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Toward a conceptual framework for food safety criteria: Analyzing evidence practices using the case of plant protection products

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ABSTRACT

Food safety has a significant influence on food markets and is of great societal importance because it protects human health and life. Most studies presume that the presence or absence of food safety can be objectively assessed based on data from natural sciences and might be further interpreted and perceived in different ways; however, there is no consensus on the definition of food safety. Disputes within the scientific community and increasing public discourse suggest that there is no generally accepted definition of what is “safe” or “unsafe”. This paper introduces a framework that describes food safety in a broader sense, using the example of plant protection products, by identifying different evidence practices through the classification of criteria from various research fields. Data were collected in an integrative literature review. Criteria for assessing food safety were classified and collected within a conceptual framework that acknowledged the multidisciplinarity of knowledge bases. The analysis highlights the questions that arise when determining these criteria. We conclude that obtaining a generalized definition of food safety is not possible. Instead, our results showed the determination of food safety by criteria at different levels: science-based criteria at knowledge and value levels that result in standards and consumer-based criteria at knowledge and value levels that result in behavior. A better understanding of food safety criteria helps to show deficits in the current risk analysis practice and points to solutions for more consistent regulations, leading to more stable market conditions and a stronger mutual understanding.

1. Introduction

The regulation of food safety receives a great deal of attention in societal and political discussions because it ensures the protection of human health. In addition, it is of high economic relevance because of its role in non-tariff trade restrictions and the potential for high losses in cases involving food scandals. It is quite challenging for regulators to determine food safety because different societal groups appear to have a different understanding of what is meant by safety, as indicated by different evidence practices[1] in food safety negotiations; therefore, public discourse in safety negotiation is vulnerable to mistrust, misunderstanding, and mutual degradation, especially in critical cases, such as it was observed in the re-approval process of glyphosate in the European Union (EU).

Since the 1990s, the Sanitary and Phytosanitary Agreement of the World Trade Organization has determined which evidence is accepted as a justification for non-tariff trade restrictions based on the risk analysis process published in the 1980s by the National Research Council (Millstone, 2009; NRC, 1983). This process is based on a scientific risk assessment that quantifies the risk to human health. For plant protection products (PPPs),[2] most empirical data stem from the field of toxicology (EC and EP, 2009), and food safety regulations control the intentional introduction of PPPs in the form of approvals as well as the unintentional presence by determining maximum residue levels in food. PPPs are an interesting case-study for several reasons. As they are human-made, their introduction, use, and safety can be regulated (IoM and NRC, 2003). In addition, their risk analysis process is highly complex in the European context and PPPs elicit a high degree of skepticism by consumers. The food safety-related literature presumes that the presence or absence of food safety can be assessed in an objective way that might be further perceived, assessed, or interpreted, depending on, for example, the risk characteristics or values and

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[1] Evidence practices are understood as procedures of evidence generation (practicing evidence) and processes of using and embedding evidence (evidencing practice).

[2] The term includes product formulations and related active substances. We avoid the term ‘pesticides’ because it includes biocides, which are regulated differently in the EU.

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worldviews of specific societal groups (Hansen et al., 2003; Kahan, 2016; Slovic, 1987). However, the following three main arguments question this presumption.

First, we find a lack of consensus on the definition of food safety. Although intensively used, neither the scientific literature in natural sciences and consumer research nor regulators consistently define the term. Some authors define food safety as the absence of hazardous substances (Herges et al., 2017), while others refer to a specific certainty or probability of an adverse effect or even the inverse of risk (Henson and Traill, 1993; OECD, 1993). Given these differing definitions, two types of assessments are necessary to determine food safety: (1) the presence or absence of a hazard that can be determined using a hazard assessment approach, and (2) the probability and severity of an adverse effect that is established using a risk assessment approach. Both approaches are used in European food safety practice with respect to PPPs: hazard-based approaches are used, *inter alia*, in classifications of carcinogenicity, and risk-based approaches are applied to determine maximum residue levels (Barlow et al., 2015).

Second, discourse among scientists and within scientific organizations demonstrates a lack of agreement in determining whether a food is safe or not. The recent discussion among various scientific assessment authorities on the inconsistent classification of the carcinogenicity of glyphosate exemplifies this issue (Portier et al., 2016). Inconsistencies might be caused by how the authorities deal with contradicting evidence and scientific uncertainty, which appears at every stage of the risk assessment process and is difficult to quantify (Barlow et al., 2015; Rhomberg et al., 2013).

Third, the mobilization of scientific knowledge in risk assessments is being increasingly questioned and discussed by the general public, which indicates that consumers use different criteria to evaluate what is and is not safe food. The assessment of food safety in terms of PPP residues is problematic for consumers because most negative effects are chronic, that is, caused by exposure to low doses over a long period of time. Neither PPPs nor their effects are usually detectable immediately following product consumption (Nau et al., 2002; Shaw, 2005). EU citizens are very concerned about pesticide residues in different food products (EFSA, 2019, 2010). Consumers in Germany consider PPP residues to be the most influential hazard pertaining to food quality and safety, although the actual risk from PPP residues in food is rated low by scientists (EFSA, 2016). This raises the question of whether consumers are using alternative criteria to determine whether a food product is safe, rather than overestimating numerical risk estimates.

In contrast to presumptions presented in the literature, the above statements indicate that there is no clear and generally accepted, value-free definition of food safety. Thus far, there appears to be no holistic consideration of the complex determination process in society; therefore, the aim of our study was to introduce a framework that describes food safety in a broader sense by identifying different evidence practices by collecting and classifying criteria from various research fields. It was built based on a systematic literature review using a grounded theory approach. The framework was developed conceptually and does not aim to describe theoretical relationships among criteria. It categorizes and summarizes multidisciplinary approaches that aim to describe various aspects in determining food safety. By comparatively analyzing either the risk analysis or the consumer part, the framework highlights the difficulties involved in determining these criteria and provides a more holistic description of food safety than would a universal definition. This exercise generates valuable insights into the different players involved in food safety discussions and might increase a mutual understanding and acceptance of different opinions. While not being able to arrive at a common framework across risk analysis and the consumer approach, the framework sets a basis for a more efficient interaction among regulators and consumers, and potentially for a better understanding of food safety regulations. A major objective of our study was to include consumers' food safety determination process not merely as a "critical interface between scientific facts and personal opinions and values" (Ropeik, 2011), but as a self-reliant evidence practice. This unconventional view of consumer food safety determination potentially provides new approaches to integration into policy.

Our paper is structured as follows: Section 2 includes the guiding theory behind data collection and the process of building the framework; Section 3 presents the criteria extracted from the literature as well as the developed conceptual framework; Section 4 discusses the results and the implications for current food safety practices and research; and Section 5 provides concluding remarks.

2. Procedure

The preceding statements suggest that determining food safety within a society is highly complex. We developed a conceptual framework by which to describe food safety not with a definition but with criteria. To that end, we defined a criterion as "a principle or standard by which something may be judged or decided" (Oxford University Press, 2017). Building on literature from various disciplines, a conceptual framework offers the possibility of developing a network of linked concepts in food safety. Jabareen (2009) describes a conceptual framework as an appropriate method by which to describe "complex phenomena linked to different bodies of knowledge"; therefore, rather than provide a theoretical explanation of relationships among variables, we provide an understanding of the complex negotiation process involved in food safety. The systematic approach to the framework and literature review is based on the guiding theory of Galison's trading zones (2010) that we introduce in Section 2.1. To build a framework, Jabareen suggested eight steps, which we summarized in three superordinate working steps as follows: collecting the data (Section 2.2), building the framework (Section 2.3), and validating the results (Section 2.4) (Jabareen, 2009).

2.1. Guiding theory

As mentioned, we based our analysis on the concept of trading zones as introduced by Galison (2010), who uses the concept to understand how knowledge and language can be combined when two disciplines interact, integrating their respective concepts and contingencies into a new body of knowledge and evidence. In his work, Galison examined the interactions and negotiation processes between two different fields of science: physics and chemistry. Despite its comparatively confined initial application, the concept of trading zones can be used to study food safety because Galison also suggested applying it to explain the interactions between two disparate societal groups (Galison, 2010); therefore, a central hypothesis of our study was that there are two zones that influence and are influenced by the evidence practices of food safety: scientific-based risk analysis and the consumer, both of which interact within the food system trading zone (for details, see Appendix A). Because the definition of evidence is controversial, we describe it here not only as being based on data but also as one based on a social phenomenon, or, more specifically, socially accepted knowledge (Cartwright, 2006; Kelly, 2016).

Galison assumes that the two spheres of reference are not hierarchical but overlapping; therefore, it is presumed that scientific risk analysis does not comprise the source that is reflected by the consumers' evaluation of food safety, but that both scientific and consumer food safety practices intersect at some point. This implies that consumers do not merely interpret the outcomes of the risk analysis process but have a self-reliant evidence practice. Within the trading zone, the definition of food safety is negotiated. Knowledge and criteria, but not necessarily their function and meaning, are exchanged. For PPPs, this implies that the relevance of knowledge taken from the natural sciences need not necessarily have the same meaning for food safety as does consumer perception, and vice versa, in the risk analysis process. Another characteristic of a trading zone scenario is an imbalance of power (Galison, 2010), which is also a characteristic of food safety

determination. There appears to be an imbalance in favor of risk analysis because consumers are viewed as mere perceivers of scientific facts influenced and misdirected by various factors (Section 3.3.2); therefore, the development of our framework is based on these two perspectives—first, science-based risk analysis, and second, consumer-based risk assessment—in order to provide a new perspective from which to negotiate the determination of food safety.

