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The definition of chemical contaminants in food: Ambiguity and consequences

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ABSTRACT

Consumers may be exposed via foods to a diverse range of substances that could be considered as contaminants. However, it is not always straightforward to understand the definition of a 'contaminant'. The present review evaluates how various categories of food-relevant substances are considered in terms of being 'contaminants'. To this end these categories of food borne constituents are evaluated against the various criteria encountered in the available definitions of a food contaminant, including unintentional presence, harmful, existence of regulatory limits, and stakeholder perception. The categories of chemicals considered include: phytotoxins, mycotoxins, (heavy) metals, persistent organic pollutants (POPs), processing aids, process related contaminants, food contact materials (FCMs), pesticides and veterinary drugs. The evaluation revealed that usage of the term appears complex, and may differ between stakeholders. A common proposed definition of the term 'contaminant' could be 'a substance considered to require control measures due to the unacceptability of its context within a food'. Use of a dimension of harm results in equivocal outcomes because risk depends on the level of exposure. As the term 'contaminant' has influence on risk management including public policy, the motivations for applying the term should be subject to more detailed analysis and understanding.

1. Introduction

Food safety management remains based on the historical aim that food should be safe, acknowledging the modern understanding that nothing is completely safe, and that societal dialogue is needed to determine what constitutes an acceptable degree of risk. This is particularly evident when the term 'food contaminant' is used, as besides any regulatory definitions that may apply in specific circumstances, the term is used loosely to mean any substance whose presence in food is considered unacceptable. *Via* food, the consumer may be exposed to a diverse range of chemicals that may be considered as contaminants, including for example natural toxins such as phytotoxins and mycotoxins, environmental contaminants, for example (heavy) metals, persistent organic pollutants (POPs) including dioxins, polychlorinated biphenyls (PCBs) and per- and poly-fluoroalkyl substances (PFAS), and process related contaminants, food contact materials (FCMs), or residues from processing aids, veterinary drugs or pesticides. These different types of contaminants generally originate from different sources, each having a different degree of intentionality, perceived risk and historical presence which are some of the reasons why definitions for what would be classified as a contaminant may vary. Increasing confusion comes from the fact that recognized food ingredients themselves are at times also referred to as 'contaminants' also by regulatory agencies, if they have an intrinsic hazard and are present unexpectedly, such as when peanut lecithin was found within the soy lecithin supply chain (Food Standards Agency, 2022), a concern for consumers allergic to peanut but not the labelled soy. This demonstrates that published definitions of a 'contaminant' may not be sufficient to describe the common use of the term by stakeholders. This is important, as the perception of the term, and the associated understanding of food contamination, impacts food acceptability and policy making.

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Abbreviations

ADI	acceptable daily intake
ALARA	as low as reasonably achievable
ARfD	acute reference dose
ATSDR	Agency for Toxic Substances and Disease Registry
CAC	Codex Alimentarius Commission
DDT	dichlorodiphenyltrichloroethane
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization of the United Nation
FCA	food contact article
FCMs	food contact materials
FDA	Food and Drug Administration
FSQA	food safety and quality assurance
HCAs	heterocyclic amines
IARC	International Agency for Research on Cancer
IAS	intentionally added substance
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MOE	margin of exposure
MOHs	mineral oil hydrocarbons
MRLs	maximum residue limits
NIAS	non-intentionally added substance
PAHs	polycyclic aromatic hydrocarbons
PCBs	polychlorinated biphenyls
PCDD	polychlorinated dibenzo-para-dioxins
PCDFs	polychlorinated dibenzofurans
PFAS	per- and poly-fluoroalkyl substances
POPs	persistent organic pollutants
SML	specific migration limit
TDI	tolerable daily intake
TWI	tolerable weekly intake
USA	United States of America
US-EPA	United States Environmental Protection Agency
WHO	World Health Organization
3-MCPD	3-monochloropropanediol

Table 1 presents an overview of published definitions of the term 'food contaminant' provided by regulatory agencies. From this overview it is clear that authoritative definitions vary widely, several definitions include an aspect of non-intentional presence, the hazardous nature of the chemical to human health, presence in amounts greater than those permitted by current regulations, or the source such as originating from environmental pollution, crop protection, processing, production, treatment, packaging, storage, transportation, conservation, preparation etc. An aspect of harm is included in a number of authoritative definitions for example by the FDA, the Chinese FDA, the Indonesian FDCA, the Chile APRUEBA. The presence of a chemical at the time of consumption and in an amount greater than permitted by regulation can be found in the definition provided by Codigo Alimentario Argentino. The presence at amounts greater than those permitted by current regulation is expressed in the definition provided by Chile APRUEBA stating: "The presence of …. and/or toxic substances in amounts greater than those permitted by current regulations, or that are presumed harmful to human health." The source of the chemical is included in definitions from the EC, the UK FSA, the Chinese FDA, the Indonesian FDCA, the Codigo Alimentario Argentino. As a result, it is not always straightforward when a chemical present in food is to be considered a contaminant, and the understanding may vary among stakeholders even within a single jurisdiction. For example, furan, which is particularly volatile, is present in roasted beans and ground coffee but may evaporate as a result of brewing which implies that based on a definition that states "any undesirable substance present in the food at the time of consumption", it may not be considered a significant contaminant, while many other definitions do not include this aspect, and would classify furan as a potential contaminant. In addition, there may be a perception by some stakeholders that furan is not a contaminant in coffee as furan and its structural congeners contribute to the traditional organoleptic properties of coffee (Hameed et al., 2018; Pavesi Arisseto et al., 2011). Also, pesticides may be classified either as a contaminant or not, based on whether they originate from environmental pollution, are due to non-compliant use on crops, or are present from intentional and compliant application to a crop. The same discrepancy would hold for chlorate, which can be present unintentionally as a result of its use as a disinfectant of food processing equipment or as a residue from its intentional use as a pesticide. When using the criterion of unintentional presence in the definition, it is also questionable whether plant-based pyrrolizidine alkaloids in botanical food supplements or teas should be considered a contaminant given that the respective plants and thus also their constituents can be intentionally present as a constituent of the food product. In contrast, when pyrrolizidine alkaloid containing botanicals would be unintentionally co-harvested with the teas, the same chemicals would be considered a contaminant. Furthermore, under definitions that do include an aspect of harm, a substance may no longer be considered a food contaminant so long as its concentration would not result in exposure that will be "disturbing, harming and endangering human health". These examples illustrate that it is not always straightforward to conclude whether a constituent in food is to be considered a contaminant or not. Food contaminants that are under regulatory requirements are so with an intention to protect public health. The agencies that establish regulation act on behalf of the public and ameliorate the public lack of understanding of toxicology and risk. However, in some jurisdictions such as the EU, it is public concern brought to bear via political channels that drives regulation, thus there is incongruity in the logic that underpins the regulatory process. Stakeholder perspectives are critical and therefore were considered in the present overview given that stakeholders are both using and impacting the definition of the term contaminant. Thus, the stakeholders perspective is also a factor to consider when investigating what would be a suitable and unequivocal definition of a food contaminant. This will ultimately facilitate uniform use of the term, not only by regulators, but also by the respective stakeholders.

From a regulatory perspective, the definition applied to 'contaminant' is inseparable from its regulatory context. The EU has a pre-market paradigm in that it seeks to define what is acceptable as being part of the food chain. As such, falling into the definition of 'contaminant' can be any substance (not intentionally added) which the EC may want to control, and that control is not limited to protecting consumer health as contaminants should be reduced to 'as low as reasonably achievable' as defined case by case by the EC. In contrast the US has a post-market paradigm for the legal control of foods. Although the definition of 'contaminant' is based on hazard including concepts of poisonous and deleterious, exposure and risk is explicitly taken into account in that food is only 'adulterated' if it is 'injurious to health'. Against these contextual differences the EU has a long and expanding list of requirements for substances that are considered as 'contaminants', whereas the US has a very limited number of requirements codified into legal text or issued as 'action limits' or 'advisory levels' by the FDA. Although at the time of writing such 'action limits' are under review and expansion.

The criterion of harm and the existence of regulatory limits for the presence of chemicals in food further complicates the matter since when present at levels below a regulatory limit a chemical would often erroneously no longer be a contaminant while in terms of the definitions that include a dimension of harm it might still be one. Furthermore, there is a

Table 1
Overview of definitions for a contaminant as provided by different (regulatory) agencies.

