysis of raw milk reveals substantial diversity influenced by herd management practices', *International Dairy Journal*, 27(1–2), 13–21.
Manning, L., Luning, P.A., Wallace, C.A. (2019) 'The Evolution and Cultural Framing of Food Safety Management Systems—Where From and Where Next?', *Comprehensive Reviews in Food Science and Food Safety*, 18(6), 1770–1792.
Marchand, S., Heylen, K., Messens, W., Coudijzer, K., De Vos, P., Dewettinck, K., Herman, L., De Block, J., Heyndrickx, M. (2009) 'Seasonal influence on heat-resistant proteolytic capacity of Pseudomonas lundensis and Pseudomonas fragi, predominant milk spoilers isolated from Belgian raw milk samples', *Environmental Microbiology*, 11(2), 467–482.
Marvin, H.J.P., Kleter, G.A., Van der Fels-Klerx, H.J., Noordam, M.Y., Franz, E., Willems, D.J.M., Boxall, A. (2013) 'Proactive systems for early warning of potential impacts of natural disasters on food safety: Climate-change-induced extreme events as case in point', *Food Control*, 34(2), 444–456.
Mcelhinney, C., Danaher, M., Elliott, C.T., O'Kiely, P. (2016) 'Mycotoxins in farm silages - a 2-year Irish national survey', *Grass and Forage Science*, 71(2), 339–352.
McElhinney, C., Danaher, M., Elliott, C.T., O'Kiely, P. (2016) 'Mycotoxins in farm silages – a 2-year Irish national survey', *Grass and Forage Science*, 71(2), 339–352.
Medina, Á., González-Jartín, J.M., Sainz, M.J. (2017) 'Impact of global warming on mycotoxins', *Current Opinion in Food Science*, 18, 76–81.
Medina, Rodríguez, A., Sultan, Y., Magan, N. (2015) 'Climate change factors and Aspergillus flavus: Effects on gene expression, growth and aflatoxin production', *World Mycotoxin Journal*, 8(2), 171–179.
Membré, J.M. (2014) 'Hazard appraisal and critical control point (HACCP): Establishment of Performance Criteria', in Batt, C.A., ed., *Encyclopedia of Food Microbiology*, Academic Press: Burlington, 136–141.
Membré, J.M. (2016) 'Microbiological risk assessments in food industry', in Kotzekidou, P., ed., *Food Hygiene and Toxicology in Ready-to-Eat Foods*, Academic Press Inc. (London) Limited: London, 337–350.
Membré, J.M., Boué, G. (2017) 'Quantitative microbial risk assessment during food processing', in *Textbook on Quantitative Tools for Sustainable Food and Energy in the Food Chain*, EUROSIS -ETI: Ghent, 183–196.
Membré, J.M., Boué, G. (2018) 'Quantitative microbiological risk assessment in food industry: Theory and practical application', *Food Research International*, 106(November 2017), 1132–1139.
Membré, J.M., Guillou, S. (2016) 'Lastest developments in foodborne pathogen risk assessment', *Current Opinion in Food Science*, 8, 120–126.
Membré, J.M., Kan-King-Yu, D., Blackburn, C. de W. (2008) 'Use of sensitivity analysis to aid

