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Thesis report

Unfit for consumption -

Application and Interpretation of the concept 'unfit for human consumption' according to Article 14 (2) (b) Regulation (EC) No 178/2002 in the European Union

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Abstract

The General Food Law seeks to harmonize general food law principles and requirements in the European Union. In order to reach this objective, it aims to establish common definitions and comprehensive guiding principles. One of these is the concept of food 'unfit for human consumption' according to Article 14 (2) (b) of the General Food Law. If a food is deemed to be unfit for human consumption or injurious to health, it is considered as unsafe and therefore not allowed to placed on the market. The description of the concept on unfitness itself is rather openly phrased within the General Food Law. Accordingly, it provides space for interpretation and the possibility to consider further criteria as those laid down in the initial description. Therefore, the aim of this study is to research how the concept 'unfit for human consumption' is interpreted and applied in practice. Focus of this research are the Member States of the European Union. For this purpose, the study is divided in two main parts: the first part consists of literature and legislation analyses in order to provide a general overview of the concept of unfitness. The second part encompasses an EU-wide survey which gives an insight how this concept is interpreted and applied in different Member States of the European Union. The results of the study show that although the concept 'unfit for human consumption' is a common principle in the European Union, the criteria whether food is unfit for human consumption can vary among Member States. Therefore, it is recommended to rephrase the terms used in Article 14 (1) and (2) GFL, to modify the description of the unfitness concept in Article 14 (5) GFL, to provide further guidance on its interpretation and to clarify under which circumstances recalls or public information should be issued if food is deemed to be unfit for human consumption.

Keywords: unfit for human consumption, unsafe, food safety requirement, EU, member state

List of Abbreviations

ADI	Acceptable Daily Intake
ARfD	Acute Reference Dose
BfR	Bundesinstitut für Risikobewertung (Federal Institute for Risk Assessment, Germany)
CAFIA	Czech Agriculture and Food Inspection Authority
EC	European Communities
EEC	European Economic Community
ECU	European Currency Unit
EFFL	European Food and Feed Law Review
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization of the Unites Nations
FBO	Food Business Operator
FSA	Food Standards Agency
GFL	General Food Law (Regulation (EC) No 178/2002)
GFL Proposal	Proposal for a Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food (COM (2000) 716 final)
GM	Genetically modified
LFGB	Lebensmittel- und Futtermittelgesetzbuch (German Foodstuffs and Consumers Goods Law)
LGL	Das Bayrische Landesamt für Gesundheit und Lebensmittelsicherheit (Bavarian Health and Food Safety Authority)
LMBG	Lebensmittel- und Bedarfsgegenständegesetz (former German Foodstuffs and Consumer Goods Law)
MRL	Maximum residue level
MS	Member State
NVWA	Nederlandse Voedsel – en Warenautoriteit (The Netherlands Food and Consumer Product Safety Authority)
RASFF	Rapid Alert System for Food and Feed Safety
SCFCAH	Standing Committee on the Food Chain and Animal Health
SFS	Svens författningssamling (The Swedish Code of Statutes)
TEU	Treaty on European Union
WHO	World Health Organization

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1. Introduction

Food is an essential element for everyone in the world. Food should be healthful, delicious, affordable, nutritious and, of course, safe. It can be proudly stated that food in the EU is among the safest in the world.[1] This is supported by the EU's strict food regulations. The core of these regulations, in the context of food law, constitutes the General Food Law, referred to as GFL. This regulation has been adopted by the European Parliament and the Council in 2002, in order to lay down the general principles and requirements of food law in the EU. The assurance of food safety represents an important aim and core principle of this regulation. Food that is unsafe is not allowed to be placed on the market.[2]

But how is unsafe food defined in this legislative context? Two components determine if a food is deemed to be unsafe: it has to be injurious to health or unfit for human consumption.[3] These elements are part of the food safety requirements, regulated in Article 14 of the GFL. The reasons that cause a food to be considered as injurious to health are very well defined,[4] but the unfitness of food for human consumption adds a mystifying element to the concept of unsafety[5] and reads as follows: in order to determine *'(…) whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.'*[6] Although this elaboration provides a first insight into the concept of 'unfit for human consumption', it is still very openly defined. The term 'unacceptable' seems subjective and leaves room for interpretation. For instance, when does food become unacceptable and how can this unacceptability be accessed? Furthermore, the expression 'regard shall be had' provides the opportunity to consider other criteria in addition to those laid down in the description of this concept.[7] Consequently, it is of interest to know what might be further criteria in the MSs, for instance if food can also be deemed unfit for human consumption if it does not comply with other legal requirements.

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[1] European Commission, "Die Europäische Union Erklärt: Lebensmittelsicherheit," (Luxembourg: Publications Office of the European Union, 2014), p. 3. As available on the internet at https://europa.eu/european-union/file/1288/download_de?token=GETML06L.

[2] Article 14 (1) GFL.

[3] Article 14 (2) GFL.

[4] Article 14 (4) GFL.

[5] B. van der Meulen, "The Core of Food Law - a Critical Reflection on the Single Most Important Provision in All of Eu Food Law," *EFFL* 7, no. 3 (2012): p. 124.

[6] Article 14 (5) GFL.

[7] K.-D. Rathke and O. Sosnitza, "Zipfel / Rathke: Lebensmittelrecht - Loseblatt-Kommentar Aller Wesentlichen Vorschriften Für Das Herstellen Und Inverkehrbringen Von Lebensmitteln, Futtermitteln, Kosmetischen Mitteln, Sonstigen Bedarfsgegenständen Sowie Tabakerzeugnissen, Band 2," (Munich, Germany: C.H. Beck, 2016), p. 16.

To restate the question: why is unfit food considered as unsafe in the EU? This categorization is remarkable in comparison to the internationally recognized Codex Alimentarius.[8] According to the Codex, the similar sounding terms 'suitability' and 'food safety' are two separate elements,[9] whereas on the level of the EU unfit food falls within the category of unsafe food.

In consideration of the issues that arise from the open character of the unfitness concept, it is necessary and recommendable to research the concept 'unfit for human consumption' in more detail. One approach in this regard constitutes the research of its interpretation and application in the MSs of the EU. An important point to note in this context is that the factors which determine if a food is deemed to be unfit for human consumption are assessed differently in the MSs of the EU.[10] These differences are likely based on the open phrasing of the concept and beg for research on the concept 'unfit for human consumption'.

1.1 Problem statement

The GFL seeks to harmonize general food law principles and requirements in the EU. In order to reach this objective, it aims to establish common definitions, comprehensive guiding principles, and legitimate objectives for food law, resulting in a high level of protection of human health but also an effective internal market.[11] One of these common elements constitutes food safety. Food that is injurious to health or unfit for human consumption is deemed to be unsafe and not allowed to be placed on the market in the EU.[12]

In consideration of this strict provision, it is important that the criteria leading to this prohibition are well defined and understood in each MS of the EU. However, due to the open phrasing of the concept 'unfit for human consumption' this common understanding might be challenging. Therefore, research is required to determine how the concept of unfitness is converted into practice and how it is interpreted and applied in the MSs. Furthermore, this research provides the opportunity to determine if the intended common understanding of the concept 'unfit for human consumption' is indeed present or if differences prevail and can be overcome.

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[8] The Codex Alimentarius is a collection of food standards, guidelines, codes of practices, and further recommendations that are internationally adopted.

[9] WHO and FAO, "Codex alimentarius - Food Hygiene: basic Texts," (Rome, Italy2009), p. 6. As available on the internet at http://www.fao.org/docrep/012/a1552e/a1552e00.pdf.

[10] W. Kulow, *Das Lebensmittelhygienerecht: Erläuterungen Und Kommentare Zu Den Verordnungen (Eg) Nr. 852/2004 Und Nr. 853/2004*, 2 ed. (Hamburg, Germany: B. Behr's Verlag GmbH and Co. KG, 2014), p. 110.

[11] SCFCAH, "Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (Ec) No 178/2002 on General Food Law," (2010), p. 4. As available on the internet at https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_req_guidance_rev_8_en.pdf.

[12] Article 14 (1) (2) GFL.

1.2 Research questions

In order to provide an insight in the interpretation and application of the concept 'unfit for human consumption' in the EU and its MSs, the following main research question is addressed in this paper:

How is the concept of 'unfit for human consumption' interpreted and applied in the Member States of the European Union?

This core question is divided into five sub-questions, which support the answer to the main research question.

Sub-questions:

1. What is the intention of the concept 'unfit for human consumption'?

2. How is 'unfit for human consumption' defined in the MSs of the EU?

3. How is unacceptability defined in the MSs of the EU? Are there differences in the understanding of this concept?

4. What are examples of food 'unfit for human consumption' in the MSs of the EU?

5. Is food deemed to be unfit for human consumption if it does not comply with other legislative provisions than those stated in Article 14 (5) GFL?

2. Approach and Methodology

The research on the concept 'unfit for human consumption' comprises two different methods: for the first part of this paper a literature and legislation study is carried out, whereas the second part is based on an EU-wide survey (see figure 1). Both methods constitute the foundation for the final discussion, conclusion, and recommendations of this paper.

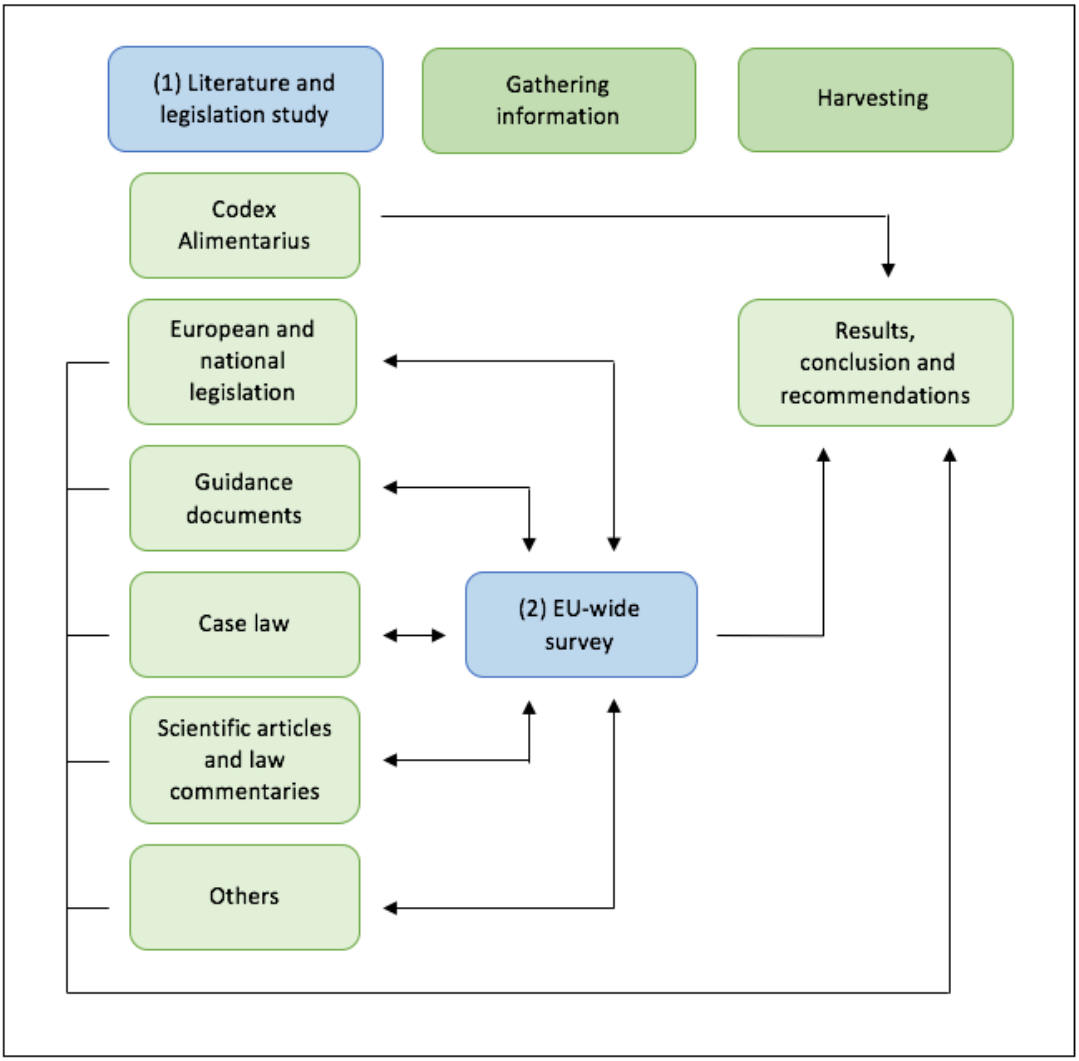

Figure 1: Simplified overview of the research design 'unfit for human consumption'

2.1 Literature and legislation study

The first part of this paper is based on an analysis of literature and legislation. The aim of this research is to achieve an overview of the theoretical background of the concept 'unfit for human consumption' and to facilitate the answer to the first sub-question concerning the intention behind this concept. The main sources of information are European and national legislation, related guidance documents, the Codex Alimentarius, and case law. Inter alia

scientific articles, law commentaries, and information issued by institutional bodies of the EU are also taken into account. The information is furthermore used as a supporting element in designing the questionnaire, which is used within the EU-wide survey in the second part of this study.

2.2 EU-wide survey

The second part of the research is based on an EU-wide survey. The objective of this survey is to acquire insight into how the concept 'unfit for human consumption' is interpreted and applied in the MSs. For that purpose, a questionnaire on the concept of unfit food is developed. With support of this questionnaire, the research sub-questions two – five will be answered. In addition to the results of the survey, the second part of this paper contains further relevant information which has been researched by literature and legal study. This research information is used in order to provide background knowledge about the survey topics and to illustrate why specific issues are addressed within the questionnaire.

2.2.1 Content

The focus of the questionnaire about the concept 'unfit for human consumption' in the MSs comprises four main areas, namely:

- National legislation and guidance documents
- Historical background
- Application of the concept 'unfit for human consumption'
- Legal consequences

These issues are approached in 12 questions and related sub-questions. The questions themselves are open-ended, thus no fixed options for responses are given. This approach is chosen in order to increase the qualitative extent of the replies. It provides the opportunity for the participants to share their knowledge in an unlimited manner and to elaborate on their responses.

The complete questionnaire is attached in the appendix.

2.2.2 Addressees

The survey was administered to three different groups: authorities and ministries in the field of food safety, country correspondents of the European Food and Feed Law Review EFFL[13] and further experts on food law (see figure 2).

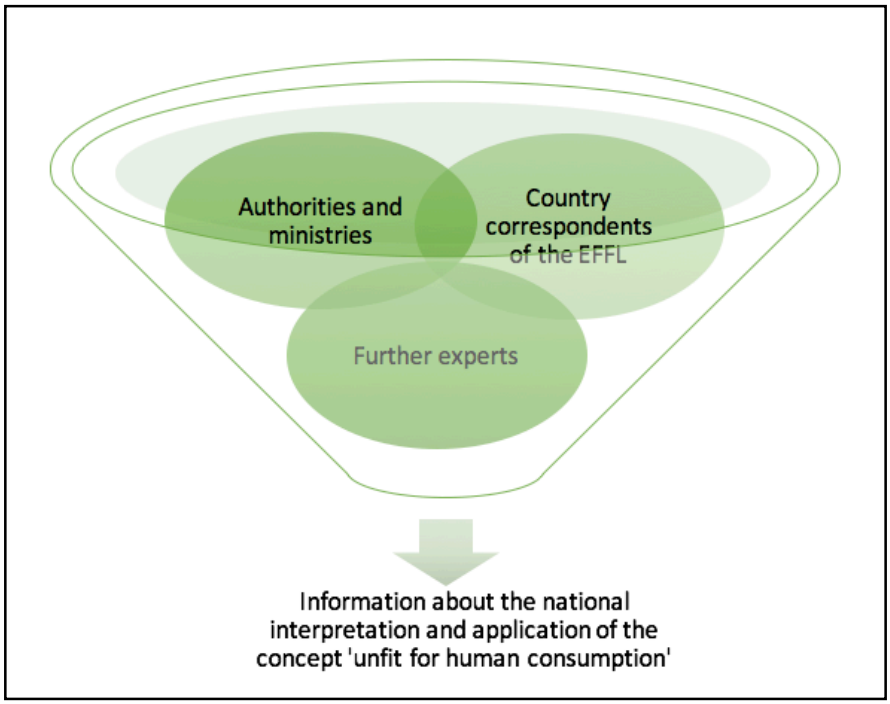

Figure 2: Clusters of addressees

These different clusters are chosen due to their expertise in the field of national food law. It is reasonable to hypothesize that this wide response base reflects a wide knowledge about the national interpretation and application of the concept 'unfit for human consumption' in specific MSs. Therefore, representatives of these clusters have been invited to participate in the survey about the concept of unfit food.[14]

[13] The EFFL is an established journal in the field of food and feed law. It provides an intellectual forum for jurisprudence, which is led by experts of this area. For further information, see http://www.lexxion.de/de/zeitschriften/fachzeitschriften-englisch/effl/about-effl.html.

[14] In total 52 invitations to participate in the EU-wide survey have been send. This number includes 31 authorities and ministries of all 28 MSs in the EU, 16 country correspondents of the EFFL and 5 further experts on food law.

2.2.2.1 Authorities and ministries

The first cluster of addressees includes authorities and ministries active in the field of food safety. These have been, inter alia, determined with support of the food safety almanac[15] and the participants list of the working group on the GFL.[16] The invitations to participate in the survey were sent via e-mail or through a provided contact form on the webpage of the authorities or ministries.

2.2.2.2 Country correspondents of the EFFL

The second target group are the country correspondents of the EFFL for the MSs of the EU. These country correspondents have been selected on the basis of being experts in the field of food law in a specific MSs. Again, invitations were sent via e-mail.

2.2.2.3 Further experts on food law

The third and last cluster of addressees includes further experts on the issue of food law which do not belong to one of the previous categories. These experts were approached by means of networking.

2.2.3 Answer forms of the questionnaire

Within the survey, two different response options have been provided. The participants could choose between a written form or a personal interview. The latter could take place via telephone or Skype.[17] In case of a telephone or Skype interview, the conversation was recorded with the obtained consent of the participants. Afterwards, the interview was transferred into a written protocol, which was forwarded to the interviewees for confirmation. The interviews themselves were semi-structured. Thus, the respondents read the questionnaire beforehand, but the sequence of the questions could differ depending on the course of the interview. Furthermore, additional follow-up questions could be asked.

[15] BfR, "Eu Food Safety Almanac," (Berlin, Germany2014), As availabe on the internet at http://www.bfr.bund.de/cm/364/eu-food-safety-almanac.pdf.

[16] European Commission Health and Consumer Protection Directorate-General, "Participants Attendance List - Working Group On regulation (Ec) No 178/2002 General Food Law – 03/3/2014." As available on the internet at https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_expg_20140303_list_participants_en.pdf.

[17] In addition, the addressees within the Netherlands could also choose a face-to-face interview.

3. Legal framework

A concept of food unfit for human consumption is present in various levels of food law but also in generally recognized standards and codes of practice. For instance, on the international level a concept referred to as 'suitability' is part of the Codex Alimentarius.[18] This Codex is a collection of food standards, guidelines, codes of practices, and further recommendations that are internationally adopted. It is issued by the Codex Alimentarius Commission, which was established by FAO and WHO in 1963. Since then, it became the most important international reference point with regard to food standards. The aim of the Codex is to harmonize international food standards in order to ensure the protection of consumer health and the promotion of fair practices in food trade. Therefore, relevant standards, but also guidelines and codes of practice, have been developed. In principle, these documents are non-binding. They need to be implemented into national legislation or regulations in order to be enforceable. Nevertheless, due to its internationally recognized status, the Codex Alimentarius is of great importance on an international level and is used as a reference point to facilitate international trade and to resolve trade disputes in international law.[19]

On the narrower level of the EU, the concept of 'unfit for human consumption' constitutes an important element of food safety. It is defined within the GFL, which can be regarded as the core of EU food law. The GFL itself is a regulation and therefore directly applicable in all MSs of the EU. It provides the general framework of European and national food law. One main objective of this regulation is the definition of common principles on which the food legislation in the EU and its MSs shall be based. This aim encompasses, inter alia, the establishment of common definitions, comprehensive guiding principles, and legitimate objectives for food law, which shall result in a high level of protection of human health but also in an effective internal market.[20]

Besides this common core of European food law, national food law is usually still in force in the MSs. This national legislation is not supposed to be contradictory to the food law principles and procedures as laid down in the GFL.[21]

For these three different levels – the international Codex Alimentarius, EU food law, and national food law – an introduction on the concepts of unfit food is given in the following subchapters. This introduction shall provide the legal foundation for the research on the interpretation and application of the concept 'unfit for consumption'. For this purpose, the

[18] WHO and FAO, "Codex alimentarius - Food Hygiene: basic Texts," p. 6.

[19] For further information on the Codex Alimentarius see FAO and WHO, "Codex Alimentarius - Understanding codex," (Rome, Italy2016). As available on the internet at http://www.fao.org/3/a-i5667e.pdf.

[20] SCFCAH, "Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (Ec) No 178/2002 on General Food Law," p. 4.

[21] In order to ensure the compliance of national food law with the European food law, existing food law principles and procedures had to be adopted until 1 January 2007 (Art. 4 (3) GFL).

most relevant definitions and provisions with regard to the issue of unfit food are laid down in the upcoming subchapters.

3.1 The Codex Alimentarius and the concept of suitability

The collection of the Codex Alimentarius includes internationally recognized standards, guidelines, and codes of practice. One important element of this collection is the Recommended International Code of Practice on General Principles of Food Hygiene. This code of practice is applicable for all foodstuff and provides the foundation for food safety, from primary production to final consumption.[22] This context also addresses the issue of 'suitability'.[23] Even though the wording of this term seems to be comparable to that of 'unfit for human consumption', it should not be automatically equated with the European concept of unfitness.[24]

According to the Codex Alimentarius, people have the right to expect that their food is safe and suitable for consumption.[25] Consequently, a differentiation between food safety and suitability is made. This distinction exposes itself in particular within the definition of both terms.

Food safety itself is defined as the *'Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.'*[26]

Whereas

Food suitability is explained as the *'Assurance that food is acceptable for human consumption according to its intended use.'*[27]

The assurance of both – food safety and suitability – is the responsibility of everyone, including farmers, growers, manufacturers, processors, and handlers, but also, food hygiene is required. Food hygiene encompasses all conditions and measures that are necessary to ensure the safety and suitability of food at every stage of the food chain.[28]

[22] FAO and WHO, "Codex Alimentarius - Understanding codex," p. 38.
[23] WHO and FAO, "Codex alimentarius - Food Hygiene: basic Texts," p. 6.
[24] For a detailed comparison between both terms see chapter 4.1.1.
[25] WHO and FAO, "Codex alimentarius - Food Hygiene: basic Texts," p. 3.
[26] Ibid., p. 6.
[27] Ibid.
[28] Ibid., pp. 3, 5.