2.2. Data collection

The data that helped create the conceptual framework comprise the literature from various scientific disciplines. Data collection included mapping the data sources as well as extensively reading and categorizing the selected data (Jabareen, 2009). This was done within a systematic, integrative literature review that followed the system of Torraco (2005), who suggests it as a possible basis for building a conceptual framework. As opposed to Jabareen's first step, Torraco suggests beginning the synthesis of a conceptual framework by structuring the topic according to a guiding theory (Torraco, 2005); therefore, the original method was adapted because it allows for a more systematic approach to dealing with the extensive amount of literature on risk analysis and risk perception in food safety. To collect the data, an adaptation of Galison's trading zones concept was used as an underlying theory. Based on this concept, there were two main areas of interest for the review: first, the risk analysis process, including the scientific, technical risk assessment that was translated into risk management and policy (risk communication, normally considered part of the risk analysis process, was excluded because it is does not determine, but rather communicates, food safety criteria); second, the main area of interest was consumers' evidence practices. Using the key words in Fig. 1, we identified the first relevant sample of scientific information, followed by a snowball procedure based on the literature identified in the first round.

2.3. Building the framework

The steps for building the framework comprised identifying and naming the relevant existing concepts, deconstructing and categorizing the concepts, and integrating and resynthesizing the new concepts within the new framework (Jabareen, 2009). The concepts were categorized in two steps. The first step included a general categorization of the data on risk analysis and consumer-related evidence practices. The second step comprised building more detailed deductive and inductive categories. The final categories and levels of the framework, as well as the final classification logic, are described in Section 3.

2.4. Validation

The last steps in building the framework comprised validating and reevaluating the process (Jabareen, 2009). As a validation method, Jabareen suggests that results be presented at a conference of experts to enable them to add to or rework unnoticed aspects; thus, the results were duly presented at an agricultural economics seminar, a university research colloquium, and at the 27th Annual Conference of the Society for Risk Analysis – Europe in Östersund, Sweden, in June 2018. To obtain feedback from the perspectives below, the three presentation formats had different target audiences: agricultural and resource economists, consumer researchers and risk analysts. Feedback discussions comprised the following points:

- discussion of the role of international organizations in the framework,
- discussion of the naming of consumer criteria,
- discussion of the differentiation of consumer criteria, and
- comprehension questions.

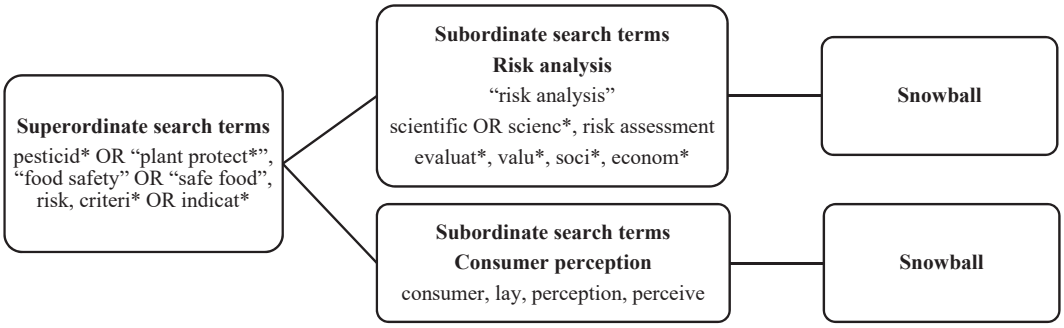

Fig. 1. Search strategy of the literature review.

The following exclusion criteria were used: not relevant, duplicate studies, related to outdated regulations, related to non-EU regulations, not related to PPPs (risk analysis context), environmental risk assessment, and conditions not comparable to EU (cultural, agricultural). The databases used were *ScienceDirect*, *Emerald*, and *Scopus* for scientific peer-reviewed articles or book chapters, and *Google* for gray literature from relevant organizations in risk assessment and management. The search was conducted in 2017 and 2018, and the data were organized in *Mendeley*. We identified 153 pieces of relevant scientific information, 78 of which were categorized as "risk-analysis"-related, 67 of which were categorized as "consumer"-related, and 8 of which were categorized as related to both concepts. In total, 120 of the identified sources were peer-reviewed papers; the other sources were books, regulatory documents, or gray literature.[3]

[3] A detailed description of the distributions of publications by year and type is provided in Appendix B.

Following feedback, the lowest level of consumer practice was changed from "assessment criteria" to "knowledge criteria". In addition, criteria definitions were refined because they were too unspecific. We identified some limitations in the suggested validation practice; these are discussed in Section 4.

3. Results

During the review, we identified the criteria for food safety within the following two different evidence practices: risk analysis (Section 3.2) and consumer evaluation (Section 3.3). The criteria are classified into different levels that are linked within a conceptual framework (Section 3.1). Both practices interact within the societal trading zone where food safety is negotiated. Because the focus of this framework is on identifying criteria and not on the negotiation process, these interactions are not closely addressed.

3.1. Conceptual framework for food safety criteria

The conceptual framework for food safety criteria comprises different criteria and related processes used to determine food safety (Fig. 2). Here, we introduce the overall framework. All components are elaborated and explained in subsequent sections.

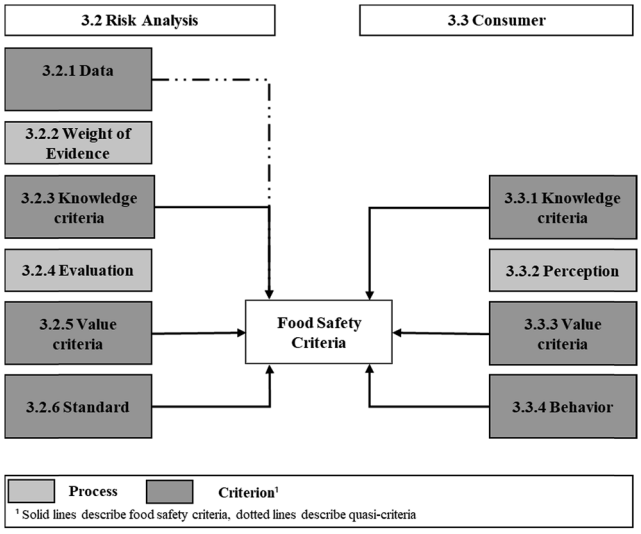

Fig. 2. A conceptual framework for food safety criteria.

Risk analysis (Section 3.2) is based on data from natural sciences, which are problematic to classify as criteria under the applied definition (Section 3.2.1). The Weight of Evidence process (Section 3.2.2) transforms data into knowledge criteria (Section 3.2.3) determined in institutionalized risk assessments. An evaluation process (Section 3.2.4), either by risk managers or by socioeconomists, leads to a determination of safety in the form of value criteria (Section 3.2.5). These are translated into legally binding standards (Section 3.2.6) comprising the final determination of safety in risk analysis.

Consumer safety determination is also based on knowledge criteria (Section 3.3.1), which describe the relevant underlying dimensions of safety and are further perceived and evaluated in the perception process (Section 3.3.2). The result of this evaluation is the determination of a value criterion (Section 3.3.3) in the form of a stated concern or decision about whether something is safe. Lastly, safety is determined by the behavior of a consumer (Section 3.3.4) and his/her decision to purchase products perceived as containing PPP residues.

Both sides of the framework are characterized by similar levels of criteria: the knowledge and the value levels. Additional evaluation processes that result in stated value decisions about safety are observable and are fixed within regulatory actions or behavior. We now offer details about the different criteria.

3.2. Evidence practice of risk analysis

Expanding on the classification of Dreyer and Renn (2009), who divided the claims used in risk analysis into knowledge and value, we categorized the (quasi-) criteria of risk analysis within the levels presented in Fig. 3 as follows: data (Section 3.2.1), knowledge criteria (Section 3.2.3), value criteria (Section 3.2.5), and legally fixed standards (Section 3.2.6). Between the levels, we present processes that transform one criterion into another (Section 3.1). These include the

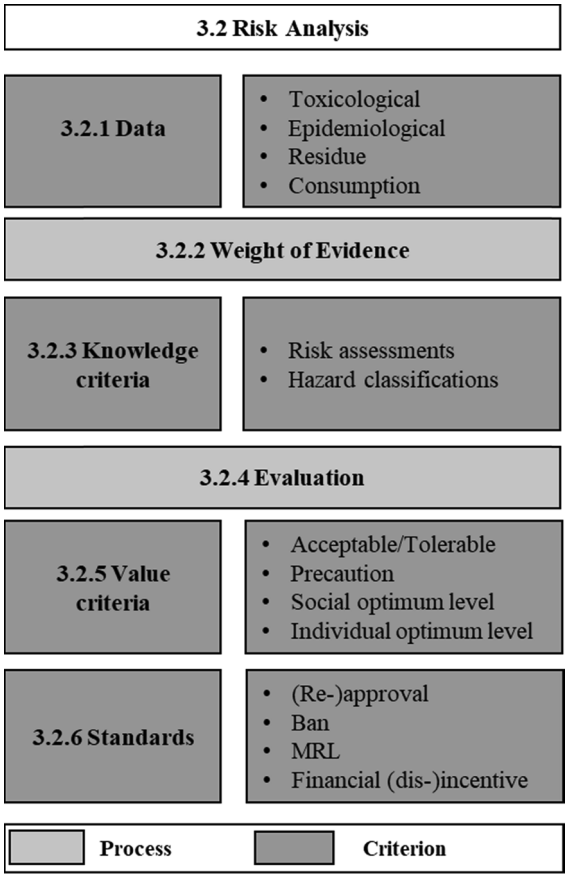

Fig. 3. Food safety criteria in the evidence practice of risk analysis.

Weight of Evidence approach (Section 3.2.2) and the evaluation (Section 3.2.4), both of which are discussed below.