interpretation of a probabilistic Bacillus cereus spore lag time model applied to heat-treated chilled foods (REPFEDs)', *International Journal of Food Microbiology*, 128(1), 28–33.
Metzger, S.A., Hernandez, L.L., Skarlupka, J.H., Walker, T.M., Suen, G., Ruegg, P.L. (2018) 'A cohort study of the milk microbiota of healthy and inflamed bovine mammary glands from dryoff through 150 days in milk', *Frontiers in Veterinary Science*, 5(OCT), 1–11.
Milićević, D., Spirić, D., Janković, S., Velebit, B., Radičević, T., Petrović, Z., Stefanović, S. (2017) 'Aflatoxin M1 in processed milk: Occurrence and seasonal variation with an emphasis on risk assessment of human exposure in Serbia', *IOP Conference Series: Earth and Environmental Science*, 85(1).
Miraglia, M., Marvin, H.J.P., Kleter, G.A., Battilani, P., Brera, C., Coni, E., Cubadda, F., Croci, L., De Santis, B., Dekkers, S., Filippi, L., Hutjes, R.W.A., Noordam, M.Y., Pisante, M., Piva, G., Prandini, A., Toti, L., van den Born, G.J., Vespermann, A. (2009) 'Climate change and food safety: An emerging issue with special focus on Europe', *Food and Chemical Toxicology*, 47(5), 1009–1021, available: http://dx.doi.org/10.1016/j.fct.2009.02.005.
Miranda, R.C., Schaffner, D.W. (2018) 'Farm to fork quantitative microbial risk assessment for norovirus on frozen strawberries', *Microbial Risk Analysis*, 10(February), 44–53.
Mohammadi, H., Shokrzadeh, M., Aliabadi, Z., Riahi-Zanjani, B. (2016) 'Occurrence of aflatoxin M^sub 1^ in commercial pasteurized milk samples in Sari, Mazandaran province, Iran', *Mycotoxin Research*, 32(2), 85.
Montebello, K., Spiteri, D., Valdramidis, V.P. (2018) 'Identification and characterisation of aerobic spore-forming bacteria isolated from Maltese cows' milk', *International Dairy Journal*, 84, 54–61.
Montel, M.C., Buchin, S., Mallet, A., Delbes-Paus, C., Vuitton, D.A., Desmasures, N., Berthier, F. (2014) 'Traditional cheeses: Rich and diverse microbiota with associated benefits', *International Journal of Food Microbiology*, 177, 136–154.
Murphy, S.C., Martin, N.H., Barbano, D.M., Wiedmann, M. (2016) 'Influence of raw milk quality on processed dairy products: How do raw milk quality test results relate to product quality and yield?', *Journal of Dairy Science*, 99(12), 10128–10149, available: http://dx.doi.org/10.3168/jds.2016-11172.
Mutegi, C.K., Cotty, P.J., Bandyopadhyay, R. (2018) 'Prevalence and mitigation of aflatoxins in Kenya (1960-to date)', *World Mycotoxin Journal*, 11(3), 341–357.
Nada, S., Ilija, D., Igor, T., Jelena, M., Ruzica, G. (2012) 'Implication of food safety measures on microbiological quality of raw and pasteurized milk', *Food Control*, 25(2), 728–731.
Nagaoka, S. (2019) 'Structure–function properties of hypolipidemic peptides', *Journal of Food Biochemistry*, 43(1), 1–8.
Nardone, A., Ronchi, B., Lacetera, N., Ranieri, M.S., Bernabucci, U. (2010) 'Effects of climate changes on animal production and sustainability of livestock systems', *Livestock Science*, 130(1–3), 57–69, available: http://dx.doi.org/10.1016/j.livsci.2010.02.011.
Nauta, M.J. (2001) A Modular Process Risk Model Structure for Quantitative Microbiological Risk Assessment and Its Application in an Exposure Assessment of Bacillus Cereus in a REPFED [online], *RIVM report*.
Neme, K., Mohammed, A. (2017) 'Mycotoxin occurrence in grains and the role of postharvest management as a mitigation strategies. A review', *Food Control*, 78, 412–425, available: http://dx.doi.org/10.1016/j.foodcont.2017.03.012.
Obonyo, M.A., Salano, E.N. (2018) 'Perennial and seasonal contamination of maize by aflatoxins in eastern Kenya', *International Journal of Food Contamination*, 5(1).
Oliveira, G., Evangelista, S.R., Passamani, F.R.F., Santiago, W.D., Cardoso, M. das G., Batista, L.R. (2019a) 'Influence of temperature and water activity on Ochratoxin A production by Aspergillus strain in coffee south of Minas Gerais/Brazil', *Lwt*, 102(December 2018), 1–7, available: https://doi.org/10.1016/j.lwt.2018.12.032.
Oliveira, G., Evangelista, S.R., Passamani, F.R.F., Santiago, W.D., Cardoso, M. das G., Batista, L.R. (2019b) 'Influence of temperature and water activity on Ochratoxin A production by

