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Summary

The Netherlands Food and Consumer Product Safety Authority (NVWA) is responsible for protecting human and animal health. For this purpose, the NVWA checks food/feed and consumer products for the presence of possible hazards for human and animal health. In order to prioritize its activities in accordance with (EC) 882/2004, the NVWA applies a risk based control focusing on the most important food safety hazards.

The aim of the current study was to make an inventory of possible chemical and physical hazards in the dairy chain, from farm-to-fork, and to evaluate the possible human health effects of the most relevant chemical hazards. Furthermore, intervention measures for reducing the presence of these hazards were studied as well as drivers and trends that may affect food safety in the dairy chain in the future. For this purpose, a scientific literature review was performed, datasets (Dutch monitoring data and RASFF) were analysed and experts were consulted. The focus was on dairy cows, but goat and sheep were also taken into consideration, if data was available. The results showed that a wide range of chemical and physical hazards may occur in the dairy chain and that most information was available for dairy cows. Therefore, it is recommended to allocate research budget to obtain more information on chemical and physical hazards associated with goat and sheep milk, although milk volumes for goat and sheep are only a fraction of the total volumes of dairy products produced in The Netherlands.

Most chemical hazards are introduced at farm level, where milk can become contaminated due to the intake of contaminated compound feed or silage, due to grazing on contaminated land, due to the administration of veterinary drugs or due to the inadequate use of detergents and disinfectants. Chemical hazards that may occur in silage are natural toxins such as mycotoxins and plant toxins, whereas compound feed may be contaminated with mycotoxins, pesticides, persistent organic pollutants and heavy metals depending on its origin and production process of the ingredients. Contaminants that are already present in the milk are usually unaffected by further processing at the farm or the dairy factory. However, in some cases contaminants may be concentrated, for example in the production of milk powder, which causes a higher level of contaminants in the final product. Organic pollutants such as dioxins and PCBs are lipophilic and will accumulate in butter, which typically contains 80% fat. Additionally, hazards may be introduced through the use of ingredients or via cleaning and disinfection. Physical hazards may be introduced through ingredients used during processing (stones, sticks and glass through the use of fruits or grains), through packaging material (paper, plastic and glass) and/or through the processing equipment itself (e.g. iron filings or parts of rubber seals).

Based on the literature review, monitoring data and expert opinion, the following chemical hazards were considered most important for dairy products: aflatoxin M_1, environmental contaminants (primarily dioxin and dioxin-like compounds) and veterinary drug residues. Metal and plastic particles are seen as the most important physical hazards. However, chemical hazards are more important than physical hazards as their human health risk is higher and physical hazards can be prevented more easily. Chemical hazards can be prevented by applying quality assurance schemes, such as GLOBAL GAP (Good Agricultural Practices) at the farm and HACCP (Hazard Analysis Critical Control Points) during dairy processing. Furthermore, most farmers are certified in the KKM-system (Foundation for Quality Assurance of Farm Milk in the Dutch Dairy Chain) in the Netherlands. For goat milk, farmers follow similar protocols described in the *Handboek KwaliGeit*. These systems describe various criteria and measures that help to produce high quality and safe dairy milk.

In order to maintain a high food safety level, quality assurance systems have to meet future developments. The most important drivers that may affect food safety are global economy and trade and climate change. Further globalization may hamper the transparency in the dairy chain, especially in the feed sector. This may increase possibilities for food fraud. Climate change is expected to affect

the presence of aflatoxin M_1 in milk, but may also have an impact on animal and plant diseases (and subsequent use of veterinary drugs and pesticides etc) and the presence of plant toxins.

The most important development in the dairy chain is the recent abolishment of the milk quota, which will result in a further intensification of the dairy chain and higher productions of milk volumes in The Netherlands. This may have positive effects on food safety as farmers will invest to improve their farm and will be more aware of possible food safety issues. On the other hand, an increased livestock population at the farm may result into a raise in the occurrence of animal diseases at farm level and subsequently more veterinary drugs use. The abolishment of the milk quota will also have an effect on dairy processing as the production of products with a long shelf life (especially milk powder) is expected to increase in The Netherlands resulting in higher export volumes. More production may also lead to a pressure on the market of animal feed, which may have its consequences for the quality and safety of these products.

As most chemical hazards are introduced through the feed and as future developments may have consequences on the supply of high quality feed products, it is advised to focus monitoring at the farm level and more specifically on the feed sector. At farm level, changes in production systems as a result of increased awareness for sustainability and animal welfare should be followed closely in order to evaluate their consequences for food safety.

In order to maintain the current food safety level in the dairy sector, the chain steps after the dairy farm should not be ignored and some level of inspection should also be arranged for steps further along the dairy chain. Furthermore, imported products from outside the EU may need increased monitoring programs, especially for veterinary drugs and aflatoxin M_1 as these compounds have been reported above the legal limit in the RASFF database.

Samenvatting

De Nederlandse Voedsel- en Warenautoriteit (NVWA) ziet toe op veilig voedsel, veilige producten, gezonde dieren en gezonde planten. De NVWA controleert hiervoor diervoeders, levensmiddelen en consumentenproducten op de aanwezigheid van mogelijke gevaren voor dierlijke en menselijke gezondheid. Om haar activiteiten te kunnen prioriteren, volgens (EG) 882/2004, past de NVWA een risicogebaseerde controle toe, gericht op de belangrijkste voedselveiligheidsgevaren.

Het doel van de huidige studie was om de mogelijke chemische en fysische gevaren in de zuivelketen te inventariseren, van boer-tot-bord en de mogelijke gezondheidseffecten van de belangrijkste chemische gevaren te evalueren. Verder zijn interventiemaatregelen bestudeerd die de aanwezigheid van deze gevaren kunnen terugdringen. Bovendien zijn de drivers en trends onderzocht die effect kunnen hebben op de voedselveiligheid in de zuivelketen in de toekomst. Hiervoor is een wetenschappelijke literatuurstudie uitgevoerd, zijn datasets (Nederlandse monitoringsgegevens en RASFF) geanalyseerd en zijn experts geraadpleegd. De focus was op melkproductie door koeien, maar geiten en schapen werden ook meegenomen indien er literatuurgegevens beschikbaar waren. De resultaten lieten zien dat er een breed scala aan chemische en fysische gevaren kan voorkomen in de zuivelketen en dat de meeste informatie beschikbaar was voor melk geproduceerd door koeien. Er wordt daarom aanbevolen onderzoeksbudget beschikbaar te stellen om informatie over chemische en fysische gevaren in geiten- en schapenmelk te verkrijgen. De volumes die geproduceerd worden door geiten en schapen zijn echter een fractie van de totale melkproductie in Nederland.

De meeste chemische gevaren worden op de boerderij geïntroduceerd, waar de melk besmet kan worden via inname van besmet krachtvoer of kuilvoer, door grazen op besmet land, door toediening van diergeneesmiddelen of door onjuist gebruik van reinigings- en desinfectiemiddelen. Chemische gevaren die kunnen voorkomen in kuilvoer zijn natuurlijke toxines zoals mycotoxines en planttoxines, terwijl krachtvoer besmet kan zijn met mycotoxines, pesticides, persistente organische verbindingen en zware metalen, afhankelijke van de herkomst en het productieproces van de ingrediënten. Verdere verwerking van melk op de boerderij of in de fabriek heeft over het algemeen geen effect op contaminanten die reeds aanwezig zijn in de melk. In sommige gevallen kunnen contaminanten echter verder geconcentreerd worden, bijvoorbeeld bij de productie van melkpoeder, waardoor hogere concentratie van contaminanten in het eindproduct aanwezig kunnen zijn. Organische verbindingen zoals dioxines en PCB's zijn vetoplosbaar en hopen op in boter, die meestal voor 80% uit vet bestaat. Gevaren kunnen verder geïntroduceerd worden door het gebruik van ingrediënten of via reinigings- en desinfectiemiddelen. Fysische gevaren worden geïntroduceerd via ingrediënten die tijdens de productie gebruikt worden (stenen, stokjes en glas door gebruik van fruit en granen), door verpakkingsmateriaal (papier, plastic en glas) en/of via de procesapparatuur zelf (bijvoorbeeld ijzervijlsel of stukjes van rubberafdichtingen).

Op basis van literatuurreview, monitoringsdata en expertkennis werden de volgende chemische gevaren als belangrijkst gezien: aflatoxine M_1, omgevingscontaminanten (voornamelijk dioxines en dioxine-achtige verbindingen) en residuen van diergeneesmiddelen. Metaal en plastic deeltjes werden gezien als belangrijkste fysische gevaren. Chemische gevaren zijn echter belangrijker dan fysische gevaren aangezien het risico voor de volksgezondheid groter is en fysische gevaren makkelijker kunnen worden voorkomen. Chemische gevaren kunnen voorkómen worden door de toepassing van kwaliteitssystemen zoals GLOBAL GAP (Good Agricultural Practices) op de boerderij en HACCP (Hazard Analysis Critical Control Points) voor de melkverwerking. Bovendien zijn de meeste boeren in Nederland gecertificeerd via het KKM (Keten Kwaliteit Melk)-systeem. Boeren die gietenmelk produceren volgen vergelijkbare protocollen die beschreven zijn in het Handboek KwaliGeit. Deze systemen beschrijven verschillende criteria en maatregelen die bijdragen aan de productie van veilige melk van een hoge kwaliteit.

Om het huidige hoge niveau van voedselveiligheid te kunnen blijven handhaven, moeten kwaliteitssystemen rekening houden met toekomstige ontwikkelingen. De belangrijkste drivers die een effect kunnen hebben op voedselveiligheid zijn de wereldeconomie en –handel en klimaatverandering. Verdere globalisering kan de transparantie in de zuivelketen, en met name in de diervoedersector, belemmeren. Hierdoor kan voedselfraude toenemen. Klimaatverandering kan een effect hebben op de aanwezigheid van aflatoxine M_1 in melk, op het voorkomen van dierziektes (en als gevolg daarvan het gebruik van diergeneesmiddelen) en de aanwezigheid van planttoxines.

De belangrijkste ontwikkeling in de nabije toekomst is het wegvallen van het melkquotum dat zorgt voor verdere intensifiëring van de zuivelketen en een toename in melkvolumes in Nederland. Dit kan een gunstig effect hebben op voedselveiligheid, aangezien boeren zullen gaan investeren in hun boerderij en ze zich meer bewust zijn van mogelijke voedselveiligheidsgevaren. Aan de andere kant betekent een grotere veestapel dat er een grotere kans is op het optreden van dierziektes en als gevolg daarvan meer gebruik van diergeneesmiddelen. Het wegvallen van het melkquotum heeft ook een effect op de zuivelverwerking, waarbij verwacht wordt dat de productie van langhoudbare zuivelproducten (voornamelijk melkpoeder) in Nederland zal toenemen, wat zal zorgen voor een toename in exportvolumes. Meer productie kan ook leiden tot een druk op de markt van diervoeders, wat gevolgen kan hebben voor de kwaliteit en veiligheid van deze producten.

Aangezien de meeste chemische gevaren op de boerderijfase geïntroduceerd worden, veelal via het voer, en toekomstige ontwikkelingen gevolgen kunnen hebben voor het aanbod aan kwalitatief hoogwaardige diervoeders, wordt geadviseerd om de monitoring te richten op de boerderijfase en dan met name de diervoedersector. Op de boerderij leidt de toenemende aandacht voor duurzaamheid en dierenwelzijn tot aanpassingen in het productieproces. Het is van belang de gevolgen hiervan op de voedselveiligheid goed in de gaten te houden.

Om het huidige hoge niveau van voedselveiligheid in de zuivelketen te kunnen blijven handhaven, moeten de verdere stappen in de keten niet vergeten worden en zou er een basisniveau aan inspecties georganiseerd moeten worden voor de verdere processtappen in de zuivelketen. Verder zou er meer gemonitord kunnen worden op producten van buiten de EU, met name op diergeneesmiddelen en aflatoxine M_1, aangezien deze stoffen boven de wettelijke limiet gerapporteerd zijn in de RASFF database.

1 Introduction

1.1 Background of the project

The main task of the Netherlands Food and Consumer Product Safety Authority (NVWA) is to protect human and animal health. For this purpose, the NVWA monitors the possible presence of possible hazards for human and animal health in food and consumer products. As it is not possible to check all food and feed products in the Netherlands, the NVWA needs to prioritize its activities. Risk based monitoring will help to identify the most important food and feed safety hazards. Risk - in this case - is defined as the combination of the probability of a hazard occurring in the product and the effects of this hazard on human health. The NVWA will perform risk based monitoring in various food chains. One of these food chains is the dairy chain, which is the focus of this research.
The aim of the current study is to make an inventory of possible chemical and physical hazards in the dairy chain, from farm-to-fork, and to establish the possible human health effects of the most relevant chemical hazards, as based on scientific literature review and expert input. This information will be used by the NVWA as input to the risk prioritization of hazards in the dairy chain. Focus is on dairy cows, but goat and sheep are also taken into account if (literature or monitoring) data is available. Products included in the research are milk, hard cheese, butter and milk powder.
The project consisted of the following tasks:

1. Literature study on the chemical and physical hazards that may occur in the dairy chain (sections 3.1 and 3.2) and evaluation of data on chemical and physical hazards from the Rapid Alert System for Food and Feed (RASFF), Notification Support System of the NVWA (Meldingenondersteuningssysteem, MOS) and KAP (Quality Programme for Agricultural Products) (section 3.3).
2. Analysis of critical points in the dairy chain, and identification of drivers that may influence the presence of these hazards (section 3.4).
3. Literature research on the human health effects of the chemical hazards that are most relevant according to the analysis in step 1, and their attribution to the total disease burden (section 3.5).
4. Identification of intervention measures that can prevent or reduce the presence of most relevant chemical and physical hazards as identified in step 1 (section 3.6).
5. Evaluation of trends in developments within the dairy chain up to 2025 that may influence the occurrence of food safety hazards (section 3.7).

1.2 Background of the dairy chain

Within the Netherlands, there are approximately 19,000 dairy farmers who have a total of 1.5 million dairy cows, which produce 12 billion kilo of milk per year. This milk is processed within 51 factories in the Netherlands into cheese (56%), milk powder (13%), consumption milk and cream (9%), condensed milk (7%), butter (2%) and other products (14%) (Anonymous, 2013). Dairy goat production in The Netherlands is much smaller with a yearly production of 220 million kilo of goat milk per year, produced by 365 goat milk farmers (www.gemzu.nl). The volume of sheep milk is even lower with a yearly production of 1.5 million kilo, produced by around 6,000 sheep (Verduin, 2013).
The composition of cow, goat and sheep milk is different, although the fat content of goat and cow milk is comparable with levels between 30-50 g/kg and between 35-40 g/kg, respectively. Sheep milk has a much higher fat content ranging from 60-82 g/kg (ter Mors and de Wit, 2011).
The general production process of dairy products is depicted in Figure 1.