(regulatory) Agency	Definition	Reference
European Commission (EC) and UK Food Standards Agency (FSA)	'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. Note that further to the definition, there are requirements that: Food containing a contaminant in an amount which is unacceptable from the public health viewpoint and in particular at a toxicological level shall not be placed on the market. and Contaminant levels shall be kept as low as can reasonably be achieved by following good practices at all the stages referred to in [the definition].	(Council Regulation (EEC) 315/93, 1993)
US Food and Drug Administration (FDA) and the US Code of Federal Regulations	Various legal and agency definitions apply to food 'contaminant': FDA enforcement context: Chemical contaminants include a broad range of chemicals that may be present in food and that have the potential to cause harm. Legal definition of 'unavoidable' contaminant: A naturally occurring poisonous or deleterious substance is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination. An added poisonous or deleterious substance is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening acts, it is an added poisonous or deleterious substance to the extent of such increase. As a part of the definition of 'adulterated food': A food shall be deemed to be adulterated: If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.	https://www.fda.gov/food/chemical-contaminants-pesticides https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-109 https://www.govinfo.gov/content/pkg/USCODE-2019-title21/pdf/USCODE-2019-title21-chap9-subchapIV-sec342.pdf
Chinese Food and Drug Administration (CFDA)	Chemical hazardous substances produced or brought by environmental pollution and are not intentionally added in foods in the process of production (including crop cultivation, animal husbandry and veterinary medicine), processing, packaging, storage, transportation, sales, eating, etc.	GB 2762–2017. National Standard of People's Republic of China (Chinese Food and Drug Administration, 2017)
Indonesian Food and Drug Control Agency	Food contaminants, hereinafter referred to as pollutants, are materials that accidently exists and/or are undesired in food that comes from the environment or as a result of processing along the food chain, in the form of biological contaminants, chemical contaminants, residues veterinary drugs and pesticides as well as other objects that can disturbing, harming, and endangering human health.	Regulation of the Food and Drug Control Agency, number 8, year 2018, about maximum limits of chemical contaminants in processed food (Indonesian Food and Drug Control Agency, 2018)
Codigo Alimentario Argentino	Any undesirable substance present in the food at the time of consumption, originating from operations carried out in the cultivation of vegetables, animal husbandry, zoo or phytosanitary treatments, or as a result of contamination of the environment, or of the equipment of elaboration and/or conservation.	RESOLUCIÓN GMC N° 18/93 (Codigo Alimentario Argentino, 1993)
MERCORSUR - Mercado Común del Sur	Any undesirable substance present in the food at the time of consumption, originating from the operations carried out in the cultivation of vegetables, in animal husbandry, in zoo or phytosanitary parameters, or as a result of environmental	MERCOSUR/GMC/RES N° 31/92 (MERCORSUR, 1992)

(continued on next page)

Table 1 (*continued*)

(regulatory) Agency	Definition	Reference
	contamination or production and/or conservation equipment.	
Chile - APRUEBA	The presence of microorganisms, viruses and/or parasites, foreign or deleterious substances of mineral, organic or biological origin, radioactive substances and/or toxic substances in amounts greater than those permitted by current regulations, or that are presumed harmful to human health.	REGLAMENTO SANITARIO DE LOS ALIMENTOS. Núm. 977 (Chile - APRUEBA, 1996)
Brazilian Health Regulatory Agency (ANVISA)	contaminant is any unintentional substance added to food and which is present as a result of production, industrialization, processing, preparation, treatment, packaging, transportation or storage or as a result of environmental contamination	RDC Nº 722, DE 1° DE JULHO DE 2022 (Brazilian Health Regulatory Agency (ANVISA), 2022)
Food Safety and Standards Authority of India	"Crop contaminant" means any substance not intentionally added to food, but which gets added to articles of food in the process of their production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging transport or holding of articles of such food as a result of environmental contamination	Regulations, 2011; Food Safety and Standards Authority of India (2011)
codex Alimentarius	"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"	codex Alimentarius (Food and Agriculture Organization of the United Nations and World Health Organization, 1995)
Australia New Zealand Food Authority (ANZFA)	"Contaminant means: any biological or chemical agent, foreign matter, or other substances that may compromise food safety or suitability"	Standard 3.1.1 (Australia New Zealand Food Standards Code, 2001)
Taiwan Food and Drug Administration	The substance not intentionally added to food, which present in food as a result of production or pollution during the manufacturing, processing, preparing, packaging, transportation, storage, or selling, or as a result of environmental contamination.	Sanitation Standard for Contaminants and Toxins in Food (Taiwan Food and Drug Administration, 2022)

common misunderstanding that regulatory limits are safety-based limits and are often treated as such. In some jurisdictions there is no direct connection between safety and regulation, such as the EU where limits can be based on the ALARA principle (reducing the contaminant to as low as reasonably achievable irrespective of the health protection goal). Given these discrepancies in the designation of a chemical as a food contaminant, depending on whether the definition applied is based on the source, its presence when consumed, potential hazards and/or risks, regulation, or other parameters, the aim of the present review is an evaluation based on the experience of the authors, of how these aspects affect the classification of different categories of what may be considered contaminants in food. This may pave the way to a better understanding by all stakeholders leading to a more holistic definition of what stakeholders consider to be a food contaminant.

In the following sections different categories of food borne constituents that may be considered contaminants are evaluated against the various criteria encountered in the definitions of food contaminants (Table 1). These criteria include unintentional presence, harmful (either referring to hazard or risk), existence of regulatory limits, and stakeholder perspectives. This evaluation will result in better insight into the consequences of the definition of chemical contaminants in food for classification of the respective chemicals and stakeholder perspectives, while at the same time providing insight in what criteria may provide the basis for an unequivocal definition of a food contaminant. The categories of chemicals considered include i) substances unintentionally present within ingredients such as phytotoxins, mycotoxins, (heavy) metals, and POPs, ii) substances that result from food preparation such as processing aids, process related contaminants and food contact materials, and iii) substances that are intentionally used as part of managing the productivity or acceptability of supply chains such as pesticides, and veterinary drugs.

From the overview of existing definitions used by regulatory bodies for the term contaminant presented in Table 1, criteria often encountered in these definitions were identified for further evaluation for each of the categories of chemicals. These criteria included: intentional versus unintentional presence, being harmful, and existence of regulatory limits. In addition, the influence of the stakeholder's perspective was considered since this may be another aspect influencing views on the designation of substances in their context as contaminants. Each section starts with a short introduction of the group of chemicals that is discussed followed by an evaluation of how the four criteria influence their classification as a contaminant followed by an overall conclusion.

1.1. Phytotoxins

1.1.1. Introduction

Phytotoxins are toxic compounds produced by plants (Chen et al., 2022). Many botanicals and derived preparations claimed to have possible human health benefits, have been reported to contain natural substances that may be of health concern when used as food or in food supplements, such as alkaloids, glycoproteins, amines, glycosides and hydroxyanthracene derivatives (Ibrahim et al., 2021; Marcus and Grollman, 2016). Therefore, the European Food Safety Authority (EFSA) has developed a database of botanicals, i.e., EFSA's Compendium of

Botanicals, including European and non-European botanical species, that are reported to contain naturally occurring substances of possible concern for human health (https://www.efsa.europa.eu/en/microstrategy/botanical-summary-report). A common example of phytotoxins are the so-called alkaloids (such as pyrrolizidine and tropane alkaloids), these are a large group of organic compounds containing amino acid-derived and nitrogen-bearing molecules, produced by several plant genera. Alkaloids can be produced also by fungi such as the ergot-producing fungus *Claviceps purpurea* (Arroyo-Manzanares et al., 2017; Robertson and Stevens, 2017; Huang et al., 2021).

1.1.2. Criterion: intentional versus unintentional

Plant toxins are substances that are generally unintentionally present in botanical materials used in the preparation of food supplements. However, some plant compounds, for instance aliphatic and aromatic terpene hydrocarbons, are used intentionally as flavouring ingredients. These natural compounds serve specific biological functions of the plant or may protect some plants from pests and pathogens. According to several food contaminant definitions based on the concept of "substances not intentionally added to food", plant toxins such as alkaloids should be considered "food chemical contaminants", whereas terpenes present in botanical ingredients added intentionally to impart flavour would not classify as contaminants, and maybe regulated as additives. Phytotoxin producing species may also grow as weeds amongst crop plants resulting in their toxins entering the food supply chain at the point of harvest, an example includes members of the *Datura* family growing amongst peas and maize. The presence of toxins within crops due to field presence of weed plants is clearly unintentional. In the experience of the authors, use of the term "unintentional presence" would lead to an unequivocal perception that the toxin was present as a 'contaminant', whereas if the toxin was present due to the deliberate use of a toxin-containing species, it would actually be equivocal whether these compounds would be 'contaminants', especially if the toxic moiety has a characterizing effect on the food.

1.1.3. Criterion: harmful

Several botanicals containing phytotoxins as natural constituents, have been claimed to have physiological effects and health benefits. In countries with a strong culture of traditional medicine (e.g., China, India) botanicals are commonly used as medicines for the prevention and treatment of diseases, and such botanicals are now commonly found in foods, particularly food supplements across the World. However, several studies have shown evidence that many of those botanical remedies and the related phytotoxins can cause severe adverse effects, which may result in classification of the respective active ingredients as contaminants based on definitions that include a dimension of harm. For instance, aristolochic acids, phenanthrene alkaloids produced by *Aristolochia* plants, have been shown to be potent human carcinogens and aristolochic acids, as well as plants containing aristolochic acids, have been classified by the IARC (International Agency for Research on Cancer) as carcinogenic to humans (Group 1) (IARC Working Group on the Evaluation of Carcinogenic Risks to Humans., International Agency for Research on Cancer., & World Health Organization, 2012). In recent years EFSA and JECFA have performed risk assessments for the major alkaloids occurring in food. For tropane alkaloids an acute reference dose (ARfD) was established, that is protective towards the general population including susceptible subgroups (EFSA, 2016; EFSA CONTAM Panel, 2017; JECFA, 2020; Binaglia, 2022). Further examples include aloe vera whole leaf extract, which is used as topical and oral therapeutic remedy, and has been classified as possibly carcinogenic to humans (Group 2B) (IARC Working Group on the Evaluation of Carcinogenic Risks to Humans., International Agency for Research on Cancer., & World Health Organization, 2016). Pyrrolizidine alkaloids have been shown to be toxic to the liver and to cause anorexia with nausea, vomiting and diarrhoea and especially 1,2-unsaturated pyrrolizidine alkaloids may act as compounds that are genotoxic and carcinogenic in humans (JECFA, 2020). IARC evaluated several pyrrolizidine alkaloids and classified lasiocarpine, monocrotaline and riddelliine as Group 2B (possibly carcinogenic to humans) (IARC Working Group on the Evaluation of Carcinogenic Risks to Humans., International Agency for Research on Cancer., & World Health Organization, 2002). Tropane alkaloids, morphine, strychnine, quinine, ephedrine, and nicotine, are well known pharmacological agents with dose dependent adverse side effects such as pupil dilation, impaired vision, palpitations, hallucinations, respiratory failure and paralysis of the parasympathetic nervous system (Akinboye et al., 2023; Arroyo-Manzanares et al., 2017; Huang et al., 2021; Robertson and Stevens, 2017).