3.2.1. Data

Data are defined as pieces of information (e.g., a single scientific study) (EFSA, 2015). Required data in the evaluation of PPP safety include toxicological and/or epidemiological data to determine the effects and residue and consumption data for exposure assessments. During this stage, there is not necessarily a consensus on what is and is not safe. This makes it difficult to classify data as a criterion for food safety if such a criterion is defined as “a principle or standard by which something may be judged or decided” (Oxford University Press, 2017). Data might also be contradictory or insufficiently available. Various approaches exist to reflect the availability of knowledge (Douglas and Wildavsky, 1983; Dreyer and Renn, 2009). These include the assessment of available data based on the following parameters:

- Level of definition of outcome, level of definition of probability (Dreyer and Renn, 2009) and
- level of consent, level of knowledge about the future (Douglas and Wildavsky, 1983).

These classifications enable a critical view of the current risk analysis practice, a view that acknowledges that risk or hazard assessments are conducted within diverse states of knowledge that go beyond the required data in the approval dossiers for PPPs (EC and EP, 2009, 2005). In contrast, technical risk assessment is viewed as only one way

of evaluating safety that is applicable in all cases of well-defined probability and outcomes, consent, and appropriate knowledge about the future. In other situations, alternative solutions are necessary. For example, if there is consensus on an effect but the knowledge of its behavior in the future is uncertain, the problem is a lack of information and the solution is not a technical risk assessment but additional research (Douglas and Wildavsky, 1983; Dreyer and Renn, 2009). In risk assessments, data are often contradictory or not sufficiently available. In addition, we have observed that the amount of available data differs among cases; therefore, data relevance for the evidence depends on the ability to meet the objective of the assessment in question. Datasets might range from irrelevant to fully relevant depending on the available data. Irrelevant data might be used in assessments under consideration of uncertainty if more specific data are unavailable and hence become relevant (EFSA, 2015). Incomplete data might stem from the existence of competing datasets, lack of perfect data, or the existence of competing theories (Rhomberg et al., 2013; Wagner, 2016). Data required for an ideal risk assessment are complex and, in most cases, not available (Reffstrup et al., 2010). Exemplary, issues of residue and consumption data are elaborated in Table 1.

Table 1
Issues in data.

Kind of data	Issues and literature
Residue data	• Variability due to agricultural practice[a] leads to uneven residue distributions in samples (Maclachlan and Hamilton, 2010; Tucker, 2008) • Overestimations of residues in supervised trials (Boobis et al., 2008) • Required field trials disregard heterogeneity of European agriculture and are only conducted in small numbers (Maclachlan and Hamilton, 2010) • Current PPP residue monitoring practice disregards cumulative and aggregate effects, levels of detection and quantification problematic for the estimation of cumulative effects[b] (Boobis et al., 2008) • Nonharmonized EU monitoring programs (Kennedy et al., 2015) • Average residue levels disregard inter-unit variability (Tucker, 2008) • Data are mostly available for agricultural commodities but not for processed food products (Boobis et al., 2008) • Different definitions for residues are used[c] (Boobis et al., 2008)
Consumption data	• Chronic intake assessments show methodological limitations through inadequate data[d] (Boobis et al., 2008; Tucker, 2008) • Nonharmonized collection of consumption data in the EU (Kennedy et al., 2015)

[a] This includes different growing practices, spray equipment or growth stages of plants (Maclachlan and Hamilton, 2010).
[b] Residues under these levels might be problematic if cumulative or aggregate effects appear among different PPPs in a commodity and the non-reported PPPs sum to hazardous levels.
[c] Maximum residue level monitoring should be chemically simple and dietary risk assessment should include metabolites if they are toxicologically relevant (Boobis et al., 2008).
[d] Eating patterns can change over time and there is the issue of decreasing accuracy of recording over time (Boobis et al., 2008).

3.2.2. Weight of Evidence approach

As previously mentioned, it is likely that data are not sufficiently available and can be contradictory. To transform data into the next level of criteria, the Weight of Evidence approach comes into play. This approach is used in numerous contexts and by many institutions. Although the Weight of Evidence process is an essential component of the risk analysis process, we find inconsistencies in its definition and its systematic use within risk assessment institutions, which can lead to contradicting results even though they are based on the same amounts of available data. This is also the case for systematic reviews if they are used as synonyms for Weight of Evidence (Ågerstrand and Beronius, 2016; Haddaway and Bilotta, 2016; Pease and Gentry, 2016; Rhomberg et al., 2013; Weed, 2005; Whaley and Halsall, 2016). Although some institutions provide a clear characterization and description of their Weight of Evidence approaches (e.g., EFSA), others remain nonspecific and refer to the need for flexibility (e.g., ECHA) (Rhomberg et al., 2013). This can be problematic in PPP risk assessments when different authorities, here EFSA and ECHA, are involved (Barlow et al., 2015). In general, the Weight of Evidence approach relies strongly on expert judgment, especially in situations in which there are conflicting or insufficient data. This might lead to inconsistencies because experts can also be biased and must make value decisions in determining which data are accepted, which need to be collected, or how to deal with uncertainty (Fraiberg and Trebilcock, 1998; Nordlander et al., 2010; Van der Fels-Klerx et al., 2018; Wagner, 2016).

3.2.3. Knowledge criteria

The evidence practice of risk analysis is based on the criteria from natural sciences provided by assessment authorities. In the literature, we find the following different terms to determine these criteria: human health impact (Fantke et al., 2012), classic technical–scientific risk assessment (König et al., 2010), and knowledge claims (Dreyer and Renn, 2009). Knowledge criteria are considered to be useful for overcoming heuristic biases in policy making and for keeping the regulatory process in check (Fraiberg and Trebilcock, 1998; Sunstein, 2002). The basic principle of toxicology and chemical risk assessment is the dose–response relationship (Benford, 2000; Nau et al., 2002). For PPPs, the following two approaches are used to evaluate safety: hazard-based assessments and risk-based assessments. Hazard-based assessments are used in the approval processes to characterize severe nonthreshold mechanisms, such as carcinogenicity. Risk-based assessments are used in the approval and maximum residue level determination processes to characterize threshold mechanisms. In general, inconsistencies can materialize if both approaches are applied to the same hazard, as is the case in some PPP assessments (Ågerstrand and Beronius, 2016; Barlow et al., 2015; Nordlander et al., 2010). The application of classical risk assessment comprises four steps that generate preliminary forms of knowledge criteria, as elaborated in Tables 2 and 3.

Table 2
Preliminary forms of knowledge criteria in different steps of risk assessments.[a]

Step	Preliminary forms of knowledge criteria
1 Hazard identification	Identification of key negative endpoint (for example, neurotoxic), intrinsic properties of the hazard (acute, short-term, subacute, subchronic, chronic)
2 Hazard characterization	Definition of lethal dose (LOD50) and "no (adverse) effect levels" (NOAEL/NOEL) based on animal data; extrapolation to humans under consideration of safety factors in the form of "acceptable daily intakes" (ADI) for chronic exposure and "acute reference doses" (ARfD) for acute exposure
3 Exposure assessment	Calculation/Estimation of exposure
4 Risk characterization	Aggregation of hazard characterization and exposure assessment

[a] Content of Tables 2 and 3 is based on Barlow et al. (2015); Benford (2000); D'Mello (2003); Dreyer and Renn (2009); EC and EP (2005); ECHA (2017); EFSA (2017); EP and EC (2002); Erlacher and Wang (2011); Herges et al. (2017); IoM and NRC (2003); König et al. (2010); Mostafalou and Abdollahi (2013); Nau et al. (2002); Nordlander et al. (2010); Renwick et al. (2003); Stornetta et al. (2015); Szajkowska (2012); Tucker (2008); van der Meulen and van der Velde (2004); Whaley and Halsall (2016).

Table 3
Preliminary forms of knowledge criteria in different steps of hazard assessments.[a]

Step	Preliminary forms of knowledge criteria
1 Hazard identification	Identification of key negative health endpoints, e.g., carcinogenicity, endocrine disruption potential
2 Hazard characterization	Hazard classification

[a] Content of Tables 2 and 3 is based on Barlow et al. (2015); Benford (2000); D'Mello (2003); Dreyer and Renn (2009); EC and EP (2005); ECHA (2017); EFSA (2017); EP and EC (2002); Erlacher and Wang (2011); Herges et al. (2017); IoM and NRC (2003); König et al. (2010); Mostafalou and Abdollahi (2013); Nau et al. (2002); Nordlander et al. (2010); Renwick et al. (2003); Stornetta et al. (2015); Szajkowska (2012); Tucker (2008); van der Meulen and van der Velde (2004); Whaley and Halsall (2016).

The outcomes of these processes are the different kinds of knowledge criteria used in determining food safety. Hazard classifications describe the severity of an effect (Henson and Traill, 1993) and the "inherent property of an agent or situation having the potential to cause adverse effects" (Barlow et al., 2015). Hazard classifications are criticized as denying real exposure probabilities (Nordlander et al., 2010). Risk characterizations might describe the levels of risk and probabilities, thresholds, likelihood and severity of an adverse effect or harmful potential and exposition (Barlow et al., 2015; König et al., 2010; Renwick et al., 2003; Whaley and Halsall, 2016). Essential in determining knowledge criteria is the detailed presentation of uncertainties that appear in the various steps determining those criteria (Barlow et al., 2015; Fraiberg and Trebilcock, 1998; Karabelas et al., 2009; Nordlander et al., 2010; Renwick et al., 2003; Tucker, 2008). Human health risk assessments suffer from data that are indirect (from animal studies) and must be extrapolated, that are incomplete (not fully understood dose–response relationships), or that present contradicting evidence (Benford, 2000; Fantke et al., 2012; Rhomberg et al., 2013). The concepts of dose–response relationships and thresholds in risk assessment are discussed because they require the exact determination of a threshold, which appears to be difficult given the uncertainties and variabilities (Benford, 2000; Crawford-Brown, 1999; König et al., 2010; Slikker et al., 2004). In addition, in setting threshold levels, multiple exposures in regulations are not taken into account, although cumulative and aggregate mechanisms are highly relevant (Boobis et al., 2008; Kennedy et al., 2015; Reffstrup et al., 2010).

