UNIVERSITÀ DEGLI STUDI DI PADOVA
Dipartimento Territorio e Sistemi Agro-forestali Department of Land, Environment Agriculture and Forestry

Corso di laurea magistrale/Second Cycle Degree (MSc) in Food and Health

Arsenic in Food: Chronology of Development of Rules and Regulations

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ANNO ACCADEMICO/ACADEMIC YEAR 2022/2023

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I hereby declare that I have read and understood the “Anti-plagiarism rules” approved by the Council of the Department of Department of Territory and Agro-Forestry Systems
and I am aware of the consequences of making false statements. I declare that this thesis has not been previously submitted – either fully or partially – for fulfilling the requirements of an academic degree, whether in Italy or abroad. Furthermore, I declare that the references used for this work – including the digital materials – have been appropriately cited in the text and in the “References” section.

Signature ....

To my loving parents, partner, and mentors

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Rebecca Zgheib.

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ABSTRACT

This thesis explores the pervasive issue of arsenic contamination in food, focusing on its impact on public health within the European Union (EU). It begins with a comprehensive introduction to arsenic, covering its properties, common uses, various exposure routes, and its presence in the environment. Notably, the thesis examines arsenic's occurrence in drinking water, air, soil, and sediments, along with its presence in food items. The toxicity of arsenic to humans is also scrutinized, encompassing both acute and chronic health effects.

The research's objectives and aims are detailed, emphasizing the significance of a thorough understanding of arsenic contamination in the food supply chain, with a specific focus on the regulatory framework within the EU.

The thesis further delves into the domain of food contaminants management in the EU. It investigates the definition of 'Food' under Regulation EC 178/2002, elucidating its scope and exclusions, thereby providing insight into the boundaries of EU food safety regulations. The role of risk analysis in EU food safety and contaminant regulations is highlighted, underscoring the importance of robust safety measures. Additionally, the study examines the pivotal role played by the European Commission in regulating food safety and contaminants within the European Union. Furthermore, it explores the contributions of the European Food Safety Authority (EFSA) in assessing and mitigating food contaminants. The research also considers the influence of the Food and Agriculture Organization (FAO) and the Joint Expert Committee on Food Additives (JECFA) in shaping food safety regulations and conducting contaminant assessments.

In summary, this thesis provides a comprehensive analysis of arsenic contamination in food and its intersection with EU food safety regulations. By shedding light on these critical aspects, the research aims to contribute to the improvement of food safety standards and the safeguarding of public health in the European Union.

Keywords: arsenic, contaminants, regulations, European Union, food safety.

Table of Contents

Abbreviations

BSE	Bovine Spongiform Encephalopathy
CA	Codex Alimentarius
CCCF	The Panel on Contaminants in the Food Chain
EFSA	European Food Safety Authority
EU	European Union
FDA	Food and Drug Administration
JECFA	Joint FAO/WHO Expert Committee on
ML	Maximum limit
PCDD/F	Polychlorinated dibenzodioxins and furans
PTWI	Provisional Tolerable Weekly Intake
UK	United Kingdom
WHO	Word Health Organization
WTO	World Trade Organization

Chapter 1

Introduction

1.1 Contaminants and restricted substances

Besides the raw material intentionally incorporated by the producer into a food item, a wide range of substances can unintentionally enter the end product before it reaches the consumer. These substances might originate from various sources, such as agricultural practices, environmental pollution, storage and transportation, or even arise during food processing. Contaminants can be categorized into two groups: those that are avoidable, which encompass veterinary drugs, pesticides, and materials used in food contact, and those that cannot be avoided, including environmental agents (like PCBs, dioxins, and heavy metals), radioactivity, natural toxins, and compounds that form during food processing (Corona et al., 2020). The Council Regulation (EEC) No 315/93[1] laying down Community procedures for contaminants in food provides the definition for a contaminant as follows: 'Contaminant' means any substance not intentionally added to food which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination. Extraneous matter, such as, for example, insect fragments, animal hair, etc, is not covered by this definition'.

Article 1

1. This Regulation concerns contaminants contained in food.

'Contaminant' means any substance not intentionally added to food which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination. Extraneous matter, such as, for example, insect fragments, animal hair, etc, is not covered by this definition.

Figure 1. Figure representing the definition of contaminants from Article 1 in Council Regulation No 315/93

[1] Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food, OJ L 37, 13.2.1993, p. 1–3.

Environmental contaminants come from a variety of sources, are ubiquitous in the environment, and can be found in food. Setting food standards is becoming increasingly important within the European Union and around the world to protect consumer health and avoid trade barriers(Schneider et al., 2007).

In order to ensure food safety on a worldwide basis and prevent trade barriers for food products across nations, the internationally recognized maximum values for environmental contaminants in food, set by the Codex Alimentarius (CA) are becoming increasingly essential. In accordance with the (the World Trade Organization) WTO's "Agreement on Sanitary and Phytosanitary Measures", CA maximum values have been accepted by the WTO to satisfy hygienic standards" (SPS Agreement)(Schneider et al., 2007).

Accordingly, in the General Standard for Contaminants and Toxins in Food and Feed, CXS 193-1995, the Codex Alimentarius defines a contaminant as follows: "Any substance not intentionally added to food or feed for food producing animals, which is present in such food or feed as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or feed, or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter"[2]. For instance, the acceptable maximum levels or guideline values for contaminants and naturally occurring toxicants in food and feed are established and supported by the Codex Committee on Contaminants in Food (CCCF). Additionally, it creates priority lists for contaminants and naturally occurring toxicants for the Joint FAO/WHO Expert Committee on Food Additives' risk assessment (JECFA)[3].

Correspondingly in the European Union (EU), a similar development occurred. Unfortunately, a number of food safety crises, including Bovine Spongiform Encephalopathy (BSE), dioxins, high pesticide and antibiotic content in several foods, high nitrate content, presence of coliforms in drinking water, use of Sudan Red 1, and acrylamide formation, have occurred within the framework of the EU over the past 15 years, resulting in significant losses in terms of both humans' lives and financial resources(Arvanitoyannis, 2008). These crises have made

[2] Commission Regulation (EC) No 194/97 of 31 January 1997 setting maximum levels for certain contaminants in foodstuffs, OJ L 31, 1.2.1997, pp. 48-50.

[3] Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food, OJ L 37, 13.2.1993, p. 1–3.

the EU citizens more alert but have also significantly increased the EU legislative task to attempt to take preventive measures instead of correction measures. One of the top priorities was the implementation of safety and hygiene directives[4]. The EU's integrated approach to food safety seeks to ensure high standards of food safety, animal health, animal welfare, and plant health within the EU through coordinated farm-to-table measures and sufficient monitoring, all while preserving the internal market's efficiency(Arvanitoyannis, 2008).

Moreover, the EU has made significant advances in harmonization in regard to the control of environmental contaminants in food. Heavy metals (lead, cadmium, and mercury), polychlorinated dibenzodioxins and furans (PCDD/F), and benzo[a]pyrene as a reference substance for polycyclic aromatic hydrocarbons all have common maximum values across the EU. Currently, more maximum levels are being studied (Schneider et al., 2007). Conversely, other contaminants have maximum levels that are only applicable nationally. For instance, in Spain, the maximum permitted concentration of arsenic only applies to fruits, vegetables, and seaweed, whereas in the United Kingdoms (UK) it extends to all food (Berg & Licht, 2010).

As a matter of fact, the legal foundation for food contamination is set down in Council Regulation (EC) no 315/93[5]. The Commission Regulations 194/97[6], as amended, established Maximum Limits (MLs) for trace elements and other contaminants in specific foodstuffs and other pertinent regulations, such as measures for the control (Berg & Licht, 2010). According to council Regulation (EC) No 315/93 of 8 February 1993: “Contaminant’ means any substance not intentionally added to food which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination. Extraneous matter, such as, for example, insect fragments, animal hair, etc., is not covered by this definition”.

[4] Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council, OJ L 131, 17.5.2019, p. 1–17.

[5] Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food, i*n* OJ L 37, 13.2.1993, pp. 1-3.

[6] Commission Regulation (EC) No 194/97 of 31 January 1997 setting maximum levels for certain contaminants in foodstuffs, OJ L 31, 1.2.1997, pp. 48-50.

Indeed, many countries have regulations[7,8] so that foods sold can't be contaminated to the extent that they can cause disease or poisoning. National legislation may be limited to such general rules or more specific. Laws are often accompanied by a maximum limit (ML) or a guideline for the tolerable concentration of contaminants in a single food or group(Berg & Licht, 2010).

It should be noted that chemical contamination might denote the presence of chemicals in areas where they shouldn't be present or in concentrations that are higher than those considered to be safe. The foods might also be contaminated with chemicals but whose concentration is under maximum tolerable limits(Faille et al., 2018). One of the primary causes of food contamination that is connected to outbreaks of foodborne illness is chemical hazards(Rather et al., 2017). The European Food Safety Authority (EFSA) Panel on Contaminants in the Food Chain (CONTAM) is responsible of offering expert scientific guidance on contaminants such mycotoxins, natural toxicants, and residues of illegal substances as well as contaminants in the food chain[9]. Apart from this, the Codex Committee on Contaminants in Food (CCCF) defines and supports permissible maximum levels or guideline levels for contaminants and naturally occurring toxicants in food and feed. Additionally, it creates priority lists of contaminants and naturally occurring toxicants for risk evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)(General Standard for Contaminants and Toxins in Food and Feed Cxs 193-1995, 1995).

Table 1. Product legislation

Legislative approach	Example
Free	conventional ingredients with a history of safe use in the EU
Conditional	additives supplements genetically modified foods (other) novel foods

[7] Regulation (EC) No 852/2004 of the European parliament and of the council of 29 April 2004 on the hygiene of foodstuffs, OJ L 139 30.4.2004, p. 1.
[8] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1–24.
[9] https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/contam

Restricted	residues of pesticides residues of veterinary drugs unavoidable contaminants radioactivity
Banned	hormones prohibited substances (e.g. nitrofurans, chloramphenicol, etc.)

An example of this is arsenic, which is one of the contaminants that have been subject to European Union intervention (setting of maximum levels)[10]. Humans are at serious risk from arsenic poisoning, which can result in a number of health issues. The potential ingestion of water or food polluted with elevated arsenic concentrations has led to the identification of certain "hotspots" almost everywhere in the world, endangering the local populations(Khosravi-Darani et al., 2022).

1.2 Legislation

Contaminant standards should be established for multiple purposes, particularly to reduce consumers' exposure to contaminants and to facilitate the free movement of products. In the European Union (EU), the fundamental principles governing the control of chemical contaminants in food are outlined in Framework Regulation 315/93[11]. This regulation commences in the initial section of Article 1, providing a definition for the term 'contaminant'. This identical definition is also employed in the Codex general standard for contaminants and toxins in food and feed (Corona et al., 2020).

Utilizing this definition reveals that the notion of a contaminant encompasses two out of the three typically separated types of hazards within food law, namely chemical hazards and specific biological hazards (i.e., substances generated by microorganisms). Physical hazards and biological hazards originating solely from microorganisms are not encompassed within the contaminant definition. In Framework Regulation 915/93, it is explicitly stated that the

[10] Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (Text with EEA relevance), *OJ L 119, 5.5.2023, p. 103–157.*
[11] Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food, OJ L 37, 13.2.1993, p. 1–3.

regulation does not pertain to contaminants governed by more specialized regulations within the Union. These regulations include, for instance, pesticides, veterinary drugs, and materials intended for food contact, all of which are addressed by distinct, specific regulations (Corona et al., 2020).

1.3 Setting legal limits

Regulatory thresholds are denoted by various terms, depending on the context. For individual products, these terms may encompass 'maximum residue levels' or simply 'maximum levels,' often expressed as the highest permissible quantity per gram or liter of the product. When establishing particular contaminant levels in legal frameworks, two critical factors come into play: necessity and safety (Corona et al., 2020).

The necessity level is determined by what is considered unavoidable when adhering to recommended best practices. Anything that can be reasonably avoided should indeed be prevented and is not permitted on the market. Conversely, safety relies on a risk assessment in which toxicology holds a significant role, and the acceptable threshold is determined by the lower of the two levels (Corona et al., 2020).

The consideration of both necessity and safety when establishing legal limits is evident in the definition of maximum residue levels (MRLs) for pesticides as outlined in Regulation (EC) no 396/2005[12]. MRL, in this context, signifies the highest allowable concentration of a pesticide residue in or on food or feed, established with reference to good agricultural practices and the minimal consumer exposure required to safeguard vulnerable individuals. Consequently, MRLs for pesticides are primarily established based on necessity, aiming to achieve the desired pesticide effects in agricultural practices while minimizing consumer exposure. Nonetheless, it is also imperative that MRLs are designed to align with toxicological safety standards.

1.4 Arsenic overview

The Earth's crust contains a lot of arsenic, a naturally occurring chemical element. Arsenic is found in both organic and inorganic forms, of which compared to the organic forms of arsenic found in food, the inorganic forms are more toxic(Sanyal et al., 2020). Arsenic is frequently

[12] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC Text with EEA relevance, OJ L 70, 16.3.2005, p. 1–16.

referred to as a metalloid or semi-metal because of its intermediate chemical and physical characteristics between metals and non-metals. There are four possible oxidation states for it: -3, 0, +3, and +5. Under reducing and oxygenated conditions, respectively, arsenite (AsIII) and arsenate (AsV) are the predominant oxidation states(IARC Working Group on the Evaluation of Carcinogenic Risks to Humans. & International Agency for Research on Cancer., 2012). Moreover, the most frequent trivalent inorganic arsenic compounds are arsenic trioxide, sodium arsenite, and arsenic trichloride, while the most frequent pentavalent ones are arsenic pentoxide, arsenic acid, and arsenates (such as lead arsenate and calcium arsenate). Arsanilic acid, methylarsonic acid, dimethylarsinic acid (cacodylic acid), and arsenobetaine are examples of common organic arsenic compounds (World Health Organization. Regional Office for Europe., 2000).