Phytotoxins and therefore the plants that produce them, have defined hazard which is expressed as risk above specific exposures. In many jurisdictions, mitigating the risk is achieved by attempting to eliminate the presence of unintended vegetation such as control of nightshade berries during pea harvesting. In some cases, this includes the setting of limits (e.g. number of nightshade berries per mass of peas), however such limits are often based on minimization and not on consideration of health risk. Therefore, the hazardous properties of the plants are the unequivocal determinants of whether they are considered a 'contaminant' in food, while including risk in the definition of a contaminant would make the classification dependent on the level of exposure and thus equivocal.

1.1.4. Criterion: regulatory limits

In order to ensure a high level of human protection, maximum permitted levels for recognized toxic alkaloids in foodstuffs have been established. In the European Union (EU), the Commission Regulation 2023/915 has repealed the Commission Regulation 1881/2006 and amendments setting maximum permitted levels for example of: (i) tropane alkaloids, i.e. atropine and scopolamine in baby food and processed cereal-based food for infants and young children and in several cereals and herbal infusions, as sum of atropine and scopolamine; (ii) pyrrolizidine alkaloids, as sum of 21 pyrrolizidine alkaloids, in fresh borage leaves, dried herbs, tea, herbal infusions, cumin and food supplements; (iii) opium alkaloids in poppy seeds and bakery products containing poppy seeds; (iv) delta-9-tetrahydrocannabinol equivalents in hemp seeds and hemp seed oil; v) erucic acid in vegetable oils and hydrocyanic acid in linseeds, almonds, apricot kernels and cassava (Commission Regulation (EU) 2023/915, 2023).

The existence of regulatory limits for these compounds within Regulatory instruments whose purpose is stated as controlling 'contaminants', indicates that from a regulatory perspective such substances are unequivocally considered as such.

1.1.5. Criterion: stakeholder perspectives

Farmers, manufacturers and food safety and quality assurance (FSQA) managers consider regulated compounds contained in botanicals, e.g., alkaloids, to be chemical contaminants. On the contrary, consumers do not appear to consider botanicals as a source of chemical contaminants (Colombo et al., 2020). In fact, botanicals and herbal infusions some of which contain toxins are traditionally considered as medicines in several countries, it appears that consumers often consider that natural equals safe. Therefore, the differences of perception between stakeholders means that overall, the influence of this criterion on whether phytotoxins are considered as contaminants is equivocal.

1.1.6. Conclusion on which aspects should and should not be in the definition of a contaminant

Intentionality is closely linked to stakeholder perception in the case of plant toxins, but it gives equivocal outcomes when the aspect of intentionality is used for a designation of phytotoxins as contaminants. On one hand they are likely to be considered as contaminants when unintentionally present within food crops, whereas the intentional use of botanical ingredients including some common spices which are known to include phytotoxic components is unlikely to result in a

contaminant designation. In contrast when there is recognition of the hazard of the material but not necessarily risk, it seems unequivocal that it would be considered a contaminant, while the dimension of risk induces ambiguity because risk depends on exposure. In the case of plant toxins that have regulatory limits established within contaminant regulations, it is clear that some stakeholders predominantly consider that they are designated as contaminants. As such, for plant toxins that do not have limits within contaminant regulations, for example aristolochic acids, it appears that their designation as contaminant is determined by hazard. In this example authority alerts and limitations or prohibitions on the sale of AA-containing herbs have been issued in the United States of America (USA), Australia, Canada, and in the EU in for example in the UK (Martena et al., 2007; Therapeutic Goods Administration TGA, 2001; Herbal Chinese medicines and the risk of aristolochic acid; Marcus and Grollman, 2016) to avoid using any botanical products containing aristolochic acids. In this example authority alerts have been issued in the United States of America (USA) and in the EU to avoid using any botanical products containing aristolochic acids. Furthermore, plants producing the substance are listed as doing so within the EFSA Compendium of Botanicals but this text has no direct regulatory implication. Notwithstanding, botanicals at market containing unregulated toxic compounds in an amount which is considered as unacceptable from a public health viewpoint are likely to be subject to market action by enforcement agencies under General Food law (food should be safe). When health-based guidance values or surrogates thereof are considered in the definition of contaminants and when the definition would include "compounds unintentionally added to food that can cause adverse effect to human health" the same chemical could classify as a contaminant or not, depending on its concentration and/or exposure assessments for the respective food. This would make the contaminant designation of substances equivocal when based solely on risk.

1.2. Mycotoxins

1.2.1. Introduction

Mycotoxins are fungal secondary metabolites produced by many fungal genera including species of *Aspergillus, Penicillium, Fusarium, Alternaria* and *Claviceps,* which occur on a variety of agricultural commodities, the most notable being cereals (mainly maize and wheat), and different types of nuts. The most recognized mycotoxins in food are aflatoxins, ochratoxin A, fumonisins, zearalenone, patulin, deoxynivalenol, T-2 and HT-2 toxins, and ergot alkaloids (Perrone et al., 2020).

1.2.2. Criterion: intentional versus unintentional

Mycotoxins are produced by toxigenic fungi under favourable environmental conditions in the field, as well as during storage of food commodities (Perrone et al., 2020). Their presence in food is always unintentional, although it cannot be overlooked that producers may deliberately market a batch contaminated by mycotoxins to avoid economic losses. The presence of these natural toxins in food can be avoided or limited by adopting specific pre- and post-harvest prevention strategies (Colović et al., 2019; Commission Recommendation (EC) 2006/583, 2006; Hamad et al., 2023; Nada et al., 2022). According to several food contaminant definitions based on the concept of "substances not intentionally added to food", mycotoxins will be unequivocally considered food chemical contaminants.

1.2.3. Criterion: harmful

Mycotoxins occur in various food products and can be present in especially high concentrations in developing countries, while the globalization of markets and climate change are changing mycotoxin patterns in developed countries, including the EU. A wide range of adverse effects of mycotoxins in humans have been shown, ranging from nephrotoxicity, cytotoxicity, gastrointestinal disorders, immune toxicity, to mutagenicity, teratogenicity, carcinogenicity and, upon acute exposure, in some cases even death. In particular, aflatoxins have been classified by the IARC as carcinogenic to humans (Group 1), and ochratoxin A and fumonisin B1 as carcinogenic to animals and possibly carcinogenic to humans (Group 2B). In addition, long-term exposure to some mycotoxins causes immunosuppressive effects which leaves humans more vulnerable to diseases by weakening their immune system (JECFA, 2001; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans., International Agency for Research on Cancer., & World Health Organization, 2002; Freire and Bezerra da Rocha, 2016; Ostry et al., 2017). Ergot alkaloids have effects on cardiovascular function, cause neurotoxic effects, and irrational behaviour, convulsions, vasoconstriction and/or hyperprolactinaemia (Akinboye et al., 2023).

EFSA and JECFA in the past years have performed risk assessment studies for the major mycotoxins occurring in food, recommending tolerable daily intake (TDI) or tolerable weekly intake (TWI) values for various mycotoxins, or identifying potential health risks based on the margin of exposure (MOE) method for mycotoxins that are genotoxic and carcinogenic like aflatoxins.

Mycotoxins should always be considered chemical contaminants, as they are toxins with no benefit to public health and their presence in foods should be avoided as far as possible. However, according to a definition that includes a dimension of harm referring to risk, a mycotoxin would not classify as a contaminant when its level in food results in intakes that are below the health based guidance value. This illustrates that such a dimension of harm/risk in the definition makes the definition dependent on risk assessment and the level of exposure. This makes the definition ambiguous. As a result it is concluded that the definition of a food contaminant should not include a dimension of harm/risk, so that a mycotoxin will always classify as a contaminant independent of its level. Therefore, hazard is unequivocally linked to their designation as contaminants. In the case of those mycotoxins for which health based guidance has been developed, it is possible that some supply chain stakeholders may consider that when the health risk is considered as acceptable the designation as contaminant may erroneously not apply, or at least the designation of the food as 'contaminated' is not applicable. As such, the dimension of risk has an equivocal baring on the designation of mycotoxins as contaminants.

1.2.4. Criterion: regulatory limits

In order to ensure a high level of human protection, maximum permitted levels for mycotoxins recognized in foodstuffs have been established worldwide (Codex Alimentarius Commission, 2019; Commission Regulation (EU) 2023/915, 2023; FAO 2004). In the EU, maximum levels have been set for aflatoxins (aflatoxin B1, total aflatoxins and aflatoxin M1), ochratoxin A, patulin, deoxynivalenol, zearalenone, fumonisins (sum of fumonisin B1 and B2), citrinin and ergot alkaloids in several commodities with the lowest levels in foodstuffs for direct human consumption and baby foods for infants and young children (Commission Regulation (EU) 2023/915, 2023). Indicative levels for the sum of T-2 and HT-2 toxins in cereals and cereal products have been recommended by the EC (Commission Recommendation (EU) 2013/165, 2013).