Aspergillus strain in coffee south of Minas Gerais/Brazil', *Lwt*, 102(December 2018), 1–7, available: https://doi.org/10.1016/j.lwt.2018.12.032.
Olivier, S.P., Jayarao, B.M., Almeida, R.A. (2005) 'Foodborne Pathogens in Milk and the Dairy Farm Environment: Food Safety and Public Health Implications', *Foodborne Pathogens and Disease*, 2(2), 115–137.
Ozcan, T., Yaslioglu, E., Kilic, I., Simsek, E. (2015) 'The influence of the season and milking time on the properties and the fatty acid compostiion of the milk in different dairy cattle farms', *Mljekarstvo*, 65(1), 9–17.
Pang, H., McEgan, R., Micallef, S.A., Pradhan, A.K. (2018) 'Evaluation of meteorological factors associated with pre-harvest contamination risk of generic Escherichia coli in a mixed produce and dairy farm', *Food Control*, 85, 135–143.
Pang, H., McEgan, R., Mishra, A., Micallef, S.A., Pradhan, A.K. (2017) 'Identifying and modeling meteorological risk factors associated with pre-harvest contamination of Listeria species in a mixed produce and dairy farm', *Food Research International*, 102(June), 355–363.
Pantoja, J.C.F., Reinemann, D.J., Ruegg, P.L. (2011) 'Factors associated with coliform count in unpasteurized bulk milk', *Journal of Dairy Science*, 94(6), 2680–2691.
Park, J., Chang, H., Kim, D., Chung, S., Lee, C. (2018) 'Long-term occurrence of deoxynivalenol in feed and feed raw materials with a special focus on south korea', *Toxins*, 10(3), 127.
Passamani, F.R.F., Bastos, S.C., Freire, L., Terra, M.F., Pereira, G.E., Batista, L.R. (2017) 'Aspergillus carbonarius in syrah grapes grown in three wine-growing regions of Brazil', *International Food Research Journal*, 24(5), 2207–2211.
Patyal, A., Singh Gill, J.P., Bedi, J.S., Aulakh, R.S. (2020) 'Occurrence of Aflatoxin M1 in raw, pasteurized and UHT milk from Punjab, India', *Current Science*, 118(1), 79–86.
Peltonen-Sainio, P., Palosuo, T., Ruosteenoja, K., Jauhiainen, L., Ojanen, H. (2018) 'Warming autumns at high latitudes of Europe: an opportunity to lose or gain in cereal production?', *Regional Environmental Change*, 18(5), 1453–1465.
Perrin, F., Tenenhaus-Aziza, F., Michel, V., Miszczycha, S., Bel, N., Sanaa, M. (2015) 'Quantitative Risk Assessment of Haemolytic and Uremic Syndrome Linked to O157: H7 and Non-O157: H7 Shiga-Toxin Producing Escherichia coli Strains in Raw Milk Soft Cheeses', *Risk Analysis*, 35(1), 109–128.
Pitt, J.I. (2013) 'Mycotoxins: Mycotoxins - General', *Encyclopedia of Food Safety*, 2, 283–288.
Pleadin, J., Vulic, A., Zadravec, M., Lesic, T., Benic, M., Tkalec, V.J., Vahcic, N. (2017) 'Presence of Fusarium mycotoxins in feedstuffs and cow milk sampled from Croatian farms during 2015', *MLJEKARSTVO*, 67(2), 102–111.
Porcellato, D., Aspholm, M., Skeie, S.B., Monshaugen, M., Brendehaug, J., Mellegård, H. (2018) 'Microbial diversity of consumption milk during processing and storage', *International Journal of Food Microbiology*, 266(November 2017), 21–30.
Pouillot, R., Delignette-Muller, M.L. (2010) 'Evaluating variability and uncertainty separately in microbial quantitative risk assessment using two R packages', *International Journal of Food Microbiology*, 142(3), 330–340.
Pujol, L., Albert, I., Magras, C., Johnson, N.B., Membré, J.M. (2015a) 'Probabilistic exposure assessment model to estimate aseptic-UHT product failure rate', *International Journal of Food Microbiology*, 192, 124–141.
Pujol, L., Albert, I., Magras, C., Johnson, N.B., Membré, J.M. (2015b) 'Estimation and evaluation of management options to control and/or reduce the risk of not complying with commercial sterility', *International Journal of Food Microbiology*, 213, 124–129.
Quevedo-Garza, P.A., Amador-Espejo, G.G., Cantú-Martínez, P.C., Trujillo-Mesa, J.A. (2018) 'Aflatoxin M1 occurrence in fluid milk commercialized in Monterrey, Mexico', *Journal of Food Safety*, 38(6).
Rama, A., Montesissa, C., Lucatello, L., Galina, G., Benetti, C., Bajraktari, D. (2016) 'A study on the occurrence of aflatoxin M1 in milk consumed in Kosovo during 2009-2010', *Food Control*, 62, 52–55, available: http://dx.doi.org/10.1016/j.foodcont.2015.10.019.