It should be noted that the amount of arsenic in the environment differs from place to place and is present in soil, water, and air. At the present time, groundwater contamination from inorganic arsenic is one of the main causes of arsenic exposure (iAs) (Sanyal et al., 2020).

The auditory, cardiovascular, developmental, hematologic, hepatic, neurological, renal, and respiratory systems are among the many organ systems that arsenic can adversely affect.

As follows, the International Agency for Research on Cancer (IARC, 1987) has categorized inorganic arsenic as group 1 human carcinogen based on the induction of primary bladder and lung cancers as well as skin, lung, and other cancers (Alexander et al., 2009).

Moreover, several different cancers have been linked to it (skin, lung, liver, and bladder). Due to its toxic and carcinogenic properties, inorganic arsenic (iAs) creates a significant risk to the health of the entire human population (Tchounwou et al., 2019).

1.5 Arsenic major uses

Commercial and industrial applications for arsenicals include the production of semiconductors, lasers, transistors, and glass, as well as the production of metal adhesives, wood preservatives, textiles, and paper. Moreover, they are employed in the tanning of hides and, to a lesser extent, as insecticides, feed additives, and medications (Mudhoo et al., 2011).

1.6 Arsenic exposure

Arsenic exposure usually occurs through ingestion, inhalation, and dermal contact. Volcanic ash, mineral weathering, and mining are examples of natural sources of human exposure to arsenic. Arsenic is mostly collected from copper refinement dust and mineralized groundwater, and it can also be found in the smelter dust from copper, gold, and lead smelters. Another exposure method is by the inhalation of air gases and dusts. Insecticides, herbicides, pesticides, and treated wood products all use arsenic trioxide. Moreover, it might be present in food, water, soil, and air. All plants normally absorb arsenic, and it is particularly abundant in green vegetables, rice, apple and grape juice, and seafood (Genchi et al., 2022).

1.7 Environmental occurrence

1.7.1 Arsenic in drinking water

Arsenite and arsenate, which are trivalent and pentavalent inorganic arsenicals, respectively, are stable forms of arsenic that are almost entirely found in water (Hughes et al., 2011).

Arsenic levels in surface freshwater sources, such as rivers and lakes, are normally lower than 10 µg/L, while they can reach as high as 5 mg/L in close proximity to anthropogenic sources. Although groundwater concentrations can reach up to 3 mg/L in locations with volcanic rock and sulfide mineral deposits, arsenic concentrations in open ocean saltwater and groundwater typically range between 1-2 µg/L (Howe et al., 2001). The main areas with high levels of arsenic in drinking water have been found to be considerable areas of Bangladesh, China, and West Bengal (India), as well as minor areas of Argentina, Australia, Chile, Mexico, Taiwan (China), the USA, and Viet Nam(International Agency for Research on Cancer, 2012).

1.7.2 Arsenic in air

Both natural and anthropogenic sources of arsenic are emitted into the atmosphere. Arsenic emissions from natural sources are thought to make up about one-third of the world's atmospheric flux (7900 tons per year). The main natural source is volcanic activity, which ranks above low-temperature volatilization, plant exudates, and wind-blown dusts (International Agency for Research on Cancer, 2012).

1.7.3 Arsenic in soil and sediments

The amounts of arsenic present in soil and sediments are a result of both natural and man-made causes. Although they can be as low as 1 mg/kg and as high as 40 mg/kg, the average background values in soil are typically about 5 mg/kg (International Agency for Research on Cancer, 2012).

This variability in naturally occurring arsenic levels in soils is connected to the presence of geological formations (e.g. sulfide ores, mineral sediments beneath peat bogs). There can be concentrations of up to several grams of arsenic per kilogram in soils that have been contaminated by anthropogenic sources of arsenic, such as mine/smelter wastes and agricultural land treated with arsenical pesticides. The highest amounts of arsenic are found in locations with anthropogenically contaminated soil, where the average sediment arsenic concentrations vary from 5 to 3000 mg/kg (Howe et al., 2001).

1.8 Human exposure

Generally speaking, consuming contaminated food or water is the main way that people are exposed to arsenic. Total daily arsenic exposure from food and beverages typically ranges from 20 to 300 g/day. Arsenic exposure through ambient air inhalation is typically low for the general population. Considering a breathing rate of 20 m3/day, the estimated daily intake may range from 20 to 200 ng in rural regions, 400 to 600 ng in cities without significant industrial arsenic emission, 1 to 10 µg/day in locations with high levels of pollution for nonsmokers, and up to roughly 10 g/day for smokers (Martorell et al., 2011).

1.8.1 Arsenic in food

Total arsenic content, which is the total amount of all arsenic species, is typically used to describe the amount of arsenic in food. Since different types of foods contain distinct arsenic species with differing toxicities, data on arsenic species is crucial. Yet, the species with the most health relevance is inorganic arsenic (Joint FAO/WHO Expert Committee on Food Additives. Meeting (72nd :2010 :Rome ,2011(. In fact, the highest total arsenic concentrations have been found in seaweed, fish and shellfish, mushrooms and fungi, rice and some meat products (Joint FAO/WHO Expert Committee on Food Additives. Meeting (72nd : 2010 :Rome ,2011(.

1.8.1.1 Inorganic arsenic species in food

The majority of inorganic arsenic species found in the environment are in the +3 or +5 oxidation state and can be found as thio complexes or, more commonly, as the oxoanions arsenite and arsenate. Viewing that arsenite and arsenate are typically the analytes (i.e., the species that are actually tested), data are frequently recorded as these two species(Alexander et al., 2009). Additionally, the prevalent As species in drinking water and terrestrial foods is inorganic As (iAs) as arsenite (As (III)), arsenate (As(V)) or a combination of both (Hackethal et al., 2021).

It should be noted that the average mean value for inorganic arsenic in foods and beverages is less than 0.03 mg/kg, and levels often do not surpass 0.1 mg/kg. However, the amounts of inorganic arsenic are higher in seaweed, rice, and several fish and shellfish items. Higher inorganic arsenic levels in food crops may result from soils contaminated by arsenic (Joint FAO/WHO Expert Committee on Food Additives. Meeting (72nd :2010 :Rome ,2011(.

1.8.1.1.1 Dietary exposure to inorganic arsenic

Table 2 provides a condensed overview of the long-term dietary exposure assessments to inorganic arsenic (iAs) conducted in 44 distinct dietary surveys spanning 23 European countries (Arcella et al., 2021).

Table 2. Summary statistics of the dietary chronic exposure assessment (lg/kg bw per day) to iAs across European dietary surveys (Arcella et al., 2021)

		Mean dietary exposure (μg/kg bw per day)					
	N	Lower bound (LB)			Upper bound (UB)		
		Min	Median	Max	Min	Median	Max
Infants	13	0.09	0.15	0.22	0.26	0.42	0.61
Toddlers	16	0.12	0.17	0.30	0.34	0.44	0.61
Other children	19	0.07	0.11	0.17	0.19	0.30	0.37
Adolescents	20	0.04	0.06	0.11	0.10	0.16	0.23
Adults	22	0.03	0.04	0.07	0.08	0.11	0.15
Elderly	20	0.03	0.03	0.06	0.06	0.10	0.14
Very elderly	15	0.03	0.03	0.05	0.08	0.10	0.14
Pregnant women	5	0.04	0.06	0.07	0.10	0.13	0.14
Lactating women	2	0.03	(a)	0.06	0.09	(a)	0.14

The greatest dietary exposure was observed among the young population, including infants, toddlers, and other children. Specifically, for lower-bound (LB) estimates, the highest mean estimate was 0.30 micrograms per kilogram of body weight per day in toddlers, while for upper-bound (UB) estimates, the maximum reached 0.61 micrograms per kilogram of body weight per day for both infants and toddlers. The highest 95th percentile exposure at the lower bound was calculated in toddlers at 0.58 micrograms per kilogram of body weight per day, and at the upper bound, it was in infants at 1.20 micrograms per kilogram of body weight per day (Arcella et al., 2021). In the adult population, which encompasses adults, the elderly, and very elderly individuals, the mean dietary exposure estimates vary between 0.03 and 0.15

micrograms per kilogram of body weight per day (minimum LB to maximum UB). The 95th percentile estimates range from 0.06 to 0.33 micrograms per kilogram of body weight per day (minimum LB to maximum UB). The dietary exposure to inorganic arsenic in specific subgroups of the population, such as pregnant and lactating women, falls within the range of exposure estimates for the general adult population (Arcella et al., 2021).

1.8.1.2 Organic arsenic species in food

The majority of the human population get most of their dietary As exposure from fish and shellfish, which includes seaweed. The organic molecules arsenobetaine (AsB), arsenosugars, and arsenolipids make up the majority of the dietary As contained in these foods. In fact, organic As is typically thought to be non-toxic (Taylor et al., 2017).

The main type of arsenic found in marine fish and the majority of other seafoods is arsenobetaine. Although typically as a minor compound, arsenobetaine has also been discovered in several terrestrial foods, particularly in some types of mushrooms (Sánez, 2008). Arsenobetaine has also been found to occur in marine algae, however its quantities are often low and it is challenging to analyze it when there are arsenosugars present which are the predominant arsenic species in algae (Nischwitz & Pergantis, 2005). Although it is probably present at trace amounts, arsenobetaine has not yet been detected in seawater. Whereas the levels are often modest (0.1 mg arsenic/kg dry mass), far lower than those reported in marine samples, there have also been numerous instances of arsenobetaine in freshwater species (Alexander et al., 2009).

Arsenosugars are typically the main source of arsenic in marine algae, accounting for 2 to 50 mg of arsenic per kilogram of dry mass. They are also present in significant amounts in animals that consume algae, such as mussels and oysters, which typically contain 0.5 to 5 mg of arsenic per kilogram of dry mass (Sánez, 2008).

Lipids that include arsenic are known as arsenolipids. Nonetheless arsenolipids in fish were initially discovered in the late 1960s, it has only been elucidated lately that the structures of some of these arsenolipids have been clarified[13].

[13] https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/contam

1.9 Arsenic toxicity to humans

Inorganic arsenic is a proven carcinogen and a major chemical contaminant in drinking water worldwide. Arsenic as previously mentioned can occur as well in organic form. Inorganic arsenic compounds such as those found in water are highly toxic, while organic arsenic compounds that are for example found in seafood are less harmful to health (Bhattacharya et al., 2017).

It should be noted that arsenic toxicity in humans is affected by a number of variables, including age, gender, arsenic concentration and species, exposure time and dose, and nutritional status (Bhattacharya et al., 2017). Epigenetic alterations such DNA methylation, RNA interference, and histone modification have been associated to arsenic toxicity in humans (Upadhyay et al., 2019).

1.9.1 Acute toxicity

Initial symptoms of acute arsenic poisoning include nausea, vomiting, abdominal discomfort, and severe diarrhea. Additionally, encephalopathy and peripheral neuropathy may happen. A common sign of iAs exposure is paresthesia in the limbs, which in certain circumstances can progress to extensive polyneuropathy (Nurchi et al., 2020).

1.9.2 Chronic toxicity

The skin typically exhibits the first signs of long-term exposure to high amounts of inorganic arsenic (e.g. through drinking water and food contamination), such as pigmentation changes, skin lesions, and hard patches on the palms and soles of the feet (hyperkeratosis). These develop after a minimum of five years of exposure and could be a sign of skin cancer (The World Health Organization, 2022).

Long-term exposure to arsenic may result as well in lung and bladder cancer in addition to skin cancer. According to The International Agency for Research on Cancer (IARC): “arsenic and arsenic compounds as carcinogenic to humans and has also stated that arsenic in drinking-water is carcinogenic to humans” (The World Health Organization, 2022).

Furthermore, chronic exposure to iAs raises the risk of developing diabetes mellitus, and unfavorable pregnancy outcomes (APO). Moreover, long-term exposure to iAs causes arsenicosis, a term for As-related health effects such as hyperkeratosis, hyperpigmentation, mee's lines, and hair hypomelanosis (Paul et al., 2007).

Chapter 2

Objectives and Aims

A rising amount of trade across borders is occurring in foods, raw materials, and ingredients for food manufacturing. Consequently, international and national legislations of contaminants are required.

Everyone could be exposed to arsenic on a daily basis. The likelihood of experiencing health issues can rise when arsenic levels in the environment have accumulated above normal levels due to natural or human activity. Generally speaking, the risk of getting sick increases with exposure.

The rules governing the presence of arsenic in food products have been strengthened by the European Commission. While there are new limitations for arsenic in various rice-based meals, newborn formula, baby foods, fruit juices, and salt, the acceptable concentration of inorganic arsenic in white rice has been decreased. The lower maximum limits are an aspect of Europe's plan to combat cancer, which aims to reduce or eliminate the risk of cancer caused by chemicals in food.

Given the above, the objectives of this manuscript are:

- To identify arsenic, its major routes of exposure, and toxicity.
- To display chronologically the history of food law regulations in the European Union.
- To highlight the work of the regulatory bodies responsible for contaminants and arsenic regulations.
- To identify arsenic maximum levels variations through time.
- Consequences of arsenic regulations on trade.

Chapter 3

Regulations and legislation history

3.1 History of EU food law

The progression of European food legislation has occurred through multiple phases. As with any field of study, comprehending current conditions and responses is most effective when there's an understanding of the historical evolution. Therefore, considering past developments is beneficial for obtaining insight into the enduring legacy of prior frameworks, recognizing errors, absorbing lessons, and forecasting potential future advancements (Corona et al., 2020). The extent of European food-related legislation is substantial, with the majority of the existing food safety regulations originating in response to the bovine spongiform encephalopathy (BSE) crisis of the mid-1990s. Consequently, the food industry has become one of the heavily regulated sectors within the European Union. However, upon closer examination, this legislation can be categorized in a fairly straightforward manner (B. M. J. Van der Meulen, 2013). It can be divided into two main components: the first involves public authorities implementing and enforcing the law, as well as managing incidents, while the second pertains to regulations aimed at food businesses. The latter category can be further subdivided into three main areas: rules governing the product, regulations concerning the production processes, and guidelines regarding the presentation of food products. This entire framework is underpinned by overarching principles and is represented in the figure below (B. M. J. Van der Meulen, 2013).