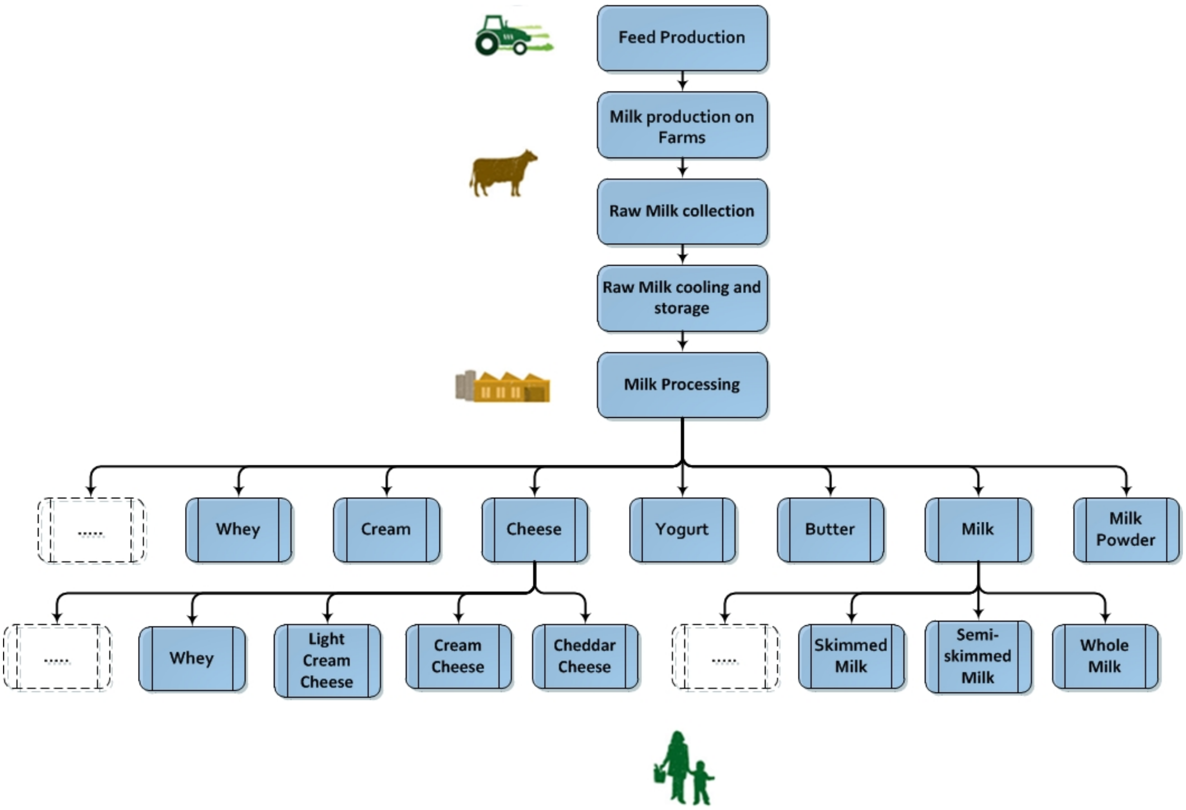

Figure 1 *Various stages in the dairy production chain from farm-to-fork.*

Most dairy cow products are exported to neighbouring countries with Germany as most important export country (see Figure 2). Cheese accounts for almost half of all exported dairy cow products (NZO, 2015). The Netherlands also imports around 2.7 billion euro of dairy products, 80% of which originate from neighbouring EU countries. Germany is the largest supplier, accounting for 45% of the total import value. Cheese is the main imported product (around 225 million kg in 2013) followed by skimmed milk powder and butter and butter oil (around 100 million kg in 2013) and non-skimmed milk powder (around 65 million kg in 2013). As export is bigger than import, dairy products contribute with around 8% to the overall Dutch trade balance (Productschap Zuivel, 2013).

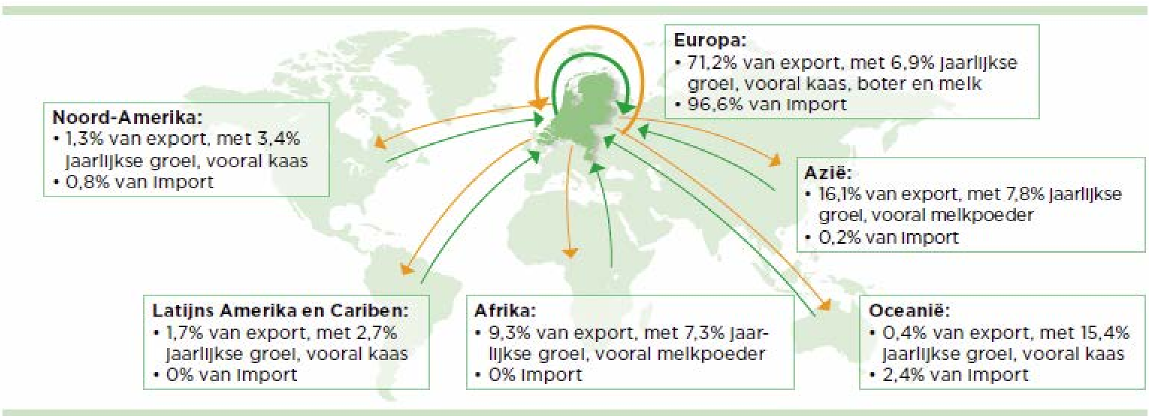

Figure 2 *Import and export of dairy products to and from the Netherlands as percentage of the total value in 2014 (NZO, 2015).*

2 Materials and methods

2.1 Literature study

A literature search was performed to evaluate chemical and physical hazards in the dairy chain using Scopus for the years 2000-2014 with the following key words:
TOPIC: "chemic* pollut*" or "chemic* contamin*" or "chemic* hazard" or "physic* hazard" AND TITLE: milk* or cheese* or "milk powder*" or butter* or dairy.
Furthermore, information was retrieved via Google and Google Scholar. Scientific papers and reports from trustworthy institutes (such as FAO, WHO) were used to retrieve the necessary information.
Experts from RIKILT, Wageningen University, Central Veterinary Institute (CVI), the National institute of Public Health and the Environment (RIVM), the Dutch Dairy organization (NZO), the Dutch Dairy Goat Organization (NGZO) and experts from the dairy industry were involved to give input on the most important physical and chemical hazards, possible intervention measures and future trends influencing their presence.

2.2 Data analysis

In order to obtain insights into the prevalence of possible hazards, monitoring data of chemical hazards were collected and evaluated. For this purpose, the RASFF portal was used to extract data from the past 5 years (2009-2014). All notifications were included, i.e. border rejections, information and alerts. Furthermore, data from the Dutch monitoring program on dairy products were retrieved for the same time period. These data are stored in KAP, a database that is part of a Quality Programme for Agricultural Products, which involves extensive cooperation between the Dutch government and agribusiness. Data originated from NZO and NVWA (2009-2010) and RIKILT (2009-2013).
Additionally, information from three databases containing information on incidentally occurring chemical hazards in the food supply chain were evaluated. These databases are: a) notifications reported in the Notification Support System of the NVWA (Meldingenondersteuningssysteem, MOS), b) notifications on food collected by the National Poisons Information Centre (Nationaal Vergiftigingen Informatie Centrum, NVIC), and c) risk assessments made by the Front Office of RIVM and RIKILT for Food and Product Safety. Information collected from the NVWA and NVIC was summarized on a quarterly basis from 2010 up to and including 2012 in a previous project (RIVM, 2010-2012). This project was a trend analysis and stopped in 2013. For the current project all available information in the trend analysis project has been screened for chemical hazards occurring in milk and dairy products. Information collected from the Front Office was summarized on a yearly basis from 2006 until today (Front Office, 2010-2014). For the current project the available information has been screened for chemical hazards occurring in milk and dairy products from 2010 up to and including 2014.

2.3 Expert study

In order to obtain information on future trends (task 5), around 10 people with expertise on different parts of the dairy chain were interviewed in collaboration with WUR- Food and Biobased Research (FBR). These people have expertise on dairy farming (cow milk and goat milk), dairy processing and dairy trade. Both experts from industry and experts with a scientific background were approached.
A predefined questionnaire was used to interview the experts. This questionnaire was developed in close collaboration with FBR.

3 Results

In total 139 scientific articles were retrieved using Scopus. Additionally, around 40 articles and reports were retrieved based on expert input and google searches. Based on the information of the literature research the chemical and physical hazards at the various stages in the dairy production chain (as described in Figure 1) were evaluated as well as possible intervention measures and drivers for change.

3.1 Chemical hazards

Chemical hazards that end up in milk or other dairy products are primarily caused by ingestion or production of these compounds by the cow. This can occur through the use of contaminated feed, via the uptake of chemical compounds due to grazing on contaminated soil or via the administration of veterinary medicines. Another cause of contamination is through fraud, which may occur at various stages along the dairy production chain. Examples are the presence of dioxins in animal feed due to the illegal use of contaminated technical fats in Germany in 2010 (Kupferschmidt, 2011), the recent incident with furazolidone in animal feed (Dijksma, 2014), and the melamine crisis in China in 2008 (Chen, 2009; Pei *et al.*, 2011).
The following sections present the various chemical hazards of concern that may occur along the dairy chain. Hazards that are expected to result in low levels in dairy products upon exposure were not considered in this study. Examples of the latter are chlorinated paraffins and acrylamide (MacLachlan, 2011).

3.1.1 Animal feed

Cows are fed with roughage, such as grass or maize silage produced at the farm, with by-products from the food industry and from fermentation processes, and with compound feed and by-products that are supplied by feed companies. The main hazards for silage are the presence of natural toxins such as mycotoxins and plant toxins, whereas compound feed may be contaminated with mycotoxins, pesticides, persistent organic pollutants and heavy metals depending on its origin and production process. Some ingredients have a higher probability of being contaminated with these compounds than others. An overview of chemical hazards that can be found in feed is given below:

3.1.1.1 Mycotoxins

Several mycotoxins may be present in feed and can be transferred into the milk. These are aflatoxins, ochratoxin-A, fumonisins, trichothecenes, zearalenone and cyclopiazonic acid (FSANZ, 2006). This report focuses on aflatoxins as these are considered the most important mycotoxins for dietary exposure from dairy products and subsequently the only mycotoxins for which maximum limits have been established in milk and milk products ((EU) 1881/2006). Kleter *et al.* (2009) established that 93% of all mycotoxin notifications to RASFF between the years 2003-2007 were for aflatoxins.
Aflatoxins (B_1, B_2, G_1 and G_2) are produced by *Aspergillus* spp. Aflatoxin B_1 (AFB_1) is the most toxic amongst the aflatoxins. It is primarily produced by *A. flavus* and *A. parasiticus* (Diener *et al.*, 1987). *A. flavus* mainly colonizes the aerial parts of plants (leaves, flowers), whereas *A. parasiticus* is mostly found in the soil (Marin *et al.*, 2013). *A. flavus* is thus common on maize and cottonseed, while *A. parasiticus* is more common in peanuts (Diener *et al.*, 1987; Prandini *et al.*, 2009). *Aspergillus* spp can colonize the plants in the field in hot, humid climates (Marin *et al.*, 2013; Prandini *et al.*, 2009). Proper farm management such as the application of crop rotation, proper fertilization, prevention of insect infestation (damaging the kernels), using resistant strains and harvesting at low moisture levels will reduce *A. flavus* infection in the field (Burgess, 2010; Prandini *et al.*, 2009). However, given the influences of the climate, a complete elimination is not always achievable (Burgess, 2010). *A. flavus* infection may increase post-harvest, if crops have not been adequately dehydrated (Prandini *et al.*, 2009). Dry storage and transport is, thus, of utmost importance to prevent growth of *Aspergillus* spp.

and subsequent aflatoxin production (Burgess, 2010; Prandini *et al.*, 2009). Contamination of feed in Europe is mainly caused by imported products. However, in rare occasions with exceptionally hot and dry growing seasons, aflatoxin contamination may occur in Southern Europe as was the case for instance in 2013 in Balkan maize (Schatzmayr and Streit, 2013).
Dairy animals (cows, sheep and goat) may be exposed to aflatoxins due to contaminated feed, such as maize. In ruminants, AFB_1 can be converted by the cow, resulting in the presence of aflatoxin M_1 (AFM_1) in the milk, which is harmful to human health (EFSA, 2004; Prandini *et al.*, 2009). In general, AFM_1 levels in dairy milk in Europe are low: around 0.06% of around 12,000 samples were above the EU limit of 0.05 µg/kg (EFSA, 2004). However, when incidents occur, this may lead to a widespread AFM_1 contamination in milk as was the case in Italy in 2003. Concentrations of AFM_1 in several thousands of tons of milk exceeded the EU limits and this milk had to be discarded (Perrone *et al.*, 2014). Monitoring program on feed should thus include aflatoxins in order to prevent cows from being fed with contaminated feed (Burgess, 2010).
Transfer of AFB_1 from feed to milk is slightly higher for sheep and goat (0.024 and 0.022, respectively) than for cattle (0.015) (MacLachlan, 2011). However, also differences between cows are observed, with higher transfer rates for high-milk producing cows (up to a maximum of 0.03) compared with low-milk producing cows (Van Eijkeren *et al.*, 2006). It is expected that the tight restrictions on controlling AFB_1 in feed intended for dairy cattle may not be applied in the same way for feedstuffs intended for other animals, such as sheep and goats. Therefore, milk from goat and sheep may exceed the legal limits for AFM_1 (EFSA, 2004).

3.1.1.2 Plant toxins

As far as known to date, the only plant toxins that may be transferred into to the milk are pyrrolizidine alkaloids (PAs). These compounds may be found in forage plants and weeds (e.g. comfrey, Patterson's curse, heliotrope, ragwort) (FSANZ, 2006). Cows in the field will omit eating these plants, but when the meadow is mown and the grass is used to produce silage or hay, these plants and their toxins may be consumed unnoticed by the cows. This may result in illnesses and even death of the animals (EFSA, 2011c).
According to a recent EFSA opinion, contamination with PAs is likely attributed to accidental exposure and, consequently, the probability of PA poisoning in livestock is limited. The amount of PAs excreted into milk of animals that are exposed to PAs is low and, therefore, milk does not contribute highly to human PA exposure (EFSA, 2011c; Hoogenboom *et al.*, 2011). Nevertheless, an investigation in an outbreak of hepatic veno-occlusive disease (HVOD) caused by 1,2 unsaturated PAs showed that goat milk was one of the sources contributing to the human poisoning (Kakar *et al.*, 2010). Furthermore, even though carry-over is low, it may still pose a human health risk due to the genotoxic and carcinogenic properties of the compounds (Hoogenboom *et al.*, 2011).

3.1.1.3 Pesticides

Sometimes pesticides are found in milk due to the use of contaminated feed. Particularly organochlorides have been found in the past such as DDT, HCH and cyclodines like aldrin, dieldrin etc. In the past, these pesticides have been extensively used especially in tropical areas and, as they are very persistent, they may still be found in the environment. Crops grown in these areas may thus become contaminated and consequently pesticide residues are transferred to milk when these crops are fed to cows (Nag, 2010b). Other polar pesticides that are frequently used in crop production such as glyphosate and chlormequat may also end up in milk. Several studies in tropical areas showed positive milk samples. For example, a recent study in Pakistan showed that more than 70% of the 150 raw milk samples contained pesticides residues (organochlorine and pyrethroid pesticides) with 35% of the milk samples polluted with aldrin (Hassan *et al.*, 2014). Another study in India showed that 9.6% of the cow milk samples and 8.9% of buffalo milk samples were contaminated with endosulphan residues. In total 6.5% of the samples had levels above the CODEX Maximum Residue Limit (MRL) of 0.1 mg/kg on fat basis. One of the factors influencing the presence of residues in milk is the farmers' lack of knowledge regarding withdrawal periods for pesticides used on crops that are fed to cows (Karabasanavar and Singh, 2013). In the Netherlands, pesticides have not been encountered in milk in the past 5 years (see 3.3.2).