3.2 Unfit for human consumption in the context of the GFL

Food law in the EU is regulated in a broad range of legislative documents of which the GFL can be considered as the centrepiece. The GFL provides the basis for the assurance of a high level of protection of human health and consumers' interest with regard to food.[29] In this context, food safety constitutes one of its main objectives. This emphasis on food safety is strikingly highlighted by the banning of unsafe foods from the market. According to the food safety requirements, food which is unsafe is not allowed to be placed on the market.[30] Food is deemed to be unsafe if it is considered as injurious to health or unfit for human consumption.[31]

Article 14 (2) GFL

Food shall be deemed to be unsafe if it is considered to be:
(a) injurious to health;
(b) unfit for human consumption.

To determine whether a food is unsafe, several factors must be taken into account. The GFL requires that regard shall be had to the *'(…) normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, (…)'.*[32] It is, for example, well known that most meat needs to be cooked correctly before it can be safely eaten.[33] Consequently, this preparation step has to be taken into account in the assessment of whether raw meat can be considered as unsafe.[34]

Furthermore, regard shall be had *'(…) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.'*[35] An example for this provision is food that contains an ingredient that may pose a risk to the health of a specific group of consumers but this mandatory

[29] Article 1 GFL.

[30] Article 14 (1) GFL.

[31] Article 14 (2) GFL.

[32] Article 14 (3) (a) GFL.

[33] SCFCAH, "Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (Ec) No 178/2002 on General Food Law," p. 9.

[34] For instance, the pathogen Campylobacter, that can be present on poultry, can be eliminated through heating for at least two minutes at a core temperature of 70° C (BfR, "Schutz for Lebensmittelbedingten Infektionen Mit C*ampylobacter*schutz for Lebensmittelbedingten Infektionen Mit Campylobacter," (Berlin, Germany2015), p. 2. As available on the internet at http://www.bfr.bund.de/cm/350/verbrauchertipps-schutz-vor-lebensmittelbedingten-infektionen-mit-campylobacter.pdf).

[35] Article 14 (3) (b) GFL.

information is not effectively communicated.[36] For instance, if a chocolate bar contains peanuts despite the fact that it is labelled as peanut-free and therefore, inter alia, intended to be consumed by a specific allergic consumer group it would be seen as an infraction of the requirement.

In the case that unsafe food[37] has nevertheless been placed on the market and has already left the immediate control of the FBO, the FBO has to initiate procedures to withdraw the food in question from the market. Furthermore, the FBO must inform a competent authority of the incident. When the product may have already reached the consumer, the FBO is required to effectively and accurately inform the consumer of the reasons for the initiated withdrawal. If necessary, the products must be recalled from consumers when other measures are not sufficient to achieve a high level of health protection.[38]

As has been pointed out, there are two categories of unsafe food: food injurious to health and food unfit for human consumption. Whereas the reasons leading to the classification as injurious to health are very well defined,[39] the concept of 'unfit for human consumption' is rather openly phrased.

Article 14 (5) GFL

In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.

The expression 'regard shall be had', provides the opportunity to consider other criteria such as those stated in Article 14 (5) GFL itself.[40] Consequently, it is likely that there are further factors which are applied in practice to deem food as unfit. Furthermore, the issue of unacceptability is of rather subjective nature, which might lead to different assessments. Therefore, although the article provides a first explanation of the concept 'unfit for human consumption', it still requires further clarification.

[36] SCFCAH, "Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (Ec) No 178/2002 on General Food Law," p. 9.

[37] Or if there is reason to believe that the food is unsafe.

[38] Article 19 (1) GFL.

[39] Article 14 (4) GFL.

[40] Rathke and Sosnitza, "Zipfel / Rathke: Lebensmittelrecht - Loseblatt-Kommentar Aller Wesentlichen Vorschriften Für Das Herstellen Und Inverkehrbringen Von Lebensmitteln, Futtermitteln, Kosmetischen Mitteln, Sonstigen Bedarfsgegenständen Sowie Tabakerzeugnissen, Band 2," p. 16.

3.2.1 GFL guidance on the concept of unfit for human consumption

To a certain extent, clarification on the concept of 'unfit for human consumption' is provided in the GFL guidance document by the Standing Committee on the Food Chain and Animal Health (SCFCAH).[41] This guidance is issued to assist all actors in the food chain to better understand the GFL and to apply it in a correct and uniform way. Important to note is that the document itself has no formal legal status. As emphasized within the guidance, the final responsibility for the interpretation of the law lies with the European Court of Justice.[42]

The guidance document provides, among others, support for the interpretation and application of the concept 'unfit for human consumption'. Furthermore, it elaborates on the criteria to deem food as unfit. The core of this elaboration reads as follows:

> 'The central concept of unfitness is unacceptability. Food can be rendered unfit by reason of contamination, such as that caused by a high level of non-pathogenic microbiological contamination (see Article 14(3) and (5) of the Regulation), by the presence of foreign objects, by unacceptable taste or odour as well as by more obvious detrimental deterioration such as putrefaction or decomposition.'[43]

In the beginning of this elaboration, the element of unacceptability is introduced, in particular, its central function within the concept of unfitness. The concept of 'unfit' relates to the issue of 'unacceptability' because, although some food may not pose a risk to health at all, it will still qualify to be unfit for human consumption because it would be reasonably considered to be unacceptable for consumption.[44] However, no indication is presented as to how unacceptability can be assessed.[45] This is relevant because unacceptability is a subjective perception and may differ among people, especially in the context of different countries and cultures.

Furthermore, the guidance elaborates on the factor of contamination and describes that contamination can, inter alia, be caused by a high level of non-pathogenic microbiological contamination. Also the presence of foreign objects or an unacceptable taste or odour, as well as more obvious detrimental deterioration, can cause a food to be unfit for human consumption. Whether these criteria are general examples of unfit food, or if they specify the exact condition under which food can be considered as unacceptable, is not provided.

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[41] SCFCAH, "Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (Ec) No 178/2002 on General Food Law."

[42] Ibid., p. 4-5.

[43] Ibid., p. 9.

[44] Ibid., p. 10.

[45] Apart from a few examples cases.

With regard to this elaboration on the concept of unfitness, the word 'can' should not be left unnoticed. Similar to the description of the concept in the GFL, it seems to provide the opportunity to consider additional criteria that can characterize food unfit for human consumption.

To summarize: the guidance document provides further elaboration on the concept of unfitness but still leaves room for interpretation and clarification.

3.3 Unfit for human consumption in the context of national law

In addition to the GFL, national food law is usually still in force in the MSs. This national food law has to be in compliance with the general principles and provisions set by the GFL. Nevertheless, it may contain further elaboration on the concept 'unfit for human consumption'. In order to determine if and how this concept is present within national food law, it is required to consult the national legislation of each country.[46]

3.3.1 National guidance documents

Besides possible elaboration on the unfitness concept in national food law, there might be also national guidance on this issue in the MSs. The content of these guidance documents may also differ, therefore, a separate consultation is again required.[47]

[46] For this purpose, in the second part of this paper a survey is carried out. The results on the issue of national elaboration on the concept 'unfit for human consumption' are presented in chapter 5.2.

[47] Whether national guidance documents are in place that elaborate on the concept 'unfit for human consumption' is in particular researched in chapter 5.2.

4. General introduction towards the concept 'unfit for human consumption'

Subsequent to the overview provided on the legal provisions about the concept of 'unfit for human consumption' a deeper insight to this concept will be provided. This general introduction covers the comparison to the Codex concept of suitability, a former approach of unfit food, its relationship to hygiene and, finally, further details on the element of unacceptability.

4.1 The concept of unfitness – a new invention?

'It's all been done before' is often said but not necessarily true. In case of the concept 'unfit for human consumption' it has already been indicated that a similar term, referred to as 'suitability', was already present in the Codex Alimentarius. Furthermore, by taking into account that the GFL seeks to harmonize general food law principles, it can be reasonably expected that some of its provisions were present within former national food law. A concept of unfit food was, for instance, contained in the former German food law.

In the following section(s), these concepts from the Codex and of the former German food law will be compared to the current concept as described in the GFL. The purpose and intention behind the concept of unfitness are also taken into account.

4.1.1 Comparison between the concept 'unfit for human consumption' and the Codex concept of 'suitability'

According to the international Codex Alimentarius, people have the right to expect that their food is safe and suitable.[48] 'Suitable' might be regarded as a similar term to 'unfit', which is used in EU food law. However, both concepts are not automatically equatable. In order to point out their similarities and differences, a comparison of the terms is given.

First of all, one term is referring to the positive (suitable) and the other one to the negative (unfit) state of a food. But the very most important difference lies within their relationship to food safety. Whereas the GFL states that food is unsafe if it is injurious to health or unfit for human consumption,[49] the issue of unfit food or lacking suitability is not addressed within the Codex definition of safety. According to the Codex, food safety is defined as the *'Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use'*.[50] Based on this definition, food safety as used within the Codex is mainly comparable to the definition of 'injurious to health' in the GFL.

[48] WHO and FAO, "Codex alimentarius - Food Hygiene: basic Texts," p. 3.

[49] Article 14 (2) GFL.

[50] WHO and FAO, "Codex alimentarius - Food Hygiene: basic Texts," p. 6.

However, 'suitability' might be regarded as the counterpoint to the concept 'unfit for human consumption'. Food suitability itself is explained according to the Codex as the *'Assurance that food is acceptable for human consumption according to its intended use'*.[51] Thus, the intent of both concepts seems to be comparable. Although the GFL concept of unfitness is more detailed than the Codex definition of food suitability, its main essence that food is not acceptable for human consumption, is the same.

Furthermore, also in the Codex, the element of acceptability is picked up, which is also a key element[52] within the GFL concept. In this regard, suitability within the Codex is comparable to the concept of 'unfit for human consumption'. Nevertheless, it should not be neglected that it is separated from food safety, whereas as in the GFL unfit food relates to unsafety.

The comparison of the relevant terminology on the concept of unfitness and safety is summarized in table 1.

Table 1: Comparison of terminology between GFL and Codex Alimentarius[53]

Food Law in the European Union	**Codex Alimentarius**
Term: **Food safety** Meaning: Ensuring that food is not injurious to health and is not unfit for human consumption	Term: **Food hygiene**[54] Meaning: All conditions and measures necessary to ensure the safety (in the sense of the Codex Alimentarius, see below) and suitability of food …
Term: **(Not) Injurious to health** Meaning (analogously): (not) susceptible to endangering or damaging human health	Term: **Food safety** Meaning: Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use
Term: **Fit for human consumption** Meaning (analogously): Ensuring that food is acceptable for human consumption	Term: **Food suitability** Meaning: Assurance that food is acceptable for human consumption according to its intended use

[51] WHO and FAO, "Codex alimentarius - Food Hygiene: basic Texts," p. 6.

[52] Respectively the opposite: unacceptability.

[53] Modified table from R. Riedl and C. Riedl, "Shortcomings of the New European Food Hygiene legislation from the Viewpoint of a Competent Authority," *EFFL* 3, no. 2 (2008): p. 65.

[54] The term' food hygiene' is also used in legislation which is applicable in the EU. According to Article 2 (1) (a) Regulation 852/2004 on the hygiene of foodstuff it means *'(…) the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use;'* This definition is comparable to the one of the Codex Alimentarius. However, the table does not include this term for the EU because the main focus of this table constitutes the comparison of the concepts 'unfit for human consumption', 'food safety' and 'injurious to health' for the purpose of this thesis.

As illustrated by means of table 1, the terminology between the GFL and the Codex Alimentarius differs. Although the selected terms have a comparable counterpoint, this shall not create the impression that the matched terms are the same. It rather points out that, despite the fact that 'suitability' and 'unfit for human consumption' are not identical, the idea of a concept of 'unfit for human consumption' is not a completely new approach. Already, according to the international Codex Alimentarius, consumers had the right to expect that their food is suitable for consumption besides the general requirement of being safe. However, the comparison between these concepts shows that this term is modified and used within a different context in the GFL. This circumstance makes the concept 'unfit for human consumption' unique in comparison to the Codex approach of 'suitability'. Nevertheless, it may also cause potential confusion over the similar expressions in international trade involving MSs of the EU.

4.1.2 Food unfit for human consumption in former national food law in Germany

In addition to the Codex Alimentarius, some former national food law in the EU MSs addressed the issue of unfit food.[55] Such a concept was, for instance, already present in former German food law. In the following, the former German view on this concept will be introduced and compared to the current concept of unfitness within the GFL.

The former German concept of 'unfit for human consumption'[56] was contained within the German food law (LMBG), which was prior to the current national food law in Germany (LFGB).[57] The LMBG entered into force in 1974 and constituted the legislative foundation for the processing of foodstuff and placing food on the market. In this context, it prohibited, among other things, to put food unfit for human consumption on the market.[58]

Although the same terminology was used, there are differences between the former German concept of unfitness and the current one of the GFL. In comparison to the current approach of 'unfit for human consumption', the former German food law did not include injurious and unfit food under the overarching expression of unsafety. In particular, a separation between food being injurious to health – referred to as prohibitions for the protection of human health in § 8 LMBG – and food unfit for human consumption was made. Food unfit for human consumption was contained within the prohibitions to protect consumers against deceiving practices.[59] [60] By first glance one might wonder about this categorization, but such a categorization can be very well justified. Simply speaking, food

[55] Further information on the issue whether a similar concept as such as the one of 'unfit for human consumption' existed in selected MSs of the EU, will be provided in the context of the EU-wide survey in the second part of this paper.

[56] The used German expression is 'Ungeeignet für den menschlichen Verzehr'.

[57] The LFGB entered into force in September 2005 and is still in force.

[58] § 17 (1) (1) LMBG.

[59] § 17 (1) (1) LMBG.

[60] § 11 (2) (1) LFGB on deceiving practices still contains the prohibition, to place food on the market that if it is unfit for human consumption for other reasons than those referred to in Article 14 (2) (b) GFL.

was defined in Germany as substances intended to be consumed by humans.[61] As the term 'unfit for human consumption' already implies, unfit food is not intended or expected to be consumed. Accordingly, it does not meet the criteria to be marketed at food. As a result, it seems to be reasonable that the placement of such 'food' on the market can be considered as a deceptive practice because it does not comply with the definition of food. Of course, there might be still the possibility that it is nevertheless eaten, but this consumption is not intended by law.

But how was unfit food itself defined at this time? The LMBG did not provide further information on this concept, but details on its interpretation can be found in literature. According to Meyer, unfit foodstuff was described as food that was, during its harvest, production, or later processing, negatively influenced either through natural or arbitrary reasons in its inside or outside status, appearance, smell or odour in a manner that its consumption is excluded in line with the prevailing public understanding.[62] This idea of prevailing public understanding was a key element of the concept of unfit food and constituted the benchmark on which the decision of whether or not the product was deemed to be unfit for human consumption was based. What exactly was considered as the prevailing public understanding per case was left to the discretion of the trial judge.[63] It was noted that guidance in this regard should be *'(…) the average sensitive consumer, but not oversensitive, but also not totally insensitive or negligent consumer'.*[64] Although this definition of an average sensitive consumer aims to define average sensitivity, it may be arguable if the provided explanation is indeed of support to explain this term. The expression 'average sensitive consumer' already indicates the average sensitivity. By implication, this kind of consumer is automatically in-between an oversensitive and negligent consumer.

With regard to the prevailing public understanding, there is also another, more specific, definition which gives an explanation of how this understanding can be determined. According to this definition, such prevailing public understanding reflects the perception of all members involved in the distribution of food. This includes producers, wholesalers, retailers, and consumers.[65]

[61] § 1 (1) LMBG.

[62] A.H. Meyer, *Lebensmittelrecht: Leitfaden Für Studium Und Praxis* (Stuttgart, Germany: Wissenschaftliche Verlagsgesellschaft Stuttgart, 1998), p. 76.

[63] Ibid.

[64] Ibid., pp. 76-77. English translation.

[65] Ibid., p. 80.

The prevailing public understanding can, among others, be determined by the following means:[66]

- Normative provisions (for instance legislations)
- Principles of the German Food Commission[67]
- Trading practices
- Recognised principles and guidelines
- Textbooks, recipes and cookbooks

The former German concept 'unfit for human consumption' encompassed food which was considered to be disgusting.[68] This category not only included food that would cause disgust or reluctance based on any exterior variances, it also addressed cases which would cause disgust by the consumer if s/he would know or be aware of the conditions under which the product had been produced or of the hygiene of the business.[69] This is indicated to be different from the current approach in Germany, according to which Article 14 GFL does not cover cases in which food without any exterior variances would cause disgust or reluctance by the consumer if s/he would be aware of specific production or processing procedures.[70] [71] Nevertheless, also in former German food law objective reasons had to be present in order to consider food as disgusting, for instance the presence of mice[72] or insufficient hygienic storage conditions.[73] Consequently, deeming food as disgusting was not just an issue of subjective perception.

If a food was once deemed to be unfit for human consumption due to reasons of disgust or reluctance, this classification could never be undone. This is different from food which was deemed to be unfit due to other reasons.[74] This approach can be very well justified. For instance, after the removal of a foreign object that caused a food to be unfit for consumption, the product might become again fit for consumption. Whereas a food which was stored under disgusting conditions would still cause disgust in the consumer even if the storage conditions were improved afterwards. Nevertheless, a later elimination of the

[66] A.H. Meyer, *Lebensmittelrecht: Leitfaden Für Studium Und Praxis* , pp. 80-81.

[67] The German Food Commission is responsible for the content of the German Food Code, a collection of guidelines that describe the manufacture, composition or other characteristics of foodstuffs which are important for marketing approval purposes.

[68] Meyer, *Lebensmittelrecht: Leitfaden Für Studium Und Praxis*, p. 77.

[69] BGHSt 29, 220; OLG Koblenz ZLR 1985, 393. In: Ibid.

[70] A.H. Meyer and R. Streinz, *Lfgb, Basisvo, Hcvo: Lebensmittel- Und Futtermittelgesetzbuch Basis-Verordnung (Eg) Nr. 178/2002, Health Claimvo 1924/2006; Kommentar*, 2 ed. (Munich, Germany: C.H. Beck, 2012), p. 151.

[71] The cases are covered by national law § 11 (2) (LFGB) on further criteria to deem food as unfit as those listed in Article 14 (4) GFL.

[72] Meyer, *Lebensmittelrecht: Leitfaden Für Studium Und Praxis*, p. 77.

[73] For instance, food which was stored in a closed container next to a dirty floor with excrements of animals was considered to cause disgust from an objective viewpoint (BayObLG DLR 1994, 156. In: Ibid.).

[74] Ibid., pp. 78-79.

reasons that caused a food to be unfit for human consumption was not always possible and depended on a case by case basis.[75]

It can be summarized that the former German and the current GFL concept of 'unfit for human consumption' show similarities. However, the most striking difference between these concepts is the relation of the GFL concept to unsafety, whereas the former German concept was classified a deceiving practice. This example illustrates very well that, although the concept of unfitness may have already been addressed in former national food law, the concept does not necessarily have to be identical to the current one.

4.1.3 Unfit for human consumption in Hygiene Regulation

The expression 'unfit for human consumption' is not solely used in the GFL. It is also used in further legislation which is applicable in the EU. A reference to (un)fitness can be found, for instance, in Regulation 852/2004 on hygiene of foodstuff.[76] Within this regulation, fitness for human consumption is mentioned whilst describing the meaning of another term, namely food hygiene:

Article 2 (1) (a) Regulation 852/2004

"food hygiene", hereinafter called "hygiene", means the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use;

Based on this definition, the impression arises that hygiene constitutes a key issue in the context of food safety.[77] This is due to the statement, that food hygiene is required in order to control hazards and to ensure fitness for human consumption. By implication, a lack of food hygiene might – but not necessarily has to – result in food which could be hazardous or unfit for human consumption. Therefore, it is of relevance to regulate how food hygiene can be achieved. This is done by issuing regulations. In their entirety, these regulations are often referred to as the hygiene package. The hygiene package includes necessary hygienic requirements which support the assurance of food safety.

[75] *Lebensmittelrecht: Leitfaden Für Studium Und Praxis*, p. 77.

[76] Furthermore, animal by–products are 'by law' unfit for human consumption (Recital 12 Regulation (EC) No 1069/2009).

[77] Also according to the Codex Alimentarius compliance with food hygiene is required to ensure suitability and safety of food.

The following regulations are included in the hygiene package:

- **Regulation 852/2004** – hygiene of foodstuff (in general)
- **Regulation 853/2004** – specific hygiene rules for food of animal origin
- **Regulation 854/2004** – specific rules for the organisation of official controls on products of animal origin intended for human consumption
- **Regulation 882/2004** – official controls performed to ensure the verification of compliance with feed and food law, animal health, and animal welfare rules

Regulation 852/2004 can be considered as the core of this hygiene package due to its general character. This centrepiece indicates the above cited relationship between fitness for human consumption and hygiene. But is this kind of fitness referring to the GFL concept 'unfit for human consumption'? If so, there would be a relationship between food hygiene according to Regulation 852/2004 and the GFL concept 'unfit for human consumption'. This hypothesis is supported by taking into account that food can become unfit due to contamination by, for instance, non-pathogenic microorganisms or foreign objects.[78] By means of food hygiene, this risk of contamination is reasonably expected to be reduced. This relationship can be very well illustrated in the example of the blue-mozzarella case in Italy in 2010.[79] At that time, consumers complained about mozzarella cheese which turned blue after the package had been opened. This discoloration was caused by the high number of the contained bacteria *Pseudomonas (P.) tolaasii* and *P. libanensis*.[80] Both bacteria are spoilage agents which are not expected to cause adverse health effects. The Italian health ministry assumed that the contamination with these microorganisms was caused by tainted water.[81] Such contamination can be prevented by good hygiene practice. In particular, the risk of contamination with spoilage agents is reduced by means of careful hygiene measures.[82] Thus, there is a relationship between hygiene and contamination that can render a food unfit for human consumption.

The issue of contamination in general is interesting with regard to Regulation 852/2004. Contamination presents a hazard within this regulation and, as such, may cause an adverse health effect according to the definition of a hazard within the GFL. Subsequently, it appears that food unfit for human consumption might, under specific conditions, even be injurious to health. This relationship can be explained as follows: according to the GFL, food can be

[78] SCFCAH, "Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (Ec) No 178/2002 on General Food Law," p. 9.

[79] Several notifications were submitted to the RASFF due to the changed organoleptic properties of mozzarella cheese. See RASFF notifications 2010.0826; 2010.0823 and 2010.0816. Available through the RASFF Portal at https://webgate.ec.europa.eu/rasff-window/portal/?event=searchForm.

[80] BfR, "Pseudomonaden Führten Zum Verderb Von Mozzarella-Käse, Aktualisierte Stellungnahme Nr. 10 010/2011 Des Bfr Vom 14. März 2011," (2011), As availabe on the internet at http://www.bfr.bund.de/cm/343/pseudomonaden_fuehrten_zum_verderb_von_mozzarella_kaese.pdf.

[81] For the production and chilling of the cheese is water required.

[82] BfR, "Pseudomonaden Führten Zum Verderb Von Mozzarella-Käse, Aktualisierte Stellungnahme Nr. 10 010/2011 Des Bfr Vom 14. März 2011."

deemed as unfit for human consumption *'(…) for reasons of contamination, whether by extraneous matter or otherwise (…)'.*[83] Exactly what is considered to be contamination according to the GFL is not further elaborated. Instead, Regulation 852/2004 provides a definition of this term. This definition is very short and states that contamination *'(…)means the presence or introduction of a hazard;'.*[84] A hazard in turn is defined in the GFL as *'(…) a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;'*[85]. Hence, by combining these different but connected definitions, a contamination can result in a food which is injurious to human health. But is this contradictory to the differentiation between food being injurious to health and unfit for human consumption? Not necessarily. One way out of this impasse is the explanation that a hazard has only the potential to cause an adverse health effect. Therefore, it does also include cases in which the food is not injurious to health but nevertheless unfit for human consumption. A further consequence which might arise due this possible relationship is the implication that food which is injurious to health, is also unfit for human consumption. However, according to the hierarchy of law, in principle, specific law has priority before generic. As a result, harmful food would be categorized as injurious to health although it may also meet the criteria of unfit food.[86] This is due to the more specific criteria of adverse health effects in Article 14 (5) GFL, laying down the criteria by which food is deemed injurious to health.