The existence of regulatory limits for these compounds, as a result of risk assessment studies, and including this as a criterion in the definition makes these compounds food chemical contaminants. Therefore, the existence of regulation unequivocally impacts the designation of specific mycotoxins as contaminants. However, mycotoxins for which regulatory limits have not been defined would then not classify as contaminants due to regulatory considerations.

1.2.5. Criterion: stakeholder perspectives

Due to regulatory limits, supply chain stakeholders consider mycotoxins to be chemical contaminants, particularly if those limits are exceeded. European citizens show increased interest in food safety-related topics and food safety is among the most important factors affecting Europeans' food-purchasing decisions (EFSA - Special

Eurobarometer, 2022). For consumers, poisonous molds (i.e., mycotoxins) in food are of low concern - Special Eurobarometer (EFSA - Special Eurobarometer, 2022). This means that consumers may not consider mycotoxins as food chemical contaminants.

1.2.6. Conclusion on which aspects should and should not be in the definition of a contaminant

Based on the above considerations (i.e., substances not intentionally added to food, harmful effects, regulatory limits, and stakeholder perspectives), mycotoxins are generally considered food contaminants. However, a large number of mycotoxins (between 500 and 600) has been identified and, with the exception of the above mentioned mycotoxins (i.e. aflatoxins, ochratoxin A, fumonisins, zearalenone, patulin, deoxynivalenol, T-2 and HT-2 toxins and ergot alkaloids), limited information is available on their occurrence and concentration in food, and this is especially the case for the so-called emerging mycotoxins (e.g. enniatins, beauvericin, moniliformin, fusaproliferin, fusaric acid, culmorin, sterigmatocystin, alternariol, alternariol monomethyl ether, and tenuazonic acid). Emerging mycotoxins are defined as "mycotoxins, which are neither routinely determined, nor legislatively regulated; however, the evidence of their incidence is rapidly increasing" (Gruber-Dorninger et al., 2017). In addition, modified mycotoxins (metabolites produced by fungi, generated as part of the defence mechanism of the infected plant, or formed during food processing and usually not detected during routine analysis, e.g., glucoside conjugated mycotoxins) are potential harmful compounds due to their conversion into the parent mycotoxin during digestion in humans and animals, although they are not currently covered by regulations (Freire and Sant'Ana, 2018). This also implies that not for all mycotoxins regulatory limits or insights into their harmful effects are available, so that the use of these criteria in the definition will result in ambiguous outcomes of the classification of a mycotoxin as a contaminant. Given however that their presence in food is for the most part unintentional (blue cheese being a possible exception), including this dimension in the definition unambiguously classifies mycotoxins as chemical contaminants.

1.3. (Heavy) metals

1.3.1. Introduction

The environmental presence of (heavy) metals may be a result of human activities, such as farming, motor vehicle emissions, industrial emissions, and increasing concentrations in environmental compartments will increase concentrations in foods that interact with those compartments. Chemical elements are classified in metals, metalloids and non-metals. When discussing food safety, a subgroup of metals – heavy metals – is defined as those elements having an atomic number greater than 20, atomic density above 5 g cm^{-3}, and exhibiting the properties of a metal. Heavy metals are further divided in essential and nonessential ones. In this publication, the term (heavy) metals will include heavy metals and metalloids.

(Heavy) metals have a dual role in food, since some are essential nutrients (e.g., copper, iron, selenium, zinc) and must be present in our diet up to a certain intake, becoming toxic when exposure increases above a tolerable intake amount. Other (heavy) metals (e.g., arsenic, cadmium, mercury, and lead) are non-essential to metabolic and other biological functions, while they can mimic the biological function of essential metals and perturb bio-processes, and therefore are often regarded as contaminants when present within food. In the latest list of dangerous substances published by the United States Environmental Protection Agency (US-EPA) and the Agency for Toxic Substances and Disease Registry (ATSDR) (Substance Priority List | ATSDR (cdc.gov)), arsenic, lead and mercury occupy the first three positions, while cadmium is the 7th based on considerations of exposure as well as hazard. It should be noted that food is just one of many routes of exposure to these substances.

1.3.2. Criterion: intentional versus unintentional

(Heavy) metals can be intentionally used in a large variety of daily used products (e.g., personal care products, fertilizers and pesticides, etc.) (Attard and Attard, 2022; Rashid et al., 2023). Their presence in food is the result of the natural occurrence of these metals in the environment combined with their unintentional release in the environment as a result of human activity. Their presence in food *per se* is always unintentional. When a food contaminant definition is based on the concept of "substances not intentionally added to food", then (heavy) metals will be regarded as food chemical contaminants.

1.3.3. Criterion: harmful

When the definition for a contaminant includes a dimension of harm, (heavy) metals have a dual classification. This because many of these metals are essential nutrients and must be included in the diet; however, excessive exposure to these same metals is of concern. (Heavy) metals may react with vital macromolecules in biological systems inducing toxicity. Following exposure to toxic metals, different acute and chronic effects are observed, affecting different body organs. Examples of the latter effects are immune system, gastrointestinal, and kidney dysfunction, nervous system disorders, and skin lesions (Balali-Mood et al., 2021). Some metals may be present in different matrices in either inorganic or organic form, with the organic form being less (e.g. methyl arsenic acid) or more (e.g. methylmercury) toxicologically potent.

EFSA published reports on the exposure to arsenic (EFSA, 2014), cadmium (EFSA, 2009), chromium (EFSA CONTAM Panel, 2014), mercury (EFSA Scientific Committee, 2015) and nickel (EFSA CONTAM Panel, 2020a), deriving TDI (or TWI) values for nickel, chromium (III) and cadmium. IARC classifies the main heavy metals in different groups: group 1, arsenic, cadmium, chromium (VI), and nickel; group 2A, lead (organic); group 2B, methylmercury; group 3, chromium (III), mercury (inorganic), lead (inorganic), and Se. Based on a definition that contains a dimension of harm, (heavy) metals classified in groups 1, 2A and 2B will be considered chemical contaminants irrespective of exposure and risk considerations.

1.3.4. Criterion: regulatory limits

For some (heavy) metals regulatory limits have been defined. Commission Regulation 2023/915 sets out the maximum levels for arsenic, cadmium, lead, mercury and tin (inorganic form). The existence of regulatory limits for these compounds, and including this as a criterion in the definition, results in a situation where these substances are considered unequivocally as food contaminants.

1.3.5. Criterion: stakeholder perspectives

Stakeholders for food-borne (heavy) metals include consumers, but also industrial stakeholders involved in production processes where such chemicals are used or produced either intentionally or unintentionally and may later be disposed in the environment. Although such industrial stakeholders may consider the use and release of these chemicals into the environment unavoidable, it is also likely that, like consumers, they will consider the compounds to be contaminants. So, whereas from a stakeholder perspective, use of the term contaminant for the category of metals that are not essential nutrients is unequivocal, this is not the case for those metals that display a risk-benefit relationship related to exposure.

1.3.6. Conclusion on which aspects should and should not be in the definition of a contaminant

Based on the above considerations, metals that serve no nutritive function or technical function in foods and possess distinct hazard profiles, are present in the environment and food unintentionally. Therefore, including the parameter of unintentional together with hazard in the designation of these substances as contaminants would be appropriate. The presence of regulatory limits unequivocally consolidates this perception.

1.4. Persistent organic pollutants (POPs)

1.4.1. Introduction

POPs have been described as follows (European Parliament and Council Regulation (EU) 2022/2400, 2022): "Persistent organic pollutants are toxic chemicals that are slow to break down. When released, they stay in the environment for a long time and accumulate in the food chain and living organisms. That's why they are also sometimes referred to as forever chemical". Important examples of POPs are chlorinated pesticides like dichlorodifenyltrichloroethane (DDT) and aldrin, dioxins, PCBs, polychlotinated dibenzofurans, and PFAS.

1.4.2. Criterion: intentional versus unintentional

Some POPs, such as for example DDT and aldrin, were used as pesticides, while others are used in industrial processes for example as solvents, in plastics, flame retardants or as coatings. In addition, they may be produced unintentionally resulting from industrial processes such as combustion upon burning of wastes. Their presence in food is always unintentional. This implies that a definition including an aspect of unintentional presence will be unambiguous while it should always also specify that this relates to unintentional presence in food, as done for example in the EU Council Regulation 315/93 regulatory EC definition (Council Regulation (EEC) 315/93, 1993) (Table 1).

1.4.3. Criterion: harmful

When the definition for a contaminant includes a dimension of harm, many POPs would formally classify as contaminants. This because for many of these compounds including chlorinated pesticides, dioxins, PCBs and recently also PFAS safety assessments by risk assessment bodies such as EFSA or JECFA indicated that the current levels of exposure exceed the established health-based guidance values like TDIs or TWIs (EFSA CONTAM Panel, 2020b; EFSA, 2023; EFSA CONTAM Panel, 2018). For others however, estimated levels of exposure may still be below such established health-based guidance values indicating that formally no harm and adverse health effects are expected upon lifetime exposure at these levels. For example, the exposure to DDT, that was used as an agricultural insecticide, and is known to be very persistent in the environment, was found to be lower than the provisional TDI of 0.01 mg/kg bw (Joint FAO/WHO Meeting on Pesticide Residues, 2001). This can be related to the fact that DTT is banned in most countries from 1970s onwards due to its persistent and bioaccumulative nature and its acute and reproductive adverse effects on human health. Current risk assessments reveal that for some POPs exposure levels may fall below the health-based guidance values at least for some parts of the population, which would indicate the absence of harm for these subgroups. Exceedance of the TDI or TWI for other subgroups raises a concern because adverse effects can no longer be excluded. However, a limited exceedance of a health-based guidance value generally does not always cause harm given that there is still a safety margin between a no adverse effect level and the established health-based guidance value to cover uncertainty over inter- and intraspecies differences. Thus, including an aspect of harm in the definition of a contaminant may raise controversy as to whether some POPs can be considered contaminants for some subgroups in the population and not for others, especially when harm is defined as risk and not as a hazard.