3.1.1.4 Organic Pollutants

A broad range of contaminants can be found in the environment due to (historical) agricultural and industrial activities. This group of compounds contains organochlorines (polychlorinated biphenyls (PCBs), dioxins, furans and dioxin-like PCBs), perfluorinated substances (such as perfluorooctane sulfonate - PFOS) and brominated flame retardants (Hoogenboom and Fink-Gremmels, 2012) (MacLachlan, 2011). Residues of organochlorine compounds are sometimes found in milk due to their presence in animal feed or via environmental contamination of the meadow (Nag, 2010a, b). The latter route is described in the following section about the dairy farm (3.1.2).

Organochlorines are very persistent chemicals. Due to their long half-life, they can remain in the environment for long periods of time (Nag, 2010a). In general, feed from animal origin contains higher levels of dioxins and PCBs than feed from plant origin (EFSA, 2012b). Fish, especially fatty fish such as salmon and mackerel, may be contaminated with dioxins and PCBs depending on their origin. When fish oils are used in animal feed for dairy cows, this may pose a human health risk (Dórea, 2006). Dioxins may also be present in ingredients used in the production process, as was the case in contaminated clay used in animal feed resulting in an incident in Austria and the Netherlands in 1999 (Hoogenboom *et al.*, 2010). Apart from the presence of dioxins in ingredients and raw materials due to environmental contamination, they may also be formed during the production process. In that case chloride and aromats are needed in combination with temperatures between 200 °C and 700 °C. These circumstances may occur, for instance, when waste materials, like preserved or painted wood, are used as fuel for open fires. This sometimes occurs in tropical areas in the production of vegetable oils. Apart from natural presence or industrial formation of dioxins, the contaminants may also end up in animal feed due to cross-contamination or adulteration (Van Asselt and Sterrenburg, 2011). Carry-over rates vary from 0.2 to 77% depending on the dioxin or furan type (Hoogenboom, 2005; Nag, 2010a).

3.1.1.5 Heavy metals

Agricultural products may become contaminated with heavy metals due to industrial pollutants or the use of sewage sludge on agricultural land or with metals that come from the soil through e.g. erosion or volcanic activity. Characteristics of the soil (such as organic matter content and pH) and the crop cultivated on the land influence the uptake of heavy metals by the plants and the subsequent contamination of dairy milk when the crop is fed to dairy cows, goats or sheep (Franz *et al.*, 2008b). The most important heavy metals are cadmium, mercury and to a lesser extent lead (de Vries *et al.*, 2007). Lead accumulates in bones, kidney and liver. Carry-over to milk is low and only significant at high intakes through feed (MacLachlan, 2011). Lead was, however, found to be present in several dairy products, including infant formulae (EFSA, 2010a). The effect of human exposure to lead is an increase in systolic pressure and neurotoxicity. Since there is no threshold of effect, a margin of exposure is used to assess the risk. Exposure of adults to lead is of low to negligible concern in adults. In infants, (young) children and pregnant women, the current exposure levels to lead are of potential concern given the effects on neurodevelopment. The largest contributors to the calculated overall lead exposure are vegetables, nuts and pulses with 19 % at the lower bound and 14 % at the upper bound, as well as cereals and cereal products at 13 % and 14 %, respectively (EFSA, 2010a). In the Netherlands, dairy products contributed with 4.9 % to the total overall dietary lead exposure (EFSA, 2010a).

Cadmium primarily accumulates in the liver and kidneys: Crout et al (2004) found a transfer from feed to milk that was a factor 100 lower (1.8×10^{-6} per day per kg) than to kidney and liver (4.2×10^{-4} and 4.5×10^{-4} per day per kg, respectively) after 10 days of feeding a contaminated diet. Cadmium occurs in dairy products, contributing (1-12%) to the overall cadmium exposure via food consumption, primarily due to a high milk consumption and not to a high cadmium content. A part of the population might exceed the TDI set based on adverse renal effects. Sprong and Boon (Sprong and Boon, 2015) investigated the cadmium exposure in the Netherlands and found that the mean life-long exposure was so low that the risk to public health is negligible. Assuming middle bound concentrations, cereals contributed most to the exposure to cadmium in both young children (2-6 years) and persons aged 7 to 69, 40 and 38% respectively. Milk contributed for 4% to the exposure in young children and less than 4% in the older age group. Contribution of milk was mainly due to high consumption levels. All cadmium concentrations in milk were below the limit of detection or quantification (Sprong and Boon, 2015).

3.1.2 Dairy farm

At the dairy farm, milk can become contaminated due to intake of contaminated compound feed or silage (see above), due to grazing on contaminated land, due to the administration of veterinary drugs or due to the inadequate use of detergents and disinfectants. Hazards associated with the intake of feed are not further discussed in this section. An overview of hazards that may be introduced at the dairy farm is given below.

3.1.2.1 Organic pollutants and heavy metals

Milk may become contaminated with organic pollutants such as polycyclic aromatic hydrocarbons (PAHs), brominated flame retardants (BFRs), dioxins and PCBs and heavy metals via the farm environment (through the soil, air or water).
PAHs (Lutz *et al.*, 2006) comprise a large group of compounds that are formed by incomplete combustion of organic matter such as forest fires or due to industrial activities that may lead to contamination of soil and pasture (MacLachlan, 2011). Benzo[a]pyrene (BaP) has been used as a marker for the group of PAHs as well as for the sum of benzo[a]pyrene, chrysene, benz[a]anthracene and benzo[b]fluoranthene (PAH4). Maximum Levels for both BaP and PAH4 have been set at 1 µg/kg in infant formulae and follow-on formulae (EU) 835/2011). The EFSA CONTAM panel collected data on PAH levels in various food products and found an average concentration for dairy products of 0.08 and 0.13 µg/kg for BaP (assuming lower and upper bound levels, respectively) and 0.28 and 0.49 µg/kg for PAH4 (assuming lower and upper bound levels, respectively), which are lower than the legal limits (EFSA, 2008a). Cow experiments on transfer of PAH from soil to milk showed that only low levels of these compounds were found in milk due to the fast metabolism and excretion of the compounds in the cow. As a result, metabolites concentrations in milk were higher than the parent compounds (Lutz *et al.*, 2006). However, these metabolites are currently not regulated (MacLachlan, 2011). When comparing transfer of various POPs, Rychen *et al.* (2008) determined that PCDD/Fs and PCBS are persistent and bioaccumulate in livestock, whereas PAHs are largely metabolized. Established transfer rates varied from 5 to 90% for PCBs, from 1 to 40% for PCDD/Fs and from 0.5 to 8% for PAHs (Rychen *et al.*, 2008).

Brominated flame retardants have been added to polymers, for example, in plastics, textiles, electronic castings, and circuitry. As a result, they are ubiquitously present in the environment and can subsequently accumulate in food and feed (EFSA, 2011a, b). The flame retardants of concern are PBDEs and HBCDDs. The EFSA CONTAM Panel used the MOE approach for the risk characterisation of HBCDDs and PBDEs and concluded that current dietary exposure to HBCDD does not raise a health concern (EFSA, 2011a). No national exposure assessments to HBCDDs are available. The EFSA CONTAM panel calculated MOEs for the PBDE congeners BDE-47, -99, -153 and -209, and found that there was no human health concern except for the dietary intake of PBDE-99 in young children (1-3 years) with MOEs for average and high exposure of 1.4 and 0.7. For this compound, a potential health concern based on the current dietary exposure in this age group could not be excluded (EFSA, 2011b). A recent Dutch study into the BDE-47, -99, and -153 intake of persons aged 2 to 69 showed that the intake of none of these congeners raised a health concern: none of the persons had an intake exceeding the relevant health-based guidance values (HBGV) (Boon *et al.*, in prep.). In this study, the intake of PBD-100 and – 183 was also estimated. No conclusion could be drawn about the health effects of these congeners, since no HBGV for these congeners is available. The main contributions to the intake of the three BDE-congeners were milk (12-40%), fruit and vegetables (15-36%) and fatty fish (0-21%). The high intake through milk and fruit and vegetables was primarily due to the high consumption of these food groups. Concentrations found in milk samples were at or around the quantification limit (2-5 pg/g), while in fruits and vegetables the majority of the samples were below the relevant quantification limits (Boon *et al.*, in prep.).

The use of phosphate fertilizers, the application of contaminated material on the soil (such as sewage sludge or industrial waste) and atmospheric deposition from nearby industrial activities in the past or via recent incidents have been related to contamination with organic pollutants and heavy metals (Logonathan *et al.*, 2008; Nag, 2010b). Grassland may also be contaminated when chlorine-containing plastics are illegally burned near pastures where animals are grazing (Esposito *et al.*, 2010). An example of an incident resulting in atmospheric deposition is the fire at Chemie-Pack at Moerdijk in

2011. When such incidents occur, dairy farmers are advised to keep their animals indoors until it is clear that the grass is free of pollutants. Previous research has shown that when cows are grazing on contaminated land, chemical contaminants may be transferred to the cow and end up in the milk (Franz *et al.*, 2008a; Van Asselt *et al.*, 2013). Heavy metals may persist in the cow for several weeks after the exposure has stopped (Nag, 2010b).
Grazing animals may take up contaminants via ingestion of the grass as well as the contaminated soil. The amount of soil ingested varies over the season, with increased amounts in wet winter/early spring when relatively more soil adheres to the grass (Logonathan *et al.*, 2008). Sheep ingest relatively more soil per kg body weight than cows. Based on an average body weight of 600 and 75 kg, cows ingest around 0.68 g/kg bw/day, whereas sheep ingest around 1.33 g/kg bw/day (de Vries *et al.*, 2007). As sheep milk is also fatter than cow milk, it is expected that sheep milk will contain higher levels of dioxins and PCBs than cow milk when these animals are grazing on the same contaminated land. As heavy metals and dioxins and PCBs mainly accumulate in the organs of the animals (kidneys and liver), levels of these compounds in milk are relatively low (Jones *et al.*, 1989; Logonathan *et al.*, 2008). However, in case cows or sheep are grazing on contaminated land, levels of dioxins and PCBs in milk may become much higher (Nag, 2010b). Overall, background levels of dioxins and PCBs in raw milk and dairy products are declining over the years within the EU (EFSA, 2012b; Hoogenboom and Fink-Gremmels, 2012).
In the Netherlands, goats are kept indoors, so they will not ingest contaminated grass or soil but can only be contaminated via the compound feed or silage.

3.1.2.2 Radionuclides

In 1986, a nuclear accident happened in Chernobyl causing nuclear pollution throughout Europe. Radionuclides were deposited to the grass and taken up by the cow during grazing. The radionuclides were then transferred into the milk. Milk was shown to be the dominant source contributing to ^{131}I exposure for the local population after the incident (Steinhauser *et al.*, 2014). ^{131}I has a short half-life of around 8 days and its uptake by the cow is thus primarily important directly after an incident. Other radionuclides, such as ^{137}Cs have a much longer half-life of around 30 years. This radionuclide can, thus, remain in the environment long after an incident (US EPA, 2015). Even years after the Chernobyl accident, milk remained the major route for intake of ^{137}Cs and contributed more than 50% to the average intake. Recent data from the affected region still show elevated ^{137}Cs-levels in milk, although they are below the EU limits (Steinhauser *et al.*, 2014).
In the Netherlands, current levels of radionuclides in the grass and soil are low and, subsequently, levels in the milk are below the detection limit (Knetsch, 2014). In case milk is imported from countries with relative high contamination levels of radionuclides in the environment, they might be present in milk.

3.1.2.3 Veterinary drugs

Veterinary drugs are prescribed to cure animal diseases. Antibiotics in dairy cattle are mainly used to control mastitis (Khaniki, 2007). They have prescribed withdrawal periods, meaning that farmers need to wait a certain period of time after treatment before they can sell products of animal origin to the consumer (directive No 2001/82/EC). These withdrawal periods have been established to prevent the occurrence of antibiotic residues in animal products above the MRLs as laid down in EU regulation (EU) No 37/2010. Antibiotics use may result in the presence of antibiotic residues in the milk when milk is delivered within the withdrawal period (Ali and Fischer, 2002; Noordhuizen and Metz, 2005; Sandhu, 2007; Silanikove *et al.*, 2010). In the Netherlands, antibiotics can in most cases only be administered by veterinarians. Since 2011, the Netherlands Veterinary Medicines Authority (SdA) registers the antibiotics use in the Netherlands in order to benchmark farms and veterinarians. Sales data show a declining trend in total antibiotics use since 2007 due to increased concerns about antibiotics residues (see Figure 3) (SdA, 2014). Dairy cows are treated individually in order to prevent mastitis. Beta-lactam antibiotics are the most frequently administered antibiotics in dairy cows followed by tetracyclines. Recently, a new guideline has been published to further reduce the use of antibiotics for drying off (KNMvD, 2013). Overall, antibiotics use in dairy cows (4.09 DDDA) is lower than in pigs (9-11 DDDA) (SdA, 2014).

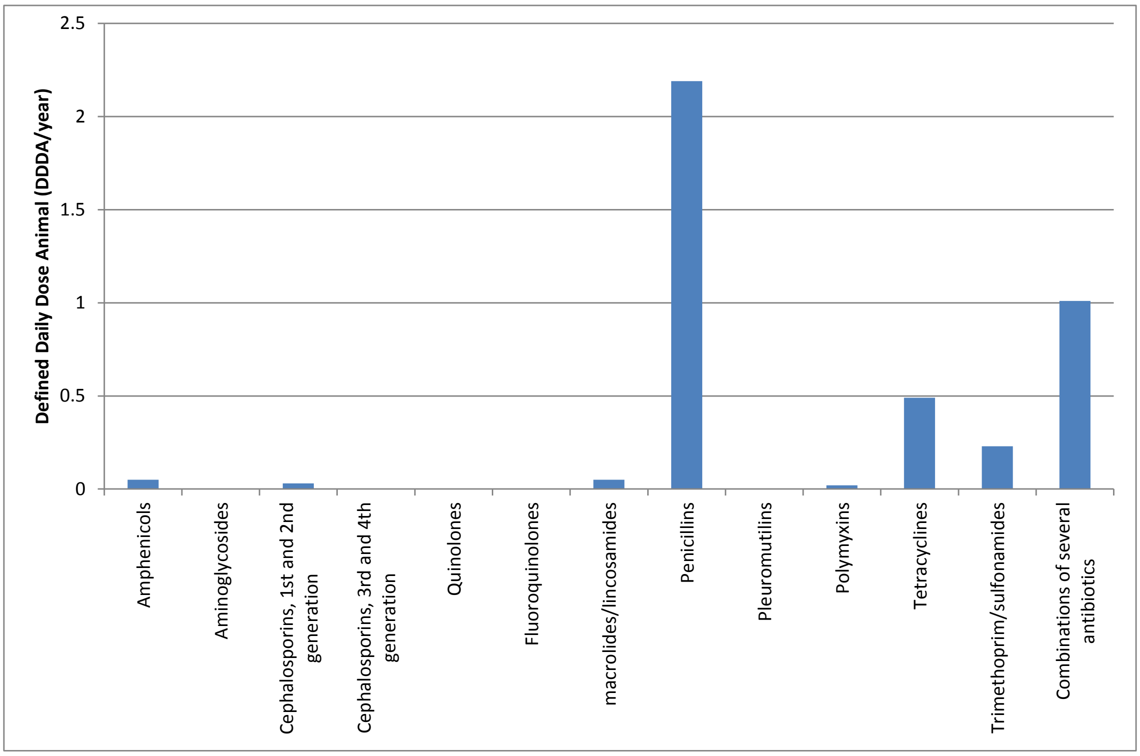

Figure 3 *Sales data of antibiotics for 2013 in dairy cows indicated as DDDA: Defined Daily Dose Animal (sum of treated kilograms of dairy cows/average kilograms of dairy cows in the Netherlands (SdA, 2014)).*

Figure 4 shows that total antibiotics sale in the Netherlands for all food producing animals is in the mid group in comparison to other European countries (EMA, 2014). A higher antibiotics use may result in a higher probability of finding residues in dairy products. Import of dairy products from high-use countries may result into a high probability of presence of antibiotics residues.