Besides contamination, further reasons may cause a foods' unfitness for human consumption. These issues involve, for example, the presence of an unacceptable taste or odour, putrefaction or decomposition.[87] In this regard, hygiene can also play a very important role to ensure the absence of these conditions. In general, food hygiene supports the prevention of putrefaction or decomposition or can at least slow down these processes. Depending on the cause of the unacceptable taste or odour, hygiene may also prevent the occurrence of these conditions.

Given these points, there is indeed a relationship between hygiene and the unfitness of food. Thus, it is highly likely that the reference to fitness for consumption within Regulation 852/2004 corresponds to the GFL concept 'unfit for human consumption'. Accordingly, food hygiene is a prerequisite to ensure fitness for human consumption in a variety of cases. If hygiene is absent, the food might become unfit for human consumption. Nevertheless, the compliance with food hygiene is only one parameter to prevent the unfitness of food. Foodstuff can also become unfit for its intended use under hygienic conditions. To take up a very simple example, even under hygienic conditions a yoghurt will start to decay after a certain period of time and become unfit for human consumption and maybe even injurious to health.

[83] Article 14 (5) GFL.

[84] Article 2 (1) (f) Regulation 852/2004.

[85] Article 3 (14) GFL.

[86] See also chapter 5.4.4 and chapter 6.1.

[87] SCFCAH, "Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (Ec) No 178/2002 on General Food Law," p. 9.

4.1.4 The purpose of the unfitness concept and why it results in unsafe food

The GFL concept 'unfit for human consumption' is certainly not a completely new approach, but it still shows differences from comparable concepts, respectively from the Codex Alimentarius or the former German food law. Its main distinguishing feature concerns its status as being a food safety requirement. Food that is unfit for human consumption is unsafe.[88] This correlation leads to the question of why this concept was included under the umbrella of safety and – to start from the very beginning – why the concept of food unfit for human consumption itself has found its way into European food law.

The aim to implement such a concept as the one of 'food unfit for human consumption' in a common EU regulation was already included in the first proposal of the GFL, which was presented by the Commission. The proposal of this concept reads as follows:

Article 12 (2) GFL Proposal

Food shall be considered as unsafe if it is:
(a) potentially injurious to human health;
(b) unfit for human consumption or contaminated.[89]

This initial concept of 'unfit for human consumption' was described as presented below:

Article 3 (18) GFL Proposal

'unfit for human consumption or contaminated' means that the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay;

Obviously, changes in the wording have been made during the drafting process until the final GFL was set up. Nevertheless, this proposal is of value since it provides insight into the background of the initial decision to include the concept of unfitness in European food law.

At the time when the GFL was drafted, the principle that only safe food was allowed to be placed on the market was already included in the legislation of several MSs. However, this

[88] Article 14 (2) (b) GFL.

[89] The former wording of the definition reveals that contamination was initially not part of the term 'unfit for human consumption' and instead a separate element.

was not applicable to all countries; therefore, the Commission decided to fill this gap by including this principle in the common GFL.[90] In their understanding, safety comprised two elements, namely that *' (…) food should not be potentially injurious to health or unfit for human consumption or contaminated in such a manner that it would not be reasonable to expect it to be used for human consumption according to its intended use.'*[91] Whereas the consideration of injurious food as unsafe seems to be reasonable, the classification of food unfit for human consumption as unsafe might require more explanation. Initially, unfit food was included in the concept of 'unsafe' in order to also cover the cases in which it may be almost impossible to prove injury or probable injury due to a food.[92] One example which was used in order to illustrate this issue was putrid food that '(…) *may or may not be potentially injurious to health but it is unacceptable for human consumption and may be injurious to health.'* [93] Consequently, it appears that unfit food was linked to the issue of potentially adverse health effects, although such effects might not be proven. Hence, a connection to the categorization as unsafe is made.

In comparison, also the current guidance document on the interpretation of the GFL underlines that *'Food can also be unfit where it <u>may also</u> pose a risk to health – depending on the level of contamination'.*[94] Provided examples are fish containing parasites, certain types of mouldy food, or food which shows an abnormally high level of non-pathogenic micro-organisms.[95] The statement on possible risks to health in relation to unfit food can be interpreted in different ways. Firstly, it can be argued that it is in line with the initial argument in the proposal that food which is unfit could also be injurious to health, but this relationship might lack proof, or, secondly, that the same origin that could cause harm to human health can render a food unfit for consumption under specific circumstances. For example, as the term 'non-pathogenic' already indicates, the microorganisms themselves are not injurious, but due to their high presence they may, nevertheless, become a risk to human health. Another reading is that these factors are an indication that there might be further major shortcomings, for instance, pathogens which have not been detected yet. Consequently, the food may also pose a risk to health additionally to the already recognized major shortcoming which influences the fitness for consumption of the food.

In addition to the reference of possible injuriousness, the GFL Proposal refers to the element of unacceptability. It outlines that, for instance with insect parts, contaminated food may not be injurious to health, but it is still not reasonable to expect this food to be used for human consumption. The proof that it may be potentially injurious to health should

[90] COM (2000) 716 final, "Proposal for a Regulation of the European Parliament and of the Council Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Authority, and Laying Down Procedures in Matters of Food," (Brussels, Belgium08.11.2000), p. 11.

[91] Ibid.

[92] Ibid.

[93] Ibid.

[94] SCFCAH, "Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (Ec) No 178/2002 on General Food Law," p. 10.

[95] Ibid.

not be required to render such food as unsafe.[96] Again, this can be read in different ways. Either only the aspect of being unacceptable for consumption renders food unfit or, due to its unacceptability, it is not required to prove that it may be potentially injurious to health to deem it unsafe. According to practice, the first is sufficient. With regard to the famous Berger Case,[97] even the European Court of Justice, as the highest legal body in the EU, has provided legal clarity that food can be unsafe even if it is certainly not injurious to human health. In its judgment the Court stated that *'(…) there was no cause to doubt the assessment of the LGL according to which the foodstuffs were unfit for human consumption, whilst not actually injurious to health.'*[98] This, however, raises the question of why unfit food is classified as unsafe when the term also includes cases which are certainly not injurious to human health.

A possible answer can be extrapolated from the overarching definition of the word 'safety' itself. According to an official definition of the term 'safety', it is *'The condition of being protected from or unlikely to cause danger, risk, or injury'* and/or *'Denoting something designed to prevent injury or damage'*.[99] Simplified: safety describes the protection from damage. In the sense of unfit food, this damage goes beyond that described in the liability directive 85/374/EEC, according to which this term encompasses *'(a) damage caused by death or by personal injuries; (b) damage to, or destruction of, any item of property other than the defective product itself, with a lower threshold of 500 ECU, provided that the item of property (…)'*.[100] This definition of damage relates more to the protection of consumers' health a described in Article 14 (4) GFL. A damage, however, in the case of unfit food has to be regarded in a much broader context. As directly stated in the beginning of the GFL, this law provides the basis to ensure a high level of protection of human health and consumers' interest with regard to food.[101] [102] It can be argued that if these objectives have not been met effectively, the objectives themselves are faulty. In order to support this line of reasoning, the concept of 'unfit for human consumption' has to be regarded in the context

[96] COM (2000) 716 final, "Proposal for a Regulation of the European Parliament and of the Council Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Authority, and Laying Down Procedures in Matters of Food," p. 12.

[97] On the 16th and 18th January 2006 the Passau Veterinary Office in Germany carried out official controls in several establishments of the Berger Wild GmbH, a producer and distributer of game meat. The authorities found that hygiene conditions were lacking. Furthermore, samples of game meat were taken and analysed by the Bavarian Health and Food Safety Authority LGL. The result of the analyses revealed that the gain meat was unfit for human consumption and therefore unsafe (Case C-636/11).

[98] Line 26 Case C-636/11.

[99] See Oxford Dictionary, as available on the internet at https://en.oxforddictionaries.com/definition/safety.

[100] Article 9 (a) (b) Directive 85/374/EEC.

[101] Article 1 (1) GFL.

[102] Interestingly in the initial proposal for the GFL it was stated that '*The primary objectives of food law established in this proposal will be to (…) provide a high level of protection of human health, safety and consumer interests.*' (GFL Proposal p. 8). Accordingly, the impression is given that safety was initially even understood in a different sense than solely the protection of health and consumers' interest.

of the consumers' interest. And, indeed, it is often related to the issue of quality and consumer interest.[103] If a consumer purchases a good, it should meet at least the quality standard which can be expected by the consumer. Otherwise the consumer will suffer an economic loss, and the economic interest of the consumer is damaged. Based on this reasoning, it can be argued that food unfit for human consumption damages the interest of consumers, which shall be protected by the GFL. Accordingly, if safety is simply understood as the protection of a damage, it can be argued that food unfit for human consumption is unsafe because it damages the interest of the consumer. Thus, the ban on unsafe food from the market not only aims to protect the consumer from health damage but also from the damage of consumers' interest. Following this line of reasoning, the classification of unfit food as unsafe can be justified. A prerequisite for this justification is the understanding of safety as protection from damage and fitness of food as a consumer interest.

Given these points, the impression is raised that the understanding of safety within the meaning of the GFL is very comprehensive. By protecting human health and consumers' interest under the umbrella of banishing unsafe food from the market, the GFL highlights the importance of both aims. This illustrates a unique and modern approach towards the significant role of consumers' interest in European food law.

4.2 How to measure unacceptability

Unacceptability seems to be the key word to the mystical concept 'unfit for human consumption'. Whenever a reference to food unfit for human consumption is made, unacceptability is usually named in this context. Already the GFL requires that *'(…) regard shall be had to whether the food is unacceptable for human consumption according to its intended use (…)'.*[104] Also the guidance document picks up this term and directly highlights that '*The central concept of unfitness is unacceptability'*[105] and *'The concept of 'unfit' relates to unacceptability.'*[106] As a result of this emphasis on unacceptability, it is of value to know how unacceptability is determined.

Although it is indicated within the literature that unacceptability has to be based on substantial changes in the food,[107] its determination might still become a challenge due to its

[103] See V. Rodríguez Fuentes, "The Berger Case: Food Risk and Public Information. Professional Secrecy and Reputation. Judgement of the Court of Justice (Fourth Chamber) of 11 April 2013.," *EFFL* 8, no. 3 (2013): p. 200. And K.P. Purnhagen, "Beyond Threats to Health: May Consumers' Interests in Safety Trump Fundamental freedoms in Information on Foodstuffs? Reflections on Karl Berger V Freistaat Bayern," *European Law Review* (2013).

[104] Article 14 (5) GFL.

[105] SCFCAH, "Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (Ec) No 178/2002 on General Food Law," p. 9.

[106] Ibid., p. 10.

[107] Meyer and Streinz, *Lfgb, Basisvo, Hcvo: Lebensmittel- Und Futtermittelgesetzbuch Basis-Verordnung (Eg) Nr. 178/2002, Health Claimvo 1924/2006; Kommentar*, p. 151.

subjective character. Something that is acceptable for one person does not have to be necessarily acceptable to somebody else. Especially when taking into account cultural differences among the MSs, unacceptability gains an even broader dimension. One example is the typical Sardinian sheep milk cheese 'casu marzu',[108] which is a very good illustration that food that is mainly perceived as disgusting can still be regarded as a delicacy by some people. It is therefore essential to know what unacceptability means within the definition of the concept 'unfit for human consumption'.[109]

4.2.1 The average consumer

One approach to determine the (un)acceptability of food is the orientation on an appropriate consumer model. Such a consumer model might be of use to decide which possible shortcomings of food are acceptable for the consumer. The difficulty, however, lies within the determination of an appropriate model.

In the literature, Dannecker and Gorny recommend making use of the average consumer model, which has been developed by the European Court of Justice.[110] This 'average consumer' is reasonably well-informed, observant, and circumspect, and has been used in several rulings.[111] The concept of this 'average consumer' has been introduced in the context of a question referred for a preliminary ruling in order to define a consumer model which can be used as a standard to determine whether a statement which was used to promote the product at issue was likely to mislead the consumer.[112] Since then, the concept of the reasonably well-informed, observant and circumspect average consumer has been used as a foundation to assess the fairness or unfairness of commercial practices whilst taking into account social, cultural and linguistic factors.[113] As Dannecker and Gorny argue, this consumer model may also be used to determine unacceptability. In particular, the 'd'Arbo Naturrein' case is given as an example because it, inter alia, deals with the issue of consumer

[108] Fly larvae are added during the cheese production. As a consequence, living maggots are contained in the final product.

[109] 'Unacceptability' is also a topic of the EU-wide survey. In this regard it has been researched if there are any national legal guidance documents on the interpretation of the term 'unacceptability'. Please see chapter 5.4.3 for the results.

[110] G. Dannecker and D. Gorny, "Behr's Kommentar Zum Lebensmittelrecht: Kommentar Zum Lfgb Und Zu Weiteren Lebensmittel-, Bedarfsgegenstände- Und Futtermittelrechtlichen Vorschriften. Band 2," (Hamburg, Germany: B. Behr's Verlag GmbH and Co. KG, 2016), pp. 11-12.

[111] See, inter alia, C-465/98 'd'Arbo Naturrein' or C-210/96 'Gut Springenheide'.

[112] Line 27 C-210/96.

[113] Health and Consumers Protection Directorate-General, "The Unfair Commercial Practices Directive: New Laws to Stop Unfair Behaviour Towards Consumers," (Luxembourg: Office for Official Publications of the European Communities, 2006), p. 10. As available on the internet at http://ec.europa.eu/justice/consumer-marketing/unfair-trade/unfair-practices/is-it-fair/pdf/ucp_en.pdf.

perception in case of ubiquitous contamination of food.[114] The product of question in this ruling was a strawberry jam, manufactured in Austria and sold under the name 'd'Arbo Naturrein' in Germany. It was argued by a German consumer organization that the name of the jam 'Naturrein' – naturally pure – would be misleading because the product contained the additive pectin, as well as traces of heavy-metal and pesticide residues. Thus, it was argued that the product could not be referred to as naturally pure. The Higher Regional Court Cologne proposed the question to the European Court of Justice whether the use of the description 'naturally pure' to describe a strawberry jam which contains the gelling agent pectin and traces of lead, cadmium, and pesticide residues in the present level would be precluded by the Labelling Directive 79/112/EEC.[115] It was ruled that an average consumer who is reasonably well-informed, observant and circumspect would read the ingredient list in which pectin was indicated and therefore know of the presence of pectin. Thus, the average consumer is not misled by the name 'naturally pure'.[116]

Furthermore, it was emphasized that it is common ground that the heavy-metals lead and cadmium are present in the natural environment. Hence, it is inevitable that garden fruits grown in such an environment are exposed to these pollutants.[117] Therefore, a well-informed average consumer would be aware of this fact and would not be misled if the jam is nevertheless referred to as naturally pure.

Although this judgement does not deal directly with the issue of unacceptability, a connection is indicated by Dannecker and Gorny. This is likely to be on the basis that it can be deduced from the ruling that the average consumer knows that these contaminants are ubiquitously present and can therefore be contained in food. By implication, the average consumer has to expect their presence. As this contamination is inevitable and below the legal limit, it can therefore be argued that it is acceptable to the consumer. Thus, the impression is given that with support of the average consumer model, the reasonably expected conditions of food can be determined. If the actual conditions deviate in a negative manner from this reasonable expectation, the food is likely considered as unacceptable, as it does not meet the expectations that an average consumer reasonably has.

One further example to illustrate the relationship between the average consumer and unacceptability is cheese of which a strong smell is a desired characteristic like Harz Mountain Cheese. A well-informed consumer will know that this kind of cheese has a characteristically very strong smell. Even if the consumer would lack this knowledge, it can be expected that s/he is observant enough to come to the conclusion that this cheese should indeed smell in this manner. Thus, the strong smell has to be expected by the consumer. If the consumer personally considers this smell as unacceptable, is not of relevance in this case. Individual preferences have to be distinguished.

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[114] Dannecker and Gorny, "Behr's Kommentar Zum Lebensmittelrecht: Kommentar Zum Lfgb Und Zu Weiteren Lebensmittel-, Bedarfsgegenstände- Und Futtermittelrechtlichen Vorschriften. Band 2," p. 12.

[115] Line 17 C-465/98.

[116] Line 22 C-465/98.

[117] Line 27 C-465/98.

Based on these points, the average consumer model can be used in order to decide whether food is unacceptable and therefore unfit for human consumption. It can be used to determine what an average consumer can reasonably expect of food. If its actual conditions deviate in a negative manner, the food is likely to be unacceptable for consumption. To which extent these actual conditions may still deviate in a negative manner is left open.

4.2.2 Further approaches

The average consumer model is not the only approach which is advocated in the literature in order to make the decision of whether food is unacceptable for consumption. According to Meyer and Streinz, another approach represents the examination of relevance. This examination, in particular, evaluates whether the circumstances in an individual case lead to unacceptability, especially with regard to the target group of a product.[118] The latter aspect of the intended target group is also required by law in Article 14 (3) (b) GFL, as the information provided to the consumer may indicate that a product is intended for a specific target group. This must be taken into account in the assessment of whether a food is considered as unsafe. Meyer and Streinz note that the presence of an undesired object does not necessarily render a food to be unacceptable.[119] For instance, the presence of cherry stones in a pastry which contains whole cherries cannot be completely excluded.[120] Thus, if such stones are nevertheless contained, the pastry is still acceptable for human consumption because the presence of the cherry stone is not a relevant factor in deeming the pastry unfit. Another example which is provided concerns additives in food. Even if the maximum level of a food additive in food is exceeded, the product does not automatically become unacceptable. Based on the safety assessment and the determined ADI for each substance there is still a certain safety margin.[121] In such cases, depending on the exceedance, it can be argued that such excess is not a relevant factor in deeming the food unfit and, therefore, unsafe because no safety risk is present.

In the assessment of whether food is considered to be unacceptable for its intended use, the impression is given that objectivity is also of importance. This impression is founded in the guidance document, according to which food will *'(…) qualify as unfit because it would be reasonably considered to be unacceptable for human consumption.'*[122] Accordingly, there have to be reasonable grounds to deem food as unacceptable such as the decomposing of

[118] Meyer and Streinz, *Lfgb, Basisvo, Hcvo: Lebensmittel- Und Futtermittelgesetzbuch Basis-Verordnung (Eg) Nr. 178/2002, Health Claimvo 1924/2006; Kommentar*, p. 151.

[119] Ibid.

[120] Line 18, BGH VI ZR 176/08 (17.03.2009) regarding product liability.

[121] Meyer and Streinz, *Lfgb, Basisvo, Hcvo: Lebensmittel- Und Futtermittelgesetzbuch Basis-Verordnung (Eg) Nr. 178/2002, Health Claimvo 1924/2006; Kommentar*, p. 151.

[122] SCFCAH, "Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (Ec) No 178/2002 on General Food Law," p. 10.

fish with a strong smell or a fingernail in a sausage roll.[123] These examples seem to be very clear cases of unacceptable food, but it can be expected that there are other cases in which the determination is not that simple. For instance, the uncharacteristic smell of an individual food might be acceptable for one person, but not for someone else. This raises the question of how to actually measure if the uncharacteristic smell is reasonably unacceptable. How sensitive are consumers expected to be? Even when taking into account the reasonable expectations of the average consumer, it might become challenging to determine to what extent deviations from this expectation are acceptable. As a result, it seems that there is still a gap to be filled in determining whether a food is reasonably unacceptable.

[123] SCFCAH, "Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (Ec) No 178/2002 on General Food Law," p. 10.

5. Survey about the concept 'unfit for human consumption' in the MSs of the EU

The concept 'unfit for human consumption' is more than just a legal term which is used in legislation. It is an applied concept within the MSs of the EU. As pointed out in the beginning of this paper, its application might differ among MSs. Possible differences are likely to arise from the rather openly phrased description of food 'unfit for human consumption'. This is, inter alia, caused by the reference to the subjective element of unacceptability and the factor that further criteria than those listed in Article 14 (5) GFL may be taken into account to deem food unfit. Subsequently, the application of the unfitness concept leaves space for interpretation and – as indicated within literature – the factors which determine a food's unfitness for consumption can be assessed differently in the EU.[124] This begs research on how the concept is used in practice. For this purpose, an EU-wide survey has been carried out. Participants of this survey have been authorities and ministries active in the field of food safety and other experts on food law in the EU. The subjects addressed in the survey are:

- National legislation and guidance documents
- 'Unfit for human consumption' in former national legislation[125]
- Application of the concept 'unfit for human consumption'
- Legal consequences

The results of this survey provide a first insight into the interpretation and application of the concept 'unfit for human consumption' in several MSs of the EU. Furthermore, they may support a closure or narrowing down of interpretation gaps that are caused by the open phrased description of the concept.

5.1 Overview of the MS within the survey

Given the legal status of the GFL as a regulation, it is directly applicable in all 28 MSs of the EU. The concept 'unfit for human consumption' is, therefore, a subject of food law in every country which is part of the EU. As a consequence, authorities and food businesses in all MSs are involved in the application of this concept. Therefore, it is likely that in all or most MSs interpretations of this element can be found. Because of this authorities and ministries active in the field of food safety and food law experts for each MS have been invited to participate in the survey about the concept 'unfit for human consumption'. For almost half

[124] Kulow, *Das Lebensmittelhygienerecht: Erläuterungen Und Kommentare Zu Den Verordnungen (Eg) Nr. 852/2004 Und Nr. 853/2004*, p. 110.

[125] This category is titled 'Historical background' within the four sections of the questionnaire.

of the MSs, replies have been received. In total, the survey was supported by authorities, ministries and food law experts of 13 countries. Based on their responses, information about the national interpretation and application of the concept 'unfit for human consumption' could be acquired. An overview of these countries and participants is given in table 2.

Table 2: Overview of the MSs for which data was provided within the survey

Member States	Participants (according to their preference indicated by name, function or anonymously)			
	Authorities and ministries	Country Correspondents of the EFFL	Further experts on food law	Anonymously
Belgium		Aude Mahy[126]		
Croatia				x
Cyprus	Ministry of Health, Food Safety Council			
Czech Republic	Ministry of Agriculture of the Czech Republic; Czech Agriculture and Food Inspection Authority (CAFIA)	Nicole Grmelová[127]		
Estonia	Ministry of Rural Affairs of the Republic of Estonia			
Finland	Finnish Food Safety Authority Evira			
Germany		Prof. Dr. Moritz Hagenmeyer[128]		
Poland			Dr. Agnieszka Szymecka-Wesołowska[129]	
Romania		Ioana Ratescu		
Spain			Vicente Rodríguez Fuentes[130]	
Sweden				x
The Netherlands	The Netherlands Food and Consumer Product Safety Authority (NVWA)			
United Kingdom		Hilary Ross[131]		

[126] Aude Mahy, attorney-at-law, Loyens & Loeff, Brussels.