3.2.4. Evaluation

Evaluating knowledge criteria is an important step in the risk-assessment process, which is part of risk management within the regulatory process. Policymakers and regulators function as filters of evidence and decide which forms of societal or scientific information are used in the decision process (Vogel and Delfini, 2008). Because approving PPPs and setting maximum residue levels is highly dependent on the outcomes of scientific risk assessment (EC and EP, 2009, 2005), regulators have few options in adapting the translated outcomes (regulations) through evaluations based on these classifications or thresholds. For PPPs, an evaluation always relies on data from the risk assessment (Travisi et al., 2006); however, in general, there is little certainty in the translation of health effects into policy (Sexton et al., 2007). Nonetheless, the Sanitary and Phytosanitary Agreement suggests an evaluation beyond the scientific risk assessment in the form of relevant economic factors and trade impacts (WTO, 1995). Furthermore, the multidimensionality of PPP risks means that important tradeoffs exist between agricultural productivity and safety, which imply a high relevance of socioeconomic evaluations (Florax et al., 2005). These evaluations of PPPs are found in the literature in various but nonharmonized forms (Table 4). Some evaluations are related more to classical risk assessment (e.g., ratings, classifications), mixed forms (e.g., multicriteria decision analysis), economics (cost–benefit analysis), or social sciences (impact assessments).

Table 4
Evaluation methods for PPPs.

Evaluation	Specification and Literature
Ratings and Classifications	• Risk ratios, scorings, risk matrices, flow charts, relative risk rankings (Stornetta et al., 2015; Van der Fels-Klerx et al., 2018)
Multi-Criteria Decision Analysis	• Fazil et al., 2008; Van der Fels-Klerx et al., 2018
Risk-Utility evaluations	• Quality of life measures, health-adjusted life years (Cope et al., 2010; Dreyer et al., 2010; Newsome et al., 2009; Stornetta et al., 2015; Van der Fels-Klerx et al., 2018)
Risk-Risk evaluations	• Fraiberg and Trebilcock, 1998; Graham and Wiener, 1995; Hansen et al., 2008; Nordlander et al., 2010
Risk-Benefit evaluations	• Cropper et al., 1992; Starr, 1969
Cost-Benefit evaluations	• Cerroni et al., 2013; Fraiberg and Trebilcock, 1998; Harper and Zilberman, 1992; Sexton et al., 2007 • Marginal Analysis of welfare costs (Lichtenberg et al., 1988) • Benefits through quality improvements (Babcock et al., 1992; Kawasaki and Lichtenberg, 2015; Sexton et al., 2007)
Cost evaluations	• Human Capital Approach, Cost of Illness (Buzby et al., 1998; Caswell, 1998; Henson and Traill, 1993; Van der Fels-Klerx et al., 2018) • Cost for innovation (Nordlander et al., 2010; Sexton et al., 2007) • Cost of resistance (Sexton et al., 2007) • Private costs for farmers (Sexton et al., 2007)
Willingness to Pay/Willingness to Accept	• Caswell, 1998; Cope et al., 2010; Eom, 1994; Florax et al., 2005; Skevas et al., 2013
Impact assessments	• Social impact assessments (Cope et al., 2010; Dreyer et al., 2010; Vanclay, 2002) • Health Impact assessments (Fantke et al., 2012)
Hazard Indices	• Cross and Edwards-Jones, 2011

The literature offers a broad set of tools with which to evaluate safety, but suffers from various issues. The main criticisms include complexity of effects that are difficult to illustrate and map in models, limited availability of required data, high effort and costs, high variability of results, and lack of comparable studies because of missing guidelines in PPP risk and hazard impact evaluations (Cope et al., 2010; Fantke et al., 2012; Hansen et al., 2008; Sexton et al., 2007; Skevas et al., 2013; Van der Fels-Klerx et al., 2018).

3.2.5. Value criteria

Value criteria are characterized by a valuing decision on safety based on a previous evaluation. In regulatory practice, we find criteria such as "acceptable" or "tolerable" levels of risk or safety as well as "precautionary" principles. In addition, in socioeconomic literature, we find criteria such as "socially optimum" and "individually optimum" levels.

Acceptability or tolerability describe judgments in risk management pertaining to the acceptability of a risk or hazard in a society. In the current practice of risk analysis within the European context, socioeconomic criteria are not taken into account; only data on the negative impacts on human health based on risk estimates are formally considered (EC and EP, 2002). The issues involved in determining these criteria are that the acceptance of risk must be value-laden and the acceptable level of risk must also have risk management or societal consideration. In general, acceptable levels of risk are difficult to determine due to the heterogeneity in consumer characteristics and preferences (Dreyer and Renn, 2009; Renwick et al., 2003; Shaw, 2005; Wagner, 2016). Regulators are decisive factors in this question because they act as filters of evidence (Vogel and Delfini, 2008). This is problematic because it has been shown that regulators, and thus regulations, are influenced by lobbyism from both the environmental and producer sides (Cropper et al., 1992; Sexton et al., 2007) and that politicians and judges suffer from heuristic biases (Sunstein, 2002).

The precaution criterion is a decision about the status of knowledge. If uncertainties are too high, precautionary bans or measures might be applied to protect public health. These might be applied in cases of incomplete risk assessments and could help avoid unintended tradeoffs in cases of scientific uncertainty (EP and EC, 2002; Hansen et al., 2008; Nordlander et al., 2010). In general, precaution suffers from incoherence, which implies that the application of the criterion is inappropriate in decisions with fatal outcomes (Peterson, 2017, 2006).

Economists introduced the concept of socially optimum levels of safety for PPPs (Henson and Traill, 1993; Sexton et al., 2007). Because there is no realistic scenario in which a society can avoid all hazardous PPPs, safety is determined through optimal levels of safety while acknowledging tradeoffs (Henson and Traill, 1993). The socially optimal level of pesticide use is an outcome of maximizing the net benefit to society, which includes net benefit to consumers, farmers, producers of chemicals, and the environment (Sexton et al., 2007). The problem with this concept is that it does not consider the distribution of risks in a society (Henson and Traill, 1993).[4]

The individually optimal level is based on a similar argument, with the difference that this optimal safety is determined not for society as a whole but for the individual. It differs from the socially optimum level by not internalizing external factors, such as environmental effects. Issues related to its determination arise through dependence on many factors, *inter alia*, risk perception (Section 4.2) (Henson and Traill, 1993; Pollak, 1998; Salanié and Treich, 2009; Sexton et al., 2007). In general, market outcomes relate to individual optimum levels because they do not include externalities, such as environmental effects; therefore, markets do not provide a socially optimum level without regulation (Sexton et al., 2007).

3.2.6. Standards

In the last step of risk analysis practice, food safety is defined by fixing legal standards based on value criteria. This step comprises the final decision on food safety, which also implies a decision on which criteria become evident and socially accepted knowledge; therefore, we define standards as the highest level of risk analysis in the framework. We find two types of standards for PPPs: approval or reapproval of PPPs with respect to intentional introduction in the production of agricultural commodities, and maximum residue levels with respect to unintentional presence in the consumption of food (IoM and NRC, 2003; van der Meulen and van der Velde, 2004). Furthermore, we find financial (dis-)incentives in the form of, for example, producer subsidies, which are not further discussed here because they are consequences, not criteria (Sexton et al., 2007).

The approval of PPPs in the EU is regulated by EC 1107/2009. The approval process is divided into the following two procedures: approval of the active substance and approval of the PPP. In terms of active substances, the approval is always limited in time: a maximum of 10 years for the first approval and 15 years for reapproval. Reapproval enables a new evaluation of the substance based on current scientific and regulatory standards. The approval of PPPs is the responsibility of the European member states but is possible only if all components, including active substances, have been approved. The time limitation depends on the approval of ingredients and active substances (BVL, 2017; Damalas and Eleftherohorinos, 2011; EC and EP, 2009).

Maximum residue levels are regulated by regulation 396/2005 in a harmonized process for all foodstuffs. National risk-assessment authorities, such as the German BfR, estimate maximum residue levels for different kinds of food taking into account PPPs in plants and consumer exposure as it relates to diet. After further EFSA assessment, EU-harmonized maximum residue levels are usually set based on the "As Low As Reasonably Achievable" principle (BVL, 2017). This is a balancing act between production and consumption, with considerations of health, misuse, and trade conditions. The issues in this case might be the heterogeneity of the farms (producers) that apply PPPs, especially in the EU, where harmonized maximum residue levels and highly heterogeneous climatic conditions exist (Maclachlan and Hamilton, 2010; Sexton et al., 2007). National and European food-monitoring programs observe compliance of products with maximum residue levels. If the maximum residue level is exceeded, possible trade restrictions are imposed (BVL, 2017); if maximum residue levels cannot be achieved in practice, PPPs cannot be approved (BVL, 2017).

Standards based on scientific risk analysis always face a fundamental contradiction: science is always understood as an evolving process in which theories are continuously developed and disproved; however, standards are needed to fix a state-of-the-art practice (Wagner, 2016). What is considered to be safe today might be disproved tomorrow by a new or alternative method. Regulations, especially in Europe, acknowledge this issue with time limitations on approvals. This implies that safety is a relative, rather than an absolute, construct. In practice, this is observed with PPPs because their safety depends on the availability of substitutes; if no less-hazardous substances are available, a critical substance might be approved and thus considered as safe (Storck et al., 2017). In addition, standards must fulfill two expectations: first and foremost, protect consumers in the best possible way, and second, avoid a possible function as a trade barrier. Thus, the harmonization of standards is necessary to maintaining trade. In many cases, it is difficult to decide whether a deviation from internationally accepted standards is justified based on consumer protection; therefore, scientific risk assessment is set as the basis for these decisions. Various authors from jurisprudence deal with the question of the extent to which science is required by the Sanitary and Phytosanitary Agreement in international trade because it remains unclear to what degree risk

[4] A similar concept used to determine safety is provided by Harper and Zilberman (1992): the "Safety minimum standard," which allows a weighting of costs and benefits conditional on some minimal safety standards (Harper and Zilberman, 1992).

assessment or precautionary reasons are decisive (Cunningham, 2005; Gruszczynski, 2007; Kerr, 2009; Wagner, 2016; Walker, 2001).