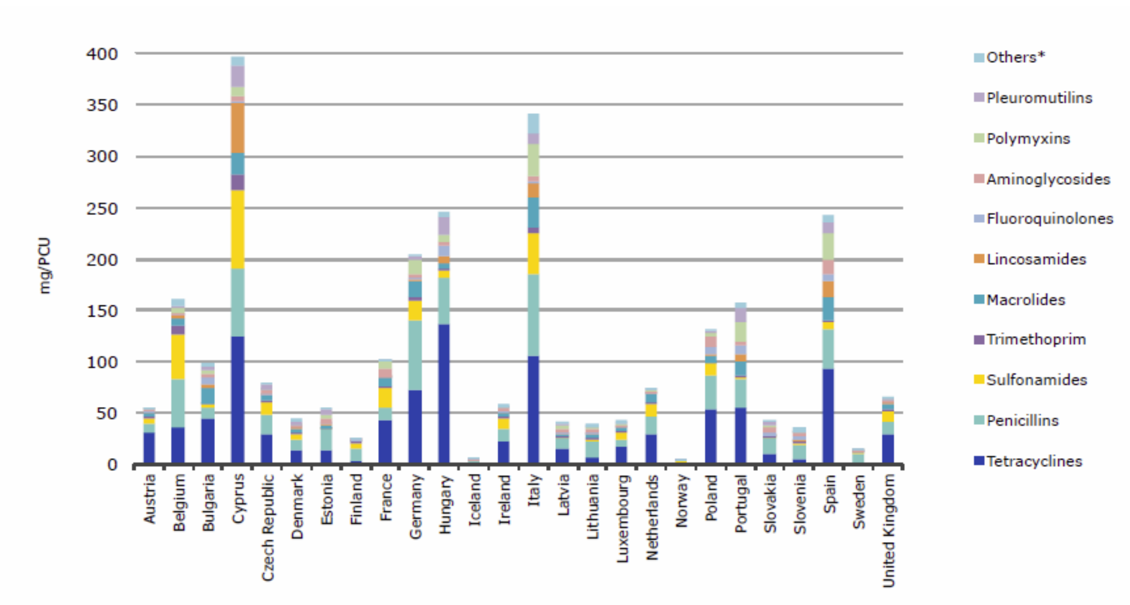

Figure 4 *Sales for food-producing species, including horses, in mg/PCU (PCU: population correction unit), of the various veterinary antimicrobial classes, for 26 countries in 2012 (EMA, 214).*

Apart from antibiotics, other veterinary medicines may be administered to cows such as painkillers (e.g. nonsteroidal anti-inflammatory drugs (NSAIDs)) and antiparasitic drugs. Painkillers that are used for lactating cows have short withdrawal periods (ranging from 0 hours to 1-2 days) (www.cbg-meb.nl). Thus, it is expected that these compounds will not be found above the indicated MRLs in (EU) 37/2010. Antiparasitic drugs are applied to cure flukes, tapeworms and nematodes. One of these antiparasitics, albendazole, is widely used around the globe. Metabolites from this parasitic drug can be transferred into the milk and have been found in dairy products as albendazole. As with antibiotics, withdrawal periods should be observed in order to prevent the presence of residues in dairy products (Khaniki, 2007) and animals are preferably treated during the dry-off period.
In case antiparasitics are prescribed, the website of the Medicines Evaluation Board (MEB) should be checked to determine whether the drugs are allowed for use in lactating animals. For example, albendazole can only be used in non-lactating sheep in the Netherlands (www.cbg-meb.nl). Therefore, the intake of albendazole (metabolites) in the Netherlands is considered negligible.

3.1.2.4 Detergents and disinfectants

In the Netherlands, cleaning is primarily performed using alkaline detergents combined with sodium hypochlorite as disinfectant (Slaghuis, 2007). Sodium hypochlorite may result in disinfection by-products in food when chlorine forms trichloromethane (TCM), also called chloroform. The maximum level of TCM in drinking water is 0.1 mg/kg. In the EU, there are no MRLs established for TCM in food. Germany, however, has set the limit for food at the drinking water limit. Moreover, target levels of <0.03 and <0.002 mg/kg in butter and milk, respectively, have been recommended (Danaher and Jordan, 2013). In order to be able to compete within the EU market, Dutch milk should aim for these values as well. As is to be expected, increased chlorine concentrations and reduced amounts of rinsing water will increase the TCM level in milk (Siobhan *et al.*, 2012). Disinfectants have emerged as a residue in milk in recent years. Iodine residues are found as well as quaternary ammonium compound (QAC) residues and trichloromethane (TCM) residues (Danaher and Jordan, 2013). Over the past 5 years, three notifications were reported in RASFF with too high levels of hydrogen peroxide in butter and desserts.

3.1.3 Milk processing

Dairy products may be produced either at the factory or at the farm itself. In the Netherlands around 1% of all farmers produce their own dairy products. In general, chemical hazards are the same for production at the factory or at the farm.

3.1.3.1 Accumulation of hazards

Contaminants that are already present in the milk are usually unaffected by further processing at the dairy factory or at the farm. However, in some cases contaminants may be concentrated, for example in the production of milk powder, which causes a higher level of contaminants in the final product (Prandini *et al.*, 2009). Organic pollutants such as dioxins and PCBs are lipophilic and will accumulate in butter, which typically contains 80% fat (Kalantzi *et al.*, 2001). When contaminants are water soluble, their levels will reduce in butter as is the case for the radionuclides ^{90}Sr, ^{134}Cs and ^{137}Cs (Nag, 2010b). The same accounts for AFM_1, which will primarily end up in skimmed milk and buttermilk and to a much lower level in butter (Prandini *et al.*, 2009). AFM_1 is predominantly associated with casein and thus cheese curd contains higher levels than whey. Due to a concentration factor, AFM_1 levels may be 5 times higher in hard cheese than in milk (Prandini *et al.*, 2009). Hazards that may be introduced during production of dairy products are outlined in the following sections.

3.1.3.2 Neoformed contaminants

When milk is heated, compounds present in dairy milk (lactose, protein) may follow the Maillard reaction resulting in the formation of neoformed contaminants such as lactulosyl- or fructosyl-lysine, pyrraline and carboxymethyllysine (CML) (Nguyen *et al.*, 2013). Carboxymethyllysine (CML) is part of the group of so-called Advanced Glycation End products (AGEs); it is considered an indicator for the presence of AGEs. The level of CML increases with increased temperatures and is also influenced by the whey-to-casein ratio as well as the lactose levels in the milk. A recent review within Europe showed a large variability in CML levels in infant formula. This may have been caused by the heat sterilization techniques applied as well as the composition of the milk used (Birlouez-Aragon *et al.*, 2010). A good control of the production process will thus diminish the CML levels in the final product (Birlouez-Aragon *et al.*, 2010; Nguyen *et al.*, 2013). Currently, there is no legislation for these compounds (Birlouez-Aragon *et al.*, 2010). Furthermore, there is currently no health based guidance value available and no exposure assessment has been performed. Therefore, it is not possible to determine the risk of dietary intake of CMLs and AGEs.

3.1.3.3 Food additives and processing aids

Food additives and processing aids such as the use of colorants, enzymes, starter cultures or the use of fruit products may introduce new hazards during processing. It would be too much to provide a complete list of chemical hazards associated with the wide range of food additives and processing aids used during processing. In general, arranging inspection of incoming goods, which is part of a HACCP-system, prevents the introduction of chemical hazards during processing.

3.1.3.4 Allergens

One of the new hazards that may be introduced through the use of food additives and processing aids is allergens. Milk itself is an allergen, but additional allergens can be found in dairy products through the use of, for example, fruit or gluten in the production of semolina porridge or pudding. Allergen-containing products should thus be produced separately from other dairy products and proper cleaning is essential to prevent cross-contamination.

3.1.3.5 Detergents and disinfectants

Alkaline detergents are used for cleaning and depending on the processing equipment and the adhering microorganisms, appropriate disinfectants are selected that are safe and easy to use, can easily be rinsed off from surfaces and leave no toxic residues that could affect the health properties and sensory values of the final products. A wide range of chemicals are currently used in dairy processing: acidic compounds, aldehyde-based biocides, caustic products; chlorine, hydrogen peroxide, iodine, isothiazolinones, ozone, peracetic acid, phenolics, biguanidines, surfactants (Simões *et al.*, 2010). If no proper rinsing is applied, these compounds may end up in the dairy product (see 3.3.2). Recently, chlorine dioxide has become more widely used in the dairy industry, predominantly in the sanitizing of hard surfaces of equipment and floor drains. The advantage of chlorine dioxide is that it is less corrosive and pH-dependent and causes less off-odours than other disinfectants. The disadvantage of its use is, however, that it can generate chlorinated by-products (chlorite and chlorate) that could be toxic (Gómez-López, 2012). EFSA recently published an opinion indicating that chlorate may inhibit iodine uptake. A TDI of 3 µg chlorate/kg body weight was set and an ARfD of 36 µg chlorate/kg body weight. Average concentrations of chlorate in milk and dairy products were reported to be 85 and 91 µg/kg assuming lower bound or upper bound respectively. Concentrations ranged between 0 and 510 µg/kg at the 95 percentile, which is still below the hypothetical MRL of 0.7 mg/kg as established by EFSA (EFSA CONTAM Panel, 2015).

3.1.3.6 Migration from packaging materials

One of the compounds that can migrate from the packaging material or equipment into the dairy products is phthalates. Phthalates are the most used plasticisers and are added to plastic polymers (such as PVC) to enhance flexibility. Phthalates are a group of plasticisers. There are several phthalates like dimethyl phthalate (DMP), diethyl phthalate (DEP), diisobutyl phthalate (DIBP), di-n-butyl phthalate (DBP), benzylbutyl phthalate (BBP), di(2-ethylhexyl) phthalate (DEHP), dicyclohexyl phthalate (DCHP) and di-n-octyl phthalate (DNOP). Various phthalate esters have been found in dairy products, presumably from PVC tubing used during the milking process or transfer from bulk milk to storage tanks but also from packaging materials such as cartons and bottles (Danaher and Jordan, 2013). In RASFF, there are in total 159 notifications of phthalates in food, of which 82 related to DEHP. Among dairy products, there were two notifications, namely DEHP in plastic tubes for raw milk vending from Italy, and migration of BBP and DEHP from jars containing sweet peppers with feta cheese in olive oil from Greece imported into Belgium via the Netherlands. Migration of some plasticizers may be of concern due to the high lipid content of dairy products (FSANZ, 2006). EFSA summarised dietary exposure assessments of DBP, DEHP, BBP and DINP performed in Denmark and the UK. The exposure to all these phthalates was below their respective TDIs; however, there is additional intake of DBP and DEHP from environmental sources like air, water and soil that was not taken into account in this exposure assessment (EFSA, 2005a, b, c, d).

Printing ink, such as 2-isopropyl thioxanthone (ITX) and 2-ethylhexyl-4-dimethylaminobenzoate (EHDAB) may also migrate from the packing material into the final product in case the packaging material is rolled in such a way that the inside and outside of the package come into contact with each other. In 2005, ITX contamination of children's milk was reported to RASFF. In this year, ITX notifications contributed to 32% of all food contact substances reported to RASFF (Kleter *et al.*, 2009). According to EFSA, young children may have a higher exposure to these printing inks as half of their food and beverages are packed in cartons printed with these inks (EFSA, 2005e). The human health impact cannot be assessed as there are no health based guidance levels available for these compounds due to a lack of toxicity studies. As a result of the ITX notifications, the EU has adopted legislation requiring that transfer of printing inks to the food contact surface (through "set-off" or migration) is prevented (2023/2006/EC) (Kleter *et al.*, 2009).
A more recent concern is the presence of aluminium in infant formula. Most packaging material contains an aluminium layer, which may result in migration of aluminium into the product (Chuchu *et al.*, 2013). Use of brand specific infant formulae can lead to higher exposure levels because there is variety in aluminium levels between brands. High exposure (P97.5) in children aged 1,5-18 years ranged from 0.7 to 2.3 mg/kg bw/week. The average exposure in adults ranged from 0.2 to 1.5 mg/kg bw/week and high exposure was up to 2.3 mg/kg bw/week. Based on these data, it was concluded that a significant part of the European population exceeds the TWI. The main foods contributing to the exposure were cereals (products), vegetables, beverages and certain infant formulae (EFSA, 2008b). Though the relative contributions of the various products to aluminium exposure were not mentioned in this report, dairy products are not the major contributor.

3.1.3.7 Melamine

A well-known example of food fraud in the dairy sector is the melamine case in China. In 2008, melamine was illegally added to milk products to produce an incorrectly high reading in the measurement of protein content based on total nitrogen (Ai *et al.*, 2009). By the end of November 2008, 294,000 infants and young children had been diagnosed to have urinary tract stone (Chen, 2009). More than 50,000 infants were hospitalised with six deaths being confirmed (WHO, 2008). In the past, melamine has also been illegally added to animal feed. For example, in 2007, melamine was found in pet feed and blamed for leading to renal disease and/or deaths in dogs and cats in United States (Burns, 2007; Lang, 2007).
In addition to fraudulent practices, when melamine was added to food products on purpose, melamine can migrate into food from the package. Also, the veterinary drug cyromazine is metabolised into melamine in cows; however, this drug is not allowed to be used in lactating animals if the milk is used for human consumption (EFSA, 2010b). In addition, upon oral administration of melamine in cows, low levels of melamine were transferred (0.7-2%) to the milk (Cruywagen *et al.*, 2009; Shen *et al.*, 2010). Melamine and cyanuric levels are found in several dairy products and specific migration limits and maximum levels are set in foods. The maximum levels of melamine and its structural analogues are 1 mg/kg in powdered infant formulae and follow-on formulae and 2.5 mg/kg in all other foods (European Commission, 2006). Melamine can cause kidney toxicity by formation of calculi with natural present uric acid. In addition, it can react with the structurally related cyanuric acid and form crystals. Exposure to melamine and cyanuric acid are below their respective TDIs; however, simultaneous exposure is more toxic and no health-based guidance value could be set for combined exposure (EFSA, 2010b).
In the Chinese case of milk fraud, it is hard to imagine how the adulterated milk could have passed all the quality inspections along their supply chains to reach the marketplace on such a massive scale (Chen *et al.*, 2014). Specific controls for milk quality like fat content should have detected such fraud, but these tests were either not carried out properly or were ineffective (Pei *et al.*, 2011).
Recently, rapid surveillance methods have been developed to detect nitrogen containing compounds in milk (Abernethy and Higgs, 2013). In the Netherlands, such adulteration is more difficult as various quality features are checked simultaneously upon arrival of the milk at the dairy factory. Protein and fat content are checked as well as freezing point. The addition of nitrogen containing compounds such as melamine causes a decrease in freezing point. Sanctions are enforced on the dairy farmer in case of deviations from the specifications (expert opinion).