[127] Nicole Grmelová, University of Economics, Prague.

[128] Prof. Dr. Moritz Hagenmeyer, KROHN Rechtsanwälte, Hamburg.

[129] Dr. Agnieszka Szymecka-Wesołowska, Legal Service, Owner at Centre for Food Law (Poland); and Food Law Lecturer at the Kozminski University.

[130] Vicente Rodríguez Fuentes, attorney in Seville (Spain); and President of the European Food Law Association (EFLA).

[131] Hilary Ross, DWF LLP, London.

5.2 National legislation and guidance documents

The first part of the survey addresses national legislation and guidelines in the MSs.[132] The aim of this section is to research whether national elaboration on the concept 'unfit for human consumption' is provided in these documents.

5.2.1 National legislation

It is indicated by most participants that no further elaboration on the concept 'unfit for human consumption' is present in national legislation. Nevertheless, in some MSs national elaboration can be found. Although the term 'unfit for human consumption' itself is not necessarily used, elements of this concept may be present. Whether national elaboration or related elements of the concept 'unfit for human consumption' are indicated for the MSs, is summarized in table 3.

Table 3: Overview of national elaboration of the concept 'unfit for human consumption' or related elements within national legislation of the MSs[133]

Member State	National elaboration or elements that relate to unfitness	No national elaboration
Belgium		x
Croatia	x	
Cyprus		x
Czech Republic[134]	x	x
Estonia	x (No direct elaboration, but elements which relate to unfitness for human consumption are part of the general requirements for food)	
Finland	x (definition of fitness for human consumption)	
Germany		x
Poland	x	
Romania		x
Spain		x
Sweden		x
The Netherlands		x
United Kingdom		x

[132] Questions 1 – 3 in the questionnaire 'Unfit for human consumption'. See Appendix.

[133] Green background: national elaboration or elements that relate to unfitness; red background: no national elaboration; white background: different indications.

[134] Different answers have been provided by the participants for the Czech Republic.

5.2.1.1 MSs in which the issue of unfit for human consumption is addressed within national legislation

The survey indicates that the subject of food which is unfit for human consumption is addressed within national legislation for **Croatia**, the **Czech Republic**, **Estonia**, **Finland** and **Poland**. In what follows this national elaboration and the elements which relate to the concept of 'unfit for human consumption' are presented for each country.

Croatia is the the first country for which the indicated national criteria to deem food unfit for human consumption will be provided. These criteria are laid down in Article 10 (2) of the Food Act (Official Gazette No 81/13, 14/14, 30/15). This Article specifies that in the meaning of Article 14 (2) (b) GFL food unfit for human consumption is considered to be food:

'- whose shelf life is expired, containing the label "use by";
- which is due to its altered properties (taste, smell, decay, deterioration and decomposition) not acceptable for human consumption;
- that contains foreign substances that are reasonably suspected to be present in the rest of the batch;
- in whose production the used food additives do not meet the criteria of purity;
- that contains other allowed substances above the permitted maximum level according to specific regulation;
- which is packaged in packaging which has been shown to be unsafe because it releases substances that are harmful to human health;
- that contains unauthorized chemical forms of vitamins and minerals according to specific regulations;
- that contains certain vitamins and minerals in an amount that poses a risk to human health;
- which is subject to illegal ionizing radiation or other technological process which can have a harmful effect on human health;
- that is designated as food for particular nutritional uses, but does not meet the special dietary needs of people to whom it is intended according to specific regulations;
- which is marked as gluten free, but which contains gluten in an amount that exceeds the amount allowed according to specific regulations;
- which contains allergens that are not labelled according to specific regulations;
- in the case of GM foods containing, and/or consisting of, or derived from approved genetically modified organism with is a proven technological contamination above 0.9% which was not labeled.'[135]

[135] Translation provided within in the context of the survey.

The next country which will be focussed on is the **Czech Republic**. It is indicated by two of the three respondents that no national elaboration on the concept 'unfit for human consumption' is present. However, according to one participant, national legislation is in force which elaborates on this issue. Although the term 'unfit for human consumption' itself is not used, it is indicated to be subject of Section 3 and Section 10 of the Act No 110/1997 on foodstuffs and tobacco products:

'Section 3 – Obligations on food business operators
q) shall exclude from further marketing of foods, food which is:
1) listed in Section 10 paragraph 1 (a) – (e)
2) packaged in a packaging that does not meet directly applicable EU regulations on materials and articles intended to be in contact with food; or decrees on hygienic requirements for products intended for contact with food and dishes
3) poorly or incorrectly labelled
4) not meeting the quality requirements specified in the implementing legislation or declared by the producer
5) smelly, if the smell is not a characteristic of the product; or otherwise damaged, distorted, dirty or overtly microbiologically or chemically damaged[136]

Section 10 – Placing on the market[137]
1. It is prohibited to place foodstuffs on the market:
a) that are misleadingly labelled or offered for consumption in a misleading manner[138]
b) that past their use by date,
c) of unknown origin,
d) that exceeds the maximum permitted level of contamination with radionuclides, as laid down in the Nuclear Act,
e) that are irradiated in contravention of the requirements, as laid down in the present Act and in Implementing Regulation.'[139]

[136] According to CAFIA only this provision could be included under the concept of 'unfit for human consumption'.
[137] These provisions are not aligned to the concept of 'unfit for human consumption' according to the viewpoint of CAFIA.
[138] Act No 634/1992 on consumer protection, as amended; Section 46 of the Commercial Code.
[139] Translation provided within in the context of the survey.

In the survey it is indicated that no national elaboration on the concept 'unfit for human consumption' is present in **Estonia**. However, elements of this concept seem to be contained in the general requirements for food. According to § 12 of the Food Act, food must be in compliance with the following requirements:

'§ 12 General requirements
(1) Food to be placed on the market must be safe for human health and comply with other requirements provided for in this Act and other legislation (hereinafter compliant).
(2) Food must not contain parasites, pests or foreign substances that harm the properties of the food or endanger human health.
(3) It is prohibited to handle food which is spoilt or contaminated or which does not comply with microbiological requirements, or food spoilt as a result of the use of an unsuitable manufacturing process or due to odour, flavour, colour or other circumstances which are not characteristic of the food.'[140]

Also for **Finland** it is indicated that the term 'unfit for human consumption' itself is not used in national legislation. Instead, factors are provided that determine whether a food is fit for human consumption. These are laid down in the Food Act (23/2006):

'Section 7 – General requirements concerning food
(1) Food must be fit for human consumption in terms of its chemical, physical, microbiological and health-related quality and composition and other properties, and must not present any hazard to human health or mislead the consumer. Provisions on general requirements for food safety are also laid down in Article 14 of the General Food Regulation and in Article 4 of the General Food Hygiene Regulation.'[141]

Poland is the last country for which direct elaboration on the concept 'unfit for human consumption' is indicated. This elaboration is part of Article 3 (3) point 46 of Act of 25th August 2006 on safety of food and nutrition. According to this Article, food unfit for human consumption[142] is of a composition or has properties that changed due to irregularities which occurred at the production stage or market stage or which have been caused by action of natural factors. These factors encompass, for instance, humidity, time, temperature and light. Furthermore, the presence of microorganisms and contamination can cause inability to consumption according to its intended purpose, as provided by Article 14 (2) (b) GFL and Article 14 (5) GFL.

[140] The translated Food Act is available at https://www.riigiteataja.ee/en/eli/521062016005/consolide.

[141] Translation provided within in the context of the survey. An unofficial translation of the Food Act (23/2006) is also available on the internet at http://extwprlegs1.fao.org/docs/pdf/fin113457.pdf.

[142] 'Spoiled food' as expressly named by the provision.

5.2.1.2 Member States without national elaboration of 'unfit for human consumption'

For most of the MSs it is indicated that no further elaboration on the concept 'unfit for human consumption' is provided in national legislation. These countries are **Belgium**, **Cyprus**,[143] **Germany**, **Romania**, **Spain**,[144] **Sweden**, **the Netherlands** and the **United Kingdom**. If national legislation, nevertheless, refers to the element of unfitness this is usually done in the context of a reference to Article 14 (5) GFL or in a translated reproduction of this concept. Such a reproduction is, for instance, indicated in present Romanian[145] food law.

5.2.2 National guidance documents

Elaboration on the concept 'unfit for human consumption' in national guidelines seems to be a scarcity in the MSs. For almost none of the countries is such a national guidance document indicated to be present. Only for **the Netherlands** and the **United Kingdom** is guidance on the concept 'unfit for human consumption' named within this survey.

In **the Netherlands** guidance with regard to unsafe food, including the subject of unfitness, is issued by the NVWA.[146] This guidance document of the Dutch Food Safety Authority addresses the FBO. It aims to support its decisions on whether a food is unsafe and which actions should be taken if the food is deemed unsafe. The so called 'Meldwijzer - onveilige levensmiddelen'[147] is a non-legal document and, therefore, not legally binding to the FBO.[148]

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[143] It should be pointed out that no national elaboration on the GFL concept of unfitness is indicated to be present in Cyprus food law although 'Unfit Foodstuff' is subject to Article 6 of the Food (Control and Sale) Law. Despite the similar wording, the terms are assigned to different concepts. The scope of 'Unfit Foodstuff' goes beyond the meaning of the GFL concept and forbids the selling, manufacturing, and/or importing of food that:

'*a) contains any hazardous or poisonous substance/matter which renders it injurious to health*
b) consists of any polluted, putrescent, infectious or repulsive substance
c) is unfit for human consumption
d) is adulterated
e) has been produced, preserved, packaged, transported or stored under unhygienic conditions'.

For purposes of applying Article 6 (1) (c) on food unfit for human consumption, Article 6 (3) (c) mentions that Article 14 (5) GFL applies.

[144] Although there is no national elaboration on the concept 'unfit for human consumption', in general, there are some products for which it is regulated whether they are fit or unfit for human consumption. This is in particular the case for olive oil. There are specific standards which olive oil products have to comply with. If, for instance, the olive oil would not meet the criteria of the standard, it would be considered 'lampante'. 'Lampante' means that the product is not bad itself, but it does not have the quality which is demanded.

[145] Article 15 Law no 150/2004 on food and feed safety.

[146] NVWA, "Meldwijzer - Onveilige Levensmiddelen," (2014). As available on the internet at https://www.nvwa.nl/documenten/communicatie/diversen/archief/2016m/meldwijzer-nvwa-onveilige-levensmiddelen.

[147] Onveilige levensmiddelen = unsafe food.

It provides among other things a decision tree about the actions that should be taken in case a food is unfit for human consumption. According to this decision tree, the FBO has to inform the NVWA about the presence of unfit food in the following cases:

- If the food has left the immediate control of the FBO, but the FBO is still the first in charge within the supply chain.
- If the food is a private label product and has left the immediate control of the FBO.

The guidance document also provides a deeper insight into the conditions under which food is considered to be unfit for human consumption. According to the guideline, food becomes unfit for human consumption due to contamination with foreign material or, otherwise, an unacceptable taste or odour, decay, or a loss of quality to an extent which makes the food unacceptable for the consumer but not (already) harmful. Products that do not comply with legal requirements – but are as such not harmful – are considered to be unfit. In case there is no legal norm for the presence of a substance, there might be still a safety limit. A safety limit means any maximum amount of a contaminant in food mentioned by the EU (EFSA, European Commission).

In general, it is noted within the guidance document that food which shows deviances in quality is not within the definition of 'unsafe'. Such quality deviances concern, for instance, food to which too little colorants have been added. However, if the nature of the product is changed to such an extent that it deviates from what a consumer may reasonably demand, the food is unfit.

For the purpose of illustration, the guidance document also provides examples of unfit food. For instance, bread is considered to be unfit for consumption if too much salt is added during the production. A further example is vegetables and fruits that can become unfit if they contain pesticide residues that exceed the MRL but are still below the ARfD.[149]

[148] According to Article 4:84 of the General Administrative Law Act, the administrative authority shall act in accordance with the policy rules. An exemption is made in the case that, due to special circumstances, this action would affect one or more interested parties in a disproportional manner in relation to the objectives of this rule.

[149] The maximum residue level, shortly named MRL, is the upper level of a concentration for a pesticide residue on or in food – but also feed – that is set according to Regulation 396/2005. It is based on good agricultural practice and the lowest consumer exposure which is necessary in order to ensure the protection of vulnerable consumers. In comparison, the acute reference dose, referred to as ARfD, constitutes the estimated amount of a substance in food that can be ingested over a short time of period without appreciable risk to the health of the consumer, as described in Regulation 396/2005.

The **United Kingdom** is the second and last country for which it is indicated that food 'unfit for human consumption' is addressed in a national guideline. This is done within the guidance notes for the FBO.[150] These guidance notes are issued by the FSA as the central authority in the field of food safety in the United Kingdom. The aim of this document is to provide advice for the FBO on compliance with the requirements of several articles in the GFL.

The provided explanation of the concept 'unfit for human consumption' within this guideline is almost exactly the same as in the guidance document of the SCFCAH. Only the example of a possible contamination as caused by a high level of non-pathogenic microbiological contamination is missing. Within the guidance notes it is emphasized that the European Court of Justice may provide further clarification of the meaning on the concept 'unfit for human consumption' through case law.

5.3 Unfit for human consumption in former national legislation

Since the GFL seeks to harmonize general food law principles, it is reasonable to expect comparable approaches and elements of the current concept 'unfit for human consumption' in former national food law. Therefore, the second section of the survey targets the issue of whether a comparable concept of unfit food existed in former national legislation.[151]

Indeed, the responses indicate that this topic was addressed within former food law in several MSs. Although the concept used in former legislation was not necessarily the same, elements of the current approach or at least a reference to the term 'unfit for consumption' was indicated. Countries for which such indications in former national legislation are named within the survey are **Estonia**, **Finland**, **Germany**, **Poland**, **Sweden**, **the Netherlands** and the **United Kingdom**.

In **Estonia,** elements of the current concept of unfitness were already contained within the general requirements for food.[152] Similar to the current general requirements, placing food on the market which contains parasites, pests or foreign substances which harm the properties of the food or which endanger human health was prohibited. Furthermore, the prohibition encompassed handling food or raw material[153] that was spoilt, contaminated or did not conform to microbiological requirements and food which was spoilt due to

[150] FSA, "Guidance Notes for Food business Operators on Food Safety, Traceability, Product withdrawal and Recall - a Guide to Compliance with Articles 14, 16, 18 and 19 of General Food Law Regulation (Ec) 178/2002," (2007). As available on the internet at https://www.food.gov.uk/sites/default/files/multimedia/pdfs/fsa1782002guidance.pdf.

[151] Question 4 in the questionnaire 'Unfit for human consumption'. See Appendix.

[152] § 12 (2) (3) Food Act (17.12.2002) on the general requirements.

[153] In the Food Act (01.07.2006) raw materials have not been addressed by these requirements.

unsuitable manufacturing process, odour, flavour, colour or other circumstances which are not characteristics for the food.

In **Finland,** the Finnish expression for 'unfit for human consumption' was already used within the former national food law. According to the national Food Act from 1995 (361/1995), food unfit for human consumption was defined to contain *'a) food injurious to human health, as well as, b) food, which is not acceptable for human consumption due to spoilage, contamination, impurities, process errors, foul smell or taste etc., which cause food not to meet the acceptable composition, authenticity, quality or other characteristics that are expected.'*[154]

Also in **Germany,** a concept of 'unfit for human consumption' was already present in former food law. According to this law, the placement of unfit food on the market was considered as a deceptive practice.[155]

Characteristics of the current concept 'unfit for human consumption' were also indicated to be contained in former **Polish** food law. The Polish Act of 25 November 1970 on Health Conditions of Food and Nutrition defined in Article 4 that foodstuff and stimulants are not allowed to be put in circulation if they contain foreign substances which are injurious for human health or cause organoleptic changes to the extent of consumption or use. The latter element is similar to specific aspects of the current concept, namely unacceptable taste or odour, which are listed in the guidance document on the GFL.[156]

Within the survey it is furthermore indicated that the issue of unfit food was already addressed in former **Swedish** legislation. According to the national Food Act – Livsmedelslagen SFS 1971:511 – *'Food that is offered for sale may not be of such a composition or quality and other respects, that it can be assumed to be harmful to consume, a carrier of infection or otherwise unfit for human consumption'.*[157]

A second reference to unfit for human consumption is made with regard to the handling of foodstuff. It was required to take precaution in order to eliminate the risk of contamination or unfitness for human consumption.[158] However, a detailed definition of what exactly was considered as unfit for human consumption was not provided within the law.

[154] Translation provided within in the context of the survey.

[155] For further information, see chapter 4.1.2.

[156] SCFCAH, "Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (Ec) No 178/2002 on General Food Law," p. 9.

[157] § 5 SFS 1971:511. An unofficial translation of the Food Act is available on the internet at http://faolex.fao.org/docs/pdf/swe20871E.pdf.

[158] § 8 SFS 1971:511.

In **the Netherlands,** former food law also contained elements of the concept 'unfit for human consumption'. The Dutch Regulation on Hygiene[159] included a reference to food and drinks that may become unfit for human consumption. In this context it was stated that the FBO shall not accept any raw material, food, or drink which is reasonably expected to contain parasites, pathogenic microorganisms, or toxic, decayed, or foreign substances which would render a food to be unfit for human consumption.[160]

The **United Kingdom** is the last country for which a former concept similar to the one of 'unfit for human consumption' is indicated. This similar concept was already present in British food law before the GFL entered into force. Although the term 'unfit for human consumption' was not mentioned itself, the issue had still been addressed. This was done in Article 14 of the Food Safety Act 1990.[161] According to this Article, placing food on the market which was not of the nature, substance or quality demanded by the purchaser was prohibited. This food was not considered to be unsafe. Generally speaking, it was just not what the consumer had asked for. Examples are Scotch Whisky or Port, which are not in compliance with the related regulations, or mouldy food, as long as the mould is not of harmful nature.

5.4 Application of the concept 'unfit for human consumption'

The third section of the survey addresses the application of the concept 'unfit for human consumption' in practice. Whereas prior to this section the topic was mainly approached from a theoretical viewpoint, this section aims to provide a more practice-oriented insight. Therefore, the application of the concept 'unfit for human consumption' is researched from different angles in the following subchapters. The focus of the first subchapter is on national case law and further examples of food unfit for human consumption. In this context, an overview is provided on whether food would be considered as unfit for human consumption in specific example cases. Secondly, the relationship between a food's unfitness and further legal requirements is researched. This is followed by addressing the question of whether food can be deemed unfit and injurious to human health at the same time. Finally, regard is given to the approach of unacceptability within the MSs.

[159] Warenwetregeling Hygiëne van levensmiddelen (29.02.2000).

[160] Article 2 (1) Warenwetregeling Hygiëne van levensmiddelen (29.02.2000).

[161] The Food Safety Act 1990 is still in force but not section 14.

5.4.1 Case law and examples of food unfit for human consumption

To put it quite simply: the easiest approach to receive an insight about the concept 'unfit for human consumption' in practice, is to illustrate its application by examples and existing case law. Therefore, one part of the survey focusses in particular on national case law and on examples of food that is considered to be unfit for human consumption in the MSs.

5.4.1.1 National case law

National case law can be of great value to demonstrate how the rather openly phrased description of the concept 'unfit for human consumption' is interpreted in front of national courts. Therefore, the participants were requested to share their knowledge whether national case law on the concept 'unfit for human consumption' is present.[162]

According to the responses, such national case law can be found in several MSs. For the purpose of this study, information about national court cases are provided for the **Czech Republic**,[163] **Finland**, **Poland**, **Romania** and **Spain**.[164]

In **Finland,** individual cases – including court cases – are indicated to be present in which the interpretation of the concept 'unfit for human consumption' has been tested. These cases involve, inter alia, food and food supplements which have been contaminated by non-pathogenic microorganisms or insects, food with deteriorated organoleptic qualities, or insufficient hygiene control measures during the production or storage of food. Furthermore, food from non-authorised establishments and withdrawals/recalls by the FBO have been named in this regard.

For **Poland** it is noted that although national case law is present which relates to the concept 'unfit for human consumption' the courts – mainly administrative ones – rarely give their interpretation of the definition of this concept which is provided in Polish legislation. One of the few examples is the judgment of the Regional Administrative Court in Krakow.[165] In this case the Polish official controls authorities referred to the concept of 'unfit for human consumption' and deemed the products – bakery components and sauces – unfit for human consumption according to the GFL. The unfitness was caused by the fact that their date of minimum durability was overdue, the packages of those products were damaged, and some of them were impossible to identify because of the absence of a label.

[162] Question 5 in the questionnaire 'Unfit for human consumption'. See Appendix.

[163] It was only indicated that case law is present but no specific case was provided.

[164] Case law about the concept 'unfit for human consumption' may also be present in the other MSs. However, specific cases on unfit food might not be to the knowledge of every participant and therefore may not be provided within this survey.

[165] III SA/Kr 1822/12.

With regard to case law in **Romania,** two court cases have been briefly outlined for the purpose of this survey. The first case concerns the decision of the Teleorman County Court,[166] which ruled that wheat became unfit for human consumption due to the absence of storage places for the harvested wheat. Instead, the wheat was stored outdoors. Based on this inadequate storage, the food was deemed to be unfit for human consumption. Consequently, this example illustrates that improper storage conditions can cause a food to be deemed unfit for human consumption. The second example of unfit food relates to a decision of the High Court of Cassation and Justice.[167] In this ruling, wine was deemed to be unfit for human consumption because it was treated with substances which normally lead to the denaturation of the alcohol.

In the survey it is also indicated that case law about food unfit for human consumption is present in **Spain**. However, in the related judgments the Spanish Supreme Court only indirectly dealt with the concept of unfit food. The main focus of both indicated cases was on the decision of whether the authority took proportional actions. Subject to one of these judgments was contaminated olive pomace oil.[168] In the second judgement, unsuitable hygienic conditions in a meat factory in Madrid were addressed.[169]

5.4.1.2 Further examples of unfit food

Within the survey also further examples of food which is considered to be unfit for human consumption are provided by the participants. In this context, it should be noted that information about recalled unfit food can often be found on the webpages of national food safety authorities. Such a database of food alerts is, for instance, provided by the FSA in the **United Kingdom**.[170] According to this database, a fruit juice has been recalled, which was classified as unfit for human consumption. In several batches of the product mould was present and led to the spoilage of the juice.[171]

Also in the **Czech Republic** a similar database is available. One of the products which is categorized as unsafe in this database is a peeled organic buckwheat product. Indicated unsatisfactory parameters of this food are an unusual scent and a strange smell and

[166] Decision no 756 of 25.10.2013.

[167] Decision no 1028 of 25.03.2013.

[168] At this time the contaminant was not considered to be carcinogenic.

[169] STS 3 March 2009, Recurso de casación 8506/2004.

[170] The database is available on the internet at https://www.food.gov.uk/enforcement/alerts.

[171] FSA, "Hancocks Cash and Carry Recalls Vidal Juice due to Presence of Mould," https://www.food.gov.uk/enforcement/alerts/2015/13554/space-juice-recalled. Last accessed on 25 March 2017.

taste after cooking.[172] Although only the overall category of unsafe food is chosen, which includes both – injurious to health and unfit for human consumption – these parameters seem to relate to the unfitness of food because the organoleptic properties of the product are addressed.