1.4.4. Criterion: regulatory limits

For some POPs regulatory limits have been defined. Commission Regulation 2023/915, on maximum levels for certain contaminants in food and repealing Regulation 1881/2006, sets out the maximum levels for non-dioxin-like PCBs, dioxins and furans and for the sum of dioxins, furans and dioxin-like PCBs in certain foodstuffs. Commission Recommendation 2013/711 also sets out action levels in order to stimulate a proactive approach to reduce the presence of polychlorinated dibenzo-para-dioxins and polychlorinated dibenzofurans (PCDDs/PCDFs) and dioxin-like PCBs in food. It regulates concentrations of PFAS compounds in food (Commission Regulation (EU) 2022/2388, 2022), while Directive (EU) 2020/2184 places limits on the presence of PFAS in drinking water. In the USA laws and regulations restricting "forever chemicals" in more than a half dozen states are entering effect in 2023. For some POPs these regulations and legal frameworks have been reported to reduce their levels and intake, resulting in a consistent decline in levels in the environment and the population in recent decades (Wong et al., 2021). For others, like the PFAS, levels are increasing and a ban may be required to reduce exposure. Since generally for POPs regulations are in place, including such a Criterion in a definition for a contaminant will not result in an unambiguous situation.

1.4.5. Criterion: stakeholder perspectives

Stakeholders for POPs include consumers but also industrial stakeholders involved in production processes where such chemicals are used or produced either intentionally or unintentionally. Although such industrial stakeholders may consider the use and/or release of these POPs into the environment unavoidable, it is also likely that they will consider the compounds to be contaminants. So, from a stakeholder perspective use of the term contaminant for this category of food borne chemicals would be adequate.

1.4.6. Conclusion on which aspects should and should not be in the definition of a contaminant

Based on the above considerations it is clear that POPs are in some cases used for technological purposes, while in all cases they end up in the environment or food unintentionally. Therefore, including this unintentional presence in the definition of a contaminant would be appropriate for POPs provided the definition also specifies that it relates to food or the environment. The fact that at the present state-of-the-art levels of exposure may be above established health-based guidance values in some cases for only part of the population, while being below the health-based guidance value for other parts of the population, implies that including a dimension of harm in the definition may lead to an ambiguous situation when harm refers to risk. The evaluation of the case of POPs also indicates that inclusion of a Criterion related to the presence of a regulatory limit will not hamper classification of POPs as contaminants since for POPs regulations will generally be in place. Also, for relevant stakeholders like industrial manufacturers or consumers use of the term contaminant for a POP may be logic as long as the definition includes its unintentional presence in food or the environment.

1.5. Process related contaminants associated with food component reactions during food preparation

1.5.1. Introduction

Process related contaminants can be formed in food during both industrial food manufacturing and home cooking. These processes include for example high-temperature cooking, smoking, drying, refining and fermentation. Many foods must be processed to improve digestibility or taste. Process related contaminants include compounds like acrylamide, 3-monochloropropanediol (3-MCPD) esters, glycidyl esters, furan, acrolein, polycyclic aromatic hydrocarbons (PAHs) and heterocyclic amines (HCAs).

1.5.2. Criterion: intentional versus unintentional

The presence of food processing contaminants is not always unintentional since some of the processes by which they can be formed are applied intentionally. For example, the Maillard reaction in which HCAs and acrylamide are formed, contributes to the browning and taste of the respective food products, like French fries and toast. Furan and its analogues that are formed upon roasting of coffee add to the traditional organoleptic characteristics of coffee (Pavesi Arisseto et al., 2011; Hameed et al., 2018) and HCAs produced during cooking meat and fish at high temperatures contribute to the distinctive taste of grilled, fried

and barbecued meat and fish. Given these considerations these process related contaminants could be considered as intentionally added (Maga and Katz, 1979; Mottram, 1994; Shahidi, 1994) . Heterocyclic compounds such as pyrazine, oxazole, and thiazoles are primarily responsible for forming flavour in roasted compound. During high heat treatment and grilling, pyrazine levels significantly increase (Shahidi, 1994; Tamanna and Mahmood, 2015). Therefore, one could argue that based on definitions that include a dimension of unintentional presence these constituents would formally not always classify as contaminants.

1.5.3. Criterion: harmful

When the definition for a contaminant includes a dimension of harm, process related contaminants would classify as contaminants. This because compounds like acrylamide, 3-MCPD esters, glycidyl esters, furan and acrolein are a public health concern, because safety assessments by risk assessment bodies such as EFSA or JECFA indicated low safety margins between human exposure and adverse effect levels observed in animal studies. The margins for PAHs and HCAs may raise less concern (EFSA, 2008).

1.5.4. Criterion: regulatory limits

For only some of the process related contaminants regulatory limits have been defined. Commission Regulation 2023/915 as amended for example sets maximum levels for PAHs in food, including smoked meat and smoked meat products and smoked fish and smoked fishery products. This regulation also sets maximum levels for 3-MCPD- and glycidyl fatty acid esters in for example vegetable oils and fats, fish oils, infant formula, follow-on formula and foods for special medical purposes intended for infants and young children. For acrylamide there is EU legislation defining benchmark levels which are not legally binding (Commission Regulation (EU) 2017/2158, 2017). However, for several food process related contaminants no regulatory limits or benchmark levels have been established, so including such a Criterion in a definition for a contaminant may result in an ambiguous situation.

1.5.5. Criterion: stakeholder perspectives

Stakeholders for the process related contaminants may find the term contaminants confusing or misleading. This does not only include the industrial manufacturers but also the consumers who are preparing the food at home and introducing levels of these compounds in the food themselves. Industrial stakeholders who apply manufacturing procedures to improve digestibility, taste or other food characteristics may not want to consider the compounds that add to the desired characteristic of the food to be contaminants, given that their presence can be an indispensable aspect of the respective food and its quality. Also, for consumer who prepare and introduce the compounds in food themselves, use of the term contaminant for this category of food borne chemicals may be confusing.

1.5.6. Conclusion on which aspects should and should not be in the definition of a contaminant

Based on the above considerations and the fact that the processes where process related contaminants can be formed are intentionally applied to the food, these compounds would better classify as intentionally added (side) products, and not as contaminants. This implies that when the definition contains an aspect of unintentional presence the process related compounds may not all classify as contaminants. The evaluation of the case of process related contaminants also indicates that inclusion of a Criterion related to harm or to the presence of a regulatory limits is not indicated since it would result in an ambiguous situation. Also, for relevant stakeholders like industrial manufacturers or consumers the use of the term contaminant for a compound that contributes to the taste, odour, digestibility or any other desirable characteristic of the food, may be undesirable and/or confusing, while for process related contaminants that do not fulfil such a technological function the term contaminant may be valid.

1.6. Food contact materials (FCMs)

1.6.1. Introduction

FCMs are materials and articles that come into contact with our food during the supply chain, such as storage containers, factory equipment, kitchen utensils and food packaging. From a regulatory perspective, there is no difference between packaging (primary FCM) and other materials that could come into contact with food.

1.6.2. Criterion: intentional versus unintentional

In the field of FCMs and regarding chemicals possibly migrating to food, we consider intentionally added substance (IAS) and non-intentionally added substances (NIAS).

IAS are raw materials, additives or processing aids that are intentionally used in the formulation of packaging materials. One example is bisphenol A that is used as starting material in (epoxy) resins and polycarbonate plastics. To ensure these materials do not present a risk to human health, there are regulatory specific migration limits (SMLs), although based on hazard and the recent EFSA evaluation (EFSA Panel on Food Contact Materials, 2023) there is political momentum to ban the material.

NIAS are chemicals that are present in a FCM or food contact article (FCA) but have not been added for a technical reason during the production process. NIAS originate from various sources and are grouped into side products, breakdown products or contaminants. As examples, side products are often formed during polymerization. Polymers as well as additives (e.g., antioxidants, ultraviolet-stabilizers) can also be degraded during manufacture and use, thus leading to various breakdown products. Contaminants/impurities in the starting substances are also sources of NIAS. In addition, recycling can introduce many different contaminants: examples are mineral oil hydrocarbons (MOHs), plasticisers, and photoinitiators in recycled paper and board and oligomers or additives in recycled plastics (Geueke et al., 2018). For FCM, both intentional use or non-intentional occurrence can be encountered. This Criterion is therefore not discriminating in a definition for a contaminant.

1.6.3. Criterion: harmful

It is well known that certain substances migrate from packaging materials to foods. This is taken into consideration by the EU regulation and therefore not prohibited. But according to article 3 of Regulation 1935/2004, it is stated that materials and articles, under normal or foreseeable conditions of use, do not transfer their constituents to food in quantities which could Click or tap here to enter text.(i) endanger human health; or (ii) bring about an unacceptable change in the composition of the food; or (iii) bring about a deterioration in the organoleptic characteristics thereof (Regulation 1935/2004, 2004).

For various packaging materials and specific chemical substances, the European Commission has drawn up guidelines for FCMs and mainly one regulation focusing on plastics/coatings. They set restrictions of use and migration limits. These limits, called SMLs (specific migration limits), are elaborated by EFSA.