3.2 Physical hazards

Apart from chemical hazards, there are also physical hazards that may influence the safety of dairy products. Physical hazards include metal parts (wire, needles etc.), sand/soil, stones, wood, plastic, rubber or glass parts and hair. They may be introduced during production of dairy products through the use of jewellery, as parts of machinery (e.g. metal parts from stirring machines or rubber from seals) or equipment, due to packaging materials or via presence in raw materials or the environment. At the farm, physical hazards may be introduced during milking (e.g. machine parts). However, in most cases, physical hazards are introduced during the further steps in the production process of dairy products. The main dairy factories in the Netherlands do not use glass in their production facilities. However, farmers that produce their own dairy products may sometimes use glass bottles for their products. Hair may be present in dairy products due to bad hygiene. This can be a source of microbial contamination. Bad cleaning and disinfection may result in the presence of soil (FAVV, 2012). Retail doesn't want recalls due to the presence of physical hazards; therefore there is a severe monitoring program to prevent these hazards (as part of the factory's HACCP system).

3.3 Results monitoring data

3.3.1 Animal feed

For the identified hazards in animal feed, RASFF notifications were gathered for the period 2009-2014. It must be noted that it was not possible to make a distinction between animal species. Results shown in Figure 5, thus, reflect the percentage of notifications in all animal feed regardless of the destiny of the feed.

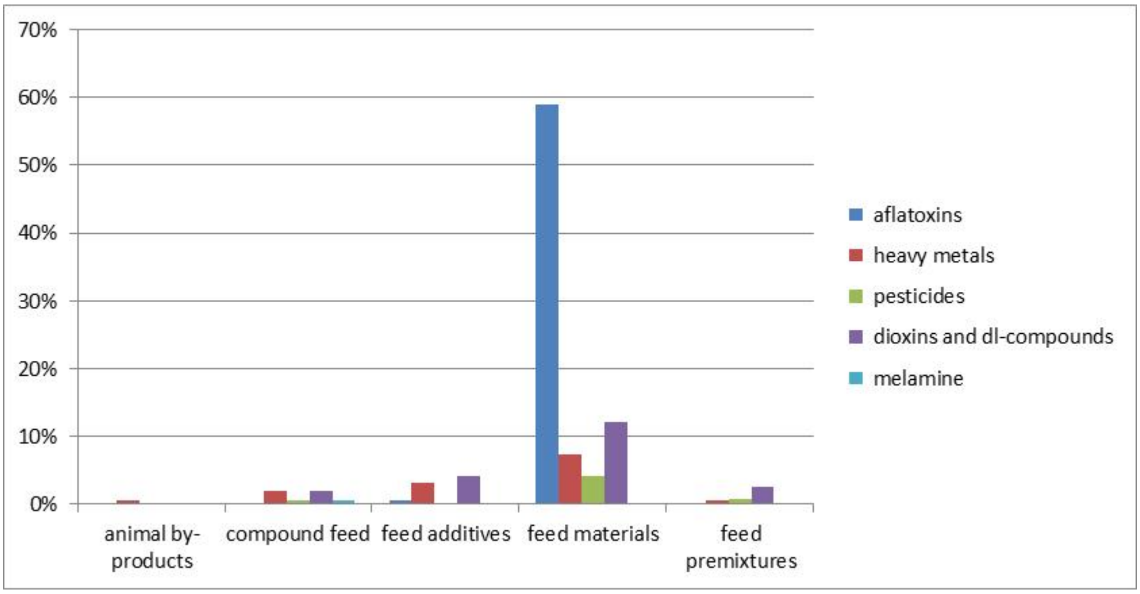

Figure 5 *Percentage of RASFF notifications in animal feed during the period 2009-2014.*

As can be seen, most notifications are for feed materials and aflatoxins have the highest percentage of notifications. Statistical analysis of data from the Dutch monitoring program shows that the number of samples above LOD declines over the years, and thus there is a declining trend in aflatoxin B_1 levels in feed (Figure 6).

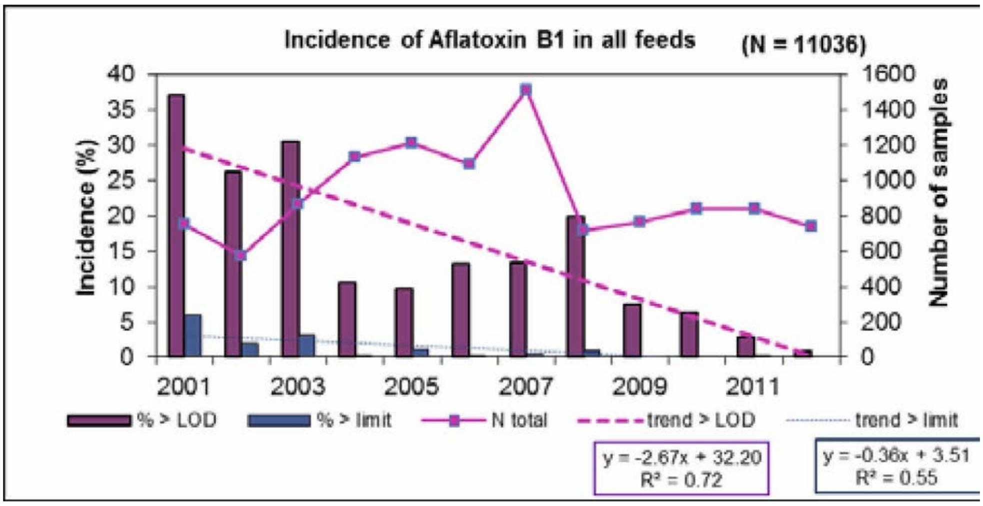

Figure 6 *Aflatoxin B_1 incidence, percentage of total exceeding LOD or MRL (Adamse, 2013).*

Based on RASFF data, literature (EFSA, 2004; Marin *et al.*, 2013; Prandini *et al.*, 2009; Schatzmayr and Streit, 2013) and trend analyses on national monitoring data (Adamse, 2013), feed ingredients have been classified in high, medium and low risk of aflatoxin contamination within the WOT-project "Statistical foundation of a risk-based National Plan for animal feed". High risk feed ingredients for aflatoxins are maize, nuts and rice. Medium risk ingredients are sunflower seed, coconut pressing residues, cotton seed, millet, sorghum and buckwheat. All other feed ingredients are seen as giving a low risk on the presence of aflatoxins. The geographic origin also influences the likelihood of an aflatoxin contamination (EFSA, 2004). Countries with expected increased risk are Argentina, Brazil, Egypt, India, Turkey, Ukraine, China and southern European countries in case of a hot and dry growing season. Within the group of compound feed, heavy metals and dioxins are most frequently reported in RASFF. Furthermore, aflatoxins, pesticides and melamine were reported. The latter was found in compound feed for dogs.

3.3.2 Dairy products

Examination of notifications recorded by NVWA and NVIC showed that during the period 2010-2012 no notifications related to specific chemical hazards occurring in dairy products were declared. In October-December 2010, three notifications were reported at the NVWA about milk with 'a chemical taste'. Contamination with a cleaning product was suspected but the chemical hazard has not been identified. Notifications by the Front Office showed that during the period 2010-2014, two risk assessments were performed related to chemical hazards occurring in milk or dairy products after an incident. The hazards in question were dioxins (including dl-PCBs) and AFB_1; the dairy product was cow's milk:

- AFB_1: transfer of AFB_1 from contaminated maize to cow's milk, 2013;
- Dioxins: transfer of dioxins from contaminated grass to cow's milk after a fire at Moerdijk, 2011.

Results of these risk assessments are described in paragraph 3.5.

Analysis of RASFF data over a four year period (2003-2007) revealed that dairy products only contribute to 1% of all RASFF notifications related to chemical hazards (Kleter *et al.*, 2009). In the current analysis, RASFF data from 2009-2014 were used, showing a total of 245 alerts and notifications. The majority of the cases (84%) involved microbiological contamination. In 6% of the cases, fraud was reported. Unauthorized operators were mentioned as well as illegal import of dairy products. The remaining cases were on aflatoxins, antibiotics, disinfectants and physical hazards (see Figure 7).

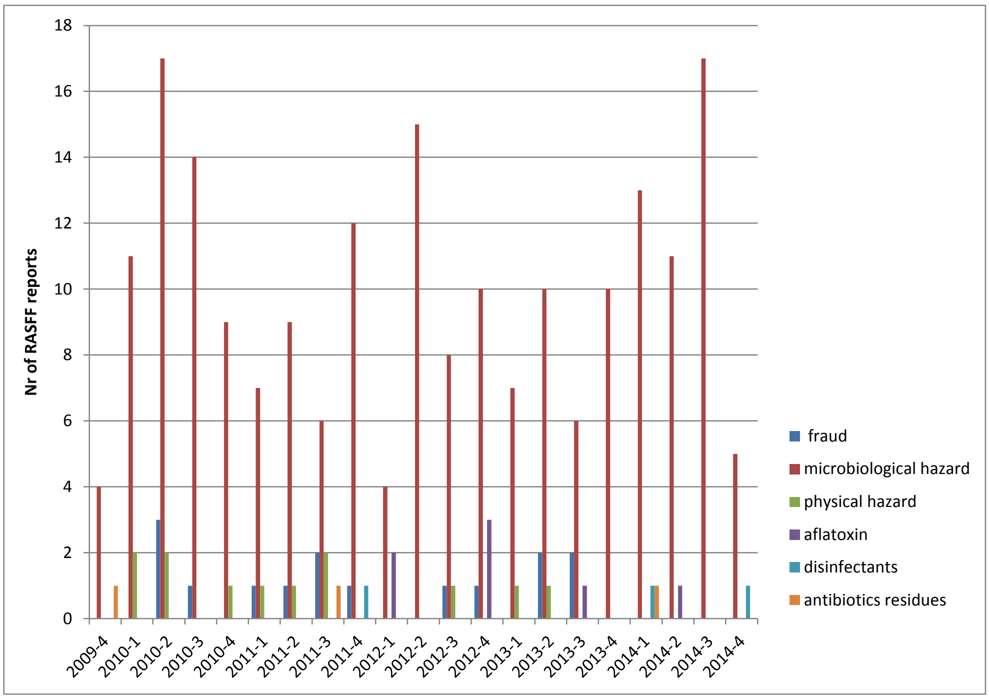

Figure 7 *Number of RASFF reports (alerts, border rejections and notifications) for fraud, microbiological contamination, physical hazards and chemical hazards in dairy products from 2009 to 2014.*

Most chemical and physical hazards were reported in milk (Figure 8). Physical hazards encountered were metal, glass or plastic parts. Three notifications reported in the disinfectants sections concerned too high contents of hydrogen peroxide in dairy products originating from France, Germany and Czech Republic.

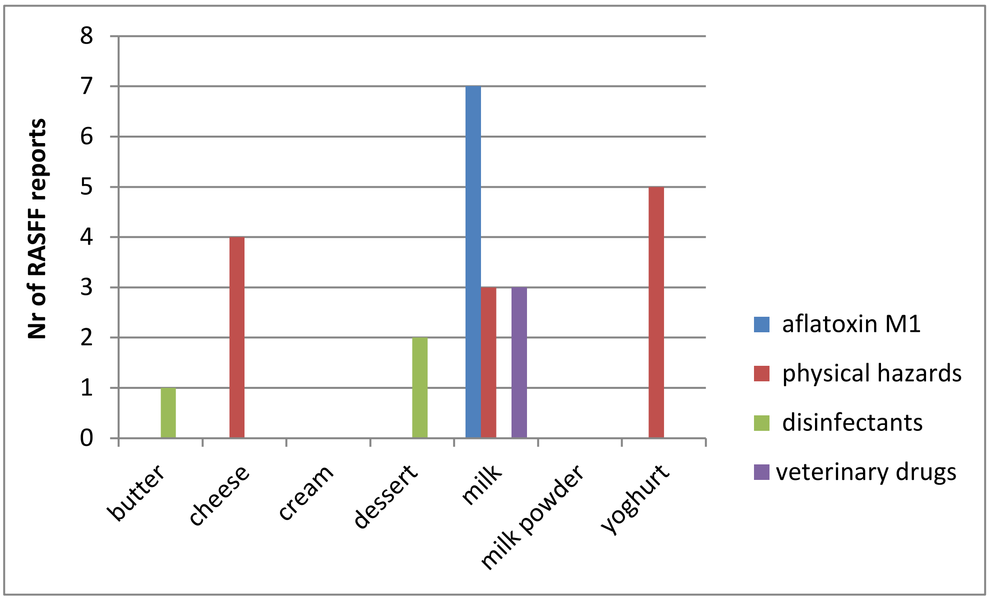

Figure 8 *RASFF reports for chemical hazards and physical hazards in various dairy products from 2009 to 2014.*

Data from the Dutch monitoring program showed that around 30,000 samples were taken for butter, cheese, milk powder and milk over the years 2009-2013. Most of the samples were taken from milk (around 20,000), the majority of which was tested for the presence of veterinary drugs (See Figure 9). For the years 2011-2013 only data on dioxins and dl-PCBs were available.

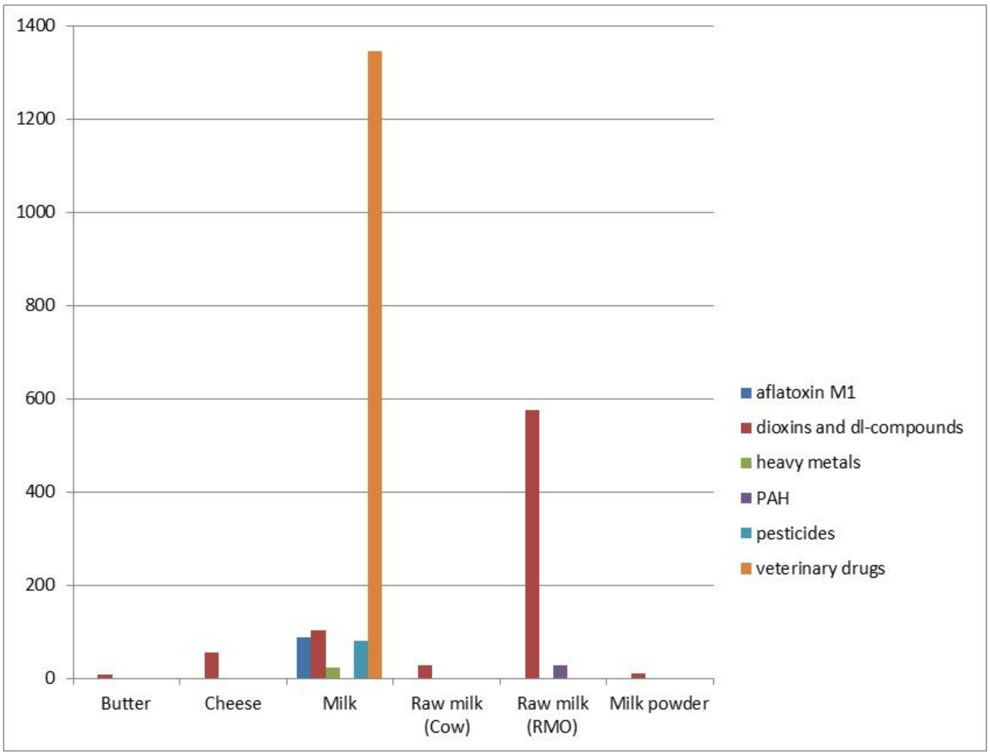

Figure 9 *The number of samples from the Dutch monitoring program for 2009 and 2010.*

Aflatoxin M_1 was detected in two of the 89 samples taken between 2009 and 2010. One sample was below the ML and the other contained 0.1 µg/kg, which is above the ML of 0.05 µg/kg as set by (EU) 1881/2006. Data from the national monitoring plan (2001-2011) showed that dioxins and dl-PCBs were present in various milk samples, but levels were below the action and maximum limits as set by Commission Recommendation 2011/516/EU and Commission Regulation (EU) No 1259/2011 (Schoss *et al.*, in preparation). Samples tested on heavy metals, PAH and pesticides between 2009 and 2010 contained levels below the LOD and all samples tested on veterinary drugs were below the MRLs.