The guidance document of the Dutch NVWA[173] provides further examples of foods which are considered to be unfit for human consumption in the **Netherlands**. For instance, bread is deemed to be unfit if too much salt is added in the production process. A further example is vegetables and fruits which can become unfit for human consumption if pesticide residues on or in the product exceed the MRL but are still below the ARfD. If the pesticide residue exceeds the ARfD, the food is deemed to be harmful.[174]

[172] CAFIA, "Food Pillory: Bio Pohanka Loupaná, Kroupy," http://www.potravinynapranyri.cz/Detail.aspx?id=14986&amp%3bamp%3blang=en&amp%3bamp%3bdesign=default&amp%3bamp%3barchive=actual&amp%3bamp%3blisttype=tiles&lang=en&design=default&archive=actual&listtype=tiles. Last accessed on 25 March 2017.

[173] NVWA, "Meldwijzer - Onveilige Levensmiddelen."

[174] For further information on the MRL and ARfD see footnote 150 in chapter 5.2.2.

5.4.1.3 Indications whether specific food would be considered as unfit for human consumption

In the last part of the subsection on case law and national examples of food unfit for human consumption, the participants were requested to indicate whether specific food would be considered as unfit for human consumption.[175] For this purpose, the following short example cases have been given:

- The food contains pesticides above the MRL
- Traceability of a food is not provided
- Horse meat is sold as beef
- Meat comes from an animal that has not been controlled before slaughtering

This approach was chosen in order to gain an overview of whether a specific food is likely to be considered as unfit within the MSs. As already indicated within literature[176] and the previous results of this survey, the factors which determine if a food is considered to be unfit for human consumption can differ among MSs. In this context, the approach taken allows a direct comparison of indications of whether a specific food may be regarded as unfit in the MSs.

5.4.1.3.1 Food contains pesticides above the MRL

The first case which is addressed in the survey concerns food that contains pesticides above the MRL. In the EU, pesticides have to be approved by the European Commission and the MSs. This approval is based on advice from EFSA. Legal limits for pesticide residues are set, known as MRLs.[177] The MRL is the upper level of a concentration for a pesticide residue on or in food that is set according to Regulation 396/2005. It is based on good agricultural practice and the lowest consumer exposure which is necessary in order to ensure the protection of vulnerable consumers. Consequently, the setting of MRLs should ensure that pesticide levels in food are safe. But what if the MRL is exceeded? Could food be considered as unfit for human consumption if it contains pesticide residues above this limit? The participants of the survey have been requested to indicate if, from their viewpoint, this assessment would be likely in the MSs.

The results show that according to most of the participants the decision depends on a case-by-case assessment, followed by the indication that the food is likely considered to be unfit for human consumption. The replies are summarized in table 4.

[175] Question 11 in the questionnaire 'Unfit for human consumption'. See Appendix.

[176] Kulow, *Das Lebensmittelhygienerecht: Erläuterungen Und Kommentare Zu Den Verordnungen (Eg) Nr. 852/2004 Und Nr. 853/2004*, p. 110.

[177] EFSA, "How Europe Monitors Pesticide Residues in Food." As available on the internet at http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/efsapesticides11print.pdf.

Table 4: Overview of the indications of whether food containing pesticides above the MRL is likely to be considered as unfit for human consumption[178]

Member State	Unfit	NOT unfit	Remarks
Belgium			Case-by-case assessment
Croatia	x		
Cyprus			Case-by-case assessment. Foodstuffs that contain pesticides above the MRL are separated into the categories unfit for human consumption and injurious to health. In order to determine the actual status, a risk assessment is applied, which is based on a model developed by EFSA
Czech Republic[179]	x		Specific EU regulation would be applied
Estonia	x		
Finland			Case-by-case assessment
Germany			Depends on the actual exceeding of the limit but generally 'no'
Poland			Case-by-case assessment. The food would be only considered as unfit if it may not potentially harm human health or life due to containing pesticides above the MRL
Romania			No information provided
Spain			Generally not in line with legal requirements
Sweden			Case-by-case assessment
The Netherlands	x		This case is likely to be considered as unfit unless the ARfD is not exceeded. In such a case the food would be considered as harmful.
United Kingdom			Case-by-case assessment

[178] Green background: unfit; red background: not unfit; yellow background: no category chosen; white background: no information provided/different assessment.

[179] Different answers have been provided by the participants for the Czech Republic.

5.4.1.3.2 Traceability of a food is not provided

The GFL requires that food and its ingredients are traceable.[180] Therefore, the FBO shall have a system in place to trace ingredients one step up and one step down.[181] In this context traceability itself is defined as:

> **Article 3 (15) GFL**
>
> '(…) the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.'

The intention of the traceability system is to quickly identify the source of a possible food safety problem. Consequently, well-aimed recalls can be facilitated, and the concerned food can be taken from the market.[182] In specific cases even the absence of traceability itself might be considered as a safety risk. This issue was, inter alia, addressed in the 'horse meat scandal' in 2013.[183]

In a similar case in the Netherlands it was suspected that meat from the meat processing company Willy Selten B.V. was mixed with horsemeat, although it was labelled as beef. The NVWA required Selten to recall the concerned beef and explained that the safety of the food could not be guaranteed because the origin of the meat could not be traced back.[184] In a provisional ruling, the Industrial Appeals Tribunal initially accepted this line of reasoning. However, in its recent judgment[185] on this subject the tribunal seems to have retracted this position. It ruled that lacking traceability generally does not render a food unsafe. This debate shows that, at least according to some, a relationship between traceability and the concept of safety may exist. For this reason, this situation has been included in the

[180] Article 18 (1) GFL.

[181] Article 18 (2) (3) GFL.

[182] R. Spirovska Vaskoska, B. van der Meulen, and M. van der Velde, "Process: Hygiene, Traceability and Recall," in *Eu Food Law Handbook*, ed. B. van der Meulen (Wageningen, the Netherlands: Wageningen Academic Publishers, 2014), pp. 357 - 58.

[183] The 'horse meat scandal' occurred 2013 in Europe when it was detected that pre-prepared food contained horsemeat instead of beef that was not labelled. This fraud was revealed after the detection of equine DNA in beef burger products by the Food Safety Authority of Ireland and spread across Europe, where further incidences came to light. Of special concern was the lacking traceability of the horse meat due to the risk that meat of horses treated with the veterinary drug phenylbutazone may have entered the food chain, despite the provision that once animals are treated with this drug they are not permitted to enter the food chain.

[184] S. Meulen et al., "Fighting Food Fraud - Horsemeat Scandal; Use of Recalls in Enforcement Throughout the Eu," *EFFL* 10, no. 1 (2015): p. 3.

[185] CBb 30 January 2017, ECLI:NL:CBB:2017:6.

questionnaire. In this context, the participants have been requested to indicate whether food is likely to be considered as unfit for human consumption if traceability is not provided.

The responses mainly tend to the assessment that the concerned food is not likely to be considered as unfit for human consumption or that this decision would depend on an individual case-by-case assessment. A summarized overview of the responses is presented in table 5.

Table 5: Overview of the indications whether food of which no traceability is provided is likely to be considered as unfit for human consumption

Member State	Unfit	NOT unfit	Remarks
Belgium			Case-by-case assessment (room for interpretation)
Croatia			Not of relevance because food without traceability must be removed from the market
Cyprus			Case-by-case assessment. Depending on further details, the foodstuff may be considered as unfit or even injurious to health
Czech Republic[186]	x	x[187]	
Estonia	x		As there is no information about the origin of the food, or where it has been handled etc.
Finland			Case-by-case assessment depending on the risk related to the food commodity in concern
Germany		x	
Poland		x	This is not a requirement of deeming a product as 'unfit for human consumption'
Romania			No information provided
Spain		x	More considered as a risk to health than unfit for human consumption
Sweden			Case-by-case assessment
The Netherlands		x	Generally not
United Kingdom			Case-by-case assessment

[186] Different answers have been provided by the participants for the Czech Republic.

[187] Indication made by CAFIA.

5.4.1.3.3 Horse meat is sold as beef

The third case addresses horse meat sold as beef. In addition to the previous example, the decision to include this case in the survey is also based on the European 'horse meat scandal'. Back then the situation was dealt with differently in the MSs.[188] Including this general example, is aimed at receiving an overview of whether, generally, horse meat which is sold as beef might be an issue of food 'unfit for human consumption'. The participants have been requested to provide their opinion on if such food is likely to be considered as unfit.

According to most responses, it is indicated that this case is, rather, subject to food fraud. Nevertheless, based on the responses, it cannot be excluded that the food might be (also) considered as unfit in some MSs. A summary of the results on this assessment is provided in table 6 on the next page.

[188] For further details the article Meulen et al., "Fighting Food Fraud - Horsemeat Scandal; Use of Recalls in Enforcement Throughout the Eu." is recommended.

Table 6: Overview of the indications whether horse meat, sold as beef, is likely to be considered as unfit for human consumption

Member State	Unfit	NOT unfit	Remarks	Subject to other non-compliance
Belgium	x			
Croatia				Not of relevance because it falls within the scope of Regulation 1169/2011 and the issue of **food fraud**
Cyprus				The meat is not necessarily unfit if it is only an issue of mislabelling. According to a national concept, it is forbidden to sell foodstuff that unfavourably affects the consumer or is not of the nature/substance/quality that the consumer demands. **Food fraud**
Czech Republic[189]	x	x[190]		Unless the safety is proven, it is likely to be considered as food fraud due to **misleading information**
Estonia				This case is about **food fraud**. Depending on the analysis, if only the labelling is false and no hazard to human health is present, the food would be considered as fit for human consumption
Finland	x			
Germany		x		This would be an issue of **misleading**
Poland				This is an issue of a **falsified product** (also defined by the Polish food law)
Romania			No information provided	
Spain				This is an issue of **food fraud**
Sweden			Case-by-case assessment	
The Netherlands				
United Kingdom				

[189] Different answers have been provided by the participants for the Czech Republic.

[190] Indication made by CAFIA.

5.4.1.3.4 Meat of an animal that has not been controlled before slaughtering

Food of animal origin may present a specific hazard to human health due to microbiological and chemical hazards that have been frequently reported in this context. Therefore, specific hygiene rules are set for food of animal origin.[191] Among other provisions, it is required that the official veterinarian carries out an ante-mortem inspection of the animal before slaughter.[192] But what happens if an animal has not been controlled before? Would the meat of this animal be considered as unsafe? And, if so, is this due to being injurious to health or unfit for human consumption? One last time the participants of the survey have been requested to indicate whether such meat may become an issue of unfit food.

The results show that, according to most responses, such an assessment as unfit for human consumption is indeed likely. A summarized overview of all responses is given in table 7.

Table 7: Overview of the indications whether meat of an animal that has not been controlled before slaughtering is likely to be considered as unfit for human consumption

Member State	Unfit	NOT unfit	Remarks
Belgium	x		It is indicated that the Belgian administration is likely to consider a product injurious to health to be also – *per se* – unfit for human consumption
Croatia			Not of relevance because meat that is not controlled must be removed from the market
Cyprus			Decision depends on further factors. If there is no potential hazard to health, the meat is likely to be considered as unfit
Czech Republic[193]	x		No decision provided
Estonia	x		
Finland	x		
Germany	x		Probably yes
Poland		x	Unlikely because it does not satisfy the legal conditions which are laid down in art. 3 (3) point 46 Act of 25th August 2006 on safety of food and nutrition
Romania			No information provided
Spain		x	It is likely to be considered as a potential risk to human health and could also become an issue of fraud
Sweden			Case-by-case assessment
The Netherlands	x		
United Kingdom	x		Probably regarded as unfit unless there are indications that the food is actually injurious to health

[191] Recital 2 Regulation 853/2004.

[192] Annex I Chapter II B (1) (a) Regulation 854/2004.

[193] Different answers have been provided by the participants for the Czech Republic.

5.4.2 Legal requirements in relation to food unfit for human consumption

As has been indicated within this paper, the concept of 'unfit for human consumption' is openly defined in the GFL. The criteria provided by the description of unfit food in Article 14 (5) GFL are not necessarily the only ones which can render a food unfit for human consumption. The expression 'regard shall be had'[194] gives the opportunity to consider further criteria to determine the unfitness of food.[195] This concept is also reflected within the examples of the previous subchapters. Some food is indicated to be likely considered as unfit for human consumption, even in cases in which it seems that the criteria provided in Article 14 (5) GFL may not be present. It is, for instance, indicated that meat may become unfit for human consumption in some MSs if the ante-mortem inspection of the animal is absent. Since this inspection by an official veterinarian is a legal requirement, the question may arise if (generally) non-compliance with legal requirements can cause a food to be deemed unfit. In order to answer this question, one part of the survey addresses the issue of whether food which does not comply with legal requirements is generally considered to be unfit for human consumption.[196]

The **majority of the participants** indicate that this decision would depend on a case-by-case assessment and on the legal requirement itself.

Within the response for **Spain** it is remarked that no generalisation can be made because legal requirements are present for various aspects of food. Among other provisions, even the font size of mandatory labelling particulars is regulated.[197] Specific legal requirements may also relate to the composition of food. In order to legally name, for example, a product 'cheese', it has to comply with specific criteria.[198] If these legal criteria are not fulfilled, using the term 'cheese' is prohibited. Nevertheless, this food may be fit for human consumption.

For **Germany** it is noted that a basic rule to deem food unfit for human consumption if such food is not in compliance with legal requirements does not exist. The provisions of Article 14 (5) GFL have to be fulfilled to consider a food unfit for human consumption.

In contrast, in the **Dutch** guidance on the issue of unsafe food it is stated that products that do not comply with legal requirements – but are as such not harmful – are considered to be unfit.[199]

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[194] As stated in Article 14 (5) GFL.

[195] Rathke and Sosnitza, "Zipfel / Rathke: Lebensmittelrecht - Loseblatt-Kommentar Aller Wesentlichen Vorschriften Für Das Herstellen Und Inverkehrbringen Von Lebensmitteln, Futtermitteln, Kosmetischen Mitteln, Sonstigen Bedarfsgegenständen Sowie Tabakerzeugnissen, Band 2," p. 16.

[196] Question 7 in the questionnaire 'Unfit for human consumption'. See Appendix.

[197] Article 13 (2) Regulation 1169/2011.

[198] In Germany these requirements are regulated in § 1 Käseverordnung ('Cheese Regulation').

[199] NVWA, "Meldwijzer - Onveilige Levensmiddelen."

5.4.3 The approach to unacceptability within the MSs

Unacceptability seems to be a key element of the concept 'unfit for human consumption'. This is also emphasized by the SCFCAH.[200] Consequently, it is of value to know how unacceptability is determined.[201] Due to the subjective character of this element, this might become a challenge. Something that is acceptable for one person does not necessarily have to be acceptable to someone else. This issue might even become more complex if cultural differences among the MSs are taken into account. Therefore, it is the aim of this survey to gain an overview of how unacceptability of food is determined in the MSs.[202]

National guidance on the interpretation of unacceptability seems to be absent, according to the participants of the survey.[203] Nevertheless, most of the participants provided information about national approaches that are used in order to support the determination of whether a food is unacceptable.

In **Estonia** this decision is indicated to be usually made in the context of a case-by-case assessment. This individual assessment is, inter alia, based on limits, visual observations, and laboratory tests.

For **Finland** it is indicated that unacceptability is usually determined in a case-by-assessment. Supporting elements of this assessment are, for instance, related court cases.

A further approach has been named in the reply for **Germany**. According to the respondent, the average consumer model[204] should be applied to determine whether food is unacceptable. It should be noted that the application of this model can lead to opposing assessments.

With regard to **the Netherlands,** it is emphasized that a special focus should be on the intended use of the food to determine if such food might be unacceptable.[205] The relevance of this focus can be illustrated in the simple example of spinach. Usually spinach is sold either fresh and mainly unprocessed or pre-processed, for instance as pre-packed creamed spinach. After its harvest from the field, the spinach may still contain soil between the

[200] SCFCAH, "Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (Ec) No 178/2002 on General Food Law," pp. 9 - 10.

[201] The results of the literature research about the element of unacceptability are presented in chapter 4.3.

[202] Question 10 in the questionnaire 'Unfit for human consumption'. See Appendix.

[203] Even in the guidance notes of the FSA in the United Kingdom, no further information on the use of the term 'unacceptability' is provided, although it refers to such as the central concept of unfitness for human consumption (FSA, "Guidance Notes for Food business Operators on Food Safety, Traceability, Product withdrawal and Recall - a Guide to Compliance with Articles 14, 16, 18 and 19 of General Food Law Regulation (Ec) 178/2002," p. 8.).

[204] See also chapter 4.3.1.

[205] Also according to Article 14 (5) GFL, regard should be taken to whether the food is unacceptable to human consumption according to its intended use.

leaves. However, the preparation of fresh spinach usually requires that the leaves be washed before they will be consumed. If soil was present, it is likely that such would be separated from the spinach during the washing process. Consequently, the presence of soil in fresh spinach might be assessed as acceptable because there is still a process step in which the soil is likely to be excluded before the spinach will be consumed.

This is different in comparison to pre-packed creamed spinach. Such spinach is already prepared and only requires cooking before consumption. At the consumer stage no step is required in which the soil would be excluded. Therefore, the presence of a certain amount of soil in pre-packed creamed spinach might not be considered as acceptable to the consumer. This example shows very well that the intended use can be an important factor in the assessment of whether a food might be unacceptable for consumption. Therefore – as indicated by the concept description in Article 14 (5) GFL – the intended use should be taken into account when determining the fitness of food.

Furthermore, within the response for the Netherlands it is indicated that the factor of visibility can be of concern in the assessment whether a food is unacceptable to the consumer. This concerns the issue of whether the consumer is able to see what s/he is actually buying. If, for instance, fruits are sold separately, the consumer has the opportunity to check whether a fruit is decayed. Based on this observation, the consumer can decide if s/he still intends to purchase the fruit. However, in cases in which the fruits are already pre-packed in a package, the consumer may not always be able to check whether the fruits are still of good quality or are already (partially) decayed. If, in this case, the fruits are decayed and this loss of quality was not visible due to the package, it might be argued that the fruits can be considered as unfit for consumption within the meaning of the GFL.

It can be summarized that, although no national guidance on the interpretation of the concept of unacceptability seems to be present, different approaches can be used in order to assess this subject. It is likely that the outcome of such assessment can differ among the MSs. Food which is acceptable in one country does not necessarily have to be acceptable in another one. One reason for possible variances might be the cultural background which shapes people's opinion on the issue of which kinds of food are acceptable for consumption.

5.4.4 Unfit vs. injurious to health – can food be both?

Article 14 (1) GFL puts a general ban on placing unsafe food on the market. In this context food is deemed to be unsafe if it is injurious to health or unfit for human consumption.[206] This concept of unsafety is indicated to be first and foremost based on the effect that the consumption of the food may have on human health,[207] although food is also deemed to be

[206] Article 14 (2) GFL.

[207] B. van der Meulen and A. Szajkowska, "The General Food Law: General Provisions of Food Law," in *Eu Food Law Handbook*, ed. B. van der Meulen (Wageningen, the Netherlands: Wageningen Academic Publishers, 2014), p. 255.

unsafe if it is unfit for human consumption. Within this paper several examples of unfit food are provided. But is only one classification applicable in each case, or can food be deemed to be injurious to health and unfit for human consumption at the same time?[208]

According to **most responses**, food can, indeed, be considered as injurious and unfit for human consumption at the same time. An indicated prerequisite is the fulfilment of the criteria for both concepts. This requires at least two different reasons, one which would cause the food to be unfit for human consumption and another which presents a hazard to human health.

An exception might be present in **Poland**. It seems that, according to the provisions in Act of 25th August 2006 on safety of food and nutrition, such a possibility is not given. The difference between injurious to health and unfit for human consumption is determined by the fact that the product can be classified as injurious to health when its normally specified consumption may cause – directly or indirectly – negative consequences for the human health or life. In turn, unfit for human consumption refers to foodstuff that demonstrates changes in composition or features caused at the production stage, market stage, or under the influence of natural factors like humidity, time, temperature, light, or due to the presence of the microorganisms and contaminations. No direct reference to the negative health consequences is made.

For **Germany** it is indicated that it is most likely that a decision for one of the two classifications has to be made. In this regard, the category of injurious to health would come first. As a consequence, even if the criteria for both concepts would be fulfilled, the product is likely to be considered only as injurious to health.[209]

This is similar in **Belgium**. It is indicated that usually, as soon as food is considered to be injurious to health, no assessment follows on whether the food would also be unfit for human consumption. The stricter criteria on injurious to health relates in this case to the issue of being unsafe.

For **the Netherlands** it is remarked that the attention mainly concentrates on the assessment of whether the FBO took sufficient corrective actions in cases in which a food was detected to be unsafe. The classification whether the food would be injurious to health or unfit for human consumption is of minor importance.

[208] Questions 1.4 and 9 in the questionnaire 'Unfit for human consumption'. See Appendix.

[209] According to Dannecker and Gorny 'injurious to health' and 'unfit for consumption' can be present cumulatively. A moulded food is, for instance, unfit for human consumption. If the mould leads also to a contamination with aflatoxins, the food becomes even (potentially) harmful to health. (Dannecker and Gorny, "Behr's Kommentar Zum Lebensmittelrecht: Kommentar Zum Lfgb Und Zu Weiteren Lebensmittel-, Bedarfsgegenstände- Und Futtermittelrechtlichen Vorschriften. Band 2," p. 4.).

5.5 Legal consequences in case food is deemed to be unfit for human consumption

The ban on unsafe food in Article 14 (1) GFL relates to placing unsafe food on the market. Placing on the market itself is defined as *'holding of food (…) for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves;'.*[210] But what happens if the FBO does place unsafe food on the market? Which measures are at issue in case of non-compliance with legal requirements? To answer these questions, a short introduction is given on possible measures if legal requirements in general are not satisfied. This is done from the viewpoint of enforcement authorities and from the position of the FBO. Secondly, in particular, the legal consequences which arise if unfit food has been placed on the market in the MSs will be addressed

In general, enforcement authorities have two options at their disposition in cases of non-compliance: measures to remedy non-compliance and measures to punish non-compliance. Often both can be taken.[211] In cases in which the competent authority identifies non-compliance, it must take measures to ensure its remedy. In the decision of which action should be taken, the authority must take account of the nature of the non-compliance and the operator's past record. The taken action can include the imposition of sanctions, a recall, withdrawal, or even a closure of all or part of the business concerned for an appropriate time.[212] In case of unfit food, public authorities may also inform the public. As it was judged by the European Court of Justice in the famous Berger Case,[213] the obligation in Article 10 GFL of public authorities to inform the public if food may present a risk to human health, does not prohibit the information of the public if food is just unfit for human consumption.[214] Consequently, the public may be informed in cases in which food is deemed to be unfit for human consumption.

Measures to punish non-compliance relate to measures that are taken in order to ensure the compliance with legal provisions. These sanctions have to be effective, proportionate, and dissuasive.[215] A common sanction is, for instance, the imposition of fines.

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[210] Article 3 (8) GFL.

[211] F. Andriessen, A. Szajkowska, and B. van der Meulen, "Public Powers: Official Controls, Enforcement and Incident Management," in *Eu Food Law Handbook*, ed. B. van der Meulen (Wageningen, The Netherlands: Wageningen Academic Publishers, 2014), p. 408.