For plastics, IAS have been subject for previous evaluations by EFSA and the setting of SMLs or other restrictions. When migration levels are below the SMLs no harm is expected. At the opposite, when the SML is exceeded, there may be a safety concern. For other FCM or NIAS, no such SMLs exist. In such cases it is the responsibility of the operators to demonstrate the safety of the packed food. However, not all IAS have been evaluated and no toxicological information is available for most of the NIAS (Muncke et al., 2020). Therefore, even when the migration levels are very low, it is not possible to conclude at the present state-of-the art whether such migrants are safe or harmful. This criterion on harm is then not discriminant to define a contaminant. However, if a migrant does possess a particular hazard profile of concern, such as potential endocrine activity it would invariably be considered as a contaminant.

1.6.4. Criterion: regulatory limits

The main regulatory requirement is that food packaging, which comes into direct contact with the product, must not present a risk to human health. In the European Plastics Regulation (EU) October 2011 (Commission Regulation (EU) 10/2011, 2011), migration limits or restrictions in use (e.g., in non-fat food) have been established. For other FCMs, national regulation or technical guidance applies and these list IAS that are allowed and in some cases also set SMLs (for review see Simoneau et al., 2016). But as already indicated above, a substantial number of IAS and NIAS are still not evaluated for their safety and then not clearly regulated (Muncke et al., 2020). This makes this indicator not relevant to define contaminants from FCM.

1.6.5. Criterion: stakeholder perspectives

Migrants from FCM are a topic for considerable debate already for several years in the EU. Some stakeholders are considering a risk benefit approach: food needs to be correctly packed to avoid environmental contamination and extend the shelf life. Then, migration is not considered as a contamination but is unavoidable and part of the "normal" use of FCMs if below the regulatory limits or concentrations that might present risk based on the best available data. When these limits are exceeded, then migrants are considered to be contaminants of food. Others have a hazard-based approach stating that any chemical from FCMs is potentially harmful and has to be considered as a contaminant.

1.6.6. Conclusion on which aspects should and should not be in the definition of a contaminant

FCMs are a source of substances in food and migrants can be considered as contaminants depending on the criteria used to define contaminants by different stakeholders. From a regulatory perspective both IAS and NIAS are considered at least for plastics. This supports the idea that these contaminants come from intentional use of the FCMs (despite the unintentionality of the migration into food).

The question on migrants harming consumers is critical: not all NIAS can be analysed and not all IAS or NIAS are harmful. However, not all IAS or NIAS have been assessed for their safety by official bodies. This implies that when including a dimension of harm in the context of risk in the definition for a contaminant would make the definition ambiguous. This lack of information makes some stakeholders reject that any IAS or NIAS should be permitted to migrate into food even if already subject for regulatory limits. For these stakeholders, migrants are unequivocally contaminants. This also demonstrates that the Criterion of having maximum limits (SML for FCMs) is not sufficient in itself for the definition of contaminant.

Current regulation does not cover all compounds that can migrate into food. This lack however illustrates that including such considerations in the definition would cause confusion and equivocal definition of the term. By analogy with pesticides below, the best way would be to consider migrants not as contaminants but rather as residues resulting from intentional use of FCMs.

1.7. Processing aids

1.7.1. Introduction

As food moves across its supply chain, a variety of substances that are not intended to be consumed may become entrained within the foodstuff. These substances may originate from production methods and processing equipment used in primary production such as harvesting, storage methods, distribution, or processing.

1.7.2. Criterion: intentional versus unintentional

Substances which are used as a part of the production of food and as such may become part of it, have an element of both intentionality and unintentionality; they are intentionally used but their presence in food is unintentional. This is reflected in the EU regulatory definition (Regulation 1333/2008, 2008) of processing aids as follows:

Processing aid refers to any substance which (i) is not consumed as a food by itself, (ii) is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing and (iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product (Regulation 1333/2008, 2008).

There are substances that by design come into direct contact with food, such as bakery release agents and filtration materials. These substances perform a function directly on the food, such as creating a non-stick surface or are used for purification respectively. There are also substances that are intentionally used in food production environments but without the intention of performing a function on the food itself, and that may regularly or sporadically come into contact with the food. In some cases the degree to which the residues are 'technologically unavoidable' may be questioned. Examples include substances used for the functioning, maintenance or hygiene of food production equipment, such as sanitation chemicals which may be further reduced or eliminated with prolonged rinsing of production systems, or lubricants used on production machinery such as conveyor systems. Substances that may only sporadically come into contact with food, include fluids, such as gearbox oil, that may penetrate past a shaft seal without preventative maintenance. In reality, the degree of intentionality and unintentionality differs between types of production aids, in some cases this may lead to the presence of a substance being more considered as a 'contaminant' whereas in other cases it may not. Therefore, additional parameters are important in determining whether a processing aid is considered as a contaminant, and the degree of intentionality is in itself equivocal to the definition of a contaminant.

1.7.3. Criterion: harmful

It is common regulatory practice that food should not be injurious to health, and in the EU this includes both General Food Law (Regulation (EC) 178/2002, 2002) and the above definition of processing aids. It is good manufacturing practice, and in some cases a regulatory or certification body requirement, that all substances used within the food production environment should be established to have a low intrinsic hazard. However, there is often debate between food safety experts on whether a particular exposure is safe or not, and in countries where production residues including processing aids do not undergo an authoritative review, it may be the case that the use of processing aids is based on precedent and information on their suitability from the substance supplier as opposed to an independent assessment via the food operator who places the food onto the consumer market. Irrespective of the factual assessment of risk based on the weight of available data, it may be the case that the presence in food of a process aid is considered as unacceptable, and therefore as a contaminant, based solely on the hazardous properties of the substance. The demarcation between which process aids are considered as food contaminants when based on a dimension of harm may vary due to both factual risk and perceived risk or rather risk acceptability. Taking bread making as an example, the use of enzymes to alter the physical properties of bread dough does not appear to be considered as resulting in the presence of contaminants, whereas upstream in flour mills, the use of mineral oil sprays to reduce dust and therefore explosion risk maybe considered to result in contaminant presence. Both are historical practices, and the difference in perception appears related to the fact that enzymes are not perceived as having intrinsic hazard, whereas there is a contemporary debate about the hazard that may be associated with mineral oil fractions. Therefore, process aids which have a notable hazard associated, even if it is suspected and not proven, may be considered as a food contaminant, with little consideration for risk. It is as such unequivocal that hazard is a motivation for considering a process aid present within food as a contaminant, whereas the impact of risk on whether a substance is considered a contaminant or not is more equivocal.

1.7.4. Criterion: regulatory limits

There are significant differences between jurisdictions on how non-food substances that may enter food due to their intentional use within supply chains are regulated. Even within a country or region there may be significant differences between how such substances are regulated. In the EU processing aids are defined in Regulation 1333/2008 and are differentiated from contact materials defined in Regulation 1935/2004 in that the former are intentionally used 'during processing' whereas the latter are intentionally used for the purpose of food contact (including but not limited to food packaging) (Regulation (EC) 1333/2008, 2008; Regulation (EC) 1935/2004, 2004) . There are limited authority controls for processing aids in the EU, and as a result, some Member States maintain national approaches to enforcement on the suitability of such substances. This is different from FCMs which are subject to extensive and increasing regulatory oversight and pre-market approval (https://food.ec.europa.eu/safety/chemical-safety/food-contact-materials/revision-eu-rules_en). The situation is different in the USA where processing aids together with contact materials are treated as food additives (referred to as indirect additives) and authority oversight including usage restrictions are established at the Federal level by the FDA (Food and Drug Administration) (Food and Drug Administration, 2002). Therefore, from a regulatory perspective in the US, non-compliant processing aids may lead to a food being considered by regulatory agencies as non-compliant, this is not the case in the EU unless there is concern that it is unsafe. However, as there is little transparency in any jurisdiction on whether process aids are present within foods, as they are rarely disclosed and not labelled, there is limited evidence to judge on whether they are considered as contaminants of food. As such, it is equivocal what is the impact of regulation on the definition of food contaminant as it applies to processing aids.

1.7.5. Criterion: stakeholder perspectives

Due to lack of transparency of when processing-related substances may be present in food, there is little stakeholder awareness beyond those individuals who work or audit supply chains. How process aids are perceived by these stakeholders appears to vary widely and case by case. Such substances may be considered as normal constituents of food managed via industry best practices, or as 'residues' or as 'contaminants'. Regarding consumers, available evidence indicates that they are concerned about non-food substances present in foods they purchase, with the source of the substance being key to its acceptability, for example residues present due to industrial processes tend to have lower acceptability (Renn and Benighaus, 2013). Other important criteria include the degree of familiarity with the process aid and the reason why it is used within the type of food in question, and the historical presence of the substance within the foodstuff. Due to the apparently wide differences between stakeholders in their perception of processing aids and differences between different types of substances, the impact of stakeholder perspectives is equivocal in terms of its impact on whether a process aid is considered as a contaminant or not.

1.7.6. Conclusion on which aspects should and should not be in the definition of a contaminant

There are many different types of processing aids, and in this context the words 'intentional' and 'unintentional' may be confusing. This is because the EU definition of process aids uses the word 'unintentional' to mean that it is not an ingredient (i.e., 'unintentional but technically unavoidable … '). In this review, the word 'unintentional' is used to indicate that the production process was designed such that the substance should not enter the food, but in some circumstances may do so. Process aids that are 'intentional' are those that systematically become part of a food by virtue of the process design.