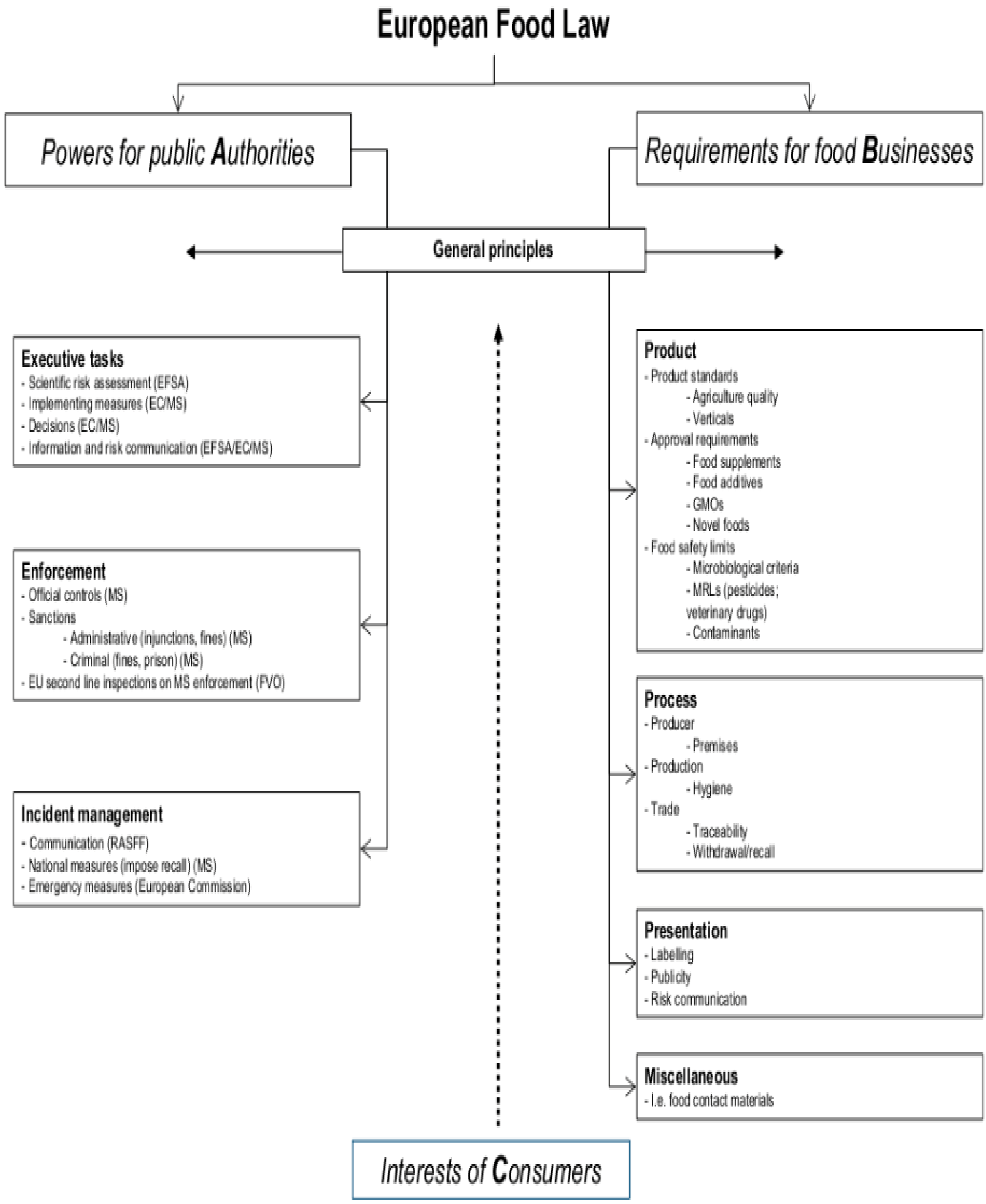

Figure 2. Structure of European food law

Figure 1 presented above illustrates the foundational principles of European food law. Positioned at the upper section are the principles themselves, while on the left-hand side are the provisions that concern public authorities, and on the right-hand side are the provisions relevant to businesses. It's essential to note that this figure does not encompass a significant facet of EU food law, which includes institutional arrangements like the establishment of specialized authorities to handle issues related to food (B. M. J. Van der Meulen, 2013).

From the early 1960s until the outbreak of the BSE crisis in the mid-1990s, European acts concerning food primarily aimed at establishing an internal market for food products within the European Union. This market-oriented period can be segmented into two phases. In the initial phase, the focus was on standardizing regulations through vertical directives, culminating in notable case law, with the 'Cassis de Dijon[14]' ruling being the most renowned. In the subsequent phase, the emphasis shifted towards standardization through horizontal directives(B. Van der Meulen, 2009) .

Table 3. Development of European food law

Phase	Turning point	Orientation	Main instruments
First	Cassis de Dijon (1979)	Market	Vertical directives
Second	BSE crisis (1997)	Market	Horizontal directives
Third		Safety first, market second	Horizontal regulations

To elaborate further, the connection between food regulation and human health received significant attention due to a series of widely publicized incidents, which prompted a strong push for the development of a more comprehensive approach to governing the operations of the food industry. One of the key catalysts was the BSE (bovine spongiform encephalopathy or "mad cow disease") crisis that occurred during the mid to late 1990s[15].

The European Union's (EU) laws and regulations on food contamination have changed throughout time to take into account new hazards, technological improvements, and consumer protection (Pettoello-Mantovani & Olivieri, 2022). It was necessary to create general principles and regulations pertaining to food and feed law at the European Union (EU) level (Pettoello-Mantovani & Olivieri, 2022). Regulations[16] at this time mostly concentrated on a few contaminants, namely heavy metals (like lead and mercury) and pesticide residues.

[14] Judgment of the Court of 20 February 1979. Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein. Case 120/78, European Court reports, 1979, p. 649.
[15] http://www.foodlaw.rdg.ac.uk/contaminants.htm
[16] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs, OJ L 364, 20.12.2006, p. 5–24, OJ L 314M , 1.12.2007, p. 558–577.

Maximum allowed limits for contaminants in food products were intended by these laws (Pettoello-Mantovani & Olivieri, 2022). In response to these incidents, the European Commission formulated a holistic and inclusive strategy for ensuring food safety, encompassing all stages of the food production process, from farm to fork[17].

The BSE crisis and various food safety concerns during the 1990s exposed significant deficiencies in the established European food regulations, highlighting the necessity for substantial changes. In January 2000, the European Commission unveiled its blueprint for the future evolution of European food law through a White Paper on Food Safety[18].

3.1.1 The White Paper: a new vision on food law

The Commission released its renowned "White Paper on Food Safety" on January 12, 2000. The Commission's vision for the future shape of EU food law was outlined in the White Paper on Food Safety. Prior to the BSE crisis, European food safety regulations were primarily focused on advancing the internal market. However, the crisis exposed significant deficiencies in the way it was managed, underscoring the need for a fresh, all-encompassing approach to food safety. The Commission's objective was to rebuild and sustain consumer trust. The White Paper aimed to revamp food legislation to make it more coherent, comprehensive, and current, while also reinforcing enforcement measures. The White Paper presents an ambitious overhaul strategy, suggesting a substantial agenda for legislative changes to fully implement the EU's 'farm to table' concept ("White Paper on Food Safety," 2000). The European Commission places utmost importance on attaining the highest food safety standards within the EU, and the White Paper underscores this commitment A key component of this plan was the creation of a new European Food Safety Authority, which would act as the central scientific authority for the entire Union, contributing to the protection of consumer health. The Action Plan on Food Safety, included in the White Paper's Annex, consisted of 84 legislative actions considered necessary by the Commission to establish a regulatory framework that would ensure a high level of consumer and public health protection("White Paper on Food Safety," 2000).

[17] https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy_en#:~:text=The%20Farm%20to%20Fork%20Strategy%20is%20at%20the%20heart%20of,if%20they%20are%20not%20sustainable.

[18] White paper on food safety of 12 January 2000 [COM/99/0719 final - Not published in the Official Journal].

As the new millennium began, the planned overhaul of European food law commenced, and over the course of a decade, most of the 84 steps were implemented. The new regulatory framework is now based on regulations rather than directives.

3.2 History of food contaminants regulations in the EU

3.2.1 Council Regulation (EEC) No 315/93

Diving in more specifically into the history of contaminants control in the EU, initially in 1993, Council Regulation (EEC) No 315/93 introduced a process for implementing controls on contaminants in food. Article 2(3) of the Regulation permits the implementation of supplementary targeted measures if they are deemed essential. The article states: *"In order to protect public health and pursuant to paragraph 1, the Commission may where necessary establish the maximum tolerances for specific contaminants. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 8(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 8(4). These tolerances shall be adopted in the form of a non-exhaustive Community list and may include:*

- *limits for the same contaminant in different foods;*
- *analytical detection limits;*
- *a reference to the sampling and analysis methods to be used"*

The additional measures encompass a significant portion of the control-related technical specifics and have been expanded to include a broad array of chemical contaminants. All the regulated contaminants are listed in the Annex of a particular regulation—originally starting with Regulation (EC) no 194/97[19], followed by Regulation (EC) no 466/2001[20] and Regulation (EC) no 1881/2006[21]—yet now superseded by Regulation (EU) 2023/915[22].

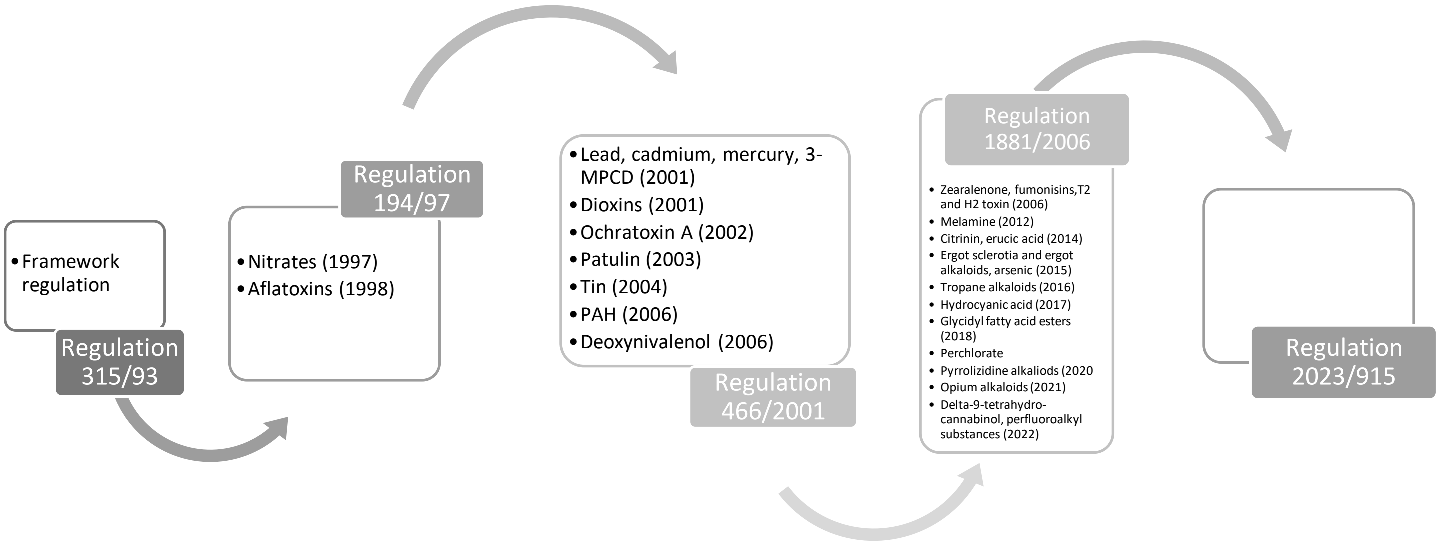

Figure 3. Introduction of EU contaminants control

3.2.2 Commission Regulation (EC) No 194/97

Regulation (EC) No 194/97 was one of the early European Community regulations related to contaminants in food products. It primarily focused on setting maximum levels for certain contaminants in specific foodstuffs: "*Whereas Regulation (EEC) No 315/93 provides that maximum levels must be set for certain contaminants in order to protect public health; whereas these maximum levels must be adopted in the form of a non-exhaustive Community list which may contain levels for the same contaminant in different foodstuffs and analytical detection limits; whereas the sampling and analysis methods to be applied may be specified*". Article 2 of this regulation denotes that: "*The products indicated in the Annex to this Regulation must not when placed on the market contain higher contaminant levels than those therein specified.*

Member States may, where justified, authorize for a transitional period the placing on the market of lettuces and spinach grown and intended for consumption in their territory with

[19]Commission Regulation (EC) No 194/97 of 31 January 1997 setting maximum levels for certain contaminants in foodstuffs, OJ L 31, 1.2.1997, p. 48–50.
[20] Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs, OJ L 77, 16.3.2001, p. 1–13.
[21] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs, OJ L 364, 20.12.2006, p. 5–24.
[22] Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006, C/2023/35, OJ L 119, 5.5.2023, p. 103–157.

nitrate levels higher than those set in point 1.1 of Part I of the Annex provided codes of good practice are applied to achieve gradual progress towards the levels laid down at Community level", the table below refers to the Annex in present in the regulation.