[212] Article 54 Regulation 882/2004.

[213] On the 16th and 18t of January 2006 the Passau Veterinary Office in Germany carried out official controls in several establishments of the Berger Wild GmbH, a producer and distributer of game meat. The authorities found that hygiene conditions were lacking. Furthermore, samples of game meat were taken and analysed by the Bavarian Health and Food Safety Authority LGL. The result of the analyses revealed that the game meat was unfit for human consumption and therefore unsafe (Case C-636/11).

[214] Number 29 – 30 Case C-636/11.

[215] Article 55 Regulation 882/2004.

In cases in which the FBO itself considers or has reason to believe that its imported, produced, processed, manufactured, or distributed food is not in compliance with the food safety requirements,[216] [217] it is also required to take actions. These responsibilities are regulated in Article 19 GFL. According to these obligations, the FBO has, inter alia, to immediately initiate procedures to withdraw the concerned food from the market when it has already left the immediate control of that initial FBO. Furthermore, the FBO must inform the competent authority thereof. In case in which the product may have already reached the consumer, the FBO is required to effectively and accurately inform the consumer of the reasons for the initiated withdrawal. If necessary, the products must be recalled from consumers when other measures are not sufficient to achieve a high level of health protection.[218] Accordingly, the assumption is wrong that a recall is inevitable whenever food is considered to be unsafe.[219] This provision seems to be especially of interest with regard to the concept of unfit food. Due to the word 'necessary' and a reference to 'a high level of health protection', the impression arises that a recall of unfit food is not necessarily required. This begs for research on whether in the MSs recalls are initiated when food is considered to be unfit for human consumption. In this context, the last section of the survey addresses the question of which legal consequences follow in cases in which a food is deemed to be unfit for human consumption.[220]

The survey results of this section are presented in three clusters. The first cluster encompasses the MSs for which it is indicated that legal consequences (are likely to) differ, depending on whether the food is injurious to health or unfit. The second cluster includes the MSs for which it is indicated that no differentiation in this regard is likely, and the third cluster encompasses the countries in which no information on this issue is provided.

For the first cluster of MSs it is indicated that legal consequences (are likely to) differ, depending on whether the food which is placed on the market is injurious or unfit for human consumption.

One of these countries is **Cyprus**. If unfit food has not already entered the market and is still at the import, production, or wholesaler stage, placing it on the market is prohibited. In cases in which the food of question has already entered the market, the responsible FBO is obliged to withdraw the product from the market. Furthermore, actions against the legally responsible party are taken. This is done in form of an administrative fine or by initiating legal actions. A recall from consumers is only issued in cases in which the food is deemed to

[216] Article 19 (1) GFL.

[217] The heading of Article 14 is 'Food safety requirements'. The issue of unfit food is, inter alia, regulated in this Article.

[218] Article 19 (1) GFL.

[219] A. Natterer, "Country Reports: Austria; Practical Application of Art 14 (6) of Regulation (Ec) No. 178/2002 - Presumption of 'Unsafe Batches'," *EFFL* 3, no. 5 (2008): p. 341.

[220] Question 12 in the questionnaire 'Unfit for human consumption'. See Appendix.

be injurious to health or a product of fraudulent practice.[221] If the food is only unfit for human consumption, no recall is initiated unless the foodstuff is also a product of fraudulent practice.

Another difference within the legal consequences is also indicated with regard to fines. Although no generalization can be made, it is noted that usually imposed administrative fines or those imposed by the court, are higher in cases in which food is deemed to be injurious to health in comparison to unfit food.

Also in one response for the **Czech Republic** it is indicated that legislation allows the imposition of higher fines in cases in which the food is deemed to be injurious to health and not just unfit. However, in another response for the Czech Republic it is noted that in general no difference between legal consequences in case of injurious or unfit food is made but that this may depend on the individual non-compliance. In cases in which a food is deemed to be unfit for human consumption, the legal consequences can include withdrawals, recalls, and public information.

Sweden is a further country for which differences in the legal consequences have been indicated to be likely. However, this always depends on a case-by-case assessment. According to the response, the measures in cases in which unfit food has been placed on the market may differ in comparison to those which are taken when the food is considered to be injurious. The legal consequences[222] in cases of unfit food itself depend on different factors. Such parameters are, for instance, the seriousness of the breach of legislation and the earlier record of the FBO.

Within the response for **the Netherlands** the main focus was on the assessment of whether the actions taken by the FBO are effective in cases in which a food is deemed to be unsafe. A differentiation between the legal consequences for unfit or injurious food could, for instance, be made with regard to the notification of the competent authority. If the FBO does not notify the authority about a harmful food, a fine will be imposed. Provided that the food is just unfit, and the FBO failed to notify the authority, it might be the case that only a warning is issued. Consequently, specific legal consequences may differ depending on the nature of unsafe food in the Netherlands.

With regard to the issue of possible differences in the legal consequences for placing unfit or injurious food on the market, there are also some countries for which it is indicated that such distinction by law is absent

[221] Examples of recalls in which the food was not injurious to health but adulterated are, for instance, fake alcoholic drinks of unknown origin, foodstuff of which durability dates have been altered, or Extra virgin olive oil that was found to contain other oils at a substantial percentage.

[222] It has been indicated that no case was known by the participant in which food has been recalled which was not injurious to health.

One of these countries is **Belgium**. According to the response, this is caused by the fact that Belgian law does not provide a distinction between the legal consequences in cases in which food is unfit for human consumption and cases in which it is injurious to health. However, in practice, such a differentiation is still possible. For instance, smaller financial sanctions might be negotiated in cases in which the food is just unfit and not injurious to health. In the context of recalls, it is noted that room for interpretation is left in the Belgian legislation as to whether a recall is required if a food is unfit for human consumption but not injurious to health.

Also for **Estonia** it is indicated that, with regard to the legal consequences for placing unfit or injurious food on the market, no difference in the legal basis is made. This is due to the circumstance that the terms are not defined separately.[223]

The **United Kingdom** is a further country for which it is indicated that the legal consequences do not have to necessarily differ between those for unfit food and for injurious food that has been placed on the market. A key issue in this context is the culpability of the FBO. Such is, inter alia, taken into consideration when determining the intended enforcement action in cases of unfit food. The culpability influences, for instance, whether more than a recall will be required or if the FBO will even be prosecuted. Consequently, the taken action depends on the circumstances rather than on the reason why a product is unsafe.

The last cluster of MSs focuses on a general overview of the legal consequences indicated in cases in which unfit food is placed on the market. Whether these may differ compared to those for injurious food is not addressed.

The first country to which regard is taken in this context is **Poland**. For Poland it is indicated that the legal consequences for unfit food, in particular the production and placement of spoiled food on the market, are regulated. According to Polish legislation, the one who produces or markets spoiled or falsified food will be subject to a fine, imprisonment, or imprisonment for a year.[224] Furthermore, a fine will be imposed if foodstuff which is harmful to health or human life, spoiled, or adulterated is not withdrawn from the market.[225]

According to the reply for **Romania,** the commercialisation of unfit food can be classified as misdemeanour. This is regulated in different legislations to which various categories of food are subject. Also financial fines might be imposed. Furthermore, food which is not in compliance with legal requirements because it is unfit for human consumption can be destroyed by the competent authority.

[223] Estonian Food Act §-s 48, 48^1 and 49 contain provisions for non-compliant food.

[224] Article 97 (1) of Act of 25th August 2006 on safety of food and nutrition.

[225] Article 103 (1) point of Act of 25th August 2006 on safety of food and nutrition.

In the context of recalls, it is shown within this survey that in **Germany** unfit food is occasionally recalled. However, it is furthermore noted that the issuing of such a recall is dealt with differently among FBOs and the competent authorities.

6. Discussion & Conclusions

The concept 'unfit for human consumption' has been researched from different angles in the previous chapters. The topic was approached by two different methods. In the first part of this paper a rather theoretical overview of the unfitness concept was provided by means of literature study and legal analysis, followed by the primarily practice-oriented second part of the study that encompassed an EU-wide survey. The objective of this survey was to gain insight into how the concept 'unfit for human consumption' is applied and interpreted in several MSs of the EU. The main findings of this survey are discussed in the following subchapters. The research questions are also answered within a short summary and the limitations of this paper are presented. Finally, recommendations arising from the research are provided.

6.1 Discussion of the results

The EU-wide survey included several topics which relate to the concept 'unfit for human consumption'. Based on the responses of this survey, an overview of how the unfitness concept is interpreted and applied in practice on a national level in almost half of the MSs of the EU was acquired. Some of these subjects require special attention and need to be discussed in more detail. In particular, attention should be given to the national elaborations on the 'concept unfit for human consumption', the relationship between unfitness and injuriousness, and the indication whether the example cases are likely to be considered as unfit for human consumption. These are the topic areas which provide most substance for discussion and will be the focussed on in this chapter.

6.1.1 Discussion of the national elaborations on the concept 'unfit for human consumption'

First, it should be pointed out that independent of whether national elaboration on the unfitness concept is present or not, the survey results show similarities and differences in terms of how the concept is approached and which food is considered to be unfit for human consumption

Observed similarities are, for example, that almost all participants indicated that food can be deemed unfit for consumption and injurious at the same time under specific circumstances. Furthermore, the majority indicated that the decision of whether non-compliance with further legal requirements would cause a food to be unfit for consumption, would depend on a case-by-case assessment and on the legal requirement itself.

In addition to similarities in the application and interpretation of the concept on unfit food there are also differences. Such differences also occur among countries like **Belgium**, **Cyprus**, **Germany**, **Romania**, **Spain**, **Sweden**, **the Netherlands** and the **United Kingdom** that

do not have national elaboration in legislation on the unfitness concept.[226] This is remarkable because the survey participants, in particular from countries without national elaboration on the unfitness concept, based their responses on the same description of unfit food provided in Article 14 (5) GFL. Accordingly, the impression is strengthening that the description of the concept provides space for wide interpretation of which food may be considered unfit.

The differences in the understanding of which food is considered to be unfit for human consumption becomes visible particularly with regard to the provided example cases. This can be very well illustrated on the question of whether meat of an animal that has not been controlled before slaughtering is likely to be considered as unfit for human consumption. Whereas for Germany it is indicated that this meat is likely to be considered as unfit for human consumption, for Spain the indication is given that the meat is likely to be considered as a potential risk to human health and could also become an issue of food fraud, and for Sweden it is indicated that the decision whether the meat is unfit is likely to depend on a case-by-case assessment. Thus, although no additional criteria are provided within most national legislation, the assessment of which food is considered unfit for human consumption can still show differences.

There are also a few MSs for which elaboration on unfit food is indicated to be present in national legislation. These countries are **Croatia**, the **Czech Republic**, **Estonia**, **Finland** and **Poland**. Their national elaboration on food unfit for human consumption will be discussed in this subsection.

The attention to detail of the elaboration in **Croatian** food law[227] stands out from other national legislations. Whereas most of them do not really enhance the scope of unfit food, the number of criteria to determine if a food is unfit for human consumption is very high in Croatia. The explicit nature of the Croatian provisions is also characteristic. Whilst the concept of unfitness as described in the GFL is rather openly phrased, the related criteria are comparably specific in Croatian food law.

Besides criteria that are already part of those in the GFL, further criteria are provided in the Croatian Food Act. In general, the criteria can be divided into the categories harmful to human health, labelling requirements, organoleptic properties, and substances outside of the scope of the previous categories which can render food unfit for human consumption.

The first cluster, which relates to adverse health effects, includes food which is packaged in a packaging that releases harmful substances, food that contains vitamins and minerals in an amount that poses a risk to human health, and food which is subject to illegal ionizing, radiation, or other technological processes which can be harmful to health. Despite a direct

[226] Although national legislation may not further elaborate on the unfitness concept, there can be still guidance on the interpretation and application of the concept, as s for instance in the Netherlands (NVWA, "Meldwijzer - Onveilige Levensmiddelen.").

[227] Article 10 (3) of the Food Act (Official Gazette No 81/13, 14/14, 30/15).

reference to harmful effects on human health, these criteria are assigned to the concept of unfitness. This is out of the common because it is reasonable to expect that these criteria are linked to the concept of injuriousness. Especially given the fact that criteria to consider food as injurious to health are regulated in very detail in Croatian law,[228] it is not apparent why some criteria which relate to adverse health effects fall in the category of unfitness. An explanation for this allocation is not provided by law. Therefore, it stands to reason that these criteria should be assigned to those of injuriousness. Otherwise, the distinction between the concepts is less obvious.

The next cluster of criteria used to determine whether food is unfit for human consumption in Croatia concerns labeling issues. These issues include food which is expired, containing the label 'use by', non-compliance with designated particular nutritional uses, and provisions to label food as gluten free, allergen labelling, and GM foods.

The first labelling criteria concerning the 'use by' date is usually related to the overall element of safety in the EU, whereas the minimum durability date 'best before' relates to quality.[229] By classifying food as unfit which exceeds the 'use by' date, Croatian law narrows the broader dimension of unsafety down to unfitness. Although it might be arguable if – depending on the intensity of exceeding the 'use by' date – such food might even become a danger to human health[230] if it is still consumed. In comparison to Croatian law, in Denmark the Danish Veterinary and Food Administration gives the advice to make use of the 'use by' date on perishable foods, like meat and fish, because such food may pose a risk to human health after that date.[231] Accordingly, there are different viewpoints in the EU concerning whether food which has a 'use by' date that is expired is unsafe due to being unfit or due to being harmful to health.

The next criteria within the cluster of labelling are linked to the issue of allergens. Food containing allergens that are not labelled in accordance with specific regulations are considered to be unfit for human consumption. On the EU-level the labelling of foodstuff is regulated in Regulation 1169/2011. All fourteen allergens listed within this regulation have to be labelled in a specific manner if they are contained. These allergens include gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame seeds, sulphur dioxide and sulphites, lupin, and molluscs.[232] These allergens only pose a safety risk to people who are allergic to them. Consumers who are not allergic to these substances can consume them without expecting harmful health effects. Bearing this in mind, it seems as if Croatian law steers a middle way in the legal assessment of insufficient allergen labeling because food which contains allergens that are not labeled is not injurious for every

[228] Article 10 (2) of the Food Act (Official Gazette No 81/13, 14/14, 30/15).

[229] C. Finardi and L.G. Vaqué, "European Food (Mis)Information to Consumers: Do Safety Risks Lie Just around the Corner?," *EFFL* 10, no. 2 (2015): p. 101.

[230] See Article 24 (1) Regulation 1169/2011.

[231] H. Møller et al., "Date Labelling in the Nordic Countries - Practice of Legislation," (Copenhagen, Denmark: Nordic Council of Ministers, 2014), p. 18. As availabe on the internet at http://norden.diva-portal.org/smash/get/diva2:790885/FULLTEXT01.pdf.

[232] The complete list of allergens is provided in Annex II Regulation 1169/2011.

consumer and only poses a health risk to allergic people. However, if the food is specifically produced and designated for a food allergic consumer group, this is a different issue. In this case, the sensitivities of the target group should be taken into account in the assessment of determining whether a food is injurious to health.[233] The GFL guidance document of the SCFCAH provides the example that food which is unintentionally cross-contaminated with nuts shall be considered as injurious to health if it is advertised for a nut-free diet.[234] In contrast, Croatian food law takes the approach that food which is labeled as 'gluten free' and as such designated for a specific consumer group, would be unfit for human consumption if is not complying with the required provisions[235]. One might ask why this criterion only relates to food labelled as 'gluten free' and why such food is not deemed to be injurious to health. The answer may lie within the growth of the 'gluten free' food industry and the increasing popularity of gluten-free products.[236] It might be argued that this food trend is not based on an actual allergy of consumers and relates more to a temporary fashion. However, considering that people who actually suffer from a gluten allergy belong to the targeted consumer group, the categorization as injurious to health should be applied.

The last criterion which relates to labeling requirements concerns GM foods. If food contains and/or consists or originates from approved genetically modified organisms in which a technological contamination is proven above 0.9%, this presence has to be labelled. In cases in which such labelling is absent, the food is deemed to be unfit for human consumption – although the genetically modified organism is approved. The outcome of this approval for GM food is only positive if, among other criteria, adverse effects on human health are absent.[237] Accordingly, from this viewpoint, the food would be considered as safe. Based on Croatian food law, however, the food may nevertheless be regarded as unsafe due to being unfit for human consumption if it is not labelled that the food contains and/or consists of or originates from approved genetically modified organisms in which a technological contamination is proven above 0.9%.

Whereas the first two clusters of national criteria in Croatia mainly enhanced the scope of unfit food and add new criteria to those laid down in Article 14 (5) GFL, the third cluster does not. The subject of these criteria is the organoleptic properties of food. According to Croatian legislation, foodstuff becomes unfit if it is not acceptable to human consumption due to altered properties including taste, smell, decay, deterioration, and decomposition. The listed elements, and especially the reference to unacceptability, are already part of the unfitness concept in the GFL and the related guidance document. Thus, this criterion of altered properties does not add new aspects to the concept of unfitness.

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[233] Article 14 (4) (c) GFL.

[234] SCFCAH, "Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (Ec) No 178/2002 on General Food Law," p. 9.

[235] This is the case if the 'gluten free' labeled food still contains gluten in an amount that exceeds the permitted limit according to specific regulation.

[236] N.R. Reilly, "The Gluten-Free Diet: Recognizing Fact, Fiction, and Fad," *The Journal of Pediatrics* 175 (2016): p. 206.

[237] Article 4 (1) (a) Regulation 1829/2003.

The last cluster, which can be summarized as substances outside the scope of the previous categories, relates to already known criteria such as contamination with foreign objects, but it also adds new factors. These additional criteria concern food additives that do not meet the criteria of purity and food that contains other substances above the permitted maximum level as regulated in specific regulations. The latter is correspondent with the indication that food would be considered as unfit for consumption if it contains pesticides above the MRL in the context of the provided example cases.[238]

Taking all these different (clusters of) criteria into account, it can be summarized that Croatian law provides a high number of criteria by which food can be deemed unfit for consumption. This fact supports and illustrates very well the thesis that the criteria provided in Article 14 (5) GFL are not necessarily the only ones which can be used to determine if food is unfit for human consumption.[239]

A further country for which national elaboration on the concept 'unfit for human consumption' is indicated is the **Czech Republic**. It represents the only MS with more than one participant in the EU-wide survey. The responses of the participants, however, show differences, in particular with regard to the indication of national elaboration on the unfitness concept but also concerning the assessment of the example cases.

According to one out of the three participants, national elaboration on the concept 'unfit for human consumption' is present in Czech legislation. A plausible reasoning for the different responses appears to be the fact that the term 'unfit for human consumption' itself is not used within the indicated elaboration. Subject to this elaboration is food which is not in compliance with the obligations of the FBO[240] and the requirements to place food on the market.[241] These provisions encompass, in summary, food which is packed in packages which are not in compliance with applicable EU regulations; insufficient, misleading or incorrect labelling; non-compliance with quality requirements specified by legislation or declared by the producer, and smelly food. Furthermore, food exceeding the 'use by' date,[242] of unknown origin, or food exceeding the maximum permitted level of contamination with radionuclides and irradiated in contravention of the legislative requirements is listed. According to the provided response, these aspects influence whether the food is determined to be unfit for human consumption. These provisions mainly refer to new factors which are not included within the description of unfit food in Article 14 (5) GFL. An exception is smelly food if the smell is not a characteristic element of the product itself. Although it has been

[238] See chapter 5.4.1.3.1.

[239] Rathke and Sosnitza, "Zipfel / Rathke: Lebensmittelrecht - Loseblatt-Kommentar Aller Wesentlichen Vorschriften Für Das Herstellen Und Inverkehrbringen Von Lebensmitteln, Futtermitteln, Kosmetischen Mitteln, Sonstigen Bedarfsgegenständen Sowie Tabakerzeugnissen, Band 2," p. 16.

[240] Section 3 of Act No 110/1997 on foodstuffs and tobacco products.

[241] Section 10 of Act No 110/1997 on foodstuffs and tobacco products.

[242] Also within the Croatian Food Act food exceeding the 'use by' date is indicated to be unfit for human consumption.

phrased in a different manner, namely as an unacceptable odour, this factor is already listed in the elaboration of the unfitness concept in the SCFCAH guidance document.[243]

Estonia is a further country in which aspects of the concept about unfit food are addressed in national legislation. These are included in the general requirements on food in § 12 of the Food Act. Criteria which relate to the concept of unfitness are, for instance, the absence of parasites, pests and foreign objects that harm the properties of the food, the prohibition to handle food which is spoiled, contaminated, in non-compliance with microbiological requirements, or food with an abbreviated odour, flavour or other circumstances that are not characteristic for the food. Whether other contained elements are linked to the unfitness of food is not clear from the paragraph because all contained provisions are summarized under the term 'general requirements'. Accordingly, only the aspects which are already part of the GFL concept can be clearly associated with this concept.

Whereas for the previous countries elaboration on the concept 'unfit for human consumption' is indicated, elaboration on the fitness for consumption is provided in **Finland**. The Food Act (23/2006) includes the element of 'fit for human consumption' within the general requirements concerning food in Section 7: *'Food must be fit for human consumption in terms of its chemical, physical, microbiological and health-related quality and composition and other properties, and must not present any hazard to human health or mislead the consumer. Provisions on general requirements for food safety are also laid down in Article 14 of the General Food Regulation and in Article 4 of the General Food Hygiene Regulation.'*[244] Although the fitness of food does not necessarily have to be the counterpart of the GFL concept 'unfit for human consumption', it still gives an idea of the factors which have to be fulfilled in order to ensure that food is fit for human consumption.

Following from the phrasing of the definition of food fit for human consumption, there are two different possible sets of factors used to define fit food. The first includes the absence of adverse health effects and misdirection, whereas the second refers to fitness, adverse health effects, and misdirection as independent elements. In case of the first approach 'fit for human consumption' is likely to be used as an overarching expression based on the common understanding that harmful food is unsuitable for consumption. However, a distinction between fitness for human consumption, injuriousness, and misdirection is more likely. An indicator for this possible separation is the phrasing of the sentence. The only time a comma is used before 'and' is in front of the statement that food must not present any hazard to human health, whereas no punctuation character is used before 'and' in the beginning of referencing to the aspects of a food's fitness. Thus, it appears that the absence of adverse health effects and misdirection are not included within the meaning of a food's fitness. As a result, only the criteria of chemical, physical, microbiological, and health-related

[243] SCFCAH, "Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (Ec) No 178/2002 on General Food Law," p. 9.

[244] Translation provided within in the context of the survey.

quality, composition and other properties are likely to address the fitness of food. In particular, 'health-related quality' is an interesting element of this fitness. Given the fact that the general requirements already require food not to present any hazard to human health, it can be argued that the term 'health-related quality' describes a separate criterion apart from adverse health effects. The exact meaning of this term is not explained. The term might refer to the support of health preservation by providing, for instance, nutrients, minerals or vitamins which are essential for human wellbeing. However, in the context of the relationship between personal health and food,[245] the individual diet is of great significance Consequently, the assessment of health-related quality might become challenging.

In comparison to most of the previous MSs, no new aspects of a food's unfitness for human consumption are added within national food law in **Poland**. Polish law explicitly addresses spoiled food as an element of unfit food. Its elaboration shows mainly similarities to the definition of the concept according to the GFL. In its essence, spoiled food relates to an irregular composition or properties of food, the presence of microorganisms and contamination. The key element of unacceptability to the consumer is not mentioned.