Ramírez, C.A., Patel, M., Blok, K. (2006) ‘From fluid milk to milk powder: Energy use and energy efficiency in the European dairy industry’, *Energy*, 31(12), 1984–2004.
Renna, M., Lussiana, C., Malfatto, V., Mimosi, A., Battaglini, L.M. (2010) ‘Effect of exposure to heat stress conditions on milk yield and quality of dairy cows grazing on Alpine pasture’, *9th European IFSA Symposium*, (July), 1338–1348.
De Rensis, F., Scaramuzzi, R.J. (2003) ‘Heat stress and seasonal effects on reproduction in the dairy cow - A review’, *Theriogenology*, 60(6), 1139–1151.
Roberts, T.A., Cordier, J.-L., Gram, L., Tompkin, R.B., Pitt, J.I., Gorris, L.G.M., Swanson, K.M.J. (2005) ‘Milk and dairy products’, in *Micro-Organisms in Foods 6*, Springer US: Boston, MA, 643–715.
Roccato, A., Uyttendaele, M., Membré, J.M. (2017) ‘Analysis of domestic refrigerator temperatures and home storage time distributions for shelf-life studies and food safety risk assessment’, *Food Research International*, 96, 171–181.
Rodriguez-Martinez, V., Velázquez, G., de Jesús Rodríguez Altaif, R., Fagotti, F., Welti-Chanes, J., Torres, J.A. (2020) ‘Deterministic and probabilistic predictive microbiology-based indicator of the listeriosis and microbial spoilage risk of pasteurized milk stored in residential refrigerators’, *Lwt*, 117(September 2019), 108650.
De Roma, A., Rossini, C., Ritieni, A., Gallo, P., Esposito, M. (2017) ‘A survey on the Aflatoxin M1 occurrence and seasonal variation in buffalo and cow milk from Southern Italy’, *Food Control*, 81, 30–33, available: http://dx.doi.org/10.1016/j.foodcont.2017.05.034.
Ropkins, K., Beck, A.J. (2000) ‘Evaluation of worldwide approaches to the use of HACCP to control food safety’, *Trends in Food Science and Technology*, 11(1), 10–21.
Sad, N., Sad, N. (2014) ‘The influence of climatic factors in serbia on mycotoxin’, First International Symposium of Veterinary Medicine (ISVM2015) One Health – New Challenges“, At Vrdnik, Serbia, 166–173.
Salvacion, A.R., Pangga, I.B., Cumagun, C.J.R. (2015) ‘Assessment of mycotoxin risk on corn in the Philippines under current and future climate change conditions’, 30(3), 135–142.
Sanaa, M., Coroller, L., Cerf, O. (2004) ‘Risk Assessment of Listeriosis Linked to the Consumption of Two Soft Cheeses Made from Raw Milk: Camembert of Normandy and Brie of Meaux’, *Risk Analysis*, 24(2), 389–399.
Santana, M.L., Bignardi, A.B., Pereira, R.J., Stefani, G., El Faro, L. (2017) ‘Genetics of heat tolerance for milk yield and quality in Holsteins’, *Animal*, 11(1), 4–14.
Schaffner, D.W., Mcentire, J., Duffy, S., Montville, R., Smith, S. (2003) ‘Monte Carlo Simulation of the Shelf Life of Pasteurized Milk as Affected by Temperature and Initial Concentration of Spoilage Organisms’, 23(12), 1014–1021.
Serraino, A., Bonilauri, P., Arrigoni, N., Ostanello, F., Ricchi, M., Marchetti, G., Bonfante, E., Albonetti, S., Giacometti, F. (2014) ‘Quantitative risk assessment of Mycobacterium avium subsp. paratuberculosis survival in pasteurized milk in three dairy plants in Italy’, *Food Control*, 45, 120–126.
Serraino, A., Bonilauri, P., Kerekes, K., Farkas, Z., Giacometti, F., Canever, A., Zambrini, A.V., Ambrus, Á. (2019) ‘Occurrence of Aflatoxin M1 in Raw Milk Marketed in Italy: Exposure Assessment and Risk Characterization’, *Frontiers in Microbiology*, 10(November).
Shuib, N.S., Makahleh, A., Salhimi, S.M., Saad, B. (2017) ‘Natural occurrence of aflatoxin M1 in fresh cow milk and human milk in Penang, Malaysia’, *Food Control*, 73, 966–970, available: http://dx.doi.org/10.1016/j.foodcont.2016.10.013.
Smith, M.C., Madec, S., Coton, E., Hymery, N. (2016) ‘Natural Co-occurrence of mycotoxins in foods and feeds and their in vitro combined toxicological effects’, *Toxins*, 8(4).
Soejima, T., Nagao, E., Yano, Y., Yamagata, H., Kagi, H., Shinagawa, K. (2007) ‘Risk evaluation for staphylococcal food poisoning in processed milk produced with skim milk powder’, *International Journal of Food Microbiology*, 115(1), 29–34.
Sperber, W.H. (2005) ‘HACCP and transparency’, *Food Control*, 16(6 SPEC. ISS.), 505–509.
van der Spiegel, M., van der Fels-Klerx, H.J., Marvin, H.J.P. (2012) ‘Effects of climate change on