This regulation was repealed by Regulation (EC) no 466/2001.

Table 4. Table indicating the maximum levels for certain contaminants in foodstuffs according to Commission Regulation (EC) No 194/97

MAXIMUM LEVELS FOR CERTAIN CONTAMINANTS IN FOODSTUFFS

I. **Agricultural contaminants**

1. Nitrates

1.1. Fresh vegetables

Product	Maximum nitrate levels (1) (mg NO_3/kg fresh product)		Sampling method	Reference analysis method
Spinach (*Spinacia oleracea L.*)	15 February 1997 to 31 December 1998: harvested 1 November to 31 March harvested 1 April to 31 October	 3 000 2 500	Directive 79/700/EEC (1)	
	From 1 January 1999	2 500 (2)		
Lettuce (*Lactuca sativa L.*) with the exception of open-grown lettuce	harvested 1 October to 31 March harvested 1 April to 30 September harvested 1 May to 31 August	4 500 (2) 3 500 (2) 2 500 (2)	Directive 79/700/EEC However, the minimum number of units per laboratory sample is ten	

1.2. Other processed vegetables for consumption

Product	Maximum nitrate level (1) (mg NO_3/kg fresh product)		Sampling method	Reference analysis method
Preserved, deep-frozen or frozen spinach		2 000	Directive 79/700/EEC	

3.2.3 Commission Regulation (EC) no 466/2001

Moving on to Regulation (EC) no 466/2001 that is a European Community (EC) regulation that establishes maximum levels for certain contaminants in food products. This regulation was adopted on March 8, 2001, and it played a crucial role in ensuring food safety within the EU by setting limits on various chemical contaminants. The regulation covers a wide range of contaminants, including heavy metals (such as lead, cadmium, and mercury), mycotoxins (like aflatoxins and ochratoxin A), pesticide residues, and other chemical substances that can potentially be harmful to human health if present in food at high levels. The regulation also includes provisions related to sampling and analysis methods for determining the levels of contaminants in food. These methods ensure that testing is accurate and consistent across EU member states (refer to Annex A). Commission Regulation (EC) no 466/2001 was then repealed by Commission Regulation (EC) no 1881/2006.

3.2.4 Commission Regulation (EC) no 1881/2006

Commission Regulation (EC) no 1881/2006 puts into effect the Framework Regulation, establishing maximum limits for specific contaminants while providing additional details on the underlying principles. When dealing with contaminants recognized as genotoxic carcinogens or situations in which the present exposure of the general population or vulnerable subgroups approaches or exceeds acceptable intake levels, the maximum limits should be set as low as practically achievable (abbreviated as ALARA).

Furthermore, this regulation includes a prohibition on decontamination through the blending of contaminated and uncontaminated foods to create a product that no longer surpasses the prescribed limits. Specifically, foods tainted with mycotoxins should not undergo decontamination via chemical treatments. However, for groundnuts, other oilseeds, tree nuts, dried fruit, rice, and maize, sorting methods to separate contaminated from uncontaminated foods, along with other physical treatments, are deemed acceptable.

The primary purpose of this regulation is to protect public health by establishing maximum allowable levels of specific contaminants in various food products. It ensures that the food consumed in the European Union is safe and complies with strict safety standards. It covers various contaminants, including heavy metals, mycotoxins, pesticide residues, dioxins, and more. In this regulation specific maximum levels are defined for various contaminants such as lead, cadmium, aflatoxins, and certain pesticides. Additionally, food products are categorized into groups (e.g., cereals, meat, dairy, fish), with distinct limits for each category.

It is important to mention that in this regulation **Arsenic** is indeed mentioned. The regulation sets limits for the presence of inorganic arsenic in specific food products to ensure food safety. These maximum levels are defined to protect public health. It was specifically mentioned in this regulation that: "*In the framework of Directive 93/5/EEC 2004 the SCOOP-task 3.2.11 'Assessment of the dietary exposure to arsenic, cadmium, lead and mercury of the population of the EU Member States' was performed in 2004. In view of this assessment and the opinion delivered by the SCF, it is appropriate to take measures to reduce the presence of lead in food as much as possible*" (refer to Annex A). Commission Regulation (EC) was then repealed by Commission Regulation (EU) 2023/915.

3.2.5 Commission Regulation (EU) 2015/1006

The primary objective of Commission Regulation (EU) 2015/1006[23] is to protect public health by regulating the levels of inorganic arsenic in food products. Inorganic arsenic is a known carcinogen, and chronic exposure to it through the consumption of contaminated food can pose significant health risks. Regulation (EC) No 1881/2006 originally established maximum levels for various contaminants, including arsenic, in certain food products within the European Union. However, this regulation did not specifically address inorganic arsenic levels. Therefore, the need for an amendment was identified to set specific limits for inorganic arsenic. The amendment introduced by Commission Regulation (EU) 2015/1006 covers various foodstuffs, including rice and rice-based products, as rice is known to be particularly susceptible to accumulating inorganic arsenic. The regulation aims to ensure that these products do not contain inorganic arsenic levels that exceed established maximum levels. The regulation defines specific maximum levels for inorganic arsenic content in different food categories, measured in milligrams per kilogram (mg/kg) or micrograms per kilogram (µg/kg) of the food product. These maximum levels are set to minimize health risks associated with arsenic exposure.

Food producers, processors, and distributors are obligated to adhere to the specified maximum levels. Regulatory authorities within EU member states are responsible for monitoring and enforcing compliance with these regulations. The regulation takes into consideration the potential vulnerability of certain population groups, such as infants and young children, who may be more susceptible to the adverse effects of arsenic exposure. Therefore, specific maximum levels may be set for certain food products intended for these groups.

3.2.6 Commission Regulation (EU) No 2023/915

Following multiple revisions to Regulation (EC) No 1881/2006 concerning contaminants, the European Commission has determined that it is necessary to introduce Regulation (EU) 2023/915 to enhance clarity, reorganize the material, incorporate new changes, and decrease the volume of footnotes for improved understanding. While the standard itself has been

[23] Commission Regulation (EU) 2015/1006 of 25 June 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in foodstuffs, OJ L 161, 26.6.2015, p. 14–16.

updated, Regulation (EU) 2023/915 retains the maximum contaminant levels set in the previous standard (Merieux NutriSciences, 2023).
The main changes in this regulation include new definitions that were introduced, including terms like "food," "food business operator," "marketing," "final consumer," "processing," "unprocessed products," and "processed products" present in article 1, with reference to other EU acts. Some changes have been made to food categories that fall under the regulation of contaminants. These adjustments are based on Annex I of Regulation (EC) No 396/2005[24], which sets maximum pesticide residue levels. The aim is to make it easier to classify plant-based products. A prohibition on detoxification through chemical treatments (Art. 4) has been established, and it is generally applicable to all foods. In the previous Regulation (EC) No 1881/2006, this prohibition only applied to mycotoxins. In this update, the maximum limit for cadmium in cereals no longer applies to cereals used for brewing beer or making spirits, as long as the remaining cereal residues are not sold as food. In Regulation (EC) No 1881/2006, this exemption only applied to malt.
Included in the changes of this update, instant or soluble coffee is now excluded from the maximum limit for polycyclic aromatic hydrocarbons (PAHs) that is relevant to powdered plant-based products intended for beverage preparation (Annex I, 5.1.2).
Moreover, concerning the contaminant melamine, a maximum limit has been incorporated into the new provision following its publication by the Codex Alimentarius for liquid preparations intended for infants (Annex I, 6.2.2.2). When dealing with contaminants composed of multiple compounds, the maximum limits will now be based on the concentrations of the lower limit, with values below the quantification limit considered as zero. However, for dioxins and PCBs, the maximum limit for the sum of concentrations will refer to the concentrations of the upper limit, considering values below the quantification limit as equivalent to the quantification limit.
The key objective of Food Contaminants Regulation (EU) No 2023/915 is to uphold food safety and, consequently, safeguard public health. Nevertheless, the European Commission acknowledges that some limits are overly stringent for specific products not directly meant for end consumers or those not serving as food ingredients.

[24] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC Text with EEA relevance, OJ L 70, 16.3.2005, p. 1–16.

Additionally, in this regulation "it is recognized that sorting or other physical treatments make it possible to reduce the content of contaminants in food. In order to minimize the effects on trade, it is appropriate to allow higher levels of contaminants for certain products, which are not placed on the market for the final consumer or as a food ingredient"[25].

[25] Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006, C/2023/35, *OJ L 119, 5.5.2023, p. 103–157.*

Chapter 4

Food contaminants management in the EU

4.1 Defining 'food' under Regulation (EC) no 178/2002: scope and exclusions

Beginning with an exploration of the topic at hand, the focus turns to the realm of food, specifically delving into the all-encompassing definitions and inclusions as outlined in Regulation (EC) no 178/2002. As per Regulation (EC) no 178/2002, the definition of "food "is provided in article 2.1: "'Food' means any substance or product, whether processed, partially processed, or unprocessed, intended to be, or reasonably expected to be ingested by humans". This includes beverages, chewing gum, and any substances intentionally incorporated during the food's manufacturing, preparation, or treatment. It also covers water beyond the compliance point defined in **Directive (EU) 2020/2184**[26]. However, "food" excludes (a) animal feed, (b) live animals unless they are specifically prepared for human consumption, (c) plants before harvesting, (d) medicinal products according to **Directive 2001/83/EC**[27] and (e) cosmetics in line with **Regulation (EC) No 1223/2009**[28], (f) tobacco and tobacco products as defined in **Directive 2014/40/EU**[29], (g) narcotic or psychotropic substances as defined in the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971, and (h) residues and contaminants[30].

4.2 Risk analysis and contaminant regulations in the EU: a vital aspect of food safety

Another important aspect for this discussion is risk analysis where in simplified terms, "risk" means a function of the probability of an adverse health effect and the severity of that effect,

[26] Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast), OJ L 435, 23.12.2020, p. 1–62.

[27] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67–128.

[28] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22.12.2009, p. 59–209.

[29] Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, OJ L 127, 29.4.2014, p. 1–38.

[30] Proposal for a COUNCIL DECISION on the position to be taken, on behalf of the European Union, in the sixty-fifth session of the Commission on Narcotic Drugs on the scheduling of substances under the Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and the Convention on Psychotropic Substances of 1971.

consequential to a hazard as per Regulation (EC) No 178/2002. "Risk analysis" means a process consisting of three interconnected components: risk assessment, risk management and risk communication. In the context of ensuring a high level of protection for human health and life, the application of food safety-risk analysis becomes crucial. Its purpose is not only to produce or manufacture safe and high-quality goods, but also to comply with international and national standards as well as market regulations, ensuring public health protection (Silano & Silano, 2017). The process of risk analysis comprises three key components: risk assessment (EFSA), risk management (European Commission, European Parliament and EU Member States), and risk communication. According to Regulation (EC) No 178/2002, "risk assessment" means a scientifically based process consisting of four steps: hazard identification, hazard characterization, exposure assessment and risk characterization. Moving on to "risk management", it is the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options. While "risk communication" means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

Hence, Regulation (EC) No 178/2002 highlights that "*recourse to a risk analysis prior to the adoption of such measures should facilitate the avoidance of unjustified barriers to the free movement of foodstuffs*" (recital no 16). The regulation denotes as well that "*where food law is aimed at the reduction, elimination or avoidance of a risk to health, the three interconnected components of risk analysis - risk assessment, risk management, and risk communication - provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health*" (recital no 17).

In order to ensure the safety of the food supply chain, stringent regulations have been established to monitor and control food contaminants. These regulations are enforced and overseen by specialized bodies within the European Union.

4.3 The vital role of the European Commission in regulating food safety and contaminants in the European Union

The Treaty on European Union underlines that "The Commission shall promote the general interest of the Union and take appropriate initiatives to that end. It shall ensure the application of the Treaties, and of measures adopted by the institutions pursuant to them. It shall oversee the application of Union law under the control of the Court of Justice of the European Union. It shall execute the budget and manage programmes. It shall exercise coordinating, executive and management functions, as laid down in the Treaties. With the exception of the common foreign and security policy, and other cases provided for in the Treaties, it shall ensure the Union's external representation. It shall initiate the Union's annual and multiannual programming with a view to achieving interinstitutional agreements." (Article 17, par. 1, TEU).

The European Commission holds a central role in regulating food contaminants within the European Union (EU). As the executive body of the EU, it bears the responsibility for proposing and implementing regulations concerning food safety and the management of contaminants. A key task is to establish Maximum Residue Limits (MRLs) for pesticides and veterinary drug residues in food products, relying on scientific guidance from the European Food Safety Authority (EFSA) and other expert bodies. In Commission Regulation (EU) 2023/915 of 25 April 2023, these MRLs define the maximum permissible concentrations of contaminants considered safe for human consumption.

Moreover, the European Commission coordinates monitoring and surveillance programs across EU Member States to assess the presence of contaminants in food, ensuring adherence to established MRLs and other food safety standards. It relies on rigorous risk assessments and scientific advice from EFSA and other committees to develop appropriate regulatory measures and protect public health (McEvoy, 2016).

An important aspect to be mentioned is that Regulation (EC) No 178/2002, also known as the General Food Law Regulation, forms the basis of EU food and feed legislation. It sets up two key components: the European Food Safety Authority (EFSA), responsible for offering scientific guidance to policymakers, and the Rapid Alert System for Food and Feed (RASFF), designed for swift crisis and emergency management across the entire food supply chain (Sorbo et al., 2022).

RASFF is specifically mentioned in Article 50 of Regulation (EC) No 178/2002. This article outlines the establishment and operation of the RASFF. The Rapid Alert System for Food and Feed is a crucial tool for ensuring the rapid exchange of information on food and feed safety issues among EU member states and facilitating coordinated actions to address potential risks to public health. It allows for the swift recall or withdrawal of unsafe food and feed products from the market and enables timely communication and cooperation between competent authorities in different EU countries.