3.4 Drivers that influence hazards

Various international and local developments may directly or indirectly influence the performance of food producing systems. Many factors of influence (referred to as “drivers”) have been identified, among them climate change, economy and trade, human behaviour, and new technologies (Boland *et al.*, 2013; GO-Science, 2011; Godfray *et al.*, 2010; Miraglia *et al.*, 2009; Tscharntke *et al.*, 2012). Besides having direct (and/or indirect) effects on food production systems as such, these drivers also may have direct and/or indirect interdependencies. In addition, the influence of local changes in drivers and/or food production systems may result in severe unintended effects on the food system across different adjacent or remote global locations.
Recently, the Directorate General for Health and Consumers (DG SANCO) of the European Commission (EC) commissioned a scoping study on ‘Delivering on EU Food safety and Nutrition in 2050 - Scenarios of future change and policy responses’ (FCEC, 2013). The objective of the study was to identify the critical challenges to the EU food safety and nutrition framework, their future evolution up to 2050, their impacts on its current structure and the potential critical changes to the current framework necessary to maintain the prevailing high standards. The study was based on three stakeholder and

expert workshops, a driver identification process, an extensive literature review, expert interviews, and a large-scale consultation of stakeholders and experts. This exercise resulted in the following key drivers of food safety and nutrition in 2050: i) global economy and trade, ii) global cooperation and standard setting, iii) EU governance, iv) demography and social cohesion, v) consumer attitudes and behaviour, vi) new food chain technologies, vii) competition for key resources, viii) climate change, ix) emerging food chain risks and disasters, and x) new agri-food chain structures (FCEC, 2013).
Certainly, all drivers will have an effect (direct/ indirect) on the performance of a food production chain, including the dairy chain, but the probability and severity will greatly differ between drivers. To identify plausible trends, 10 different scenarios were developed and evaluated in their study.
Here, we have assessed the potential influence that the described drivers and their perceived trends may have on the occurrence of chemical or physical hazards in the dairy chain. Only, those drivers for which we expected an impact on hazard development in the dairy chain were assessed. Based on this (non-exhausting) evaluation, five out of the 10 drivers described in the FCEC report were identified as potentially affecting the hazard occurrence in the dairy chain (Table 1). These drivers (and their sub-drivers), their perceived trends and their potential effect on a hazard are described below. Additional literature has been used to further elaborate on the specified drivers.

Table 1
Overview of relevant drivers for the dairy chain (FCEC, 2013)

Driver	Trends and uncertainties identified
Climate change	• Rising temperatures • Changing precipitation patterns • Changing agricultural productivity according to species and regions • Emerging biological threats • Increasing ‘environmental migration’
Global economy and trade	• Globalisation of trade in food and feed • Increasing number of countries covered by free trade agreements • Emerging economies exporting more high added-value products & engaging in standard-setting • Global economic development • Increasing and more volatile food prices • Increasing pressure on public finances from financial and expenditure on health and pensions
New agri-food chain structures	• Industrialisation of agriculture, from small-scale and subsistence farming to large agri-business • Increasing concentration and integration of food chain industries to achieve economies of scale • Reduction in the agricultural labour force • Increase in organic farming • Increasing importance of regional, local and alternative food chains • Pressure of increased recycling and less waste all along the food chain
New food chain technologies	• Expected increase in the use of biotechnology and GMOs • Increase in productivity from other primary production technologies (e.g. aquaculture) • Expected increase in the use of nanotechnology • Increased medicalization of food and new forms of food • Increased use of information and communication technologies (ICTs) • New processing and packaging technologies
EU governance	• Further EU enlargement, potentially coupled with further market integration • Continuing reform of the Common Agricultural Policy (CAP) • Continued consolidation of the food safety and nutrition legislative framework • Continuing challenge of ensuring enforcement • Rise in importance of communication concerning food safety and nutrition

The following paragraphs give a further explanation of the various drivers mentioned in Table 1.

3.4.1 Climate change

Marvin et al (2013) have described in detail which potential impacts the various climate induced effects such as drought, heavy rainfalls etc. may have on the development of a hazard in the food production chain. These weather extremes have been shown to induce the development of a food safety hazard. Some of these may have an effect on the dairy chain which we will elaborate further below. Climate is an important driver that influences fungal growth such as *Aspergillus* growth and subsequent aflatoxin contamination. Due to increasing temperatures a shift in occurrence of fungal infections and mycotoxin contamination is to be expected (Perrone *et al.*, 2014). The different climate conditions demonstrated to influence milk contamination with the AFM_1 toxin, as a higher contamination was verified in raw milk samples from the dry period in tropical areas. In the wet season, cows graze on the pastures, whereas in the dry period they get mixed feed that may be contaminated with AFB_1 (Picinin *et al.*, 2013). The contamination of milk with aflatoxins and the concentration of these toxins in dairy products may vary according to geographic location, development level of the country and climatic conditions. High temperatures and extreme weather events such as droughts and floods may influence milk production and its quality as a result of changes in the availability and quality of food and water provided to animals (Bakirci, 2001; van der Spiegel *et al.*, 2012). Many other factors can affect the formation of aflatoxins in feed, such as: moisture, the air, the nature of the substrate, specific nutrients (vitamins, fatty acids, amino acids and energy source) (Wyatt, 1991). Synthesis of aflatoxins in feeds is increased at temperatures above 27°C and high humidity levels depending on agricultural productivity according to species and regions. In a study among stakeholders in the Netherlands 10 critical factors were identified that are mostly affected by climate induced hazard development (van der Spiegel *et al.*, 2012). The stakeholders ranked feed-related issues (raw materials, pasture, silage, storage and manufacturing of compound feed) and animal health as most important.

3.4.2 Global economy and trade

An important driver that may affect the performance of the dairy chain and the introduction/appearance of a (new) hazards is economic gain resulting in food fraud. Examples of food incidents occurring due to such a driver are the previously mentioned dioxin crisis in Germany and the melamine crisis in China (Duchowski *et al.*, 2009; Pinior *et al.*, 2012a) Global trade is another driver that may affect the presence of food safety hazards. It can, for example, contribute to the spread of aflatoxicogenic fungi in feed (Perrone *et al.*, 2014).
Trading volume of the milk, the number of trading partners and their organization in the dairy supply chain are essential for the potential spread of a milk contamination. Actors with a high production and trading volume can cause a great deal of damage and, therefore, should be checked more often (Pinior *et al.*, 2012b). Pinior *et al.* (2012b) showed that inter-dairy trade influenced vulnerability in a milk chain, a minor inter-dairy trade (1.8%) led to a 4-fold increase in the vulnerability of the milk producer and to a 3-fold increase in the vulnerability of the consumer.

3.4.3 New agri-food chain structures

The change in organization in the dairy chain is illustrated by the fact that every year around 15 dairies and 2% of milk producers terminate their businesses. Assuming invariable milk consumption and continuous structural change, the concentration and integration of dairy chain actors will increase in the future. This is true for the distances and the trade volume between dairies and milk producers as well as the trade volume between dairies (Pinior *et al.*, 2012b).
According to Pinior *et al.* (2012b) the milk trade network is developing into a more and more central network, which is becoming more vulnerable and, therefore, less robust with respect to food crises. They observed that the milk chain network is experiencing a dynamic change: critical control points identified as important today with respect to food safety may not be important tomorrow and vice versa.

3.4.4 New food chain technologies and scientific progress

A driver that influences food safety in the dairy chain is new food chain technologies and scientific progress related to food production (van Duijne, 2010). For example, The Helmut Kaiser Consultancy (2009) estimates an increasing growth in the development of food and dairy related nano products. Nanotechnology can be applied to develop nanoscale materials, controlled delivery systems, contaminant detection and to create nano devices for molecular and cellular biology from how food is grown to how it is packaged.
An example of scientific progress is the development of predictive models. Mycotoxin models may help to identify regions with increased probability of aflatoxin contamination and/or help to mitigate a potential contamination with this hazard (Perrone *et al.*, 2014). This will help to target monitoring programs and more effectively use pesticides to prevent incidents. Models are also used to predict mastitis risk per cow per day, suggesting an increased or decreased sampling frequency (Chagunda *et al.*, 2006). Models can also be used to predict the effect of incidents. For example, kinetic models have been used to predict the effect of dioxins in potato by-products or the effect of grazing on PFOS-polluted soil on contaminant levels in the milk (Hoogenboom *et al.*, 2010; Van Asselt *et al.*, 2013).
The downside of scientific progress is that regulatory limits are sometimes adjusted based on better analytical techniques that allow for lower detection limits. However, in practice it may not always be possible to meet these low limits. As a result, alternative compounds need to be used, which may enhance other food safety hazards. For example, in case it is not possible to meet the residue limits for detergents and disinfectants, alternative detergents will be used that may be less effective against pathogens and/or are more toxic for humans.

3.4.5 EU governance and legislation

Changes in MRLs will affect the dairy chain, but also changes in regulations regarding management of dairy processing will have their influence on the presence of chemical and physical hazards. Changing EU policy, such as lifting of the milk quota will also affect the dairy industry. It is expected that this will stimulate the increase in farm size, but will also push the Dutch dairy sector towards more cost-effective production and consolidation (van der Spiegel *et al.*, 2012). Furthermore, stricter environmental legislation such as demands for reduced energy use, decrease of nutrient losses and greenhouse gas emissions will lead to innovations in animal breeding, animal nutrition, livestock waste management etc. (Demeter *et al.*, 2009). These changes will affect the dairy sector although it is uncertain to which extent and how.

3.5 Human health effects of the most relevant chemical hazards

3.5.1 Introduction

Based on literature review on chemical hazards that may occur in dairy products and subsequently cause human health effects and based on data obtained from monitoring programs (KAP and RASFF), four chemical hazards were seen as relevant for evaluating their effects on human health: dioxins (including dl-PCBs), aflatoxins, penicillins and tetracyclines. Although background levels of dioxins in dairy products are low, dioxins are a re-occurring problem in feed as recent incidents have shown. These incidents may result in human health problems. The same accounts for aflatoxins: background levels are below the MRLs, but incidents with aflatoxin B_1 in feed, such as the recent incident at the Balkan, may lead to elevated levels in milk. Due to problems with antibiotic residues, antibiotics use has decreased over the years. Furthermore, antibiotics use is strictly regulated and farmers need to comply with withdrawal periods in order to prevent the presence of residues. Nevertheless, RASFF notifications indicate that residues are still sometimes found in dairy products. Based on these considerations, these four chemical hazards were further explored for possible human health effects.

Exposure to residues of veterinary drugs, like penicillins and tetracyclines, in milk is rare in the Netherlands due to high compliance with withdrawal periods related to the use of these drugs in

ruminants (mostly through intramuscular administration). Moreover, an incidental low level of veterinary drug residues in milk present at farm level is usually non-detectable in milk processed in the milk factory (due to the continuous mixing of different milk batches). Based on the absence of data on residues of penicillins and tetracyclines in milk over the past four years in the Netherlands (see 3.3.2), no human health effects have been described for these hazards in this report.
Exposure to dioxins in the Netherlands via food is characterized by a chronic dietary exposure and sometimes an incidental exposure whereas exposure to aflatoxins is (usually) characterized by an incidental (acute) exposure. In 2004, RIVM performed a preliminary estimate of a burden of disease related to AFB_1 and dioxins (van Kreijl and Knaap, 2004). Since then only two scientific papers have addressed the burden of disease of these two contaminants. Therefore, in the following sections (3.5.2 and 3.5.3) the toxicity, exposure and the burden of disease of aflatoxins and dioxins are described.

3.5.2 Aflatoxins

Consumers are only incidentally exposed to aflatoxins and usually this occurs through low level contamination of peanuts and peanut products (like peanut butter). Exposure to aflatoxin present in milk is rare in the Netherlands but does occur incidentally in Europe (EFSA, 2014). In section 3.5.2.2 (theoretical) acute exposure scenarios to aflatoxin are described after an actual contamination of animal feed with aflatoxin. These scenarios are based on an incident that occurred in the Netherlands in 2013 with aflatoxin-contaminated maize fed to lactating cows.

3.5.2.1 Toxicity

Acute toxicity
AFB_1 causes acute hepatotoxicity in humans and experimental animals. Animal studies have found two orders of magnitude difference in the median lethal dose for AFB_1. The oral LD50 of AFB1 in rats ranged from 5.5 to 17.9 mg/kg bw (EFSA, 2007).
There have been a few reports of human poisoning with aflatoxins, most recently in two consecutive years in Kenya (EFSA, 2007). In April 2004, one of the largest aflatoxicosis outbreaks occurred, resulting in 317 cases and 125 deaths. Fifty-five percent of maize products from markets and maize vendors in the affected areas had aflatoxin levels above the Kenyan regulatory limit of 20 µg/kg.
Due to the import of contaminated maize intended for feed in 2013 in the Netherlands (see 3.5.2.2), RIVM has evaluated several acute toxicity studies in order to be able to calculate a bench mark dose (BMD), which is a dose that produces a defined response (called the benchmark response) of an adverse effect compared to background. A distinction was made between a non-carcinogenic effect in rabbits (liver damage) and an acute carcinogenic effect in mice (liver tumour). The lower limit of the confidence interval of the BMD (BMDL) for liver damage and liver tumour was respectively 5.8 and 59 µg/kg bw.

Chronic toxicity
Studies have consistently shown AFB_1 to be both genotoxic and carcinogenic in experimental animals (EFSA, 2007). Sufficient experimental evidence is also available for the carcinogenicity of AFM_1, the main metabolite of AFB_1 in milk. FAO considered the carcinogenic potency of AFM1 to be 10% of that of AFB1 (FAO/WHO, 2001).