food safety hazards in the dairy production chain', *Food Research International*, 46(1), 201–208, available: http://dx.doi.org/10.1016/j.foodres.2011.12.011.

Stoev, S.D. (2015) 'Foodborne mycotoxicoses, risk assessment and underestimated hazard of masked mycotoxins and joint mycotoxin effects or interaction', *Environmental Toxicology and Pharmacology*, 39(2), 794–809, available: http://dx.doi.org/10.1016/j.etap.2015.01.022.

Strawn, L.K., Fortes, E.D., Bihn, E.A., Nightingale, K.K., Gröhn, Y.T., Worobo, R.W., Wiedmann, M., Bergholz, P.W. (2013) 'Landscape and meteorological factors affecting prevalence of three food-borne pathogens in fruit and vegetable farms', *Applied and Environmental Microbiology*, 79(2), 588–600.

Sulaiman, S.H., Jamaluddin, R., Sabran, M.R. (2018) 'Association between urinary aflatoxin (AFM1) and dietary intake among adults in Hulu Langat District, Selangor, Malaysia', *Nutrients*, 10(4), 1–15.

Tajkarimi, M., Shojaee Aliabadi, F., Salah Nejad, M., Pursoltani, H., Motallebi, A.A., Mahdavi, H. (2007) 'Seasonal study of aflatoxin M1 contamination in milk in five regions in Iran', *International Journal of Food Microbiology*, 116(3), 346–349.

Tangni EK, Pussemier L, Hove, V.F. (2013) 'Mycotoxin Contaminating Maize and Grass Silages for Dairy Cattle Feeding: Current State and Challenges', *Journal of Animal Science Advances*, 3(10), 492–511.

Tenenhaus-Aziza, F., Daudin, J.J., Maffre, A., Sanaa, M. (2014) 'Risk-based approach for microbiological food safety management in the dairy industry: The case of listeria monocytogenes in soft cheese made from pasteurized milk', *Risk Analysis*, 34(1), 56–74.

Tidona, F., Criscione, A., Guastella, A.M., Zuccaro, A., Bordonaro, S., Marletta, D. (2009) 'Bioactive peptides in dairy products', *Italian Journal of Animal Science*, 8(3), 315–340.

Tiwari, U., Cummins, E., Valero, A., Walsh, D., Dalmasso, M., Jordan, K., Duffy, G. (2015) 'Farm to Fork Quantitative Risk Assessment of Listeria monocytogenes Contamination in Raw and Pasteurized Milk Cheese in Ireland', *Risk Analysis*, 35(6), 1140–1153.

Tong, J., Zhang, H., Zhang, Y., Xiong, B., Jiang, L. (2019) 'Microbiome and Metabolome Analyses of Milk From Dairy Cows With Subclinical Streptococcus agalactiae Mastitis—Potential Biomarkers', *Frontiers in Microbiology*, 10(November), 1–14.

Udovicki, B., Djekic, I., Kalogianni, E.P., Rajkovic, A. (2019) 'Exposure assessment and risk characterization of aflatoxin m1 intake through consumption of milk and yoghurt by student population in Serbia and Greece', *Toxins*, 11(4), 1–11.

Ul Hassan, Z., Al Thani, R., A. Atia, F., Al Meer, S., Migheli, Q., Jaoua, S. (2018) 'Co-occurrence of mycotoxins in commercial formula milk and cereal-based baby food on the Qatar market', *Food Additives and Contaminants: Part B Surveillance*, 11(3), 191–197, available: https://doi.org/10.1080/19393210.2018.1437785.

Vandicke, J., De Visschere, K., Croubels, S., De Saeger, S., Audenaert, K., Haesaert, G. (2019) 'Mycotoxins in flanders' fields: Occurrence and correlations with fusarium species in whole-plant harvested maize', *Microorganisms*, 7(11), 1–21.