In summary, it can be concluded that the scope and extent of national elaboration on the concept 'unfit for human consumption' differs among the legislation of the MSs. These national elaborations often include criteria which are already addressed within Article 14 (5) GFL but also introduce new factors to determine if food is unfit for human consumption. These additional criteria relate, among other things, to labelling issues or even harmful effects to health.

6.1.2 Discussion of a relationship between unfitness and adverse health effects

The possible relationship between adverse health effects and unfitness requires special attention. Given the point that, within some former food laws, injurious food was considered to be unfit for consumption, the current presence of criteria linked to adverse health effects in the Croatian elaboration on unfitness and the indication that – *per se* – injurious food is considered to be unfit for human consumption in Belgium,[246] the relationship of unfitness and harmfulness begs for discussion.

[245] Although the consumption of unhealthy food may lead to health problems, it has been noted within literature that the scope of the food safety requirements in Article 14 GFL can hardly be extended to encompass 'unhealthy' food in general (A. Faeh, "Obesity in Europe: The Strategy of the European Union from a Public Health Law Perspective," *European Journal of Health Law* 19, no. 1 (2012): p. 77.).

[246] Similar approaches have been noted during the survey. Although food injurious to human health was not directly used as a criterion to deem food unfit within food law, it was sometimes remarked that food which is injurious to human health could generally be regarded as unfit for human consumption. This correlation of the two concepts arises from the underlying understanding that food which is harmful to health is also unfit for human consumption.

Within this survey there are two countries for which it is indicated that the former national concept of unfitness included food that was considered injurious. These countries are **Finland** and **Sweden**.

In **Finland** food was considered unfit for human consumption if it was harmful to health. In this specific case, 'unfit for human consumption' was used as an overarching expression which included (a) food injurious to human health and (b) food which was not acceptable for human consumption due to, for instance, spoilage, contamination, impurities, process errors, or foul smell or taste. These unacceptable parameters caused food not to meet the criteria of acceptable composition, authenticity, quality or other characteristics that were expected of the food.[247] This former understanding of unfit food is, to a certain extent, comparable to the overarching term 'unsafe' which is used in the GFL.[248] Indicators of the similarities of the two terms are, for example, the related subcategories of food harmful to health – comparable to Article 14 (2) (a) GFL – and the described criteria of the second subcategory which are also part of the current concept 'unfit for human consumption' in Article 14 (2) (b) GFL. The second former subcategory seems to be comparable to the current concept of unfitness because it refers to the key element of unacceptability which renders food unfit for consumption.

Also in former **Swedish** food law, it seems that food injurious to health was considered as unfit for human consumption. According to the national Food Act – Livsmedelslagen SFS 1971:511 – *'Food that is offered for sale may not be of such a composition or quality and other respects, that it can be assumed to be harmful to consume, a carrier of infection or otherwise unfit for human consumption'.*[249] The term 'otherwise' gives the impression that food which was injurious to health was considered to be unfit for human consumption.

However, in national food legislation, although injuriousness is indicated to have been an element of former unfit concepts, unfitness in general was mainly linked to major quality shortcomings. But how is the relationship between unfitness and injuriousness in the GFL? The results of the survey call for discussion of this topic.

The description of the unfitness concept in Article 14 (5) GFL itself does not provide a direct reference to adverse health effects, but a possible connection is indicated in the GFL guidance document. According to this guideline *'(…) some food may not pose a risk to health at all, but will still qualify as unfit (…).*[250] This sentence gives the impression that injurious food is also unfit within the meaning of the concept 'unfit for human consumption'. If this is so, it might have been appropriate to use the expression 'otherwise unfit for human

[247] Food Act 1995 (361/1995).

[248] Article 14 (2) GFL.

[249] § 5 SFS 1971:511.

[250] SCFCAH, "Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (Ec) No 178/2002 on General Food Law," p. 10.

consumption' in Article 14 (2) (b) as it would clearly emphasize this relationship. Otherwise, both concepts seem to be independent categories under the definition of unsafe food.

However, although there is no elaboration given in the guideline why injurious food still qualifies as unfit, there are different approaches that can explain this possible relationship. The first one relates to the factor of contamination, which is used in the explanation of unfitness in Article 14 (5) GFL.[251] If such contamination is solely understood as the introduction of a hazard,[252] a reference to injurious food as unfit can be explained. This is due to the fact that a hazard has the potential to cause an adverse health effect.[253] Therefore, a food which is injurious to health would also meet the definition of unfit food.

Secondly, it can be argued that unacceptability as a key element in Article 14 (5) GFL might cause injurious food to be regarded as unfit. This is based on the hypothesis and common understanding that injurious food is always unacceptable to the consumer. The third and last explanation for the possible overlap between injurious and unfit food might trace back to the use of the term 'unfit for human consumption' as an overarching expression (see figure 3).

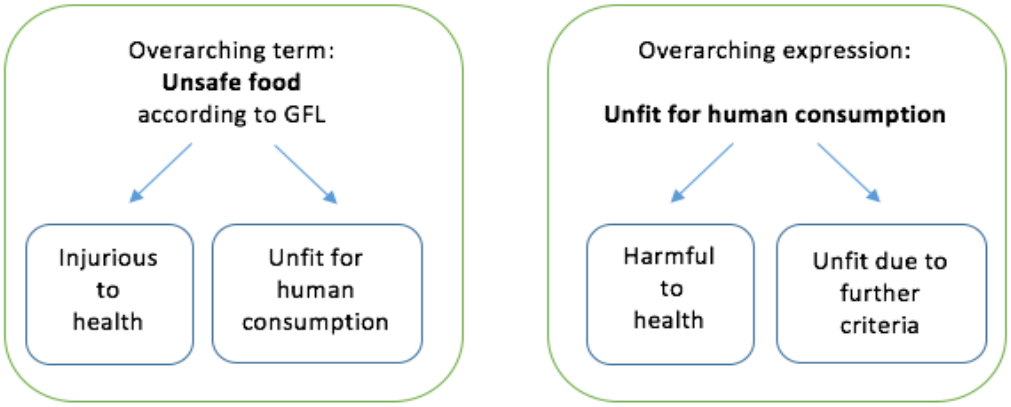

Figure 3: The use of 'unfit for human consumption' in different contexts

When the term 'unfit for human consumption' is used as an overarching expression, its scope goes beyond the criteria laid down in Article 14 (5) GFL. Generally speaking, all food which is harmful to human health or not in compliance with further criteria that are associated with unfitness of food, such as serious quality shortcomings including decay or deterioration, could be considered as unfit for human consumption. This understanding is similar to the definition of 'Unfit Foodstuff' in Cyprus food law, which should not be mistaken with the GFL concept of unfitness.[254] 'Unfit Foodstuff' encompasses food that contains any hazardous or poisonous substance which renders it injurious to health; that consists of any polluted, putrescent, infectious or repulsive substance; which is unfit;

[251] See also chapter 4.1.3.

[252] As defined in Article 2 (f) Regulation 852/2004.

[253] Article 3 (14) GFL.

[254] Article 6 of the Food (Control and Sale) Law.

adulterated or is assigned to unhygienic conditions. Thus, the scope of 'Unfit foodstuff' is quite comprehensive and is used as an overarching expression for a broad variety of faults in relation to food. In this case, it appears that the term 'unfit' is used as an overarching expression for a variety of major shortcomings related to food.

That the GFL concept of unfitness also includes injurious food does not clearly follow from Article 14 GFL. As already outlined, there are arguments for both sides: whereas from the common understanding of unfitness for consumption the inclusion of injurious food under the scope of unfitness is reasonable, the framing and phrasing in particular Article 14 (2) GFL give a different impression.

6.1.3 Discussion of the example cases

The last elements to be discussed in this section are the example cases introduced in chapter 5.4.1.3, which address the following subjects:

- The food contains pesticides above the MRL
- Traceability of a food is not provided
- Horse meat is sold as beef
- An animal to be used for meat has not been controlled before slaughtering

For all four cases no common determination among the MSs is present as to whether the food is likely to be considered as unfit or not. Nevertheless, some trends can be observed. Based on these trends it can be to a certain extent extrapolated whether the example cases tend to be within or outside the scope of the concept 'unfit for human consumption'. Therefore, the results of each example case are shortly discussed here, followed by an outline of the observed trends. Afterwards, the results in general are discussed independent from specific example cases.

The subject of the first example case is food that contains pesticides above the MRL. This is the only example for which no direct indication is given that the concerned food would not be unfit for human consumption. This does not, however, imply that such food would always be considered as unfit. The final decision depends mainly on a case-by-case assessment, followed by the indication that the food is likely to be unfit for consumption. In the context of factors that determine the assessment of unfitness, the participants for Cyprus, Poland and the Netherlands highlighted that the relation to possible harmfulness is of relevance. If the product does not become injurious to health due to exceeding the MRL, it is likely to be classified as unfit. In particularly for the Netherlands it is explained that the food is considered to be unfit if the exceedance of the MRL is below the ARfD. In this context the ARfD marks the limit from which the food is assessed to be harmful to health. On which variables the case-by-case assessment in Belgium, Finland, Sweden and the United Kingdom depends is not provided in the survey. It might be the case that the same or a similar approach is applied, but other aspects could be of relevance.

In summary, based on the trend of the replies, the impression is given that food which contains pesticides above the MRL tends to be within the scope of the concept 'unfit for human consumption'. The indicated restricting factor is a possible harmfulness originating from the exceedance of the MRL. Further limitations have not been explicitly named but might be present.

A different trend is shown in the case of food for which no traceability is provided. It is indicated that such food is not likely to be considered as unfit for human consumption or that this determination would depend on a case-by-case assessment. Only for Estonia it is noted that the food is likely to be considered as unfit. Although this information is also provided by one of the participants for the Czech Republic, it would be short sighted to draw the conclusion that such food is likely to be considered as unfit in the Czech Republic. The reason for this is the indicated opposite by another participant of the Czech Republic according to whom an assessment as unfit for consumption is not likely.

Therefore, based on survey responses, absent traceability of food tends to be outside the scope of the unfitness concept from the viewpoint of the participants.

For the third example case the addressees of the survey were requested to give their opinion on whether horse meet sold as beef is likely to be considered unfit for human consumption. Based on the majority of the replies this case is not subject to the unfitness concept and relates instead to food fraud. However, there are also a few replies according to which the meat is likely to be considered as unfit or at least may be deemed unfit depending on a case-by-case assessment.

In general, this example case is indicated to be subject to another non-compliance with legal requirements, specifically food fraud. Therefore, based on the survey results, horse meat sold as beef tends to be outside the scope of unfit food.

In comparison to the previous example case, meat of an animal that has not been controlled before slaughtering is mainly assessed to be unfit for human consumption. Although there are two indications that the meat is unlikely to be considered as unfit, the trend follows another direction. Meat of an animal without ante-mortem inspection tends to be within the scope of the concept 'unfit for human consumption' according to the opinion of most participants.

In view of the responses for the four example cases, it is often indicated that the final determination of whether a food is unfit for consumption depends on a case-by-case assessment. This recurring annotation shows that the concept 'unfit for human consumption' may not always be of a simple nature. Specific and sometimes complex cases require an in-depth analysis to decide if the food of concern would be indeed unfit for human consumption. It is also remarkable that opposing standpoints are present. Whereas for some countries the indication is given that the food might be regarded as unfit for human consumption, other participants note that this classification is unlikely.

Consequently, one might ask why and how such impressive difference among the answers can arise. There are probably several reasons for this inconsistency. Firstly, the example cases are very briefly defined, and no background information is provided. As a result, some participants might base their decision on non-stated details, which they associate with the example case. Secondly, although Article 14 (5) GFL defines criteria to which regard shall be given when determining whether a food is unfit for human consumption, additional national criteria might be existent upon this subject. Based on these additional national criteria, the example cases might be rendered unfit for human consumption. This can be illustrated on the example of food which contains pesticides above the MRL. According to the guidance document of the Dutch NVWA, fruits and vegetables are considered to be unfit for human consumption if the MRL for pesticide residues is exceeded but still below the ARfD.[255] Hence, the guideline already supports the determination in the Netherlands as to whether such food would be considered as unfit. In other countries such specific guidance on the MRL may not exist; therefore, the participants were required to indicate which decision was most likely without additional supporting material. Another reason for the contradictory responses might be related to the key element of 'unacceptability' of the concept 'unfit for human consumption'. It might be the case that in some countries the provided example of food is still assessed to be acceptable to the consumer, whereas it is not according to the viewpoint of the participant from another MS.

Given these points, it would have been recommendable to request that the participants elaborate on their opinions. This way the exact reason behind the position taken would have been known. Furthermore, it would have been of value to know how the food would be classified instead. These elements would have provided a better insight on the reasons why a food has been assed as unfit or not by the participants. Nevertheless, the objective to receive a first insight into the interpretation and application of the concept 'unfit for human consumption' in several MSs of the EU is supported by the survey.

6.2 Summary

The objective of the study was to provide an overview of the interpretation and application of the concept 'unfit for human consumption' in the EU and its MSs. For this purpose, the main research question "**How is the concept of 'unfit for human consumption' interpreted and applied in the Member States of the European Union?"** was addressed in this paper. In order to facilitate the answer to this main research question, a literature and legal analysis was carried out and an EU-wide survey initiated. Participants of the survey were authorities and ministries in the field of food safety and experts on food law. Based on their replies, detailed knowledge about the concept 'unfit for human consumption' in 13 MSs was gained. Countries represented in the survey are Belgium, Croatia, Cyprus, the Czech Republic, Estonia, Finland, Germany, Poland, Romania, Spain, Sweden, the Netherlands and the United

[255] NVWA, "Meldwijzer - Onveilige Levensmiddelen."

Kingdom. The main findings of the study are grouped around the five sub-research questions that were formulated at the beginning of this paper and which answer the main research question.

1. What is the intention of the concept *'unfit for human consumption'*?

The concept 'unfit for human consumption' is part of the food safety requirements as laid down in Article 14 (2) (b) GFL. Food that is unfit for human consumption is deemed to be unsafe and is not allowed to be placed on the market. The general principle of banning unsafe food from the market was already included in the legislation of several MSs before the GFL was drafted. However, this was not applicable to all countries. Furthermore, no common definition of (un)safe food was present. Therefore, the European Commission decided to fill this gap by prohibiting the placement of unsafe food on the market in the common GFL and by defining the parameters of unfit food. The intention to incorporate the unfitness of food as one element of unsafe food was due to the fact that it may be almost impossible to prove that a certain food is injurious or even probably injurious. By implementing the concept 'unfit for human consumption' within the meaning of unsafe food such cases would be covered and consequently such foods would be banned from the market.

However, in the famous Berger case the European Court of Justice, as the highest legal instance in the EU, ruled that food can be unsafe even if it is certainly not injurious to health. Consequently, the impression is given that the actual application of the concept goes further than the initial intention for including the unfitness concept in the category of unsafe food. Given the current application of the concept, the subject of unfit food is also related to the issue of quality and consumers' interest, which is often referred to in the context of unfit food. From this perspective the application of the concept 'unfit for human consumption' can also be regarded as a protection of the consumers' interest. This interest is protected by banning food from the market which does not comply with the quality that can be reasonably expected by the consumer

2. How is *'unfit for human consumption'* defined in the MSs of the EU?

The concept 'unfit for human consumption' is described in Article 14 (5) GFL. The Article states that *'In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay'.* This concept, as laid down in the GFL, is subject of food law in every country which is part of the EU. This is due to direct application of the GFL which arises from its legal status as a regulation. However, the description of this common concept is rather openly phrased and provides the opportunity to consider further criteria to deem a food unfit for human consumption. These further criteria can, inter alia, be present within national food law as shown by the results of the EU-wide survey. According to the

survey results, national food law of several MSs elaborates on this concept or includes elements that relate to the unfitness of food. Such elaboration or related elements are indicated to be present in national food law of Croatia, Estonia, Finland (description of the requirements to be fit for human consumption) and Poland. The scope of this elaboration differs among MSs. The main categories referred to in the survey are insufficient hygiene, appearance, organoleptic properties, contamination and non-compliance with specific legal requirements like the ante-mortem inspection in the meat production or legal limits like the MRLs for pesticides in food. In some MSs the national elaboration includes additional criteria to those included within the definition of unfit food in the GFL. These additional criteria relate, for instance, to labelling issues or even harmful effects to health. The specific national elaborations and definitions of the concept 'unfit for human consumption' are presented in chapter 5.2.1.1.

3. How is unacceptability defined in the MSs of the EU? Are there differences in the understanding of this concept?

Unacceptability constitutes a key element of the concept 'unfit for human consumption'. To put it quite simple: food is unfit for human consumption if it is unacceptable to be consumed according to its intended use. However, this definition of the unfitness of food is rather subjective. A national definition or guidance document as to how to define if food is unacceptable seems not to be present within the MSs. Whether a food might be unfit for human consumption due to unacceptability is usually determined in a case-by-case assessment in the countries. Parameters for this assessment are, for instance, visual observations, laboratory tests, or references to court cases (see chapter 5.4.3). For Germany, the average consumer model has also been indicated to be of use in the determination of whether a food might be unacceptable to the consumer. However, since unacceptability is of subjective nature, the outcome of these assessments is likely to show variances in and among MSs. Food that is acceptable in one country does not necessarily have to be acceptable within another. It is indicated that one reason for these possible differences lies within the cultural background which influences the understanding of which food is (un)acceptable and therefore unfit for human consumption.

4. What are examples of food *'unfit for human consumption'* in the MSs of the EU?

As described in chapter 5.4.1, there are several examples of food which is considered to be unfit for human consumption in the MSs. Some of these relate, inter alia, to issues of contamination, insufficient hygiene or organoleptic properties. Examples of contamination are present in Finland, where the contamination by non-pathogenic microorganisms or insects caused food to be deemed unfit for human consumption. Insufficient hygiene, on the other hand, rendered meat to become unfit for human consumption in Spain. Also, inadequate storage conditions caused the unfitness of wheat in Romania. Further parameters relate to the unacceptable changes of organoleptic properties. For instance, in

the Netherlands bread is considered to be unfit for human consumption if during the production process too much salt is added. A further example can be found in the Czech Republic, where the unusual smell and taste of a peeled organic buckwheat product led to its general classification as unsafe. These cases are only a few examples of food which is deemed to be unfit for human consumption in the MSs. They show how the concept of 'unfit for human consumption' is applied and converted into practice within the MSs of the EU.

5. Is food deemed to be unfit for human consumption if it does not comply with further legislative requirements?

Whether food is deemed to be unfit for human consumption if it does not comply with legislative requirements mainly depends on a case-by-case assessment and on the legal requirement itself (see chapter 5.4.2). Legal requirements are present for various aspects of food law. For instance, even the font size of particularly labelling requirements is regulated in Regulation 1169/2011. If this provision is not fulfilled, the food itself would still be considered as fit for human consumption. There are, however, also indications that in cases of non-compliance with specific legal requirements the food might be considered as unfit. For instance, in the Netherlands fruits and vegetables are deemed to be unfit for human consumption if the present level of pesticide residues exceeds the legal limit of the MRL but not the ARfD.

6.3 Limitations of the study

The approach and findings of this paper face certain limitations. Firstly, the study of the concept 'unfit for human consumption' was, inter alia, motivated by to its open-phrased definition and 'mystifying' character. Consequently, the research was limited by the limited literature on relevant aspects of the unfitness concept. Although unfit food is subject to scientific literature and case law, these documents often do not address sufficiently the topics which have been of importance for this paper. Examples are the initial and current purpose of the concept of unfit food and the relationship between unfitness and injuriousness. Therefore, it was often necessary to hypothesize based on available information. Although these theories are well-founded, it should be born in mind that they are nevertheless only hypotheses.

In order to overcome the gap of limited relevant literature, an EU-wide survey was initiated. The objective of this survey was to research how the concept 'unfit for human consumption' is interpreted and applied in the MSs of the EU. Although for almost half of the countries surveyed responses were received, it cannot be neglected that for 15 out of 28 MSs no information about the application of the unfitness concept is provided. Therefore, the results of the survey reflect only on a fraction of the EU. With regard to the MSs for which information is provided, it must be considered that usually only one participant was approached for each MS. If further authorities, ministries, or food law experts of a country

would have been addressed, a more diverse insight about the concept of unfitness for each MS might have been acquired. Therefore, the indications about the interpretation and application of the concept of unfit food in the MSs may not be representative of the whole country and may only represent the viewpoint of one participant. In this context, the example of the Czech Republic shows very well that different points of view can be present. Generally, it should also be noted that only three target groups[256] have been invited to participate in the survey about the concept 'unfit for human consumption', whereas, for instance, FBOs have not been addressed within this survey.

Further limitations of the study lie within the questionnaire itself. The questionnaire was developed to be used primarily in personal interviews in which a more vivid exchange of information on the concept 'unfit for human consumption' would have included the opportunity to ask follow-up questions or to clarify subjects if required. However, personal interviews were the minority and most respondents responded in written form.

Independent of the form of correspondence, there is also the risk that due to language issues questions and replies have been understood differently than intended. Therefore, this paper provides only a first insight on the national interpretation and application of unfitness concept in several MSs.

6.4 Conclusions

The research on the national interpretation and application of the concept 'unfit for human consumption' shows that the criteria to deem food unfit are assessed differently in the European MSs. To meet the goal of establishing one common concept on food 'unfit for human consumption' it will be necessary to take effective measures in order to facilitate one harmonized approach to determine if food is unfit for human consumption. It is advised that the concept of unfitness should be revised and redefined. On the basis of this study, a three step approach is recommended: renaming of the current terms in Article 14 (1) and (2) GFL, redefining the current concept 'unfit for human consumption' in Article 14 (5) GFL, and revising the guidance on the concept itself. Details on this revision are provided below.

6.4.1 Relevance of the unfitness concept

Given its status as a core of food law, Article 14 GFL is of major importance within EU food legislation. Changes should only be made in this article if the objectives for such changes are relevant. Therefore, this subchapter focuses on the central question of why one harmonized approach to deem food unfit for human consumption in the EU is required. Attention is given to the position of the internal market, food safety and the subsidiarity principle.

[256] Addressees of this survey have been ministries and authorities involved in the issue of food safety, country correspondents of the law journal EFFL, and further national experts on food law.

As highlighted in the beginning of this paper, the GFL seeks to harmonize general food law principles and requirements in the EU. To reach this objective, it aims to establish common definitions, comprehensive guiding principles, and legitimate objectives for food law, resulting in a high level of protection of human health but also in an effective internal market.[257] The facilitation of one internal market is a main objective of the EU. From the very beginning of the formation of the European Community in 1958, to the mid 1990s, European food legislation was driven by the objective of reducing trade barriers and establishing one integrated internal food market.[258] This desired free movement of food within the internal market can be achieved if harmonization of legislation is completed. Uniform application of food law provisions among the MSs is crucial. The principle of mutual recognition completes the full free movement of food within the EU.[259] Although the last decades have been characterized by increasing legislative efforts to harmonize European food legislation, the interpretation and application of the legislation is still not consistent among MSs.[260] The present study on the concept of unfitness confirms this finding. As shown by the results of the EU-wide survey, there are still differences in the application of the concept of food unfit for human consumption. The results indicate that it is likely that specific food would be deemed to be unfit within one MS, whereas it would be considered fit for consumption in another. Accordingly, the crucial factor of harmonized interpretation and application of central elements to ensure the effective functioning of the internal market is not entirely provided. Given that the creation of one internal market was the mainspring for the establishment of the European Community and Union, action should be taken. So far, there are no indications that different understandings of unfit food has led to an actual barrier to trade within the EU. Consequently, the issue may not seem to be urgent, but the risk of a future barrier to trade requires attention and should not be neglected.