3.5.2.2 Exposure

In March 2013, several alerts were reported in the RASFF system regarding maize imported from Eastern Europe, intended for use in animal feed that was contaminated with AFB_1. In the Netherlands, the contaminated maize was fed to lactating cows before all contaminated batches were withdrawn from the market. Consequently, at farm level, cow's milk became contaminated with AFM_1, the main metabolite of AFB_1. The NVWA declared that the contaminated milk was not brought on the market. Nevertheless, the NVWA asked the Front Office to estimate levels of AFB_1 and AFM_1 in milk and edible tissues (meat and liver) assuming that lactating cows were exposed to fictive levels of AFB_1 in contaminated feed. In addition, the NVWA asked to calculate the dietary risk associated with the corresponding levels of AFB_1 and AFM_1 in milk and edible tissues (RIVM-RIKILT FRONT OFFICE VOEDSELVEILIGHEID, 2013). Since no exact levels of AFB_1 in contaminated feed were known at that time, it was assumed that maximum EU levels in feed and milk were present or levels exceeding these

maximum levels by a factor of 10 and 100. The risk assessment was based on an acute exposure scenario through consumption of milk, meat and liver because the exposure period of lactating cows was short.
When feed was contaminated with AFB_1 at a level of 5 µg/kg (maximum EU level), the estimated concentration of AFM_1 in milk was 0.06 µg/kg; a bit higher than the maximum EU level of AFM_1 in milk which is 0.05 µg/kg (FrontOffice). Establishing the EC limits for AFB_1 in feed and in milk was not a full joint process. But both empirically and in the FrontOffice (RIVM-RIKILT FRONT OFFICE VOEDSELVEILIGHEID, 2013) model study these limits showed to match with each other. The estimated levels in milk correlated linearly with levels in feed. Therefore, a 10- or 100-fold increase of AFB_1 concentration in feed led to 0.6 and 6 µg AFM_1/kg milk, respectively.
A steady-state level in milk for an average Dutch dairy cow was already reached after three days of contaminated feed consumption meaning that concentrations have reached a plateau level. When a steady-state level was reached after consumption of feed contaminated with 5, 50 and 500 µg AFB_1 per kg feed and exposure was stopped, it would take respectively 1, 2 and 4 days to obtain levels of AFM_1 in milk below its maximum EU level in milk. In short, steady-state levels in milk are reached in a few days, but depletion to acceptable levels in milk is also a matter of days.
A so-called Margin of Exposure (MOE) was calculated for AFM_1, which is the ratio of the lower limit of an effective dose to the theoretical or estimated (dietary) exposure, thereby expressing the margin between the dose at which a small but measurable adverse effect can be observed and the (dietary) exposure. Taking Dutch milk consumption and three different AFM_1 contamination levels in milk (0.05, 0.5 and 5 µg AFM_1/kg) into account, the MOE was calculated compared to the dose with an acute effect in animal studies (a non-carcinogenic effect in rabbits (liver damage) and an acute carcinogenic effect in mice (liver tumour), see also section 3.5.2.1). For the non-carcinogenic effect, a minimum MOE of 100 is required to account for the default assessment factors of 10 for interspecies differences and 10 for intraspecies differences. Milk concentrations of 5 µg AFM_1/kg and a high consumption of milk (upper confidence level of the 95^{th} percentile) resulted in a MOE of 26 for children aged 2 to 6 years and 83 for the population aged 7 to 69 years. Milk concentrations of 0.5 µg AFM_1/kg or lower gave MOEs above 100.
For substances with a carcinogenic effect, EFSA proposed that an MOE of 10,000 or higher, based on a $BMDL_{10}$ from an animal study, would be of low concern from a public health point of view (EFSA, 2005). Milk concentrations of 5 µg AFM_1/kg and a high consumption of milk (upper confidence level of the 95th percentile) resulted in a MOE of 2700 for children aged 2-6 years and 8400 for the population aged 7-69 years. Milk concentrations of 0.5 µg AFM_1/kg or lower gave MOEs above 10000.
Summarised, whenever milk concentrations exceed the maximum EU level in milk more than 10-fold, acute health risks for the consumer could not be excluded because the MOEs that were calculated for these two types of acute effect were too small.

3.5.2.3 Burden of disease

A “burden of disease” analysis refers to the estimation of morbidity and/or mortality resulting from chemical exposure. Prerequisite to this approach, which is commonly known as the Disability-Adjusted Life Years (DALY) approach, is the availability of exposure data and corresponding toxicity data, the translation of toxicity in morbidity and mortality, and the attribution of a severity score to morbidity and mortality (“disability weight”). In the case of chemical hazards the available data usually refer to exposure and corresponding toxicity, with no information on morbidity, mortality and disability weight. In general, this (yet) limits the application of the DALY approach in the field of chemical exposure.
Van Kreijl *et al.* (2004) mention in their report that one additional case of cancer every sixteen years was related to an average daily intake of AFB_1 in the Netherlands of approximately 0.03 ng/kg bodyweight per day. Assuming cancer to result in premature death with an average loss of five life-years, this is the equivalent of approximately 5 x 1/16 = 0.3 DALYs/year. To put this number in perspective: van Kreijl *et al.* estimated 1500 – 2000 DALY’s for the total of chemicals and allergens.
Liu *et al.* (2010) mention a prevalence of 0.04 cancer cases per 100.000 persons in one year for Western Europe corresponding with an exposure to AFB_1 of 4 ng/kg bw/day. In 2013-2014 RIVM has carried out a mycotoxin dedicated total diet study in the Netherlands (Sprong *et al.*, submitted). Dietary exposures (50^{th} and 95^{th} percentile) to aflatoxins were calculated for Dutch children aged 2-6 years and the Dutch population aged 7-69 years. The average dietary exposure (50^{th} percentile) to AFB_1 for children aged 2-6 years and the population aged 7-69 years varied from 0 to 0.9 and from 0 to 0.4 ng/kg bw/day, respectively. Extrapolating the prevalence of 0.04 cancer cases per 100.000 to

a current Dutch population size of approximately 14 million persons within the population aged 7-69 years results in maximum of 0.4/4 x 0.04 x 140 = 0.56 cancer cases/year. For reasons of comparison, assuming the same loss of live-years as has been suggested by Van Kreijl (2004), this would result in 0.56 x 5 = 2.8 DALYs/year.

3.5.3 Dioxins

Due to the fact that dioxins (term used here includes both dioxins and dl-PCBs) occur in food products containing animal fat (milk, eggs, meat and fish) and, to a lesser extent, in food products containing vegetable oil, consumers are exposed to dioxins frequently via food, almost on a daily basis (depending on the diet). Therefore, the 'normal' exposure to dioxins is characterized by a chronic exposure. The contribution of milk (fat) to the overall dioxin exposure will be described in section 3.5.3.2. The consumer may be additionally exposed to dioxins when, due to an incident, dioxins levels in milk are elevated, see also section 3.5.3.2.

3.5.3.1 Toxicity

Acute toxicity
Several LD50 values have been reported: in mice: 180 – 2600 µg/kg bw; rat: 25 – 3000 µg/kg bw; rhesus monkey: 50 – 70 µg/kg bw; guinea pig: 0.6-2.1 µg/kg bw (JECFA/FAO/WHO, 2002).
The following acute effects have been observed after 13 weeks of exposure (JECFA/FAO/WHO, 2002):

- Hepatic porphyria (mouse): LOAEL of 45 ng/kg bw/day for 2,3,7,8-TCDD.
- Decreased body organ weight (rat): NOAEL of 10 ng/kg bw/week for 2,3,7,8-TCDD.
- Hepatic EROD induction (rat): NOAEL 0.35 ng/kg bw/day for 2,3,7,8-TCDD.

Chronic toxicity
In 2001, EFSA's predecessor the Scientific Committee on Food (SCF) determined a provisional Tolerable Weekly Intake (pTWI) of 14 pg TEQ/kg bw per week (SCF, 2011). This pTWI was derived on the basis of reproductive toxicity observed in experimental animals, i.e., the disturbance of the development of the male reproductive system, in particular sperm formation. In deriving the pTWI, this toxicity was extrapolated to man.
In the derivation of the pTWI a "body burden approach" was used. Intake below this pTWI ensures that the chronic daily exposure to dioxins from food does not lead to an 'internal' level that might induce the above-mentioned reproductive toxicity.
Finally, the pTWI is deliberately defined on a weekly basis. Within this time frame the pTWI thus corresponds with an average daily exposure of 2 pg TEQ/kg bw/day.
Recently, the Environmental Protection Agency (EPA) in the US (2012) derived a "Reference Dose" (RfD) of 0.7 pg TEQ/kg bw per day (US EPA, 2012). This health based guidance value is based on two epidemiological, human studies. In concordance with SCF's derivation of the pTWI the epidemiological studies indicated reproductive toxicity and thyroid toxicity, as the most sensitive non-carcinogenic effects of dioxins in humans.

3.5.3.2 Exposure

In 2014, the chronic dietary exposure to dioxins was estimated for two Dutch populations: young children (2-6 years) and persons aged 7-69 years (Boon *et al.*, 2014). These two populations were addressed because two separate food consumption databases were available for these population groups. To assess the chronic dietary exposure to dioxins (including dl-PCBs), consumption data were linked to dioxin concentrations analysed within the Dutch monitoring programme on dioxins, dioxin-like PCBs, indicator PCBs and flame retardants in primary agricultural products (Van Leeuwen, 2015b), as well as the one on contaminants in Dutch fish and fishery products (van Leeuwen, 2015a).
According to this exposure assessment, milk (fat) contributed most to the chronic dietary exposure to dioxins: 38% in young children and 34% in persons aged 7-69 years. These percentages can be used to assess the exposure to dioxins due to the consumption of milk (fat) based on the reported exposure estimates for the whole diet (including also the consumption of e.g. eggs, meat and fish). The median exposure to dioxins via the consumption of milk (fat) ranged in young children from 0.30 TEQ pg/kg bw per day in 6-year olds to 0.38 TEQ pg/kg bw per day in 2-year olds. Since the exposure declined with age and the exposure in the young children at the highest estimated level (99^{th} percentile (P99))

did not exceed the relevant health based guidance value for dioxins (see section 3.5.3.1), the exposure in persons aged 7-69 years was not estimated per age, but an overall exposure estimate for the whole age range was calculated. The median exposure to dioxins for this age group via the consumption of milk (fat) could be calculated to equal 0.17 pg TEQ/kg bw per day. Corresponding dioxin exposure estimates via the consumption of milk (fat) for the P99 level of exposure were 0.57 pg TEQ/kg bw per day for 6-year olds, 0.76 pg TEQ/kg bw per day for 2-year olds and 0.44 pg TEQ/kg bw per day for persons aged 7-69 years.
It should be noted that the estimated contribution of milk (fat) to the dioxin exposure via the whole diet was based on the total exposure distribution. At the upper tail of the exposure distribution, the contribution of food products to the exposure may be different. The contribution to the upper tail of the exposure distribution was, however, not reported in Boon *et al.* (2014), making a more precise estimation of the P99 level of exposure via the consumption of milk (fat) not possible.

3.5.3.3 Burden of disease

With respect to the carcinogenicity of dioxins Hänninen (2014) mentions an Environmental Burden of Disease (EBD) of 10794 DALYs per 1.000.000 people. Given a current population size of 16.9 million in the Netherlands this results in 16.9 x 10794 = 182419 DALYs. Approximately 2.1% of the EBD results from dioxin exposure, i.e. 227 DALYs per million, or a total of 3831 DALYs.
This calculation is based on the dietary dioxin exposure in the Netherlands in 2004. However, it cannot be deduced from this publication if this means that the total of 3831 DALYs can be interpreted as 3831 DALYs/year. Part of the problem is the fact that dioxins accumulate in the human body over time and it is uncertain whether this EBD is based on an acute or chronic carcinogenic effect of dioxins.
In 2004, RIVM performed a preliminary burden of disease assessment on dioxins and dioxin like PCBs. At that time no burden of disease related to *non*-cancer dioxin effects was attributed (van Kreijl and Knaap, 2004). Currently, within WHO's Foodborne Disease Burden Epidemiology Reference Group (FERG) a DALY approach has recently been developed for the non-cancer effect of dioxins (Zeilmaker *et al.*, in preparation).

3.6 Possible intervention measures

3.6.1 intervention measures at the farm

At primary production, GAP (Good Agricultural Practice) is established, which is a good practice code developed for practices at farm level. At global level, Global GAP, also known as the Integrated Farm Assurance Standard (IFA), can be used, which consists of requirements on good agricultural practices demanded by European retailers (obligated and recommended). These requirements are mainly focused on food safety and traceability, but also on animal welfare, environment, and workers' health, safety and welfare. Global GAP includes Integrated Crop Management (ICM), Integrated Pest Control (IPC), Quality Management System (QMS), and HACCP (www.globalgap.org).
An important route for chemical hazards to the animal (and its milk) is via feed and water. The former Product Board for Animal Feed published a report on measures for producing safe feed with a good quality at farm level (Productschap Diervoeder, 2005). Some of these measures will overlap with requirements in GAP or Keten Kwaliteit Melk-KKM (Foundation for Quality Assurance of Farm Milk in the Dutch Dairy Chain). Details on the measures can be found in the report mentioned; we will only give a summary here:

> It is important that all feed and raw feed materials are traceable from buying (or growing) until feeding. Feeding materials and products, both from own cultivation and from purchase, should fulfil legal standards. Feed should be bought from Good Manufacturing Practices (GMP+) producers. Transport of feed (materials) should comply with the GMP code for transport. Transporting trucks should be cleaned and disinfected. Different feed materials should not come in contact with each other, and also not with other materials like manure, medicines or cleaning and disinfection materials. Conditions of storage should be such that decay, growth of fungi and cross contamination is not possible. At the entire farm and during all processes on the farm a high level of hygiene should be kept. Damage of the wrapping foil of silage bales, for example by pets, rodents

or birds, should be prevented. The process of ensilaging should be carried out adequately. Heating of the silage (fungal growth) must be prevented. Feeding systems and water/drinking systems should be checked regularly for proper functioning. Furthermore, drinking water for the animals must be of good quality. In case of calamities on the farm or in the neighbourhood it is important to estimate the risks for feed and feeding materials as well as for the grazing cows.

Apart from a proper feed management, farmers should comply with withdrawal periods in case veterinary drugs are used and discard milk of treated cows in order to remain below the MRLs as established in (EU) 1881/2006. Furthermore, farmers should be aware of the condition of the soil used for grazing by animals and should for example not use sewage sludge on their land (Nag, 2010a; Silanikove *et al.*, 2010).
In the Netherlands, food safety is controlled within KKM. Dairy farms with KKM certification comply with the specified criteria for hygiene, but also for animal health, animal welfare, nourishment, hygiene and environmental aspects. These criteria have been based on Dutch and European legislation, but are usually more stringent. Criteria are set for veterinary treatment, such as compliance to withdrawal periods after administration of veterinary drugs, but also for cleaning and disinfection. KKM is a joint initiative of Dutch dairy industries and the dairy farmers association. Dairy farms who participate in KKM are regularly inspected. Milk samples are taken and quality checks are established (cell counts (associated with mastitis), freezing point (water content of the milk), pH value of the fat, bacterial counts, antibiotics residues, butyric acid bacteria and visual purity). Furthermore, milk is monitored for chemical hazards such as dioxins, PCBs, aflatoxin, heavy metals, and traces of pesticides (Productschap Zuivel, 2015). Moreover, farms are audited by the Laboratory for Quality Assurance in Agri-Food (QLIP) by visiting the farms and checking for compliance with the pre-set criteria in KKM (Qlip, 2015). For goat milk production, a similar approach is used based on the KKM-system and described in the *Handboek KwaliGeit*. This handbook describes measures and criteria for dairy goat farmers on hygiene, the use of veterinary medicines, animal health and welfare, feed and drinking water and milking and cooling (VKGN, 2010).