4.4 Assessing food contaminants: EFSA's contributions to EU food safety

Regulation (EC) No 178/2002[31] of the European Parliament and of the Council of 28 January 2002 laid down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. According to article 22, "The Authority shall provide scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. It shall provide independent information on all matters within these fields and communicate on risks".

EFSA was established as an integral component of a comprehensive initiative aimed at enhancing food safety standards within the EU, guaranteeing robust consumer protection, and rebuilding and sustaining trust in the European food chain.

The main regulation that establishes EFSA and outlines its functions is Regulation (EC) No 178/2002. Article 22 of the regulation establishes the European Food Safety Authority (EFSA) and outlines its mission and responsibilities. In article 23 the tasks of EFSA are specified from which: "to provide scientific and technical assistance, when requested to do so by the Commission, in the crisis management procedures implemented by the Commission with regard to the safety of food and feed".

Article 24 outlines the bodies of EFSA, " The Authority shall comprise: (a)a Management Board; (b)an Executive Director and his staff; (c)an Advisory Forum; (d)a Scientific Committee and Scientific Panels". It should be mentioned that EFSA aids the European Commission, European Parliament, and EU Member States in making well-informed and prompt risk management

[31] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1–24.

choices (Sorbo et al., 2022). Based on its risk assessments, EFSA establishes maximum residue limits (MRLs) and acceptable levels for various contaminants in food products. These safety levels are crucial for ensuring consumer protection and maintaining food safety standards (Silano & Silano, 2017). With referral to article 22, "The Authority shall contribute to a high level of protection of human life and health, and in this respect take account of animal health and welfare, plant health and the environment, in the context of the operation of the internal market".

EFSA's scope includes food and feed safety, nutrition, animal health and welfare, plant protection, and plant health. In all these domains, EFSA's primary dedication lies in offering impartial and autonomous science-driven counsel, accompanied by transparent communication built upon the latest scientific data and expertise. The primary responsibility of EFSA is to evaluate and convey information about any potential risks related to the food chain. As its advice plays a crucial role in shaping risk management policies and decisions, a significant portion of EFSA's efforts is dedicated to responding to specific requests for scientific advice. These requests come from various entities, such as the European Commission, the European Parliament, and EU Member States. Additionally, EFSA also initiates scientific research independently, which is referred to as self-tasking[32].

The next aspect to consider is the EFSA CONTAM Panel which is comprised of approximately 20 experts from diverse national backgrounds and fields of expertise. They receive support from the BIOCONTAM Unit, which is responsible for handling biological hazards and contaminants[33].

Within EFSA's scientific evaluations of substance safety, various panels are responsible for distinct categories. The Panel on Contaminants in the Food Chain (CONTAM) addresses food contaminants, while the Panel on Plant Protection Products and their Residues (PPR) focuses on pesticides. In the case of veterinary drugs, the scientific assessments are not conducted by any EFSA panels but instead fall under the purview of the European Medicines Agency (EMA) (Corona et al., 2020).

[32] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1–24.

[33] https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/contam

In essence, the risk assessment of diverse chemicals present in foods hinges on a comparison of two key elements: the daily human exposure to the substance through food and other exposure routes, and the dose that has been identified as not causing adverse health effects. While most panels can perform their risk assessments based on applications and data submitted to EFSA, the CONTAM Panel primarily relies on publicly available scientific information. To complement these publicly accessible data sources, EFSA's Data Collection and Monitoring (DCM) Unit periodically initiates requests for data regarding the presence of the substances of interest and collects data on food consumption (Corona et al., 2020).

The main responsibility of the EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) is to provide scientific assessments concerning contaminants found in food and feed, including related areas and undesirable substances like natural toxicants, mycotoxins, and residues of unauthorized substances not covered by other Panels (Silano & Silano, 2017). The primary goal is to determine whether exposure to a chemical contaminant in food could potentially lead to adverse health effects in the European population, or if exposure to a contaminant in feed could have adverse health effects on farm animals, fish, and pets in Europe (Silano & Silano, 2017). Additionally, the CONTAM Panel evaluates whether these contaminants pose risks to consumers of animal-derived foods. By doing so, the panel aims to ensure a high level of protection for both human and animal health (Silano & Silano, 2017).

4.5 FAO and JECFA's influence on food safety regulations and contaminant assessment

In the same vein, the Food and Agriculture Organization (FAO) contributes significantly to the management of food contaminants by offering its member countries advice, knowledge, and assistance in addressing concerns about food safety and the presence of contaminants in food (Berg & Licht, 2002). In 1961, the FAO and the WHO came together to form the Joint FAO/WHO Codex Alimentarius Commission (CAC). The main objective of this commission was to develop global standards and codes of practice concerning food-related matters. Other primary objectives of this Program include safeguarding consumer health, ensuring fair trade practices in the food industry, and fostering coordination among international governmental and non-governmental organizations engaged in food standards-related efforts (Silano & Silano, 2017). During its initial years, the Codex Alimentarius Commission focused on creating various standards for specific food products. This included guidelines for handling contaminants, which were developed through the efforts of specialized Codex Committees known as Commodity Committees, each having expertise in a particular area of food production (Berg & Licht, 2002). During the 1980s, a shift in approach became evident, emphasizing the importance of focusing on General Standards instead. These standards were developed by General Subject Committees, such as the Codex Committee on Food Additives and Contaminants (CCFAC). Within the CCFAC, fundamental principles and procedures for establishing general standards concerning contaminants and toxins in food products were elaborated throughout the 1990s (Berg & Licht, 2002). Initially, the responsibility of addressing contaminants was divided between various Commodity Committees and the CCFAC.

Another scientific committee worth mentioning is the Joint FAO/WHO Expert Committee on Food Additives (JECFA) which is an international committee of scientific experts jointly managed by FAO and the WHO. Established in 1956, its primary focus has been the assessment of food additive safety. Over time, its scope has expanded to include the evaluation of contaminants, naturally occurring toxic substances, and residues of veterinary drugs in food products (Silano & Silano, 2017).

JECFA carries out thorough risk assessments by examining available data and toxicological studies to assess the potential health hazards posed by contaminants. Based on these evaluations, the committee establishes Acceptable Daily Intakes (ADIs) for chronic effects and sets Maximum Residue Limits (MRLs) to regulate and monitor the presence of contaminants in food items. By providing essential scientific advice to the Codex Alimentarius Commission, which sets international food standards, guidelines, and codes of practice, JECFA facilitates the harmonization of food regulations and enhances food safety in global trade (Huggett et al., 1998).

JECFA's assessments and recommendations play a vital role in protecting public health by ensuring that food contaminants are controlled and regulated at safe levels in food products. However, it is important to note that while JECFA offers scientific advice, individual countries or regions, such as the EU, hold the responsibility of adopting and implementing these assessments into their specific food safety regulations and standards879. The EU and its Member States may use JECFA's evaluations to inform their decision-making process when establishing regulations and safety limits for food contaminants within their jurisdiction (Huggett et al., 1998).

Chapter 5

Arsenic regulation in the EU

The history of arsenic regulation in the European Union (EU) represents a comprehensive and evolving approach to addressing the risks associated with arsenic contamination, particularly in food and the environment.

In Commission Regulation (EC) No 1881/2006, maximum levels for contaminants were set in food, covering a wide range of substances, including arsenic. It provided specific limits and rules for arsenic in various food products. This regulation was repealed by Commission Regulation (EU) 2023/915.

5.1 Report of experts participating in Task 3.2.11

In 2004, the European Commission conducted an exposure assessment using data obtained within the scope of SCOOP task 3.2.11. This study concluded that, based on the data provided by Member States, fish and other seafood products constitute the primary source of dietary arsenic for the average adult population. However, the SCOOP study, as well as numerous other investigations concerning arsenic, predominantly focused on total arsenic because methods to distinguish between inorganic and organic arsenic forms were not yet widely available. It is well-established that in fish and seafood, arsenic is primarily found in its less toxic organic forms[34].

In the Reports on tasks for scientific cooperation entitled "Assessment of the dietary exposure to arsenic, cadmium, lead and mercury of the population of the EU Member States"[35], nine Member States supplied data concerning the presence and consumption of arsenic in fish, which serves as the primary source of arsenic in the food supply, particularly for the average adult population. However, there was a notable scarcity of data pertaining to arsenic levels in other food categories. Consequently, in most Member States, it is challenging to make a precise assessment of the overall intake of arsenic.

[34] https://food.ec.europa.eu/system/files/2016-10/cs_contaminants_catalogue_scoop_3-2-11_heavy_metals_report_en.pdf

[35] Reports on tasks for scientific cooperation: Report of experts participating in Task 3.2.11, Assessment of the dietary exposure to arsenic, cadmium, lead and mercury of the population of the EU Member States, March 2004.

5.1.1 Guidance on intake limitations according to SCOOP 3.2.11

A Provisional Tolerable Weekly Intake (PTWI) has been established for inorganic arsenic in drinking water at a rate of 0.015 mg per kilogram of body weight. However, such guidelines have not been set for other food items as of the 1989 WHO report. The report from 1989 also noted that specific ethnic and regional populations with high fish consumption had arsenic intake, in the form of organoarsenicals, at approximately 0.050 mg per kilogram of body weight, with no reported adverse effects. This equates to a daily intake of 3.5 mg for an individual weighing 70 kg. There were no recommendations available for children's arsenic intake.

5.2 WHO food additives series: "63: safety evaluation of certain contaminants in food"

Epidemiological research examining the presence of inorganic arsenic in drinking water has established it as a known human carcinogen. This type of arsenic occurs naturally in food and water due to geological factors, leading to substantial variability in exposure levels across regions and even within specific areas. Such disparities are mainly attributed to the presence or absence of arsenic in local groundwater sources for drinking water (Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), 2011).

An epidemiological study conducted on a highly-exposed population provided data that allowed the calculation of the lower limit on the benchmark dose for a 0.5% increased incidence of lung cancer due to inorganic arsenic. The calculated value was 3 µg/kg body weight per day, with a range of 2–7 µg/kg body weight per day. This calculation incorporated various assumptions to estimate the total dietary exposure of the study population to inorganic arsenic from both drinking water and food sources (Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), 2011).

As a result of this analysis, the Committee determined that the current Provisional Tolerable Weekly Intake (PTWI) for arsenic (2.1 µg/kg body weight per day) no longer provided adequate health protection. The reason for this conclusion was that the benchmark dose lower limit for a 0.5% increased incidence of lung cancer fell within the same range as the PTWI value. Consequently, the PTWI for inorganic arsenic has been withdrawn (Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), 2011).

The Committee observed the necessity for more precise data regarding the inorganic arsenic levels in foods as they are consumed in order to enhance assessments of dietary exposure to inorganic arsenic compounds. The challenges in achieving this goal stem from analytical limitations, such as the absence of validated techniques for the selective quantification of inorganic arsenic species in various food matrices, as well as the absence of certified reference materials for inorganic arsenic in food items. Additionally, it was found that the proportion of inorganic arsenic in certain foods exhibited significant variations, underscoring the need for dietary exposure assessments to be based on actual data rather than relying on generalized conversion factors derived from total arsenic measurements (Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), 2011).

5.3 EFSA assessment of arsenic in food

Inorganic arsenic species are more hazardous in comparison to organic arsenic forms. However, up to this point, the data regarding the presence of arsenic in food, gathered through official food control procedures, primarily report the total arsenic content without distinguishing between the different arsenic species (EFSA, 2009).

More recently, methods for detecting inorganic arsenic have become accessible. In addition to well-recognized sources like drinking water, which is known to be a significant contributor to inorganic arsenic exposure, some research suggests that rice and rice-based products may also play a substantial role in inorganic arsenic exposure. Other potential sources of inorganic arsenic exposure that have been identified include fish and seafood, cereals, root vegetables, seaweed, dietary supplements, mushrooms, and tea. Given that rice-based products are frequently incorporated into infant weaning foods, it is crucial to evaluate arsenic exposure among infants, highlighting its significant importance (EFSA, 2009).

On October 12, 2009, the Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) within the European Food Safety Authority (EFSA) rendered an assessment regarding arsenic in food. In this evaluation, the CONTAM Panel determined that the provisional tolerable weekly intake (PTWI) of 15 µg/kg body weight, initially established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), was no longer appropriate. This decision was based on new data revealing that inorganic arsenic not only leads to skin-related issues but also causes lung and urinary bladder cancer. Furthermore, a range of adverse effects had been observed at exposure levels lower than those previously assessed by the JECFA.

In 2009, the EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) set a reference range of 0.3 to 8 micrograms per kilogram of body weight per day as the benchmark dose lower confidence limit (BMDL01) for a 1% increased risk of lung, skin, and bladder cancer, as well as skin lesions (Arcella et al., 2021).

The CONTAM Panel pinpointed various benchmark dose lower confidence limit (BMDL01) values ranging from 0.3 to 8 µg/kg body weight per day for lung, skin, and bladder cancers, along with skin lesions. Their scientific assessment ultimately determined that the estimated dietary exposures to inorganic arsenic among both average and high-level consumers in Europe fall within the spectrum of the BMDL01 values identified. Consequently, there is minimal or no safety margin, and the potential risk to certain consumers cannot be ruled out.

5.4 Commission Regulation (EU) 2015/1006 amending Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in foodstuffs

Article 1 of this regulation declared that "The Annex to Regulation (EC) No 1881/2006 is amended in accordance with the Annex to this Regulation". Additionally, "the maximum levels of arsenic in subsection 3.5 (Arsenic (inorganic)) of the Annex to Regulation (EC) No 1881/2006, as amended by this Regulation, shall apply from 1 January 2016".