Viegas, S., Assunção, R., Nunes, C., Osteresch, B., Twarużek, M., Kosicki, R., Grajewski, J., Martins, C., Alvito, P., Almeida, A., Viegas, C. (2018) 'Exposure assessment to mycotoxins in a Portuguese fresh bread dough company by using a multi-biomarker approach', *Toxins*, 10(9), 342.

Viegas, S., Assunção, R., Twarużek, M., Kosicki, R., Grajewski, J., Viegas, C. (2020) 'Mycotoxins feed contamination in a dairy farm – potential implications for milk contamination and workers' exposure in a One Health approach', *Journal of the Science of Food and Agriculture*, 100(3), 1118–1123.

Vita, V., Clausi, M.T., Franchino, C., Pace, R. De (2016) 'Aflatoxin B^sub 1^ contamination in feed from Puglia and Basilicata regions (Italy): 5 years monitoring data', *Mycotoxin Research*, 32(4), 229.

Vithanage, N.R., Dissanayake, M., Bolge, G., Palombo, E.A., Yeager, T.R., Datta, N. (2016) 'Biodiversity of culturable psychrotrophic microbiota in raw milk attributable to refrigeration

conditions, seasonality and their spoilage potential', *International Dairy Journal*, 57, 80–90.
Wang, Q., Zhang, Y., Zheng, N., Guo, L., Song, X., Zhao, S., Wang, J. (2019) 'Biological System Responses of Dairy Cows to Aflatoxin B1 Exposure Revealed with Metabolomic Changes in Multiple Biofluids', *Toxins*, 11(2), 77.
Weldeabezgi, L.T., Atsbha, T.W., Kassegn, H.H., Gebremichael, T.F., Berhe, M.H. (2019) 'A quantitative risk assessment model for Staphylococcus aureus and Salmonella associated with consumption of informally marketed milk products in Tigray, Ethiopia', *Journal of Food Safety*, (November).
West, J.W. (2003) 'Effects of heat-stress on production in dairy cattle', *Journal of Dairy Science*, 86(6), 2131–2144.
Wheelock, J.B., Rhoads, R.P., VanBaale, M.J., Sanders, S.R., Baumgard, L.H. (2010) 'Effects of heat stress on energetic metabolism in lactating Holstein cows', *Journal of Dairy Science*, 93(2), 644–655.
WHO (2015) ' WHO estimates of the global burden of foodborne diseases'. Foodborne disease burden epidemiology reference group 2007-2015. ISBN 978 92 4 156516 5.
Xu, X., Madden, L. V., Edwards, S.G., Doohan, F.M., Moretti, A., Hornok, L., Nicholson, P., Ritieni, A. (2013) 'Developing logistic models to relate the accumulation of DON associated with Fusarium head blight to climatic conditions in Europe', *European Journal of Plant Pathology*, 137(4), 689–706.
Yan, Z., Wang, L., Wang, J., Tan, Y., Yu, D., Chang, X., Fan, Y., Zhao, D., Wang, C., De Boevre, M., De Saeger, S., Sun, C., Wu, A. (2018) 'A quechers-based liquid chromatography-tandem mass spectrometry method for the simultaneous determination of nine zearalenone-like mycotoxins in pigs', *Toxins*, 10(3), 129.
Yu, J., Ren, Y., Xi, X.X., Huang, W., Zhang, H. (2017) 'A novel lactobacilli-based teat disinfectant for improving bacterial communities in the milks of cow teats with subclinical mastitis', *Frontiers in Microbiology*, 8(SEP).
Yuan, L., Sadiq, F.A., Burmølle, M., Wang, N., He, G. (2019) 'Insights into psychrotrophic bacteria in raw milk: A review', *Journal of Food Protection*, 82(7), 1148–1159.
Zhang, M., Wang, X., Cui, M., Wang, Y., Jiao, Z., Tan, Z. (2018) 'Ensilage of oats and wheatgrass under natural alpine climatic conditions by indigenous lactic acid bacteria species isolated from high-cold areas', *PLoS ONE*, 13(2), e0192368.
Zucali, M., Bava, L., Tamburini, A., Brasca, M., Vanoni, L., Sandrucci, A. (2011) 'Effects of season, milking routine and cow cleanliness on bacterial and somatic cell counts of bulk tank milk', *Journal of Dairy Research*, 78(4), 436–441.