The only characteristic that the authors consider consistently results in a process aid being considered as a 'contaminant', is if it has a notable hazard associated, such as a potential endocrine effect, in many cases this is irrespective of actual risk. As diligent food manufacturers produce food which does not present unacceptable risk to consumers, process aids that may become part of food are not known to have high intrinsic hazard. Therefore, in many cases the concern is related to perception of hazard and this drives confidence in the use of the substance. Perception is often based on emerging evidence with high associated uncertainty.

Other aspects such as intentionality or regulatory control measures may in some circumstances influence whether a process aid is considered as a contaminant, but this appears to be case-specific. It is perhaps helpful to consider scenarios wherein processing aids would be unlikely to be considered as a contaminant. These are likely to include when the presence in the food is anticipated by process design, appropriate prior safety and regulatory diligence has been performed, or if the substance is a known foodstuff.

1.8. Pesticides

1.8.1. Introduction

A pesticide can be defined as "a substance that acts against harmful organisms, such as pests or diseases, which affect plants" (EFSA glossary). As a result of their use on food crops they may end up as residues in the related foods, while they may also contaminate the soil, water, and surrounding vegetation and end up in food or drinking water via a contaminated environment. The regulations define pesticide residues as "residues, including active substances, metabolites and/or breakdown or reaction products of active substances currently or formerly used in plant protection products (Regulation (EC) 396/2005, 2005).

1.8.2. Criterion: intentional versus unintentional

Pesticides can enter the food chain in different ways. The presence of pesticides as residues originating from their use in crop protection is not unexpected and thus also not unintentional since upon pesticide use food residues can be expected. The presence of pesticides in food can however also result from unintentional but often predictable environmental contamination by for example drift to neighbouring fields or water when spraying and or wash off by rain. Since this presence is unintentional but at the same time predictable one may argue that it is an inherent part of pesticide use and thus intentional. This indicates that including the Criterion of intentional versus unintentional presence to this group of food borne constituents is not straight forward. This is reflected by the fact that some may consider these pesticides, especially when resulting from intentional pesticide use, residues rather than contaminants (National Research Council (USA), 1993).

1.8.3. Criterion: harmful

Pesticides and their uses are heavily regulated, and use of a pesticide will not be allowed unless risk assessment concludes that the proposed uses and use levels do not raise a health concern. Therefore, it can be concluded that including a dimension of harm in a definition of a contaminant would not make pesticides classify as contaminants (Regulation (EC) 396/2005, 2005). On the other hand, when harm would refer to a hazard instead of a risk, pesticides, which are intrinsically toxic, would classify as contaminants. Thus, using a dimension of harm without specifying whether harm refers to a hazard or a risk would make the use of such a term equivocal.

1.8.4. Criterion: regulatory limits

As already indicated pesticides and their uses are heavily regulated in most jurisdictions, and so-called maximum residue limits (MRLs) are defined for the different crops on which a pesticide is allowed to be used. In the EU, Regulation 396/2005 and its amendments harmonise pesticide MRLs, and set a common assessment scheme for all agricultural products used for food or animal feed in the EU. These MRLs are defined based on good agricultural practice and evaluated against established health-based guidance values like ARfDs and acceptable daily intakes (ADIs) to ascertain that at the established MRLs exposure of the

population remains without a health concern. Regular monitoring of the food chain is also in place, which for example in Europe is in line with Regulation 396/2005, which indicates that EFSA is to provide an annual report assessing the pesticide residue levels in foods on the European market (Regulation (EC) 396/2005, 2005). The results presented in these annual reports reveal that exceedance of the MRLs may occur to a very limited extent but usually without concomitant exceedance of the corresponding ARfD or ADI (EFSA, 2023). This definition of legally binding MRLs implies that when a dimension of the existence of regulatory limits is included in the definition of a contaminant pesticide residues would classify as contaminants.

1.8.5. Criterion: stakeholder perspectives

Stakeholders may have different views on whether pesticide residues should classify as contaminants. Regulators, risk assessors, farmers and food producers may likely consider the compounds, also based on the above considerations, to be residues rather than contaminants. Consumers, on the other hand would consider even residues from approved uses that are proven to not cause any health concern to be unwanted constituents and thus contaminants. This however illustrates that including such considerations in the definition would cause confusion and equivocal outcomes for the classification of pesticides.

1.8.6. Conclusion on which aspects should and should not be in the definition of a contaminant

Based on the above considerations it becomes clear that deciding whether pesticides should classify as contaminants is not straightforward. Several aspects generally included in the definition of a contaminant create equivocal outcomes for the classification of pesticides. This holds for the dimension on intentional versus unintentional presence, the dimension of harm, especially when harm relates to a risk, and/or the stakeholder perspectives. The best way forward may turn out to be to classify the pesticides not as contaminants but rather as residues and argue their presence in food or feed is always the result of intentional use.

1.9. Residues of veterinary drugs

1.9.1. Introduction

Veterinary drugs may be used as a part of farm animal husbandry practices and as such there may be residues within animal tissues such as those consumed as human food. As a part of the authorization of veterinary drugs (for example in the EU as per Regulation 2019/6, 2019), the safety for consumers of such residues is considered and permitted animal posology includes this consideration. Therefore, in markets where there is effective oversight of the use of veterinary drugs, there should only be risk from the perspective of authoritative bodies, if usage conditions have not been adhered such as the withholding period prior to slaughter, or if animals not intended to be eaten enter the food chain. As veterinary drugs should not be marketed without explicit approval, and regulations refer to their residual presence in foods as 'residues' not 'contaminants', the term 'contaminant' does not apply unless the respective regulation has been exceeded.

1.9.2. Criterion: intentional versus unintentional

Veterinary drugs are deliberately administered and therefore unintentional presence is not relevant. However, some veterinary drugs cause consumer controversy such as hormones for increased milk and meat production which are permitted in the US but banned in the EU. In the US it is often the case that products within supermarkets differentiate based on the absence of such drugs in the animal supply chain, so clearly the intentional use of the drugs is considered important for food choice by some consumers.

1.9.3. Criterion: harmful

The EU requires by law "that foodstuffs such as meat, milk or eggs must not contain residue levels of veterinary medicines or biocidal products that might represent a hazard to the health of the consumer" (https://www.ema.europa.eu/en/veterinary-regulatory-overview/research-and-development-veterinary-medicines/maximum-residue-limits-mrl). If there was a veterinary drug which unlawfully entered the food chain and had a notable hazard associated, it would be unequivocal that it would be considered as a 'contaminant' irrespective of the risk presented to consumers.

1.9.4. Criterion: regulatory limits

Residues that are present within animal-derived foods and are not compliant with their usage conditions are commonly referred to as 'contaminants'. In the EU, such situations are managed as if the contaminated food is injurious to health even when this is not the case. Therefore, it is unequivocal that non-compliance can result in a change of terminology from the legal definition of veterinary 'residue' to food 'contaminant'. An example is the dramatic impact on the egg industry and their downstream customers, when the veterinary drug fipronil was discovered to have been used off-label within laying barns with resulting residues within eggs (Munoz-Pineiro and Robouch, 2018). Although a number of governmental authorities assured consumers that there was no risk to health, the common language used was that the eggs were contaminated and there was mass destruction of products across the implicated supply chains.

1.9.5. Criterion: stakeholder perspectives

The presence of residues such as veterinary residues within food products is rarely known to stakeholders past the earliest stages of supply chains, as this information does not travel with the food (and there is no requirement for it to do so). As such it is equivocal what would be the view of stakeholders who are not involved in animal husbandry, authorization or enforcement.

1.9.6. Conclusion on which aspects should and should not be in the definition of a contaminant

Veterinary drugs that may be present within animal-derived foods, similar to pesticides are under stringent regulatory control, and also similar to pesticides there are substantial differences between permitted uses and restrictions between trading countries. As such there is significant potential for non-compliance. Recent incidents of non-compliance have demonstrated the behaviour of many stakeholders in that non-compliance irrespective of risk renders the residue to be considered as a 'contaminant', and this is especially the case if there is a perception of potential hazardous properties.

2. Discussion

Available definitions of food contaminants illustrate that a number of parameters are common, such as intentionality and harm. Based on the experience of the authors, we have attempted to consider how these parameters influence the contemporary reality of how 'contaminants' are designated. Table 2 provides an overview of the ambiguity caused by the evaluated criteria in the definitions used to consider what is a contaminant, thereby facilitating a conclusion on what should and what should preferably not be included in the definition for a contaminant.

This overview reveals that for many categories of food-borne substances generally considered as contaminants, the different parameters may result in equivocal outcomes in terms of their influence on stakeholder perception that the substance is in fact a contaminant. One reason for these equivocal outcomes is that chemicals may be present in food for a technological reason and are in such cases intentionally added or present in the food chain. This obviously holds for regulated chemicals like pesticides, veterinary drugs and compounds migrating from packaging, but also for chemicals with a potential dimension of harm such as the food processing related contaminants furan and acrylamide and phytotoxins like methyl eugenol and estragole which may contribute to

Table 2
Overview of evaluation of the effects of items included in the definition of a contaminant on the outcome of the qualification of different groups of food-borne compounds as a contaminant. When the item results in unequivocal classification of the chemicals as contaminants the box is coloured blue, when the classification would be equivocal the box is coloured yellow, and when the item would result in classification of the chemicals as not being a contaminant, for example because there is no risk or unintentional presence is unlikely, the box is coloured green.