3.6.2 Intervention measures for processing

Food safety during processing can be secured by implementing basic requirements and a HACCP-plan or hygiene codes. Basic requirements are described in Good Practices, like GMP (Good Manufacturing Practice) and GHP (Good Hygienic Practice). GMP is the most common good practice code (IFST, 2013). It consists of fundamental principles, procedures and means needed to design the basic environmental and operating conditions for food production (Van der Spiegel, 2004). Guidelines are prescribed on aspects like buildings and facilities, personnel, equipment, production and process control (ECFR, 2014). GHP is a good practice code specifically focused on hygiene. The guidelines of GHP describe hygienic aspects, like cleaning and disinfection, health and hygiene of personnel, pest control, and training. Although GHP primarily focuses on microbial hazards, it also describes how to prevent physical and chemical hazards entering the food product. For example, detergents and disinfectants need to be stored properly, separate from food products, and food products need to be covered to prevent entrance of chemical and physical hazards (Codex Alimentarius, 1969, 2004).
Large food producing companies work according to HACCP systems. For smaller companies, these HACCP systems are costly to implement and, furthermore, knowledge and expertise are usually lacking for establishing such systems. Therefore, hygiene codes have been established, which are practical guidelines for implementing HACCP in certain food production systems (FASFC, 2012). Farmers who process their milk into dairy products usually work according to these hygiene codes. In the Netherlands, two hygiene codes have been developed for the dairy sector: *Hygiënecode voor Boerderijzuivelbereiding* (Hygiene code for processing at the dairy farm) available at: www.boerderijzuivel.nl and *Hygiënecode voor de kleinschalige detailhandel in zuivel* (Hygiene code for small-scale retail business in dairy) available at: www.gemzu.nl. These codes describe precautionary measures to prevent microbial, chemical and physical hazards.
In general, chemical hazards can be prevented by a good quality control of raw materials entering the production process and properly performing cleaning and disinfection. Physical hazards can be prevented by good maintenance of the equipment and by applying visual inspections.

3.7 Trends in the dairy chain

Based on interviews with scientific experts and experts from the dairy industry, dairy organizations and dairy farmers, the upcoming trends for the coming 10 years were identified. Furthermore, published reports on this topic were consulted for input on changes in the dairy sector. The changes foreseen at the various steps in the dairy chain are described below.

3.7.1 Animal feed

It is expected that dairy production will increase globally leading to increased demands for animal feed. Furthermore, as a result of climate change, higher mycotoxin occurrence is expected in animal feed. This results in a higher demand for mycotoxin-free feed. Finally, there is a trend towards more GMO-free feed. These factors may cause scarcity in certain areas and thus shifts to either other trade partners, other regions or other feed ingredients. This may lead to a more complex and dynamic feed chain with increased number of trade partners, with consequences for food safety as the chain will become less transparent. In order to secure the feed supply, more feed materials will be grown within Europe resulting in new or other grain varieties (NZO, 2015), such as lupine, which may contain the mycotoxin phomopsin (EFSA, 2012a). Furthermore, it is expected that alternative protein sources will be used, such as from insects or algae. It is unclear how these new feed materials will affect feed and food safety.
Increased demands for organic milk will lead to higher demands for organic feed. As a result feed may be obtained from less suited areas (e.g. with high levels of environmental contaminants or a high probability of mycotoxin presence).
Another trend affecting feed materials is the increased production of biofuel. Some of the raw materials used may contain chemical hazards. For example, maize may be contaminated with mycotoxins, sorghum may contain plant toxins and castor beans (used in oil production in Africa) contain the toxic ricin. Due to the production process, chemical hazards present in the raw materials for biofuel will be concentrated in the by-products such as Dried Distillers Grains with Solubles (DDGS) that are used in the feed industry (van Asselt *et al.*, 2011).

3.7.2 Dairy farm

The pre-dominant trend foreseen for the coming 10 years is the further intensification of the dairy sector both for cow and goat milk. This is caused by several factors. First of all the milk quota was abolished on 1 April 2015, which allows producers of cow milk to increase their production (LTO Nederland, 2011; Rabobank, 2015). It is expected that the cow milk production in the Netherlands will increase with 2% per year until 2020. Secondly, the world-wide population is growing with around 1% per year and is becoming wealthier, which causes an increased demand for animal products, such as dairy products. Upcoming countries in Asia and Africa will not be able to fulfil this increasing demand for dairy products (NZO, 2015). As a result of the abolishment of the milk quota, price fluctuations will increase. As cost prices are high in the Netherlands, profit margins are small. Only large and strong companies will be able to remain in business under these increased price volatility. This will consolidate the sector. The advantage of further intensification is that farmers will be able to invest in their farm and will become more aware of food safety (NZO, 2015). Another expected effect of the price volatility is an increased number of farms with various livestock species (pigs and chicken next to cows), which will enable farmers to respond to price fluctuations. This development may affect the occurrence of animal diseases.
Within the Netherlands, there is an increased awareness for animal welfare and sustainability. Farmers who will enhance their production will also need to take these issues into account (LTO Nederland, 2011; NZO, 2015; Rabobank, 2015), for example by investing in sustainable stables. Such investments contribute to a higher average age of the cow and increased animal health (NZO, 2015; Rabobank, 2013). Sustainability measures may also negatively affect food safety, for example by the implementation of recycling at the farm or the use of alternative materials for which effects on the milk quality and safety are unclear.
Furthermore, it is expected that the educational level of Dutch farmers will continue to increase. This will have a positive effect on food safety (expert opinion).

3.7.3 Milk processing

Increased global demands for dairy products will result in increased trade in dairy products, predominantly products with a long shelf-life such as milk powder, butter and to a lesser extent cheese. Dairy processors have to be flexible and be able to adapt their product mix based on global supply and demand (NZO, 2015). Within the goat milk processing there is a growing diversification of goat products, ranging from milk powder to hard cheese and fresh cheese (with or without certain flavourings).

It is expected that the dairy chain will become simpler as traders are increasingly buying factories, which will shorten the dairy chain from farmer to consumer. As a result traceability in the Dutch dairy chain will grow (expert opinion).

Furthermore, there are consumer trends affecting dairy processing. It is expected that organic farming will increase over the years. Additionally, there is a trend towards raw and slow food with increased demands for raw milk. This may affect microbial safety of the milk. There is also an increased demand for goat milk causing increased goat milk processing. However, it is expected that goat milk will remain a marginal product compared to cow milk production, especially after the abolishment of the milk quota (expert opinion).

4 Conclusions and recommendations

4.1 Conclusions

At various points within the dairy chain, chemical and physical hazards may be introduced (Figure 10). This section describes the conclusions regarding the chemical and physical hazards that may be encountered in the dairy chain.

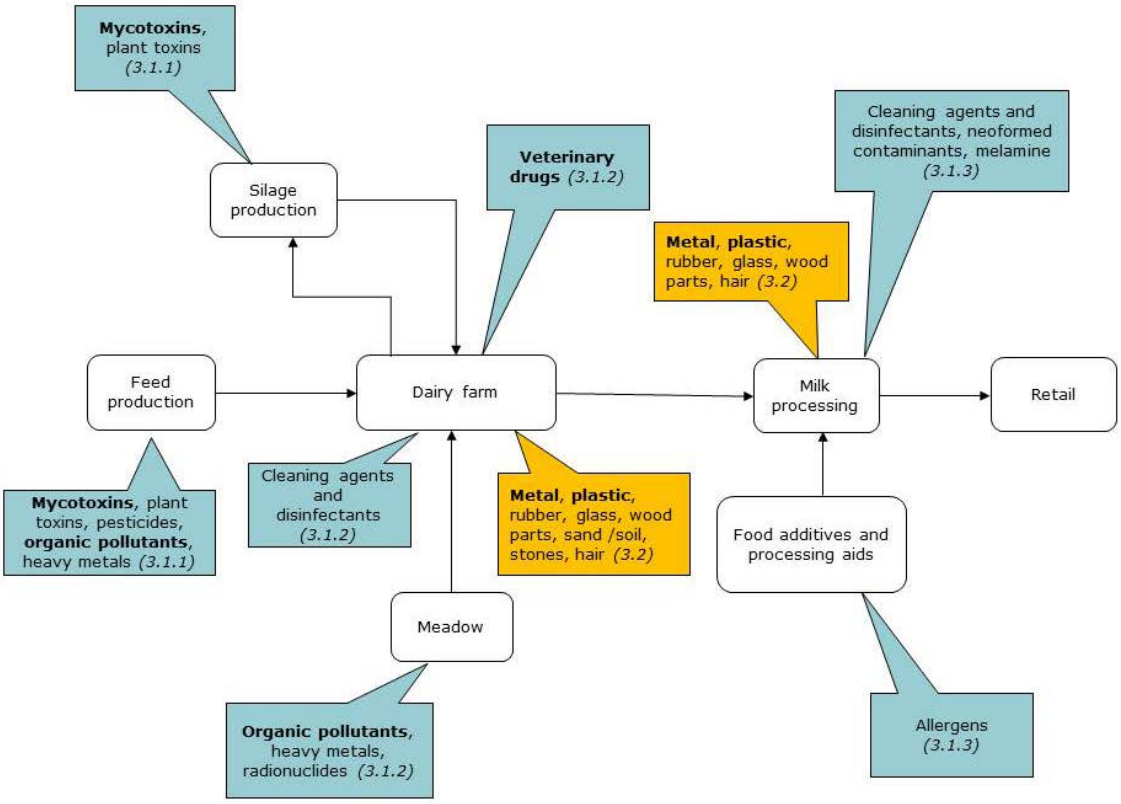

Figure 10 *Overview of chemical (blue) and physical (yellow) hazards introduced within the dairy chain. The most important chemical and physical hazards are depicted in bold. The numbers refer to the section in the report that provides information on these hazards.*

Physical hazards most frequently encountered in RASFF were metal, glass and plastic particles. Within the Netherlands, glass is hardly used within the production process and thus metal and plastic particles are seen as the most important physical hazards. However, as indicated previously, dairy producers have an incentive to prevent the presence of physical hazards and, therefore, these hazards are covered well in HACCP plans and controlled accordingly.
A recent study identified the risks of various hazards in dairy products based on occurrence of the hazard, severity of the hazard and possibilities of detecting the hazard. This revealed that microbiological hazards give the highest risk followed by chemical hazards. Physical hazards gave the lowest risks for dairy products (Kurt and Ozilgen, 2013).

Based on literature review, monitoring data (RASFF and Dutch monitoring data) and expert opinion, the following chemical hazards are seen as the most important for dairy products:

- Aflatoxin M_1:
  Human exposure to aflatoxins is only incidental and usually through the consumption of nuts. However, the incident in the Balkan in 2013 showed that contaminated feed may result in elevated AFM_1 levels in milk. Aflatoxins may cause chronic and acute effects in humans. When milk concentrations exceed the maximum EU level more than 10-fold, acute health risks for the consumer cannot be excluded.
- Environmental contaminants (primarily dioxin and dioxin-like compounds):
  Dioxins have been reported in RASFF to be present above legal limits in feed. As cows may take up these compounds, they can be transferred into the milk. Dioxins occur in food products containing animal fat (milk, eggs, meat and fish) and consumers are exposed to these compounds almost daily. Milk contributes most to this daily exposure. Dioxins accumulate in the body and may cause human health problems on the long term. Thanks to the current quality and monitoring programs, the intake estimated based on dioxin levels in milk and milk products remains below the established pTWI.
- Veterinary drugs:
  In the RASFF database, antibiotics residues are sometimes reported above legal limits. These results were, however, not confirmed in the Dutch monitoring program. Furthermore, when the KNMvD guideline is followed, antibiotic levels are expected to decrease further in the Netherlands. The focus should thus be on dairy products imported from abroad.

Most chemical hazards are introduced at the farm either via the feed or administered to the cows in the form of veterinary drugs. It is, therefore, important to control the feed provided to the cows. For this purpose quality assurance schemes have been developed, such as GLOBAL GAP describing Good Agricultural Practices. In the Netherlands, most farmers are certified in the KKM-system. This system describes various criteria in order to produce safe dairy milk of a good quality.
Such quality assurance systems have to meet future developments. The most important drivers that may affect food safety are global economy and trade, and climate change. Further globalization may hamper the transparency in the dairy chain, especially in dairy feed. This may facilitate fraudsters in the global dairy chain to take actions that will increase their profit but may have adverse effects on food safety (as was the case in the melamine incident). Climate change is expected to affect the presence of AFM_1 in milk, but may also have an impact on animal diseases (and subsequent antibiotics use) and the presence of plant toxins.
The most important development is the recent abolishment of the milk quota, which will result in a further intensification of the dairy chain and higher productions of milk volumes. This may have positive effects for food safety as farmers will invest to improve their farm and will be more aware of possible food safety issues. However, an increased livestock population and multiple species at the farm may result in a raise in the occurrence of animal diseases at farm level and subsequently more veterinary drugs use. The abolishment of the milk quota will also have an effect on dairy processing as the production of products with a long shelf life (butter, milk powder and cheese) is expected to increase resulting in higher export volumes. More production may lead to a pressure on the market of animal feed, which may have its consequences for the quality and safety of these products.

4.2 Recommendations

The majority of chemical and physical hazards are controlled by the implementation of quality assurance systems at the farm and the dairy factory. Both industry and government have to make efforts in order to ensure that food safety remains at a high level. The government should invest in knowledge developments towards future trends that may affect food safety (e.g. the application of nanoparticles or effects of climate change on food safety). Furthermore, a proper food safety control as performed by the NVWA is essential. However, the NVWA cannot control all food safety hazards at the different stages of the dairy chain and, therefore, inspections are organized on a risk basis, focusing on the most important food safety hazards at the main steps of the dairy chain.

Based on the current hazard analysis, it is recommended to focus monitoring on:

- Aflatoxins in feed and imported dairy milk
- Dioxins (including dl-PCBs) in feed and/or dairy milk at farm level
- Veterinary drugs in dairy milk at farm level, especially from imported milk

As most chemical hazards are introduced through the feed and as future developments may have consequences on the supply of good quality feed products, it is advised to focus monitoring at the farm level and more specifically on the feed sector. At farm level, changes in production systems as a result of increased awareness for sustainability and animal welfare should be followed closely in order to evaluate its consequences for food safety.
In order to maintain the current food safety level in the dairy sector, the other chain steps should not be ignored and some level of inspection should also be arranged for steps further along the dairy chain. Furthermore, imported products from outside the EU may need increased monitoring programs, especially for veterinary drugs and AFM_1 as these compounds have been reported above the legal limit in the RASFF database.
In this research, chemical and physical hazards in the dairy chain were studied for milk produced by cows, goat and sheep. Most information was available for dairy cows; information for goats and sheep was limited. Therefore, it is recommended to allocate research budget in order to establish more information on chemical and physical hazards for goat and sheep milk. However, it must be noted that goat milk and especially sheep milk represent only a fraction of the total volumes of dairy products produced. Another data gap that is the lack of toxicological information for some chemical hazards, such as the Maillard products CML and AGEs, and the printing ink ITX.

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