The EU's PPP regulations do not take into account socioeconomic criteria in deciding on legally fixed safety. Regulations formally rely purely on data about the negative impacts on human health based on risk estimates (Cope et al., 2010; König et al., 2010; Reinert, 2015; Verstraete, 2014). This might be problematic, as different levels of PPP regulations have a significant impact on production and trade[5] and must address wider societal concerns. In general, PPP regulations face the issue that food safety problems can easily spread globally as a result of trade and require a uniform policy; however, the use of PPPs and consumption is local and heterogeneous (Sexton et al., 2007). In the EU, PPPs are regulated within a complex regulatory landscape comprising various national and supranational institutions and processes that increase the likelihood of inconsistencies (EC and EP, 2009, 2005; ECHA, 2017; Handford et al., 2015; Rhomberg et al., 2013; Storck et al., 2017).

PPP bans can be problematic because they decrease the number of available active substances and increase a buildup of resistance (Karabelas et al., 2009; Sexton et al., 2007) or the application of even worse substitutes (Nordlander et al., 2010). Policy often ignores the possibility of risk-reduction measures (e.g., application and drainage requirements to reduce risk) and bans pesticides without considering their economic benefits (Sexton et al., 2007).

3.3. Evidence practice of consumers

Risk analysis in food safety is a highly institutionalized evidence practice. While standardized risk assessments attempt to achieve an objective and fair safety determination, risk management must negotiate various interests, such as consumer safety and trade. The second relevant process in determining food safety is the evidence practice by consumers, which is more vague. In line with Galison (2010), we considered this not as a reflection or interpretation of the risk-assessment process, but as one of self-reliance. This differs from recent definitions describing consumer evidence practice as, for example, risk perception and "a critical interface between scientific facts and personal opinions and values" (Ropeik, 2011). In the literature, we find various terms for consumer practice, such as intuitive toxicology (Kraus et al., 1992), risk perception (Slovic, 1987), people's risk assessment (Bieberstein and Roosen, 2015), risk evaluation (Bouyer et al., 2001), subjective food safety (Grunert, 2005), and qualitative criteria (Henson and Traill, 1993).

This indicates two things. First and foremost, the literature recognizes that consumers use their own determination processes to evaluate food safety and risks. Second, these differences in definitions show inconsistencies in the understanding of the consumer evaluation process. In the literature on food quality, food safety is described as a credence attribute because consumers are not able to directly evaluate the safety of the offered products before and after purchasing (Grunert, 2005). This is especially true for PPPs because their effects are mostly chronic and delayed; therefore, they cannot be directly related to a specific consumption event (Henson and Traill, 1993; Shaw, 2005). Nevertheless, consumers have their own understanding and definition of food safety independent of single purchases, which differs from an understanding of the definition in risk analysis. In the following section, we collect different expressions of safety as found in research and classify them in the criteria structure. Contrary to risk analysis, it is not possible to separate criteria on an institutional basis because all safety-determination criteria are used by the consumer. Additionally, it is difficult to separate consumer criteria conceptually because the entire safety determination process is inclusive and interconnected.

[5] The literature reports mixed results regarding the effects of PPP regulations on trade (Disdier et al., 2008; Drogué and Demaria, 2012; Essaji, 2008; Handford et al., 2015; Wilson and Otsuki, 2004).

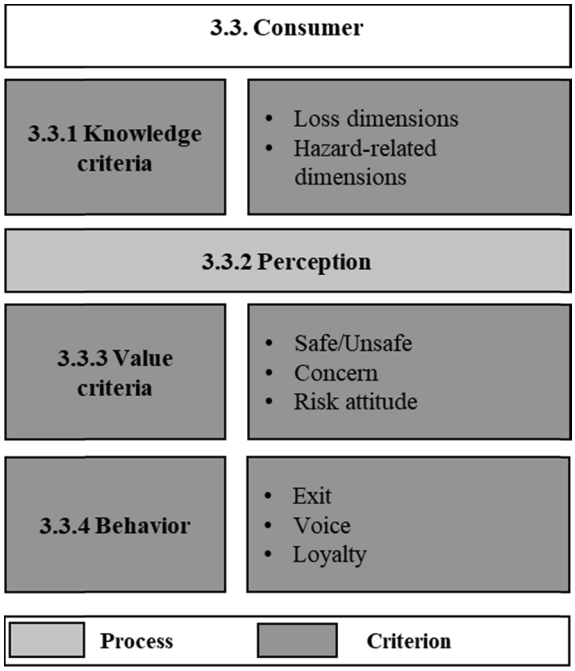

Fig. 4. Food safety criteria in consumer evaluation.

Nevertheless, we decided to split them because it is common in the recent literature to differentiate between "objective" and "subjective" elements in safety determination. The terms used in our framework follow the classifications in the risk analysis process: (1) knowledge criteria (Section 3.3.1), (2) value criteria (Section 3.3.3), and (3) behavior (Section 3.3.4), as summarized in Fig. 4. Between levels (1) and (2), we place the perception process (Section 3.3.2).

3.3.1. Knowledge criteria

Following the classification of risk analysis criteria, knowledge criteria represent the relevant underlying dimensions used by consumers for safety determination. As this classification has not been used systematically in the literature thus far, we determined the following conditions for their characterization: All concepts describing relevant safety dimensions for consumers and their reasonable determination require some kind of knowledge and could be determined objectively using science or scientific methods. In addition, they should fulfill the general definition of criteria, which are required to be the basis for decisions or judgments. Because we do not claim that consumers are able to determine these criteria in the form of unbiased quantifications or numerical expressions, these criteria are seen as non-numeric, qualitative descriptions. The various concepts describing factual dimensions in consumer safety determination are elaborated below.

3.3.1.1. Personal loss dimensions. The first type of knowledge criteria describes the types of losses that are relevant to consumers and stem from a concept introduced by Yeung and Morris (2001), who determined six individual loss dimensions to predict overall risk, specifically food risks based on the components of perceived risk in product purchase in Kaplan et al. (1974). The first dimension, "physical losses", understood as a safety criterion, describes negative health effects. In the case of PPPs, this might include acute intoxications or chronic diseases (Yeung and Morris, 2001). In other research contexts, this criterion is considered a "fatality of consequences", including acute or chronic effects and type of death (Fife-Schaw and Rowe, 1996; Mullet et al., 1993; Slovic, 1987; Sparks and Shepherd, 1994). Second, "psychological losses" describe food-risk concerns, for example concerns about a PPP when buying a certain product. Third, "financial losses" describe possible replacement costs for risky foods,

the cost of medications and income losses while recovering from the adverse effects of food containing hazardous substances. Fourth, "time losses" refer to the time wasted in replacing affected food or in illness as a result of consuming a PPP-contaminated product. Fifth, "performance losses" describe the possible adverse effects of the hazard on taste or nutritional value, and sixth, "social losses," are the social embarrassments resulting from the use of contaminated food products (Kaplan et al., 1974; Yeung and Morris, 2001). The authors describe the theoretical concept as suitable for all types of food risks. To the best of our knowledge, there is no application of these loss categories in PPP safety determination[6]; nevertheless, the concept offers the possibility of describing relevant effects for consumers, including various health effects and wider financial, social, and psychological concerns.

3.3.1.2. Hazard-related dimensions. The second type of knowledge criteria stems from the psychometric paradigm invented by Slovic (1987). The concept describes two hazard-related dimensions in consumers' risk determination: the "unknown" and the "dread" factors, both of which comprise multiple items that include relevant safety dimensions for consumers.

The unknown factor comprises a "lack of observability", whether the hazard is "known to the people exposed" and "known to scientists", whether it is a "new or known risk" and whether "effects are delayed or immediate". In different studies, PPPs score low to middle on the unknown factor. The second factor in the psychometric paradigm is the dread factor, which includes the "potential for a global catastrophe," the "level of control of the hazard" (including the possibility of reducing it) and the "general development of risk" (either decreased or increased) of a PPP. PPPs score medium to high on the dread factor (Fife-Schaw and Rowe, 1996; Slovic, 1987; Sparks and Shepherd, 1994).

Classical psychometric paradigm studies indeed show high explanatory power but use mainly aggregated data, which ignores individual differences among consumers. This has been criticized because individual differences have been shown to be highly important in explaining risk perception. The inclusion of individual data lowers, but does not neglect, the relevance of hazard-related dimensions (Bronfman et al., 2008; Marris et al., 1997; Siegrist et al., 2005b).[7] Additionally, the concept ignores the socio-political conditions which influence public opinion on hazards (Boholm, 1998). Nevertheless, the psychometric concept describes a validated set of relevant dimensions determining safety that are characterized as knowledge criteria in this study.

3.3.1.3. Knowledge criteria as food safety criteria. In both concepts, the individual and the hazard-related, we find various, differentiated dimensions that play a role in determining food safety in relation to PPPs and can function as food safety criteria. They include direct health effects but also concerns for indirect and wider effects on individuals or society. Thus, they confirm that public safety determination is not based on a reflection of statistical numbers. The consumer knowledge criteria concepts confirm the influence of qualitative understandings of hazards such as PPPs (Boholm, 1998). However, few concepts are specified at the level of the relevant underlying safety dimensions for specific hazards. In existing studies, it is unclear how dimensions of food safety are derived, indicating that there might be dimensions missing because they are outside the concept frames. The previously described concepts partly overlap and we can categorize most of the dimensions of consumer knowledge criteria content-wise using the basic qualitative structure of risk analysis knowledge criteria, hazard identification and exposure.