	Unintentional presence	Harm: hazard	Harm: risk	Regulatory limit	Stakeholder perception	Comment
Substances unintentionally present within ingredients						
Phytotoxins						Some are flavours resulting in intentional use. Some have no regulations
Mycotoxins						Often missing data for risk assessment. Some have no regulations
(Heavy) metals						Some metals are essential nutrients
POPs						Always unintentional in food
Substances that result from food preparation						
Processing aids						Some are 'residues' (present by design), whereas others are not
Process related contaminants						May contribute to odour, taste
Food contact materials						IAS and NIAS; Residues rather than contaminants
Substances used as a part of managing the productivity or acceptability of supply chains						
Pesticides						Residues rather than contaminants
Veterinary drugs						Residues rather than contaminants

the odour and/or taste of a food product but at the same time raise a health concern because they may be genotoxic and carcinogenic. In spite of this the aspect of intentional versus unintentional presence is a Criterion providing at least for some categories of food-borne chemicals an unequivocal definition: mycotoxins, heavy metals and POPs are always unintentionally present and both industrial and consumer stakeholders agree that they should be considered contaminants. This consideration leads to the conclusion that an appropriate definition that could reflect the parameter of unintentional presence is "without a nutritional or technological function in the food". Inclusion of a pre-fix 'unintentional presence' would even work for the categories of chemicals that may in some cases be present for technological reasons upstream and thus using the parameter 'unintentional' is not accurate and therefore should not designate a substance as a contaminant. For example, processing aids, FCMs, pesticides or veterinary drugs that would be intentionally used and predictably present in a food, may not be considered a contaminant. These chemicals might rather be classified as residues, and they are often designated as such. This consideration leads to the conclusion that an extended definition may better reflect the parameter of unintentional presence, such as "without a nutritional or technological function in the food or its production".

This conclusion is not in line with most of the definitions provided for contaminants. The EC definition for example states (Table 1): "… 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''. This implies that residues from veterinary medicine, pesticides, and FCMs would all classify as contaminants. This also holds for the definition provided by MERCORSUR stating (Table 1): "Any undesirable substance present in the food at the time of consumption, originating from the operations carried out in the cultivation of vegetables, in animal husbandry, in zoo or phytosanitary parameters, or as a result of environmental contamination or production and/or conservation equipment". In contrast, the definition from the Chinese Food and Drug administration is in line with the proposal since it defines contaminants as "Chemical hazardous substances produced or brought by environmental pollution and are not intentionally added in foods in the process of production (including crop cultivation, animal husbandry and veterinary medicine), processing, packaging, storage, transportation, sales, eating, etc.". Thus, the various definitions for contaminants vary in whether they do or do not restrict the unintentional presence in food to the situations without a technological need in the food itself.

With respect to the dimension of harm in a definition for a contaminant this Criterion also creates equivocal outcomes. This is because the term harm can be interpreted in different ways, as either related to hazard or to risk. When considering harm as a *potential* to cause adverse effects, so to reflect a hazard, we believe that substances in all categories considered would most likely be unequivocally designated as a contaminant (Table 2). This may contribute to the general negative association that the term contaminant generally has, especially for consumers. Considering harm as actually causing adverse effects and thus representing a risk, the definition could cause more controversy, since in that case classification of a chemical as a contaminant would depend on the level of exposure and thus a substance could be a contaminant when exposure exceeds a health based guidance value, while the same substance would not be considered a contaminant in products where the exposure as a result of consumption would not exceed the safety value. The disadvantage of including the term risk in the definition therefore implies that one would have to perform a risk assessment to evaluate whether the hazard posed by a chemical represents a risk to consumers, before it would be clear how the substance should be described and therefore managed. Thus, when considering whether a chemical should classify as a contaminant use of terms that refer to risk will likely result in confusion, whereas reference to intrinsic hazard would provide a more consistent understanding.

Notwithstanding, the use of hazard within a contaminant definition as a surrogate of harm is complicated in regulatory jurisdictions wherein regulatory limits are not linked to risk but based on ALARA (as low as reasonably achievable), such is the case within the EU. In such countries, regulatory limits for some food components may be lower or higher than is needed for consumer protection, and the impact of limits on mitigating consumer risk would not be understood. These considerations lead to the conclusion that this aspect of harm is better not included in the definition of a contaminant.

This also implies that aspects on the presence of regulatory limits based on health-based guidance values should also not be included in

the definition of a contaminant since, as explained above, an aspect related to risk or risk assessment should not be included because then designation as contaminant would rely on both the substance and its concentration in specific matrices, as well as the consumption quantity of those matrices, resulting in different designations depending on the exposure. Use of an aspect related to regulatory limits irrespective of what those limits are based upon (e.g. ALARA or risk) would also result in an equivocal definition of a contaminant because not all substances potentially considered as contaminants have regulatory limits established.

Given these considerations and the conclusion that use of the dimension of harm in a definition for a contaminant creates ambiguous results, it is of interest to note that many regulatory bodies do use a dimension of harm in their definition of a contaminant (Table 1). EFSA for example uses the phrase "may be harmful", the Indonesian Food and Drug Control Agency uses the term "disturbing, harming and endangering human health", the definition form Chile APRUEBA states "that are presumed harmful", the Chinese Food and Drug Administration uses the wording "Chemical hazardous substances", and in USA, FDA define contaminants as "chemicals that have the potential to cause harm"(Table 1). It is clear that in some of these definitions the term used refers to hazard (hazardous) while in others it refers to risk which makes it even more confusing. Taking it all together it is concluded that the definition for a contaminant provided by various regulatory agencies result in equivocal understanding of substances as contaminants because they include a dimension of harm. The results presented in Table 2 illustrate that this is especially the case when the harm refers to risk and the occurrence of adverse health effects. When the definition refers to a hazard its use in the definition is without meaning since all chemicals can present a hazard.

Concerning food chain stakeholders, our analysis revealed that the perception of what is considered a contaminant may vary considerably. Our experience is that consumers are most worried about substances which they perceive as having a characterizing hazard (such as endocrine activity) or that they dread for other reasons such as when it is believed to be an unnatural or artificial substance. These concerns are mitigated somewhat when there is a high degree of familiarity with the substance and its presence is not hidden, and there is an ability to make food choices. In general pesticides, and FCMs may be viewed more as 'contaminants' rather than as 'residues', however as discussed above an inverse designation is more constructive. Other stakeholders may provide additional arguments about intentionality of chemicals to provide for example taste related to process formed contaminants, thus leading to the argument that they should not be considered as contaminants at all. Rather, substances whose control should consider acceptability and tolerable risk related for the food in question. Thus, including stakeholder perspectives in defining what should be classified as a contaminant leads to equivocal results. It is likely that different stakeholders view the designation of contaminants, and contaminated food using different frames of reference. Consumers for example may focus on dread and avoidability, whereas food safety agencies are more likely to focus on hazard or data and controllability. An analysis of motivations for different stakeholders can provide insight into their expectations in terms of both whether a substance is considered a contaminant, and appropriate actions to take, for example whether the precautionary principle is expected as opposed to a risk-based approach or social discourse. In the EU, a precautionary approach is the expectation of many stakeholders and authorities, except where there is a judgement of very high uncertainty or when control measures will have knock-on impact such as the availability of nutritious traditional foods.

Taking it all together it is concluded that making an unambiguous definition for a contaminant based on existing definitions is almost impossible. As a result, it can also be concluded that the current formulations from different regulatory bodies to define a contaminant in food lead to equivocal outcomes and confusion. This holds especially for inclusion of a dimension of harm or a dimension of the existence of regulatory limits. Including the aspect of unintentional presence is helpful provided that this refers to the unintentional presence in food without a technological need in the food itself. Therefore processing aids, FCMs, pesticides or veterinary drugs that are unintentionally but predictably present in a food because of a technological need in the processing of the food should be considered as residues unless there is exceedance of an applicable regulatory limit. It is clear that for all stakeholders the designation of a substance as a 'contaminant' has a negative connotation, and therefore a suitable umbrella definition could be that a contaminant is '*a substance considered to require control measures due to the unacceptability of its context within a food*'. In this way the term contaminant can apply to its common use across food safety, hygiene and quality aspects. Understanding the varying stakeholder motivations for perception of acceptability and thus the use of the term 'contaminant', should be considered in policy decision-making and therefore subject to more detailed analysis including the distinction whether a substance is perceived as a contaminant, residue or component of food. Notwithstanding the outcomes of the present review, it is clear that the current state-of-the-art in contaminant management will not readily clarify existing definitions. Nevertheless, we think that the outcomes of this preliminary review could help stimulate clarifications in defining a substance in food as a contaminant, not least due to the impact on control measures that may be applied across supply chains.

The analysis presented in this review illustrates that the definitions for what is considered a contaminant by different regulatory bodies are not harmonized and also not unequivocal in terms of the criteria used to define a contaminant, while at the same time it reflects the differences in what stakeholders consider a contaminant. This leads to a situation where use of the term contaminant is not harmonized, and the term contaminant is used where terms like food constituent or residue may fit better. These insights may facilitate future efforts to better harmonise the definition and use of the term contaminant.

CRediT authorship contribution statement

Ivonne M.C.M. Rietjens: Writing – review & editing, Writing – original draft, Validation, Conceptualization. **Michelangelo Pascale:** Writing – review & editing, Writing – original draft, Conceptualization. **Gloria Pellegrino:** Writing – review & editing, Writing – original draft, Conceptualization. **Daniel Ribera:** Writing – review & editing, Writing – original draft, Conceptualization. **Armando Venâncio:** Writing – review & editing, Writing – original draft, Conceptualization. **Danlei Wang:** Writing – review & editing, Writing – original draft. **Konrad Korzeniowski:** Writing – review & editing, Writing – original draft, Supervision, Project administration.

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Data availability

No data was used for the research described in the article.

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