Table 5. Annex to Commission Regulation (EU) 2015/1006 representing maximum levels for Arsenic in food

	Arsenic (inorganic)	**Maximum level (mg/kg)**
Inorganic arsenic (sum of $As^{(iii)}$ and $As^{(v)}$)	Non-paraboiled milled rice (polished or white rice)	0.20
	Paraboiled rice and husked rice	0.25
	Rice flour	0.25
	Rice waffles, rice wafers, rice crackers	0.30
	Rice destined for the production of food for infants and young children	0.10

5.5 Commission Regulation (EU) 2023/915 on setting maximum levels for Arsenic

In the spring of 2023, Regulation (EC) no 1881/2006, which established maximum levels for specific contaminants in food products, was superseded by Regulation (EU) 2023/915. Before this transition, the initial regulation had undergone nearly 50 amendments, incorporating additions and modifications to the roster of contaminants, maximum levels, and food categories. Given the prospect of further revisions, the Commission chose to substitute Regulation (EC) no 1881/2006 (Markkinen Niko, 2023).

Regulation (EU) 2023/915 establishes maximum limits for lead, cadmium, mercury, and arsenic in a broad spectrum of food items. The most recent revisions for lead and cadmium were made in 2021, for mercury in 2022, and for arsenic in 2023. The concentration of heavy metals is expressed in milligrams per kilogram of the product's wet weight (Markkinen Niko, 2023).

The items necessitating arsenic testing primarily encompass products derived from rice, along with baby food, fruit juices, and salt, which also mandate examination. The allowed arsenic levels in regulated goods vary from 0.01 to 0.5 mg/kg (Markkinen Niko, 2023).

Table 6. Annex I to Commission Regulation (EU) 2023/915 representing maximum levels for Arsenic in food

	Arsenic		**Maximum level (mg/kg)**	**Remarks**
Inorganic arsenic (sum of $As^{(iii)}$ and $As^{(v)}$)	Cereals and cereal based products	Non-paraboiled milled rice (polished or white rice)	0.15	Rice, husked rice, milled rice and parboiled rice as defined in Codex Standard 198-1995
		Paraboiled rice and husked rice	0.25	
		Rice flour	0.25	
		Rice waffles, rice wafers, rice crackers, rice cakes, rice flakes and popped breakfast rice	0.30	
		Rice destined for the production of food for infants and young children	0.10	
		Non-alcoholic rice-based drinks	0.030	
	Infant formulae, follow-on formulae and food for special medical purposes intended for infants and young children	Placed on the market as powder	0.020	The maximum level applies to the product as placed on the market

	(*) and young child formulae			
		Placed on the market as liquid	0.010	
	Baby food		0.020	The maximum level applies to the product as placed on the market
	Fruit iuices, concentrated fruit iuices as reconstituted and fruit nectars		0.020	
Total arsenic	Salt		0.50	

Chapter 6

Consequences of contaminants regulations on trade

Globalization and the growing consumer desire for diverse food options have led to an expanding cross-border exchange and commerce of food between nations, encompassing both imports and exports. In 2014, the total value of global food trade amounted to a substantial 1,486 billion US dollars (International Trade Statistics 2015 published by WTO).
Due to the ongoing expansion of the global food distribution network and the movement of food across borders, there is a heightened risk of contamination, underscoring the global emphasis on safety and quality. The significance of food safety cannot be overstated, as unsafe food can result in foodborne illnesses, malnutrition, food wastage, and losses, as well as diminished access to domestic and international markets due to rejections, consignment destruction, and withdrawals. These issues, in turn, have a far-reaching impact on consumer trust, economic growth, and a nation's reputation, among other factors (*Facilitating Compliance to Food Safety and Quality for Cross-Border Trade | ESCAP*, 2018).

6.1 Key food safety and quality issues that impact cross-border trade

Standards and conformity assessment have become increasingly significant in the context of international trade. On one side, nations are imposing more rigorous regulations to safeguard the health and safety of their citizens, covering both domestically produced and imported goods. Meanwhile, the private sector is establishing its own standards, utilizing them as a means of distinguishing products and gaining a competitive edge. To prevent the arbitrary application of standards, measures, or technical requirements by governments, the World Trade Organization (WTO) has established specific rules and regulations within the realm of non-tariff agreements, including the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement) (*Facilitating Compliance to Food Safety and Quality for Cross-Border Trade | ESCAP*, 2018). These Agreements, while allowing countries to establish standards for the protection of their populations and the promotion of fair trade, necessitate the maintenance of certain rules and principles. The objective is to ensure that standards, measures, and regulations do not create unjustified trade barriers. The SPS Agreement, with its specific focus on food safety and the health of animals and plants, primarily aims to preserve a government's sovereign right to determine the level of health protection it deems appropriate. However, it also aims to prevent the misuse of these sovereign rights for protectionist purposes and the creation of unnecessary obstacles to international trade. In the case of trade in food products, the TBT Agreement is also of significance and pertains to standards and technical regulations beyond health and safety considerations, encompassing areas such as quality, environment, social aspects, and welfare standards (*Facilitating Compliance to Food Safety and Quality for Cross-Border Trade | ESCAP*, 2018).

In recent years, there has been a growing focus on the ethical aspects of food production and consumption. This has resulted in increased attention to health protection, food quality, and the dynamics of European and international trade. On the consumer side, there is a rising awareness of potential food-related risks and a heightened concern for food safety. Consumers are now more inclined to purchase products that minimize health risks, and they are wary of the impact of technological advancements in the food industry. This heightened awareness has also influenced the food industry, prompting a greater emphasis on the entire production process. This, in turn, has encouraged the adoption of Good Agricultural Practices and proper methods for sourcing, processing, packaging, storage, and distribution. As a result, there has been a significant increase in efforts to monitor product traceability, enhance supervision, assess risks, and review the substances used in food production (Pettoello-Mantovani & Olivieri, 2022).

Additionally, the global trade in both unprocessed agricultural commodities used in food production and the finished food products themselves is on a consistent rise. This phenomenon has the effect of turning food regulation, including guidelines regarding trace elements and chemical contaminants in food, into a matter of international significance. Consequently, the effective regulation of food safety and quality will increasingly rely on international standards and cooperation in the future. The interconnectedness of the food supply chain, which spans across countries, emphasizes the necessity for a unified, globally coordinated approach to ensure food safety and quality for consumers worldwide (Berg & Licht, 2002).

To strike a reasonable balance among the interests of the stakeholders involved, it is imperative to foster maximum cooperation among the countries participating in this endeavor. This cooperation should be particularly emphasized at the EU level and also among nations with trade agreements related to food marketing. The goal is to mitigate protectionist measures and promote the unfettered trade of food products both within the European Union and on a global scale.
Furthermore, it is essential to acknowledge the substantial influence of technological innovation in the realm of food production. This influence requires increased oversight to prevent potential abuses and violations of legal regulations. Simultaneously, it is important to consider the significance of changes in dietary habits and food traditions. This must be done without succumbing to the often extreme or manipulative positions advocated by pressure groups and opinions (Pettoello-Mantovani & Olivieri, 2022).

6.2 Ensuring the safe flow of food products: European Union regulations and food safety

The primary challenges regarding food safety revolve around the varying implementation of product safety laws among different Member States. This results in a complex set of legislative requirements for economic operators who must navigate multiple legislative acts when dealing with food products. Moreover, additional inconsistencies have arisen within product legislation, including the utilization of diverse terminologies to describe concepts that are common in European legislation (Pettoello-Mantovani & Olivieri, 2022).
Another issue arises from the conflicting interests and behaviors of the parties involved, with a tension between safeguarding the unhindered movement of food products in the European market and ensuring public health. The unimpeded circulation of goods is a fundamental pillar of the single market and serves as a cornerstone in the establishment of the European Union. Since the 1970s, European Union legislation has consistently aimed to provide uniform protection for consumers, the environment, and energy resources by facilitating the free flow of goods within the Union. To achieve this, a comprehensive strategy has been devised to uphold a high standard of health protection through consistent measures and effective monitoring (Pettoello-Mantovani & Olivieri, 2022).
Within this framework, the European Union's actions pertaining to health complement those of its Member States, with the EU playing a coordinating role, as opposed to the European harmonization policies seen in the agricultural sector. Consequently, European efforts to

safeguard the right to health have led to both direct measures through secondary legislation and the development of soft law policy documents. This approach is mindful of the individual needs and preferences of member states. Concerning consumers, European policy has supported and integrated national policies aimed at preserving food safety and public health (Pettoello-Mantovani & Olivieri, 2022).

6.3 Regulating the trade of food products in the European Union

Article 36 of the TFEU (Treaty on the Functioning of the European Union) specifies that quantitative restrictions on imports and measures with similar effects (as outlined in Article 34 TFEU), as well as quantitative restrictions on exports and measures with similar effects (as stated in Article 35 TFEU), can be imposed on imports, exports, and goods in transit based on grounds related to public morality, public order, public security, health protection, life, animal protection, or plant preservation. However, it is essential to note that such prohibitions or restrictions must not serve as a means of arbitrary discrimination or a concealed means to hinder trade between Member States.

In this context, before importing animals or products of animal origin from another European Union country, a Member State may conduct non-discriminatory inspections. Specifically, Article 125 of **Regulation (EU) 2017/625[36] mentions:**

"The Commission shall request third countries which intend to export animals and goods to the Union to provide the following accurate and up-to-date information on the general organisation and management of sanitary and phytosanitary control systems in their territory:

(a) any sanitary or phytosanitary rules adopted or proposed within their territory;

[36] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)Text with EEA relevance., *OJ L 95, 7.4.2017, p. 1–142.*

(b)risk-assessment procedures and factors taken into consideration for the assessment of risks and for the determination of the appropriate level of sanitary or phytosanitary protection;

(c) any control and inspection procedures and mechanisms, including, where relevant, on animals or goods arriving from other third countries;

(d) official certification mechanisms;

(e) where appropriate, any measures taken following recommendations provided for in the first paragraph of Article 122;

(f) where relevant, results of controls performed on animals and goods intended to be exported to the Union; and

(g) where relevant, information on changes made to the structure and functioning of control systems adopted to meet Union sanitary or phytosanitary requirements or recommendations provided for in the first paragraph of Article 122".

The fundamental requirement for exporting food products is compliance with the food hygiene regulations in force in the exporting country, and exporting countries are expected to adhere to the regulations of the European Commission. Consequently, it is crucial for producers to ensure the traceability of food products from their origin to the consumer's table (Pettoello-Mantovani & Olivieri, 2022).

European legislation dictates that in situations where there is a potential threat to the consumer due to the production of a food product, procedures capable of identifying the product in the market and recalling it must be applied, even if it has been exported to other countries. Ensuring the safety of exported products necessitates adhering to conditions of reciprocity with third countries, and initiatives related to this requirement aim to strengthen and enhance product safety through effective market surveillance across the EU (Pettoello-Mantovani & Olivieri, 2022).

Chapter 7

Managing food contaminants: How the EU ensures that the food is safe

Regarding food contaminants, European Union legislation specifies that food containing an unacceptable level of contaminants from a public health perspective, particularly at a toxicological level, cannot be allowed in the market. Given that many contaminants occur naturally, it is not feasible to impose a complete ban on these substances. Instead, the most appropriate approach to safeguard public health is to maintain these substances at the lowest possible levels, determined based on sound scientific evidence[37].

The several crises and scandals related to food, lead to the development of what is known as the Hygiene Package, which was designed with the objectives of setting stringent safety standards, facilitating the unimpeded movement of food products, and restoring consumer trust in control mechanisms within the EU. The Hygiene Package incorporates Regulation (EC) no 882/2004[38] (repealed by Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017[39]), titled 'Official Controls to Ensure Compliance with Feed and Food Regulations and Animal Health and Welfare Guidelines.' This regulation established European Union reference laboratories (EURLs) responsible for offering scientific and technical support to the Commission. They collaborate closely with the national reference laboratories (NRLs) in each Member State (MS). Similarly, the NRLs are tasked with coordinating and assisting the official laboratories (OLs) responsible for analyzing feed and food products at the national level (Sorbo et al., 2022).

[37] https://food.ec.europa.eu/safety/chemical-safety/contaminants_en

[38] Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, OJ L 165, 30.4.2004, p. 1–141.

[39] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation), OJ L 95, 7.4.2017, p. 1–142.

The control and response mechanisms of the European Union rely on Member States conducting random inspections. In the event of a risk being detected, swift and suitable measures are promptly implemented.

Member States conduct random sampling and analysis of food products and regularly report their findings. If any samples are found to be non-compliant with legislation, appropriate actions are taken. These findings are then made available to all Member States. In the event that national authorities discover a potential risk during their inspections, they have the authority to temporarily suspend or limit the production or distribution of affected products. However, they must immediately notify other Member States and the European Commission while providing reasons for their decision. This process is facilitated by the Rapid Alert System for Food and Feed (RASFF), which enables the swift exchange of information among national competent authorities, the European Commission, and the European Food Safety Authority (EFSA). The RASFF network includes Member States, the European Commission, EFSA, as well as Norway, Iceland, and Liechtenstein (Sorbo et al., 2022).

7.1 The rapid alert system for food and feed

The European Commission established the Rapid Alert System for Food and Feed (RASFF) as an effective mechanism for food and feed control authorities to exchange information regarding actions taken in response to significant risks associated with food or feed. This information sharing serves to enable member states to respond more swiftly and in a coordinated manner when faced with health hazards linked to food or feed. RASFF notifications typically pertain to risks identified in food, feed, or food contact materials either being introduced into the market within the notifying country or being held at an EU border entry point. The notifying country reports the risks it has detected, along with details about the product, its traceability, and the measures taken in response. Following an assessment of the seriousness of the identified risks and the product's distribution in the market, the RASFF notification is categorized after review by the Commission contact point. These categories include alert, information, or border rejection notifications, which are subsequently shared with all network members (*Facilitating Compliance to Food Safety and Quality for Cross-Border Trade | ESCAP*, 2018).