In risk analysis, hazard identification is defined as follows: "the identification of the type and nature of adverse effects that an agent has an inherent capacity to cause in an organism, system, or (sub)population" (Barlow et al., 2015). Among consumer knowledge criteria concepts, we find criteria such as health effects and indirect effects such as financial or social losses, primarily in the concept of loss dimensions. This is different to knowledge criteria from risk analysis, which consider exclusively the direct negative health effects of PPPs (König et al., 2010).

In risk analysis, exposure is defined as the "evaluation of the exposure of an organism, system, or (sub)population to an agent (and its derivatives)" (Barlow et al., 2015). In consumer safety determination, the following related criterion can be found mainly in the psychometric paradigm but also in other studies: concern for future generations (Miles and Frewer, 2001; Slovic, 1987), concern for vulnerable groups (Miles and Frewer, 2001), and the distribution and equity of risks and benefits (Dreyer et al., 2010; Fischhoff et al., 1978; Slovic, 1987).

Additionally, we find other relevant dimensions that go beyond the risk analysis knowledge criteria frame, for example, the possibility of reducing a risk or the risk trend (decreasing or increasing).

The authors of the original concepts, Yeung, Morris and Slovic, see the dimensions as being mostly relevant in effective policy or communication. Comparison with risk analysis knowledge criteria shows that the qualitative dimensions can also be useful during the risk assessment stage or in framing risk analysis. Underlying dimensions used as safety criteria could also be relevant in the conceptual definition of socially acceptable safety levels (Aven, 2018; Klinke and Renn, 2002).

3.3.2. Perception

In the context of our framework, risk perception is the evaluation process located between the knowledge criteria and the value criteria. This follows the argument that perception might lead to the social amplification of risk and that risk perception influences risk attitudes and thus indirectly influences behavior (Kasperson et al., 1988; Lobb et al., 2007). As described in the preceding sections, it is impossible to draw a clear conceptual line between knowledge criteria and perception factors; therefore, perception includes all factors not clearly classifiable as knowledge criteria. Most studies do not measure how consumers determine safety with respect to risk, but rather how different, non–rational factors influence the safety–risk evaluation; thus perception is not a separate criterion because it does not describe a determination of safety but rather a process that influences the determination of safety and that is influenced by a variety of factors. These factors are identified in the following section and might influence or bias an individual evaluation of safety and explain interindividual or group differences in the risk perception of PPPs. These factors might explain why different consumer groups are concerned about different types of food risks (Cunha et al., 2010; Roosen et al., 2005), or why there exist controversial opinions on food safety in terms of PPPs.

Following Bouyer et al. (2001), we classified the influencing factors in the "perceiver-linked" and "hazard-linked" factors. In addition, we found "external factors." Because the literature on influencing factors is very extensive but not the focus of this paper, these factors are not discussed in detail. In addition, because this paper does not aim to provide a quantitative meta-analysis, comparability of study designs and the strengths of effects (positive or negative) are not discussed.

3.3.2.1. Perceiver-linked factors. In addition to physiological processes, such as brain mechanisms, the perception process can be influenced by various factors, which are summarized in Table 5. We categorized "perceiver-linked" factors into psychological factors, sociodemographic determinants, and sociocultural determinants.

[6] Studies on other food hazards have shown good performance in predicting overall risk perception and significant differences among the loss categories, which might support the argument to include these loss dimensions in food safety determination (Hornibrook et al., 2005; Mahon and Cowan, 2004; Yeung and Yee, 2002).

[7] Research on individual differences is elaborated in the next section, 3.3.2, on perception.

Table 5
Psychological factors in the explanation of risk perception.

Factors	Specification and Literature
Psychological factors	
Bounded rationality*	• Examples: Framing or subconscious mental shortcuts, specifically optimism bias or loss aversion (Ropeik, 2011; Sunstein, 2002)
Affective heuristics*	• Representativeness, availability and anchoring comprise simplifying mechanisms to evaluate risks (Kasperson et al., 1988) • Strong drivers of intuitive judgments • Might lead to systematic errors of risk estimates (Sunstein, 2002)
Personality factors*	• Level of anxiety (Bouyer et al., 2001)
Emotions*	• Used by various authors in different theoretical concepts (for example Loewenstein et al., 2001; Peters et al., 2004) • Emotions connected to outcome seem to be more important than probability (Sunstein, 2002)
Sociodemographic factors	
Gender	• Bieberstein and Roosen, 2015; Bouyer et al., 2001; Byrne et al., 1991; Dosman et al., 2001; Dunlap and Beus, 1992; Knight and Warland, 2004; Miles et al., 2004; Nayga, 1996; Siegrist et al., 2005; Verbeke et al., 2005
Age	• Bouyer et al., 2001; Dosman et al., 2001; Dunlap and Beus, 1992; Knight and Warland, 2004; Lin, 1995; Miles et al., 2004; Nayga, 1996; Siegrist et al., 2005; Verbeke et al., 2005
Education	• Byrne et al., 1991; Nayga, 1996; Verbeke et al., 2005
Household income	• Byrne et al., 1991; Dosman et al., 2001; Miles et al., 2004
Number of children	• Dosman et al., 2001
Sociocultural factors	
Values	• Generally important in explanation of risk perception (e.g., Dreyer et al., 2010; Hansen et al., 2003) • Self-centered and altruistic values (Bieberstein and Roosen, 2015) • Group or cultural values, cultural attitudes, worldviews, and political orientation (Bouyer et al., 2001; Douglas and Wildavsky, 1983; Hansen et al., 2003; Kahan, 2016; Kahan et al., 2007; Kasperson et al., 1988; Peters et al., 2004; Ropeik, 2011)
Normative heuristics*	• Shaped by the normative concept or accepted societal rules[a] (Sunstein, 2002)
Cultural handling of food*	• Right or wrong, based on traditional processes whose importance appears to be decreasing (Lusk, 2013; Pollan, 2006; Spiekermann, 2011)

* Factor is a general concept in risk perception but not proven explicitly for PPPs, to the best of our knowledge.
[a] An example would be the neglect of risk-benefit estimations because calculating deaths is not accepted in cases of human harm (Sunstein, 2002).

Table 5 shows that a great variety of individual factors has an influence on the food safety determination process, which might lead to under- or overestimating the risk of a PPP and thus influence safety determination. First, psychological phenomena might cause systematic errors in the determination of safety. Second, individual characteristics influence how people determine safety; how hazardous PPPs in food are perceived depends to some extent on age, gender or education. Third, some research aims to explain risk perception differences using sociocultural factors. For PPP safety determination, this means that the value orientation and normative context of a person or a group influence the outcome of the safety evaluation. Safety concerns regarding PPPs and the acceptance of safety-related information might be motivated through political intention, or as a part of identity-building processes (Kahan, 2016). It is important to keep these various factors in mind when assessing public safety determination. Doing so may help one avoid misinterpretations or explain why certain consumer groups are dissatisfied with safety standards while others are not at all concerned. This is especially the case when interpreting the value criteria, elaborated in Section 3.3.3.

3.3.2.2. Hazard-linked factors. In addition to perceiver-linked factors, risk perception is influenced by nonrational hazard-linked factors connected with a hazard's intrinsic characteristics. Research finds a numerical overestimation of risk from PPPs (Williams and Hammitt, 2001). Different approaches explain why some hazards are generally overestimated when compared to statistically derived numbers in public safety perception or to other hazards. These factors include the "nature of the hazard." The type of hazard affects perception (Dosman et al., 2001; Kher et al., 2013). The literature specifically identifies differences between natural and technical hazards (Fischhoff et al., 1978; Kaptan et al., 2017; Kraus et al., 1992; Ropeik, 2011; Sjoberg, 2000; Williams and Hammitt, 2001), and technological or lifestyle issues (Miles et al., 2004). PPPs are a technological hazard in foods and are therefore likely to be overestimated compared to other food hazards. Related to this idea is the phenomenon of the "stigmatization" of, for an example, a technology. Stigmatization might be an additional mechanism whereby perceived risk is amplified in certain cases (Kasperson et al., 1988); specific hazards or PPP substances might be stigmatized. Another important influencing factor is weighing the "perceived risks and benefits" associated with the substance of interest (Alhakami and Slovic, 1994; Finucane et al., 2000; Miles and Frewer, 2001; Peters et al., 2004; Ropeik, 2011; Siegrist et al., 2000; Starr, 1969; Sunstein, 2002; Verbeke et al., 2007, 2005). Here, the relationship is reversed: if high risks are associated, perceived benefits are reduced and vice versa (Alhakami and Slovic, 1994; Finucane et al., 2000; Peters et al., 2004). It has been shown that certain consumer types acknowledge the benefits of PPPs (Saba and Messina, 2003), but generally the risks of pesticides are rated higher than their benefits (Alhakami and Slovic, 1994). It appears that safety concerns related to PPPs are rather high unless PPPs bring about significant benefits in agricultural production, food safety, or food security (Sexton et al., 2007). The inverse risk-benefit perception might contribute to overestimating the risks and, vice versa, underestimating the benefits of PPPs. Additionally, the mechanism might increase perceived risk if the focus of public communication and discourse is predominantly on risks rather than benefits (Kaptan et al., 2017). All these hazard-linked factors indicate that PPP risks are, in terms of their characteristics, likely to be overestimated in food safety determination. This should be kept in mind if consumer food safety criteria are used in decision-making processes.

3.3.2.3. External factors. External factors influence the risk perception process but are not related to the hazard or the perceiver. They are somewhat situational and depend on external influences. Under external factors, we include "food scandals", which might amplify the risk perception of related hazards during certain time periods (Kasperson et al., 1988; Lobb et al., 2007; Rieger et al., 2017; Verbeke et al., 2007). Additionally, safety perception is influenced by "the general situation of traceability and recall" (Hobbs et al., 2005; Kher et al., 2013; Van Rijswijk and Frewer, 2008), "the amount of available information" (Buzby et al., 1998; Eom, 1994; Finucane et al., 2000; Henson and Traill, 1993; Peters et al., 2004; Travisi et al., 2006) and "media influence" (McCluskey and Swinnen, 2004; Verbeke et al., 2007; Sunstein, 2002). "Trust" in various situations was shown to be an important influencing factor on risk perception, but its influence depends on the related institution or stakeholder (Chryssochoidis

et al., 2009; Kaptan et al., 2017; Lobb et al., 2007; Ropeik, 2011; Siegrist et al., 2005a, 2000; Williams and Hammitt, 2001).[8] The preceding list of factors indicates that the evaluation of public safety determination in the case of PPPs must take into account related framework conditions independent of the hazard itself.