An 'alert notification' or simply 'alert' is dispatched when a food, feed, or food contact material is found on the market and poses a serious risk, necessitating rapid action beyond the notifying country. These alerts are initiated by a member of the network that identifies the issue and initiates corresponding measures, such as product withdrawal or recall. The purpose of this notification is to provide all network members with the information needed to determine if the implicated product is present in their markets, enabling them to take appropriate measures. Products subject to an alert notification have already been withdrawn from the market or are in the process of being removed (*Facilitating Compliance to Food Safety and Quality for Cross-Border Trade | ESCAP*, 2018).

An 'information notification' pertains to a food, feed, or food contact material where a risk has been identified, but it does not require immediate action. This could be because the risk is not deemed severe or the product is not currently available on the market at the time of notification. Information notifications have two subtypes: 'information notifications for follow-up,' which relate to a product that is or may be introduced to another member country, and 'information notifications for attention,' which concern products that are either solely in the notifying member country, have not been placed on the market, or are no longer available in the market (*Facilitating Compliance to Food Safety and Quality for Cross-Border Trade | ESCAP*, 2018).

A 'border rejection notification' relates to a shipment of food, feed, or food contact material that was denied entry into the European Community due to potential risks to human health, animal health, or the environment in the case of feed products (*Facilitating Compliance to Food Safety and Quality for Cross-Border Trade | ESCAP*, 2018).

Chapter 8

Conclusion

The journey through this thesis has explored the multifaceted realm of food contaminants, with a particular focus on arsenic, and the legal framework governing its presence in foodstuffs within the European Union.

In the opening chapter, we established a foundational understanding of contaminants and restricted substances in food. Contaminants encompass a wide array of substances, both avoidable and unavoidable, which may find their way into food products. These substances may originate from diverse sources such as agricultural practices, environmental pollution, storage, transportation, or even emerge during food processing. These contaminants span various categories, from veterinary drugs to heavy metals, natural toxins, and compounds formed during food processing. The Council Regulation (EEC) No 315/93 provides a pivotal definition of contaminants, creating the framework for subsequent regulation within the European Union.

The findings underscore the necessity of maintaining a balance between protecting public health and facilitating the free movement of safe food products within the EU. Striking this balance is a continuous process, requiring ongoing research, monitoring, and adaptation to ever-evolving scientific knowledge.

As we look to the future, the challenge lies in not only sustaining the effectiveness of existing regulations but also in responding to emerging contaminants and risks, reflecting the dynamic nature of the food safety landscape.

The international perspective of this issue is addressed by the Codex Alimentarius (CA), setting maximum values for environmental contaminants in food to ensure global food safety and promote the free movement of products. In this interconnected world, harmonization of food standards, as upheld by the World Trade Organization (WTO), is increasingly vital. The work of the Codex Committee on Contaminants in Food (CCCF) also plays a crucial role in setting permissible maximum levels and guidelines for contaminants in food and feed, aligning with the standards endorsed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

Within the European Union, a series of food safety crises over the past few decades, including Bovine Spongiform Encephalopathy (BSE), dioxins, and high pesticide and antibiotic content, have prompted substantial legislative efforts to prevent crises rather than merely react to them. The EU has adopted an integrated approach to food safety, seeking to maintain high standards while facilitating the efficient functioning of the internal market. As a result, the EU has made significant progress in harmonizing regulations for environmental contaminants in food, establishing common maximum levels for substances like heavy metals and polychlorinated dibenzodioxins and furans (PCDD/F), while also leaving room for nationally specific regulations.

Chapter 3 examined the historical development of food legislation in the European Union, which underpins the current regulatory framework for contaminants. The legislative history is marked by key regulations such as Council Regulation (EC) No 315/93, Council Regulation (EC) No 194/97, Council Regulation (EC) No 466/2001, Council Regulation EC No 1881/2006, Commission Regulation (EU) 2015/1006, and Council Regulation (EEC) No 2023/915, each playing a crucial role in shaping the EU's approach to contaminants in food.

These regulations underscore the EU's commitment to setting standards for contaminants and restricted substances in food products. The European Union's response to these food safety crises, epitomized by the establishment of regulatory authorities and rigorous standards, represents a paradigm shift toward proactive measures and preventive actions to protect the health and safety of European consumers. Understanding this historical context is pivotal to grasp the depth and significance of the EU's commitment to food safety.

Chapter 4 delves into the management of food contaminants in the European Union, examining the definitions and scopes outlined in Regulation (EC) No 178/2002. The core principles governing the control of chemical contaminants in food, as defined by Framework Council Regulation (EC) no 315/93, stress the importance of understanding what constitutes a "contaminant" in food law. This all-encompassing definition, shared with the Codex Alimentarius, unifies chemical and specific biological hazards under a single umbrella, emphasizing the need to prevent the presence of such substances in food.

The concept of maximum residue levels (MRLs) for pesticides provides an illustrative example of how necessity and safety underpin the establishment of legal limits for contaminants. MRLs are founded on what is deemed unavoidable within recommended best practices. Anything that can reasonably be avoided must be prevented and is not allowed on the market. Safety, in contrast, relies on a risk assessment rooted in toxicology, ensuring that legal thresholds align with established safety standards. The interplay between these two factors, necessity and safety, exemplifies the complexity and thoroughness of the EU's approach to food safety.

Chapter 5 narrows our focus to arsenic regulation within the European Union. Arsenic, as a prime example of a highly toxic contaminant, serves as a poignant case study in understanding the EU's regulatory prowess. We delve into the Report of experts participating in Task 3.2.11 and its implications, as well as the guidance on intake limitations provided by SCOOP 3.2.11.
Understanding the work of organizations such as the Food and Agriculture Organization (FAO) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in assessing food safety and contaminants is pivotal to comprehend the broader international context. The European Food Safety Authority (EFSA) also plays a pivotal role in ensuring food safety and contaminant assessment within the EU. The issuance of Commission Regulation (EU) 2015/1006, which amended Regulation (EC) No 1881/2006 to establish maximum levels of inorganic arsenic in foodstuffs, marked a significant milestone in the EU's commitment to controlling arsenic contamination. Furthermore, Commission Regulation (EU) 2023/915 sets maximum levels for arsenic in various food categories, emphasizing the ongoing evolution of regulations to adapt to emerging scientific knowledge and protect consumers from potential risks.
Chapter 6 explores the intricate relationship between contaminants regulations and international trade. As the EU upholds stringent regulations to protect its consumers, trade dynamics are inevitably influenced. Stringent regulations may serve as non-tariff barriers to trade, posing challenges for exporters and importers alike. However, these regulations are essential for ensuring that the products entering the European market meet the highest standards of safety and quality. The EU's approach to regulating contaminants in food is fundamentally intertwined with its commitment to protecting public health and the well-being of its citizens.
In conclusion, this thesis has provided a comprehensive exploration of contaminants in food, with a primary focus on the regulation of arsenic within the European Union. The European Union's approach to managing contaminants in food is underpinned by a robust legislative framework, grounded in historical context, and evolving to address emerging challenges. The EU's commitment to food safety is unwavering, as evidenced by its harmonization with international standards and continuous efforts to adapt to new scientific knowledge and protect consumers from potential risks.
This research underscores the critical importance of regulating contaminants in food to ensure the safety and quality of food products and protect consumers.

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Annex A

Table 7. Table indicating the maximum levels for nitrates in foodstuffs according to Council Regulation (EC) No 466/2001

MAXIMUM LEVELS FOR CERTAIN CONTAMINANTS IN FOODSTUFFS

Section 1: Nitrates (1)

Product	Maximum level (mg NO_3 / kg)		Sampling method	Reference analysis method
1.1. Fresh spinach (2) (*Spinacia oleracea*)	Harvested 1 November to 31 March: Harvested 1 April to 31 October:	3 000 (3) 2 500 (3)	Commission directive 79/700/EEC (4)	
1.2. Preserved, deep-frozen or frozen spinach		2 000	Directive 79/700/EEC	
1.3. Fresh Lettuce (*Lactuca sativa L.*) (protected and open-grown lettuce)	Harvested 1 October to 31 March: Harvested 1 April to 30 September: with the exception of open-grown lettuce harvested from 1 May to 31 August	4 500 (3) 3 500 (3) (5) 2 500 (3) (5)	Directive 79/700/EEC. However, the minimum number of units per laboratory sample is 10	

Table 8. Table indicating the maximum levels for mycotoxins in foodstuffs according to Council Regulation (EC) No 466/2001

Section 2: Mycotoxins

Product	Maximum level (µg / kg)			Sampling method	Performance criteria for methods of analysis
	B_1	$B_1 + B_2 + G_1 + G_2$	M_1		
2.1. AFLATOXINS (1) 2.1.1. Groundnuts, nuts and dried fruit					
2.1.1.1. Groundnuts, nuts and dried fruit and processed products thereof, intended for direct human consumption or as an ingredient in foodstuffs	2 (6)	4 (6)	—	Directive 98/53/EC (7)	Directive 98/53/EC
2.1.1.2. Groundnuts to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	8 (6)	15 (6)	—	Commission directive 98/53/EC	Directive 98/53/EC

Product	Maximum level (µg / kg)			Sampling method	Performance criteria for methods of analysis
	B_1	$B_1 + B_2 + G_1 + G_2$	M_1		
2.1.1.3. Nuts and dried fruit to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	5 (6) (8)	10 (6) (8)	—	Directive 98/53/EC	Directive 98/53/EC
2.1.2. Cereals (including buckwheat, *Fagopyrum* sp.)					
2.1.2.1. Cereals (including buckwheat, *Fagopyrum* sp.) and processed products thereof intended for direct human consumption or as an ingredient in foodstuffs	2	4	—	Directive 98/53/EC	Directive 98/53/EC
2.1.2.2. Cereals (including buckwheat, *Fagopyrum* sp.) to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	— (9)	— (9)	—	Directive 98/53/EC	Directive 98/53/EC
2.1.3. Milk (raw milk, milk for the manufacture of milk-based products and heat-treated milk as defined by Council Directive 92/46/EEC (10), as last amended by Council Directive 94/71/EC (11)).	—	—	0,05	Directive 98/53/EC	Directive 98/53/EC

Table 9. Table indicating the maximum levels for heavy metals in foodstuffs according to Council Regulation (EC) No 466/2001

Section 3: Heavy metals

Product	Maximum level (mg/kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
3.1. LEAD (Pb)			
3.1.1. Cows' milk (raw milk, milk for the manufacture of milk-based products and heat-treated milk as defined by Directive 92/46/EEC)	0,02	Commission directive 2001/22/EC (12)	Directive 2001/22/EC
3.1.2. Infant formulae and follow-on formulae as defined in Directive 91/321/EEC (13)	0,02	Directive 2001/22/EC	Directive 2001/22/EC

Product	Maximum level (mg/kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
3.1.3. Meat of bovine animals, sheep, pig and poultry as defined in Article 2(a) of Council Directive 64/433/EEC ([14]), as last amended by Directive 95/23/EC ([15]), and Article 2(1) of Council Directive 71/118/EEC ([16]), as last amended by Directive 97/79/EC ([17]), excluding offal as defined in Article 2(e) of Directive 64/433/EEC and Article 2(5) of Directive 71/118/EEC	0,1	Directive 2001/22/EC	Directive 2001/22/EC
3.1.3.1. Edible offal of cattle, sheep, pig and poultry as defined in Article 2(e) of Directive 64/433/EEC and Article 2(5) of Directive 71/118/EEC	0,5	Directive 2001/22/EC	Directive 2001/22/EC
3.1.4. Muscle meat of fish as defined in category (a), (b) and (e) of the list in Article 1 of Council Regulation (EC) No 104/2000 ([18]), excluding fish species listed in point 3.1.4.1	0,2	Directive 2001/22/EC	Directive 2001/22/EC
3.1.4.1. Muscle meat of wedge sole (*Dicologoglossa cuneata*), eel (*Anguilla anguilla*), spotted seabass (*Dicentrarchus punctatus*), horse mackerel or scad (*Trachurus trachurus*), grey mullet (*Mugil labrosus labrosus*), common two-banded seabream (*Diplodus vulgaris*), grunt (*Pomadasys benneti*), European plichard or sardine (*Sardina pilchardus*)	0,4	Directive 2001/22/EC	Directive 2001/22/EC
3.1.5. Crustaceans, excluding brown meat of crab	0,5	Directive 2001/22/EC	Directive 2001/22/EC
3.1.6. Bivalve molluscs	1,0	Directive 2001/22/EC	Directive 2001/22/EC
3.1.7 Cephalopods (without viscera)	1,0	Directive 2001/22/EC	Directive 2001/22/EC
3.1.8. Cereals (including buckwheat), legumes and pulses	0,2	Directive 2001/22/EC	Directive 2001/22/EC

Product	Maximum level (mg/kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
3.1.9. Vegetables as defined in Article 1 of Council Directive 90/642/EEC [19], as last amended by Directive 2000/48/EC [20], excluding brassica, leafy vegetables, fresh herbs and all fungi. For potatoes the maximum level applies to peeled potatoes	0,1	Directive 2001/22/EC	Directive 2001/22/EC
3.1.9.1. Brassica, leafy vegetables and all cultivated fungi	0,3	Directive 2001/22/EC	Directive 2001/22/EC
3.1.10. Fruit as defined in Article 1 of Directive 90/642/EEC, excluding berries and small fruits	0,1	Directive 2001/22/EC	Directive 2001/22/EC
3.1.10.1. Berries and small fruits as defined in Article 1 of Council Directive 90/642/EEC	0,2	Directive 2001/22/EC	Directive 2001/22/EC
3.1.11. Fats and oils, including milk fat	0,1	Directive 2001/22/EC	Directive 2001/22/EC