3.3.3. Value criteria

3.3.3.1. Stated safety, concerns, and risk attitudes. Equivalent to the risk analysis process, there is a level of value criteria for consumers to determine safety. Value criteria comprise a valuing decision about safety that might be determined based on or influenced by knowledge criteria or perception. The literature mentions three types of value criteria: first, the stated claim that something is or is not safe (Leiss and Powell, 2004), and second, stated concerns about PPPs (Bruhn et al., 1992; Byrne et al., 1991; Dunlap and Beus, 1992; Knight and Warland, 2004; Miles et al., 2004; Nayga, 1996). Often levels of concern are measured in numerical, unidimensional scales. Concerns with PPP risks appear to be highly rated compared to other food risks (BfR, 2016; EFSA, 2010).[9] Third, various scholars describe risk attitudes in a way that allows one to classify them as value criteria. For example, Pennings et al. (2002) describe attitudes as "the decision-maker's interpretation of content of the risk and how much (s)he dislikes the risk"; Wilcock et al. (2004) describe attitudes as "permanent and stable evaluative summaries". Attitudes have been shown to influence intentional behavior. This relationship links value criteria and behavior, which are considered the final step in determining safety in consumer evidence practice (Section 3.3.4).

3.3.3.2. Value criteria as food safety criteria. Value criteria in the form of closed survey questions or item batteries are frequently used in studies as dependent variables in risk perception studies or to measure public safety determination. The literature comprises a broad base of validated instruments and empirical evidence. These carry some weight in discussions of public safety determination and are used in official EU and national consumer surveys (BfR, 2016; EFSA, 2010); nevertheless they must also be examined critically. First, they must always be seen as depending on the many influencing factors described in Section 3.3.2. Second, they are dependent on survey instruments. For example, studies show overestimations of food risks in closed survey questions. The proportion of respondents expressing worries about chemical contaminants in closed questions is 85%. In open questions, 17% of respondents mention concerns (Gaskell et al., 2017). Third, they can provide no information on the underlying reasons for concerns or decisions about safety or about actual behavior, but rather help to identify critical issues.

3.3.4. Behavior

3.3.4.1. Exit, voice, and loyalty. The last level in the consumer determination of safety is the actual behavior of the consumer. This must be differentiated from "value criteria" because, for example, "different attitudes do not necessarily lead to behaviors that increase the safety of the food consumed" (Wilcock et al., 2004). Numerous studies have attempted to explain, *inter alia*, the relationship between consumer attitudes and behavior. These relationships are not elaborated in this study because our aim was to examine different types of food safety criteria. In the case of PPPs, handling or cooking practices are not effective behavior options to improve safety; therefore, there are limited behavioral options to determine safety. Generally, consumers can use various strategies to respond to inadequate policy and/or safety supply only in cases in which quality failures exceed tolerance levels (Hirschman, 1971). According to Hirschman, these possible strategies are "exit", "voice" or "loyalty". Exit strategies might include stopping, reducing, or shifting consumption from one product to another (Roselius, 1971). For PPPs, the exit option is difficult to put into practice because most available products on the market are conventionally produced. An option might be to stop or reduce the purchase of conventional food and to switch to organic products produced without synthetic PPP applications.[10] Existing studies indicate a reduction in purchases due to concerns about PPP residues in fruits and vegetables (Bruhn and Schutz, 1999; Unusan, 2007) and in meat and meat products (Unusan, 2007).[11] The "voice" option includes expressing dissatisfaction directly to the producer or as a general protest (Hirschman, 1971). Here, consumers face different barriers in the case of PPPs. As safety concerns are not related to a specific food product but instead to a PPP, the recipient of complains is not easily identifiable. Information on risk assessment and underlying studies are partially confidential and not available to the public (EC and EP, 2009; Hirschman, 1971; Rosman, 1993). Additionally, consumers require the technical knowledge and financial resources necessary to effectively understand and interact with the complex process of risk analysis; for example, in public consultation rounds in the approval process. Such resources are available to interest groups rather than to individuals (Sunstein, 2018). The voice option is more costly than exiting, especially in cases involving a large number of affected products (Hirschman, 1971). This might be a reason why (successful) complaints of consumers and citizens appear in the form of (publicly supported) third-party actions. Successful examples of the voice option in the US include the ban on DDT or Alar initiated by public complaints (Rosman, 1993). A more recent example from the EU is the initiative "ban glyphosate and protect the people and environment from toxic pesticides" (European Commission, 2017). The efforts surrounding initiatives are high and therefore only appear in critical cases (Rosman, 1993). The "loyalty" option would be to continue to purchase "and absorb the unresolved risk, indicating that the perceived risk associated with a particular product is tolerable and no greater than alternatives" (Roselius, 1971). This implies that the final consumer determination of safety is highly dependent on purchasing alternatives but also on tolerance levels.

3.3.4.2. Behavior as a food safety criterion. In general, behavior is relatively easy to assess. It is possible to analyze decreasing sales or the number and types of complains. Exit and voice are in general good instruments with which to express dissatisfaction, but managers need time to react and to adapt the system accordingly. Behavior can have a rather destructive potential in critical cases (Hirschman, 1971); a prominent example is the Bovine Spongiform Encephalopathy crisis in Europe in the 1990s, which entailed high costs for the food system (Leiss and Powell, 2004). For the case-study of PPPs, the preceding arguments show that it is difficult for consumers to express their concern with safety violations through changes in behavior. The barriers and costs involved in complaining or choosing other options are high. Therefore, purchases might not be a suitable food safety criterion in dealing with PPPs but might still be relevant to other cases of safety determination. With PPPs, it is important to be aware of the behavioral options consumers have and the barriers they face. Related organizations must find solutions and reduce costs to enable consumers to express dissatisfaction (Hirschman 1971).

[8] For example, trust in EU institutions as an information source varies between 88% and 40% across EU member states (EFSA, 2019).

[9] These results are also confirmed by a more recent version of the Eurobarometer published after the literature search (EFSA, 2019).

[10] Organic food products may reduce the intake of PPP residues but have been shown to be partially contaminated (Smith-Spangler et al., 2012).

[11] Additionally, the Eurobarometer, published after the literature search, indicates that European consumers react differently to information on food risks in general: some indicate changes in their behavior while others do not, although the latter remain concerned (EFSA, 2019).

4. Discussion

The aim of this study was to provide a conceptual understanding of the complex determination processes in food safety. The developed framework shows that a generalized definition of safe food, as evidenced by socially accepted knowledge, remains impossible. Food safety cannot be described merely as the absence of a harmful substance (Herges et al., 2017) or the inverse of risk (Henson and Traill, 1993). Conceptually, it is determined instead by various criteria at different levels in the risk analysis process or by consumers and also requires valuing decisions. This contradicts recent studies that assume the existence of one well-defined level of safety that can be determined empirically and objectively but might be perceived or interpreted differently. Our framework introduces the issue of determining safety and illustrates how regulators can include science-based thresholds, a socioeconomic optimum, or a safety determination made by the consumer.

The case of PPPs offers interesting insights into safety determination processes because absolute safety in the form of the absence of harmful substances is unrealistic in today's agriculture and nutrition (Babcock et al., 1992; Henson and Traill, 1993; Kawasaki and Lichtenberg, 2015; Sexton et al., 2007). Moreover, Galison's trading zone concept related to evidence practices offers a fruitful basis from which to explain and categorize the process of determining food safety. It provides a different perspective on consumers' determination practice and might also be an interesting approach for structuring other complex social negotiation processes. A characteristic of the trading zone concept is that it can uncover misunderstandings in the exchange of criteria because the concepts themselves, but not necessarily their meanings, are shared among the different zones and actors.

There were limitations to this study that must be considered when interpreting its results. Because the framework was developed based on the literature, which was unable to resolve biased interpretations, the study might suffer from a confirmation bias. To reduce this risk, a systematic literature review and discussions with uninvolved researchers were conducted. The validation procedure could also be a limitation. Following the validation procedure suggested by Jabareen (2009), we discussed the results with experienced researchers within different conference settings. This was problematic because it was not possible to select the audience and researchers attending the presentations; therefore, it might be that, as opposed to an expert workshop, the participating audience had no experience of the topic being discussed. Because this is a somewhat weak and nonspecific validation method, various arguments support the framework's validity. One argument for its credibility or internal validity was the use of studies from different perspectives and disciplines. Transferability or external validity is not the aim of qualitative research and the justification of transfer is not the responsibility of the developing, but rather of the applying, researcher (Bitsch, 2005). Another limitation might be the topic's high complexity; thus we assume that the literature examined is incomplete. Because this is not a quantitative meta-analysis, we justify our approach with reference to the concept of theoretical saturation. It is possible for researchers applying this conceptual framework to extend or adapt it with their own classification schemes.

The framework points out the relevance of the differences and peculiarities among the criteria involved in evidence practices. While criteria in risk analysis are determined via a highly institutionalized process and are mostly consistent with each other, consumers' safety evaluations are more complex, interconnected, and hardly tangible. Conceptual and semantic differences among safety determinations lead to various issues and related implications in the societal discourse on food safety.

First, we observe safety determination by consumers as being inconsistent in itself: consumers do not show noticeable forms of "exit" or "voice" at a behavioral level in the general evaluations of PPPs; however, this does not appear to be the case at the value level. Here, we observed a high level of concern about PPPs (BfR, 2016; EFSA, 2010), even if the safety level is deemed acceptable by conformity with regulations. This raises the question as to when inadequate safety exceeds tolerance levels and leads to a change in behavior and what barriers for behavioral options exist (Hirschman, 1971). This question is of major economic relevance because changes in behavior caused sudden economic losses and decreases in consumer trust in previous food scandals, as seen in the aftermath of the Alar scare related to apples in the US in the 1980s (Syddell, 1990) or the Bovine Spongiform Encephalopathy crisis in the 1990s in the EU (Leiss and Powell, 2004; Raude et al., 2005; Vos, 2000). Therefore, an interesting area of research involves determining tolerance thresholds in food safety.

Second, disregarding or overprotecting consumers can lead to under- or overregulating PPPs (Fraiberg and Trebilcock, 1998). This raises the question of how regulators integrate evidence practices by consumers in their processes, a question discussed in the existing literature (e.g., Salanié & Treich, 2009). We aim to enrich this discussion by identifying different types of criteria. This study shows that numerous factors might influence and bias individual safety evaluations; therefore, the currently used measurements of stated perceptions or concerns might be unsuitable for determining rational and evidence-based safety. An alternative approach is recognizing relevant underlying knowledge criteria, which might be assessed in scientific risk assessments and extend the current dimension of direct negative health effects. One relevant example could be equality of risk (EC and EP, 2009, 2005; König et al., 2010). In this case, the weak scientific basis for these criteria related to food safety and PPPs is problematic, which might be an interesting area for future research. Regarding behavior, the last level of safety determination, one can argue provocatively whether we need to consider stated concerns as long as consumers do not actively react, as this is their final decision about safety (Finn and Louviere, 1992). Hence it is important to be aware of existing barriers in order to interpret consumer behavior. We emphasize that regulators and policy consultants must recognize the existence of consumers' different levels of safety determination and decide on which level to base their measurements.

Third, there is the question of how to determine the value criteria in the risk analysis process and how to define societal acceptability. As with many risks in modern societies, PPPs always result in tradeoffs in their applications, which are relevant at different policy levels (Beck, 1986; Graham and Wiener, 1995; Sexton et al., 2007). In addition, PPP regulations are directly linked to the continued functioning of free trade; therefore, non-optimal regulations of PPPs as food hazards might threaten consumer safety, societal welfare, or food security (Handford et al., 2015; Wagner, 2016; WTO, 1995). This implies the need for the integration of socioeconomic evaluations, at least in the process of determining value criteria; therefore, transparent and harmonized evaluation methods for socioeconomic impacts, which thus far do not exist, are necessary. In addition, these evaluation methods neglect the distribution of risks and benefits, but these should be integrated because they appear to be relevant to consumer evaluations. It should be acknowledged that in evaluations optimal levels of safety will most likely vary among different stakeholders depending to what degree the complex externalities of PPPs are internalized (Henson and Traill, 1993; Sexton et al., 2007). This might also be important for risk communication and to justify regulatory measures. If a communicator or regulator knows the actor involved and his/her specific individual optimum of safety, he/she might be able to explain deviations from this optimum with the internalization of further socially relevant externalities. Similarly, risk regulators can also consider the internalization of externalities deemed relevant by other stakeholders to achieve a socially acceptable optimal level of safety.

Fourth, in the process of risk analysis, it should be recognized that the selection of knowledge criteria is contested and cannot be deemed entirely objective. Knowledge criteria provide a solid and comparable basis for safety evaluations but also exhibit weaknesses. As shown in Section 3.2, the main issues are the critical evaluation of available knowledge (Douglas and Wildavsky, 1983; Dreyer and Renn, 2009) and the Weight of Evidence harmonization (Ågerstrand and Beronius, 2016; Rhomberg et al., 2013; Weed, 2005). Furthermore, determining food safety with regard to PPPs is never conclusive and depends on the state-of-the-art practice in science, which is addressed by time-limited approvals (Erlacher and Wang, 2011). This illustrates how difficult it is to formulate an ultimate definition of food safety.

Fifth, a vacuum between the determinations of safety by risk analysis and by consumers can develop that would provide room for communication among nongovernmental interest groups, the media, or private companies.[12] In a worst-case scenario, this might generate social panic, which often does not even need to be connected to a change in the underlying risk (Leiss and Powell, 2004; Loewenstein et al., 2001; Verbeke et al., 2007); consequently, purely science-based risk assessments may be in danger of becoming the subject of instrumentalization. For example, interest groups can neglect or emphasize aspects of scientific uncertainty to support their own agenda (Jasanoff, 1990). In these cases, well-founded decisions based on socioeconomic analysis and consumer determination might be easier to justify.

Based on the above arguments, we emphasize that in food safety discussions, participating individuals should recognize the existence of different levels of safety criteria and their related issues in order to improve public discourse and optimize safety determination. This might lead to more consistent regulations, an increase in trust, and mutual understanding.

5. Conclusion

Overall, this study shows that food safety, as an issue of scientific, economic, and societal relevance, cannot be determined at one generally accepted level. Rather, a common understanding of the issue is the result of complex negotiation processes. The framework developed here provides an overview of the influencing factors and issues in this negotiation process, and highlights semantic and conceptual inconsistencies in the literature. This helps one understand this complex social issue and such related phenomena as public discourses. The framework integrates various types of knowledge in a conceptual manner, which is a major task of risk research (Aven, 2018; Jabareen, 2009). It offers the possibility of reassessing, contextualizing or generating hypotheses for empirical research in the individual disciplines. In addition, it raises our awareness of how food safety is determined at different levels, which leads to the question of the level at which safety should be based. In risk research and analysis, which criteria should be used to determine acceptable risk or safety is a decisive and nonobvious question. Conceptual research can help answer this question by providing an overview of how existing criteria and issues are determined and by placing them in context (Aven, 2018). In this study, the framework illustrates the difficulties involved in existing risk analysis procedures and the possible sources of public dissatisfaction. This may help foster an understanding among different social groups and also in research, or to justify a reconsideration of currently used criteria in food safety. The framework might provide interesting approaches to solutions to existing issues and ideas for future research, either in the risk assessment process, the field of safety evaluation by consumers, or in their interactions. The conclusions reached might be very different for each discipline – a critical consideration of scientifically based criteria or a more differentiated view of the criteria used by consumers. The study further shows the potential of applying conceptual framework research to risk research, which is often characterized by multidisciplinary and complex areas of interest.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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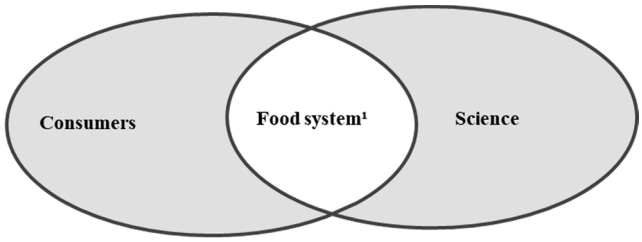
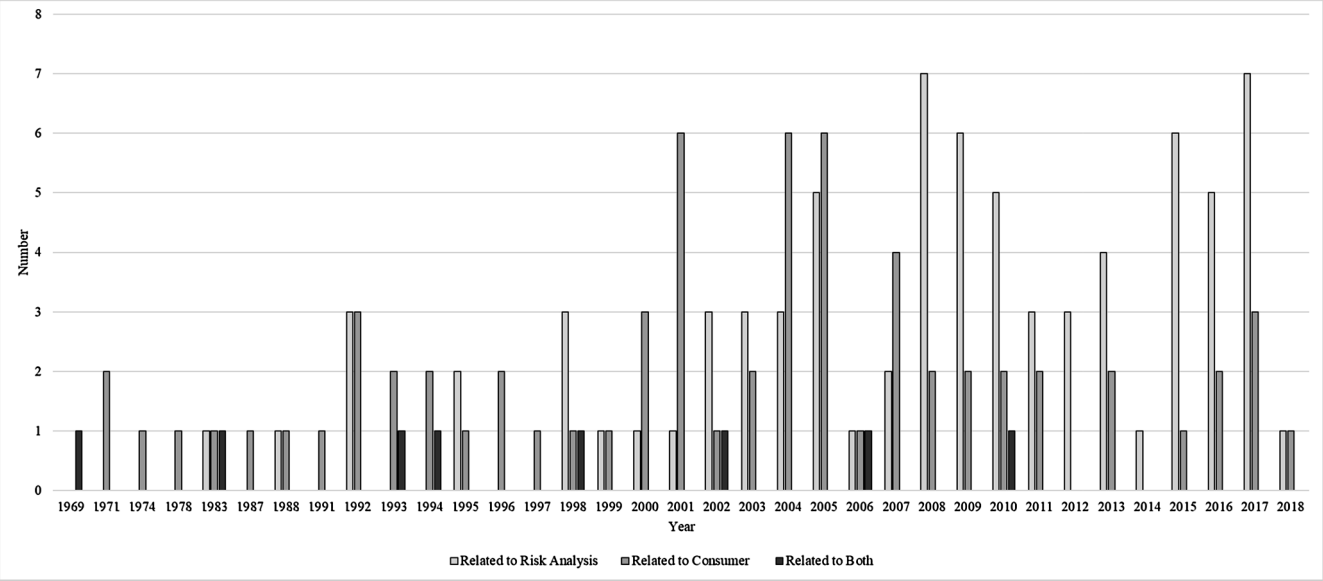
Appendix A. Guiding theory: an adaption of Galison's trading zones



¹ The food system includes all activities in producing food, processing food, packaging and distributing food, and retailing and food consumption. A variety of actors controls and participates in these activities (for a more detailed description s. Ingram (2011)).

[12] An example is the German food retailer ALDI SÜD, which determines its own PPP residue standards for fruits and vegetables at a stricter level than the regulatory requirements (Mempel, 2015).

Appendix B. Distributions of publications by related evidence practice and year



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