3.1.12. Fruit juices, concentrated fruit juices (for direct consumption) and fruit nectars as defined in Council Directive 93/77/EEC ([21])	0,05	Directive 2001/22/EC	Directive 2001/22/EC
3.1.13. Wines as defined in Council Regulation (EC) No 1493/1999 ([22]) (including sparkling wines and excluding liqueur wines), aromatised wines, aromatised wine-based drinks and aromatised wine-product cocktails as defined in Council Regulation (EEC) No 1601/91, and ciders, perry and fruit wines. Maximum level applies to products produced from the 2001 fruit harvest onwards	0,2	Directive 2001/22/EC	Directive 2001/22/EC

Table 10. Table indicating the maximum levels for nitrates in foodstuffs according to Council Regulation (EC) No 1881/2006

Maximum levels for certain contaminants in foodstuffs ([1])

Section 1: Nitrate

	Foodstuffs ([1])	Maximum levels (mg NO_3/kg)	
1.1	Fresh spinach (*Spinacia oleracea*) ([2])	Harvested 1 October to 31 March	3 000
		Harvested 1 April to 30 September	2 500
1.2	Preserved, deep-frozen or frozen spinach		2 000
1.3	Fresh Lettuce (*Lactuca sativa* L.) (protected and open-grown lettuce) excluding lettuce listed in point 1.4	Harvested 1 October to 31 March:	
		lettuce grown under cover	4 500
		lettuce grown in the open air	4 000
		Harvested 1 April to 30 September:	
		lettuce grown under cover	3 500
		lettuce grown in the open air	2 500
1.4	Iceberg-type lettuce	Lettuce grown under cover	2 500
		Lettuce grown in the open air	2 000
1.5	Processed cereal-based foods and baby foods for infants and young children ([3]) ([4])		200

Table 11. Table indicating the maximum levels for mycotoxins in foodstuffs according to Council Regulation (EC) No 1881/2006

Section 2: Mycotoxins

Foodstuffs (1)		Maximum levels (μg/kg)		
2.1	**Aflatoxins**	B_1	Sum of B_1, B_2, G_1 and G_2	M_1
2.1.1	Groundnuts to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	8,0 (5)	15,0 (5)	—
2.1.2	Nuts to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	5,0 (5)	10,0 (5)	—
2.1.3	Groundnuts and nuts and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs	2,0 (5)	4,0 (5)	—
2.1.4	Dried fruit to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	5,0	10,0	—
2.1.5	Dried fruit and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs	2,0	4,0	—
2.1.6	All cereals and all products derived from cereals, including processed cereal products, with the exception of foodstuffs listed in 2.1.7, 2.1.10 and 2.1.12	2,0	4,0	—
2.1.7	Maize to be subjected to sorting or other physical treatment before human consumption or use as an ingredient in foodstuffs	5,0	10,0	—
2.1.8	Raw milk (6), heat-treated milk and milk for the manufacture of milk-based products	—	—	0,050
2.1.9	Following species of spices: *Capsicum* spp. (dried fruits thereof, whole or ground, including chillies, chilli powder, cayenne and paprika) *Piper* spp. (fruits thereof, including white and black pepper) *Myristica fragrans* (nutmeg) *Zingiber officinale* (ginger) *Curcuma longa* (turmeric)	5,0	10,0	—
2.1.10	Processed cereal-based foods and baby foods for infants and young children (3) (7)	0,10	—	—
2.1.11	Infant formulae and follow-on formulae, including infant milk and follow-on milk (4) (8)	—	—	0,025
2.1.12	Dietary foods for special medical purposes (9) (10) intended specifically for infants	0,10	—	0,025

2.2	**Ochratoxin A**	
2.2.1	Unprocessed cereals	5,0
2.2.2	All products derived from unprocessed cereals, including processed cereal products and cereals intended for direct human consumption with the exception of foodstuffs listed in 2.2.9 and 2.2.10	3,0
2.2.3	Dried vine fruit (currants, raisins and sultanas)	10,0
2.2.4	Roasted coffee beans and ground roasted coffee, excluding soluble coffee	5,0
2.2.5	Soluble coffee (instant coffee)	10,0
2.2.6	Wine (including sparkling wine, excluding liqueur wine and wine with an alcoholic strength of not less than 15 % vol) and fruit wine (11)	2,0 (12)
2.2.7	Aromatised wine, aromatised wine-based drinks and aromatised wine-product cocktails (13)	2,0 (12)
2.2.8	Grape juice, concentrated grape juice as reconstituted, grape nectar, grape must and concentrated grape must as reconstituted, intended for direct human consumption (14)	2,0 (12)
2.2.9	Processed cereal-based foods and baby foods for infants and young children (3) (7)	0,50
2.2.10	Dietary foods for special medical purposes (9) (10) intended specifically for infants	0,50
2.2.11	Green coffee, dried fruit other than dried vine fruit, beer, cocoa and cocoa products, liqueur wines, meat products, spices and liquorice	—
2.3	**Patulin**	
2.3.1	Fruit juices, concentrated fruit juices as reconstituted and fruit nectars (14)	50

	Foodstuffs (1)	Maximum levels (μg/kg)
2.3.2	Spirit drinks (15), cider and other fermented drinks derived from apples or containing apple juice	50
2.3.3	Solid apple products, including apple compote, apple puree intended for direct consumption with the exception of foodstuffs listed in 2.3.4 and 2.3.5	25
2.3.4	Apple juice and solid apple products, including apple compote and apple puree, for infants and young children (16) and labelled and sold as such (4)	10,0
2.3.5	Baby foods other than processed cereal-based foods for infants and young children (3) (4)	10,0

2.4	**Deoxynivalenol** (17)	
2.4.1	Unprocessed cereals (18) (19) other than durum wheat, oats and maize	1 250
2.4.2	Unprocessed durum wheat and oats (18) (19)	1 750
2.4.3	Unprocessed maize (18)	1 750 (20)
2.4.4	Cereals intended for direct human consumption, cereal flour (including maize flour, maize meal and maize grits (21)), bran as end product marketed for direct human consumption and germ, with the exception of foodstuffs listed in 2.4.7	750
2.4.5	Pasta (dry) (22)	750
2.4.6	Bread (including small bakery wares), pastries, biscuits, cereal snacks and breakfast cereals	500
2.4.7	Processed cereal-based foods and baby foods for infants and young children (3) (7)	200
2.5	**Zearalenone** (17)	
2.5.1	Unprocessed cereals (18) (19) other than maize	100
2.5.2	Unprocessed maize (18)	200 (20)
2.5.3	Cereals intended for direct human consumption, cereal flour, bran as end product marketed for direct human consumption and germ, with the exception of foodstuffs listed in 2.5.4, 2.5.7 and 2.5.8	75
2.5.4	Maize intended for direct human consumption, maize flour, maize meal, maize grits, maize germ and refined maize oil (21)	200 (20)
2.5.5	Bread (including small bakery wares), pastries, biscuits, cereal snacks and breakfast cereals, excluding maize snacks and maize based breakfast cereals	50
2.5.6	Maize snacks and maize based breakfast cereals	50 (20)

Foodstuffs ([1])		Maximum levels (μg/kg)
2.5.7	Processed cereal-based foods (excluding processed maize-based foods) and baby foods for infants and young children ([3]) ([7])	20
2.5.8	Processed maize-based foods for infants and young children ([3]) ([7])	20 ([20])
2.6	**Fumonisins**	Sum of B_1 and B_2
2.6.1	Unprocessed maize ([18])	2 000 ([23])
2.6.2	Maize flour, maize meal, maize grits, maize germ and refined maize oil ([21])	1 000 ([23])
2.6.3	Maize based foods for direct human consumption, excluding foods listed in 2.6.2 and 2.6.4	400 ([23])
2.6.4	Processed maize-based foods and baby foods for infants and young children ([3]) ([7])	200 ([23])
2.7	**T-2 and HT-2 toxin** ([17])	Sum of T-2 and HT-2 toxin
2.7.1	Unprocessed cereals ([18]) and cereal products	

Table 12. Table indicating the maximum levels for metals in foodstuffs according to Council Regulation (EC) No 1881/2006

Section 3: Metals

Foodstuffs ([1])		Maximum levels (mg/kg wet weight)
3.1	**Lead**	
3.1.1	Raw milk ([6]), heat-treated milk and milk for the manufacture of milk-based products	0,020
3.1.2	Infant formulae and follow-on formulae ([4]) ([8])	0,020
3.1.3	Meat (excluding offal) of bovine animals, sheep, pig and poultry ([6])	0,10
3.1.4	Offal of bovine animals, sheep, pig and poultry ([6])	0,50
3.1.5	Muscle meat of fish ([24]) ([25])	0,30
3.1.6	Crustaceans, excluding brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (*Nephropidae* and *Palinuridae*) ([26])	0,50
3.1.7	Bivalve molluscs ([26])	1,5
3.1.8	Cephalopods (without viscera) ([26])	1,0
3.1.9	Cereals, legumes and pulses	0,20
3.1.10	Vegetables, excluding brassica vegetables, leaf vegetables, fresh herbs and fungi ([27]). For potatoes the maximum level applies to peeled potatoes	0,10

Foodstuffs [1]		Maximum levels (mg/kg wet weight)
3.1.11	Brassica vegetables, leaf vegetables and cultivated fungi [27]	0,30
3.1.12	Fruit, excluding berries and small fruit [27]	0,10
3.1.13	Berries and small fruit [27]	0,20
3.1.14	Fats and oils, including milk fat	0,10
3.1.15	Fruit juices, concentrated fruit juices as reconstituted and fruit nectars [14]	0,050
3.1.16	Wine (including sparkling wine, excluding liqueur wine), cider, perry and fruit wine [11]	0,20 [28]
3.1.17	Aromatized wine, aromatized wine-based drinks and aromatized wine-product cocktails [13]	0,20 [28]
3.2	**Cadmium**	
3.2.1	Meat (excluding offal) of bovine animals, sheep, pig and poultry [6]	0,050
3.2.2	Horsemeat, excluding offal [6]	0,20
3.2.3	Liver of bovine animals, sheep, pig, poultry and horse [6]	0,50
3.2.4	Kidney of bovine animals, sheep, pig, poultry and horse [6]	1,0
3.2.5	Muscle meat of fish [24] [25], excluding species listed in 3.2.6 and 3.2.7	0,050
3.2.6	Muscle meat of the following fish [24] [25]: anchovy (*Engraulis species*) bonito (*Sarda sarda*) common two-banded seabream (*Diplodus vulgaris*) eel (*Anguilla anguilla*) grey mullet (*Mugil labrosus labrosus*) horse mackerel or scad (*Trachurus species*) louvar or luvar (*Luvarus imperialis*) sardine (*Sardina pilchardus*) sardinops (*Sardinops species*) tuna (*Thunnus species, Euthynnus species, Katsuwonus pelamis*) wedge sole (*Dicologoglossa cuneata*)	0,10
3.2.7	Muscle meat of swordfish (*Xiphias gladius*) [24] [25]	0,30
3.2.8	Crustaceans, excluding brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (*Nephropidae* and *Palinuridae*) [26]	0,50
3.2.9	Bivalve molluscs [26]	1,0
3.2.10	Cephalopods (without viscera) [26]	1,0

	Foodstuffs ([1])	Maximum levels (mg/kg wet weight)
3.2.11	Cereals excluding bran, germ, wheat and rice	0,10
3.2.12	Bran, germ, wheat and rice	0,20
3.2.13	Soybeans	0,20
3.2.14	Vegetables and fruit, excluding leaf vegetables, fresh herbs, fungi, stem vegetables, pine nuts, root vegetables and potatoes ([27])	0,050
3.2.15	Leaf vegetables, fresh herbs, cultivated fungi and celeriac ([27])	0,20
3.2.16	Stem vegetables, root vegetables and potatoes, excluding celeriac ([27]). For potatoes the maximum level applies to peeled potatoes	0,10
3.3	**Mercury**	
3.3.1	Fishery products ([18]) and muscle meat of fish ([24]) ([25]), excluding species listed in 3.3.2. The maximum level applies to crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (*Nephropidae* and *Palinuridae*)	0,50
3.3.2	Muscle meat of the following fish ([24]) ([25]): anglerfish (*Lophius species*) atlantic catfish (*Anarhichas lupus*) bonito (*Sarda sarda*) eel (*Anguilla species*) emperor, orange roughy, rosy soldierfish (*Hoplostethus species*) grenadier (*Coryphaenoides rupestris*) halibut (*Hippoglossus hippoglossus*) marlin (*Makaira species*) megrim (*Lepidorhombus species*) mullet (*Mullus species*) pike (*Esox lucius*) plain bonito (*Orcynopsis unicolor*) poor cod (*Tricopterus minutes*) portuguese dogfish (*Centroscymnus coelolepis*) rays (*Raja species*) redfish (*Sebastes marinus, S. mentella, S. viviparus*) sail fish (*Istiophorus platypterus*) scabbard fish (*Lepidopus caudatus, Aphanopus carbo*) seabream, pandora (*Pagellus species*) shark (all species) snake mackerel or butterfish (*Lepidocybium flavobrunneum, Ruvettus pretiosus, Gempylus serpens*) sturgeon (*Acipenser species*) swordfish (*Xiphias gladius*) tuna (*Thunnus species, Euthynnus species, Katsuwonus pelamis*)	1,0
3.4	**Tin (inorganic)**	
3.4.1	Canned foods other than beverages	200
3.4.2	Canned beverages, including fruit juices and vegetable juices	100

Foodstuffs (1)		Maximum levels (mg/kg wet weight)
3.4.3	Canned baby foods and processed cereal-based foods for infants and young children, excluding dried and powdered products (3) (29)	50
3.4.4	Canned infant formulae and follow-on formulae (including infant milk and follow-on milk), excluding dried and powdered products (8) (29)	50
3.4.5	Canned dietary foods for special medical purposes (9) (29) intended specifically for infants, excluding dried and powdered products	50