The main reason to take action in regard to a consistent definition of unfit food is the relationship between unfit food and unsafe food. Ensuring food safety is the core element of European food law. This central focus arose due to various food crises in the 1990s which the EU had to face. As a consequence, the focus of EU food law shifted from the functioning of the internal market to food safety. The vision to reform EU food safety law was introduced by the White Paper on Food Safety.[261] It was accompanied by the need to *'(…) re-establish public confidence in its food supply.'*[262], which loss was caused due to various food crises. Food safety requirements have become the central element of the GFL as the centerpiece of EU food law. Its implementation supports food safety as well as the

[257] SCFCAH, *Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on General Food Law* (2010), p. 4.

[258] S. Hoffmann and W. Harder, "Food Safety and Risk Governance in Globalized Markets," *Health Matrix: Journal of Law-Medicine* 20, no. 1 (2010): p. 30.

[259] K.M. Terlicka and D.J. Jukes, "From Harmonization to Better, Smart and Fit Food Law," 5 (2014): p. 312.

[260] *ibid*.

[261] S. Hoffmann and W. Harder, "Food Safety and Risk Governance in Globalized Markets," *Health Matrix: Journal of Law-Medicine* 20, no. 1 (2010): p. 33.

[262] COM (1999) 719 final, "White Paper on Food Safety," (Brussels, Belgium12.01.2000), supranote 7.

harmonization of EU food law to facilitate the functioning of the internal market. Although the foundation to meet these major objectives is given, the implementation needs improvement. The different application of the unsafety concept due to different understandings of unfit food is only one example. Critical evaluators may even argue that such discrepancies detract from progress toward the main objectives and jeopardize consumers' trust in EU legal framework on food safety. If the understanding of food unfit for human consumption can differ among MSs, this leads to different levels of food safety in the EU. Is it possible to justify the fact that food is unfit and therefore unsafe for consumers in one MS but fit for consumption and safe for consumers in another MS?[263] Should not the same level of food safety apply throughout the EU? If unsafe food and unfitness were separate elements, the different understanding of unfitness would not influence the formal level of food safety throughout the EU. In contrast to the food laws in the EU, the internationally recognized Codex Alimentarius differentiates between food safety and food suitability.[264] For example, given their history as traditional dishes some food may be considered suitable for consumption in one country whereas due to the missing traditional consumption, suitability is a an arguable factor in a different country. Safety, in comparison, should not be a factor to argue about. This relationship between unfitness and lack of safety in food is the key reason why the concept of unfitness should be applied and interpreted in the same manner throughout the EU.[265]

An argument that may justify the different approaches to unfitness is the subsidiarity principle[266] as one fundamental element in the EU. The objective of the principle is to regulate the use of powers rather than to allocate powers. It focuses on the question of whether the EU is the most appropriate decisions-maker.[267] The subsidiarity principle itself takes a neutral position about the optimal degree of centralisation and does not imply that power should be delegated to the lowest level possible.[268] In the context of the concept 'unfit for human consumption' the subsidiarity principle expresses whether the concept interpretation should be left to the MSs themselves, taking into account the description provided by the common GFL. There are two tests to verify if the subsidiarity principle is applicable. Firstly, it must be demonstrated that the aim of the intended action cannot be sufficiently achieved by the MSs, either at central, regional or local level. Secondly, it should be demonstrated that the proposed action can be better achieved at Union level with regard

[263] Except the food would be considered injurious to health and therefore also be deemed to be unsafe.

[264] WHO & FAO, *Codex Alimentarius - Food hygiene: Basic texts* (Rome, Italy, 2009), p. 6.

[265] A possible solution of this short pass is either separation of the unfitness concept and food safety or the revision and redefinition of Article 14 (1) GFL and the concept of unfitness. In this paper the latter approach is chosen in order to maintain the structure of Article 14 GFL as the core of EU food law.

[266] Regulated in Article 5 (3) TEU.

[267] N. de Sadeleer, "Principle of Subsidiarity and the Eu Environmental Policy," *Journal for European Environmental and Planning Law* 9.1 (2012): p. 7.

[268] G. Gelauff, I. Grilo, and A. Lejour, "Subsidiarity for Better Economic Reform?," in *Subsidiarity and Economic Reform in Europe*, ed. G. Gelauff, I. Grilo, and A. Lejour (Heidelberg, Germany: Springer-Verlag Berlin Heidelberg, 2008), p. 10.

to its scale or its effect.[269] If both tests prove that the MSs successfully achieve the defined objectives, the interpretation of the unfitness concept should be left to the MSs. In case the assessment is negative, the interpretation should be delegated to the EU as the most appropriate decision-maker.

The first step is the demonstration that the aim of the intended action can sufficiently achieved by the MSs themselves. The intended action behind the concept of unfitness, as well as injuriousness, is to ban unsafe food from the EU market. This action shall ensure a high level of safety, including the protection of human health and consumers' interest. The ban on unsafe food in Article 14 GFL distinguishes between injurious and unfit food. Given that Article 14 (2) (a) GFL covers food products that could harm human health, the aim of the unsafety concept to protect human health is assigned to this Article. Therefore, the focus is on whether the protection of consumer interest is successfully achieved by the ban on unfit food as it is currently interpreted in the MSs. A final decision as to whether MSs can achieve this protection by themselves cannot be taken in this study. The protection of consumer's interest in the MSs was not specifically researched from the angle of the unfitness concept. From a theoretical viewpoint, however, it can be argued in both directions. On the one side there seem to be no consumer complaints that their interest is not protected by the current application. On the other side, consumers are likely not aware that the concept is interpreted differently among MSs. This could mean that due to the absence of awareness, their interest seems to be protected but a possible breach of consumer's interest could be concealed. It is likely that consumers would expect the same level of fitness for consumption throughout the EU. Whether this is indeed the case was not a subject of this study; therefore, no conclusion can be drawn for the first test question.

In the second step, it should be demonstrated that the proposed action can be better achieved at Union level with regard to its scale or its effect.[270] The proposed action is the ban of unfit food from the market. As shown by this study, the concept of unfitness is interpreted differently among MSs. This may lead to a situation in which food is considered unfit and banned from the market in one MS but not in another. Accordingly, there can arise an unequal ban of food throughout the EU. As a consequence, the proposed action to ban unfit food from the market is more achievable if the EU provides a less open definition of the unfitness concept.

To sum up both results of the test: whether the aim (protection of health and consumer interest) of the action (ban of injurious and unfit food) is successfully achieved by the MSs themselves cannot be clearly answered within this study. In comparison, the proposed action (banning of unfit food) can be better achieved at Union level with regard to its scale and effect. This weakens the argument that due to the subsidiarity principle no action is required to support one common understanding of unfit food throughout the EU. Based on the relevance of the concept 'unfit for human consumption', it is therefore recommended to

[269] Sadeleer, "Principle of Subsidiarity and the Eu Environmental Policy."

[270] *ibid*.

take measures in order to facilitate one common application and interpretation of the concept throughout the EU.

6.4.2 Recommendations

The recommended measures encompass a three step approach: renaming of the current terms in Article 14 (1) and (2) GFL, redefining the current concept 'unfit for human consumption' in Article 14 (5) GFL, and revising the guidance on the concept itself.

Based on the present study it is recommended to rename the term 'unsafe' in Article 14 (1) GFL. As shown in this research, the relationship between food injurious to health and food unfit for human consumption requires clarification. In some countries health related criteria are included within the provisions to deem food unfit, or all food which is injurious to health is – *per se* – considered to be also unfit for human consumption This indicated relationship between injuriousness and unfitness is based, for the most part, on the wording of the concept 'unfit for human consumption'. From a general point of view, all food which is injurious to health is also unfit for human consumption. Consequently, the impression arises that the expression 'unfit for human consumption' can be used as a substitute for 'unsafe' as used within in the GFL. Therefore, a reconsideration of the use of the terms 'unfit for human consumption' and 'unsafe' is recommended. This reconsideration of both terms is also supported by the development of the purpose of the unfitness concept because the current approach to unfitness goes beyond the initial intention to include this concept within the definition of unsafe food because it might be almost impossible to prove that certain food is injurious to health. Nowadays, unfit food also relates to major shortcomings which certainly do not represent a risk to health. The categorisation as unsafe is therefore no longer reasonable. It is recommended that the EU follows the example of some former national food laws and the approach of 'Unfit Foodstuff' in Cyprus according to which the expression of unfitness is used as an overarching classification which encompasses food injurious to health and further criteria which cause food to be unfit for human consumption. This could be done by rephrasing Article 14 (1) as follows: *food shall not be placed on the market if it is unfit for human consumption. Food shall be deemed to be unfit for human consumption if it is injurious to health or otherwise unsuitable for consumption*. The term 'unsafe' would therefore be replaced by 'unfit for human consumption', whereas the current concept of unfitness would be renamed as 'otherwise unsuitable for consumption'. This wording is chosen in order to differentiate between the overall categorization as unfit for human consumption and the subcategory of unsuitable food.

The new concept of 'otherwise unsuitable for consumption', currently referred to as 'unfit for human consumption' should also be redefined in Article 14 (5) GFL. The current description of the concept is very openly phrased and provides for consideration of an almost unlimited extent of criteria to deem food as unfit. Consequently, the current approach supports a wide variety of assessments of whether a food is unfit for human consumption or not. This gap should be closed by defining explicitly the causes to render

food unfit for human consumption, respectively 'otherwise unsuitable for consumption'. In order to determine which criteria should be contained in this revised concept, the current common understanding of the reasons to render food unfit in the MSs should be reflected. Therefore, the prevailing criteria should be summarized and grouped into main categories, followed by an individual assessment as to whether they should be part of the revised concept. Advisable parameters in this decision process are, for instance, if the actual consumption of the food is still reasonable to the consumer or if a consumption can no longer be reasonably expected.

The categories of unfit food that appear within this study are insufficient hygiene, appearance, organoleptic properties, contamination, and non-compliance with legal requirements such as specific labelling provisions, absence of ante-mortem inspection in the meat production, lacking traceability, or exceedance of the MRL for pesticide residues. Based on the observed categories, a revised concept should be defined. The first step in the revision is to asses which criteria, considering the findings of this study, should be within the scope of the revised concept 'otherwise unsuitable for consumption'. The previously listed categories should be evaluated, beginning with the category of insufficient hygiene. This main category should be part of the revised concept, as insufficient hygiene can change properties of the food in a negative manner which results in food that is not reasonably expected to be eaten. Furthermore, Hygiene Regulation 852/2004 emphasizes that hygiene is a prerequisite to ensure the fitness of food.

The category of appearance, on the other hand, is not recommended for inclusion within the concept of unsuitability. Taking into account that food waste is an increasingly discussed topic in the EU, it seems to be inconsistent to ban food from the market solely because its appearance does not comply with the expected standard for the exterior of the product. Of course, the appearance gives a first lead as to whether a food might be unfit for consumption or even injurious to health. For example, in the blue mozzarella case the cheese clearly showed colour deviations, indicating faults of the food. These were, however, caused through contamination with non-pathogenic microorganisms. Accordingly, by keeping contamination within the scope of unsuitability, such cases would still be covered. This does not imply that the appearance of food is not of relevance at all, but it may not be an independent reason to consider food unsuitable for consumption.

In comparison, deviations in organoleptic properties should be kept as an independent reason to deem food unsuitable. Depending on the extent of deviations in taste and smell, they may cause a food to be unsuitable for consumption because such deviations stimulate adamant reluctance.

The last category of unfit food in this study encompasses products which do not comply with legal requirements such as labelling, ante-mortem inspection, traceability, or defined MRLs. As indicated within this research, non-compliance with legal requirements does not necessarily render food unfit for consumption. Food can, for instance, still be fit for consumption if a smaller font size is used on the label than required by law. On the other hand, there are indeed legal requirements that are linked to food safety. In the decision which of these requirements should be within the scope of unsuitability, their purpose

should be taken into consideration. Whereas the setting of legal limits like the MRL or an ante-mortem inspection aims to ensure that only safe food is placed on the market, traceability systems help authorities and FBOs to quickly identify the source of a possible food safety problem. Thus, traceability itself does not keep unsafe food off the market and should be outside of the unsuitability concept. Non-compliance with legal obligations that facilitate the marketing of safe food, respectively food fit for consumption, should be inside the concept of 'otherwise unsuitable for consumption'.

Given this assessment, the main categories of insufficient hygiene, organoleptic properties, contamination, and non-compliance with legal requirements that aim to ensure that only safe food, respectively food fit for consumption, is placed on the market are recommended for inclusion in the revised concept.

Different from the current approach, which resembles more a description of what can be unfit for human consumption, the new concept should be an actual definition with fixed categories of criteria in Article 14 (5) GFL. One possible phrasing of this definition for food 'otherwise unsuitable for consumption' is for instance:[271] *food is defined to be otherwise unsuitable for consumption if it is unacceptable for consumption for reasons of insufficient hygiene, organoleptic properties, contamination, or non-compliance with legal requirements that shall ensure that only food fit for consumption is placed on the market.* Based on this narrow definition, the intended common application of the concept is supported.

As provided by the recommended revision of the concept 'unfit for human consumption', it is advisable to keep the reference to unacceptability as a key element. Acceptability should remain part of the concept of unfitness, respectively unsuitability, because it provides a margin of appreciation in the assessment of whether food is deemed to be unfit for human consumption. For example, if the organoleptic properties of food slightly deviate, the food does not necessarily become unfit for human consumption. Only if the taste or odour highly deviate to a negative extent, should the food be considered unfit for consumption. Therefore, it is reasonable to keep the element of unacceptability in the concept. Otherwise, the detailed parameters of each category would have to be elaborated, thus leading to a high number of criteria.

However, if the element of unacceptability is kept, it is advisable to provide more guidance on the assessment of when food becomes unacceptable. It is recommended that this issue be approached per category in order to provide specific reference points to determine whether the food is unacceptable for consumption. For instance, examples for each category that are unacceptable and acceptable should be provided. To include examples of acceptable food for each category is of advantage because the difficulty on the

[271] Within this study the concept of 'unfit for human consumption' was researched in 13 out of 28 MSs. Therefore, it is further recommended that this research be extended to all 28 MSs in order to determine which categories of wrongness are used under the concept of unfitness. The results should be taken into account in the redefinition.

issue of unacceptability lies within its subjective nature. By illustrating when a food would be still considered as acceptable, more orientation in the individual assessment is provided.

One last aspect which should not be left unnoticed in the revision concerns clarification about recalls (Article 19 GFL) and public warnings (Article 10 GFL) in cases in which food is deemed to be unfit, or 'otherwise unsuitable for consumption'.[272] Although recalls and warnings are both applied in practice, the impression is given that the choice of which of the two is used is based on an individual assessment that sometimes lacks any clear system. Therefore, it should be clarified whether and in what cases a public warning or recall of unsuitable food is required.

Within this paper the position is taken that with regard to unsuitable food, one criterion should be whether the major shortcoming is noticeable before consumption. A noticeable unsuitability of food does not demand a legally required public warning or even a recall[273] because the shortcoming itself is clearly noticeable for the consumer. Consequently, it is reasonably expected that such food will not be eaten by the consumer. This is different from food for which unsuitability is not noticeable, for instance, if the food is unsuitable due to unhygienic production or storage conditions. It is recommendable to publicly inform the consumer about such conditions and, depending on the extent of the shortcoming, to recall the product. However, if, for example, a product is unsuitable because the taste is unacceptable this might become a different issue. Therefore, the decision of whether a product should be recalled or a public warning is required should depend on a case-by-case assessment if the unsuitability is not noticeable before consumption.

Taking into account these recommendations, a common interpretation and application of the current concept of 'unfit for human consumption' is supported. Thus, the extent of the GFL objective to establish common definitions and comprehensive guiding principles in order to harmonize the general food la principles in the EU is increased.

6.4.3 Possible impact of the recommended measures

Every action has a reaction. The same is true for the recommended measures. The recommended approach for the revision of the concept 'unfit for human consumption' is one possible method to facilitate one common and harmonized understanding of unfit food among the European MSs. Due to the broad scope of these recommendations, they are likely to be accompanied by further consequences and may have an impact on all actors in the food chain. The recommendation which is most likely to have the highest impact is the revision of the concept 'unfit for human consumption' itself. In comparison to the recommended definition of the unfitness concept, the current concept resembles a

[272] In the following, the recommended revision of the current concept 'unfit for human consumption' will only be referred to as 'otherwise unsuitable for consumption' for reasons of readability.

[273] Unless there is reason to believe that it might even be injurious to health.

description. It refers to factors which should be considered when determining if food is unfit for human consumption.[274] This is the main reason why the concept is applied differently. The generic character of the current concept has also advantages. Compared to specific provisions, generic provisions have a broader scope. By means of generic descriptions all relevant factors can be covered, without laying down complex and detailed provisions[275] – including those that may arise in the future.[276] To balance the advantages and disadvantages of both, generic and specific provisions, the recommended revision steers a middle way. Therefore, the applied criteria that have been determined within the EU-wide survey have been transposed into different categories. This allows a specific definition of the unfitness concept, including generic categories that would render food unfit for human consumption.

The categories of unfit food that appear within this study and which are recommended as part of the revised definition are: insufficient hygiene, organoleptic properties, contamination, or non-compliance with legal requirements that shall ensure that only food fit for consumption is placed on the market. The first category of insufficient hygiene encompasses, for instance, the presence of insects in food (Finnish example) or lacking hygienic conditions that render food unfit (Spanish example). The second category of organoleptic properties addresses, inter alia, the adding of too much salt in bread (Dutch example) and very unusual smell and taste of food (Czech example). The category of contamination ensures that contamination that may not only be caused by unhygienic conditions is covered. Finally, the last category addresses non-compliance with legal requirements that shall ensure that only food fit for consumption is placed on the market.[277] Examples present in this study are the indication that meat would be considered unfit if no ante-mortem inspection is carried out before slaughter or if food contains pesticides above the MRL. These recommended fixed categories still contain the advantage of the current generic description on unfit food but limit the criteria used to deem food unfit to the defined categories.

Due to the high impact that fixed categories may have, their effects and feasibility are the focus of the assessment how the recommended measures are likely to affect different parties involved which are the EU and its internal market, enforcement authorities, the food business operators and consumers.

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[274] Article 14 (5) GFL.

[275] As for example the detailed factors by which food is deemed unfit for human consumption in Croatian Law.

[276] A historical example of a gap in food law due to very specific provisions constitutes the German food law from 1879. This law prohibited only misleading terms for the advertisement of spoiled, imitated or adulterated food. No generic prohibition of misleading terms for food was addressed (T. Mettke, "A 1 Geschichte Und Bedeutung Des Lebensmittelrechts," in *Kommentar Lfgb 06 10 01* (Hamburg: Behr's Verlag), p. 9.).

[277] This category aims to summarize further legal provisions that are relevant for the fitness of food. The challenge of this category is, however, the decision which legal provisions are relevant for the fitness of food. It is likely that different views are present. Therefore, the scope of this category might be further shaped through case law.

EU and its internal market

The potential of a real internal market is still not completely realized due to incomplete legislation harmonization.[278] Therefore, a common legal framework and one common 'language' based on definitions for the most important notions is required.[279] The concept of unfitness is one of these. A definition with fixed categories would support the facilitation of a common language. It would clarify throughout the EU which food is considered to be unfit for human consumption. This would allow an aligned understanding of unfit food among all actors involved in the food chain and would reduce the risk of a trade barrier due to a different application of the unfitness concept. Even if no barrier to trade would arise, the communication between trading partners would be simplified.

Furthermore, renaming the terms 'unsafe' (recommended to be referred to as 'unfit for human consumption') and the current concept 'unfit for human consumption' (recommended to be referred to as 'otherwise unsuitable for consumption') would provide clarification on the relationship between the current concepts of unfitness and injuriousness. Such renaming is likely to simplify communication among all actors and reduce the risk of miscommunication about the status of food. The potential of such misunderstandings is indicated within the EU-survey. Major disadvantage of renaming the current terms, however, would be the need to adjust various legislative documents that still refer to unsafety. Given the central position of food safety within EU food law, this would affect a high number of legislative documents and guidelines.

Enforcement authorities

The quality of EU food law provisions depends on the right application by those they are binding for. Consequently, their effective enforcement is crucial.[280] It is therefore important that enforcement authorities know how to interpret and apply food law. In particular, provisions that can have a huge impact for food business operators and consumers, such as the ban of unfit food, are of concern. A clear definition of unfit food with fixed categories would support enforcement authorities in their application of the concept. Moreover, it would facilitate that food is deemed unfit based on the same criteria throughout the EU.[281]

The provided clarification may encourage enforcement authorities to use the concept more frequently. It can be assumed that enforcement authorities may have been reluctant to apply the concept due to missing clarity about its scope. On the other side, by limiting the definition of unfit food to fixed categories, its application could also be reduced. Some criteria that are currently applied in order to deem food unfit would not be covered

[278] K.M. Terlicka and D.J. Jukes, "From Harmonization to Better, Smart and Fit Food Law," 5 (2014): p. 312.

[279] B. van der Meulen and A. Szajkowska, "The General Food Law: General Provisions of Food Law," in *Eu Food Law Handbook*, ed. B. van der Meulen (Wageningen, the Netherlands: Wageningen Academic Publishers, 2014), p. 230.

[280] M. Hagenmeyer, "Modern Food Safety Requirements - According to Ec Regulation No. 17872002," *Zeitschrift für das gesamte Lebensmittelrecht.* 4 (2002): p. 457.

[281] Enforcement authorities would also receive more guidance in their decision when food is unacceptable. This would support the intended interpretation and application of the concept – throughout the EU.

anymore.[282] Given the possibility of both scenarios, it is not foreseeable whether enforcement authorities would apply the concept of unfitness less or more often.

Besides clarification of the concept scope, the main advantage of the recommended measures is likely to be the increased clarity about recalls or public information on unfit food. Currently, the impression is given that the choice to recall or issue a public warning is based on an individual assessment that sometimes lacks a clear system. Therefore, it is recommended that more legal clarity should be provided about the consequences that should be applied when food is unfit. Within this paper the position is taken that one criterion should be whether the unfitness for consumption is noticeable before consumption. A noticeable unfitness does not demand a legally required public warning or even a recall[283] because the shortcoming itself is clearly noticeable to the consumer. With increased guidance when a recall or public warning should be issued, enforcement authorities will have more confidence in deciding which measures should be taken. A positive side effect of the increased legal clarity could be an improved communication between authorities and food business operators because the action of enforcement authorities would be more transparent.

Food business operators

The GFL highlights that the food business operator should have primary legal responsibility for ensuring food safety because such operators are best placed to ensure that the food supplied is safe.[284] The basis for ensuring food safety is a clear understanding by the operator of what food is safe and which food is unsafe. Given that food unfit for human consumption is deemed to be unsafe, it is important that the food business operator knows when food would be considered unfit. In practice, this can be critical because the current description of the unfitness concept provides the possibility to consider further criteria beyond those laid down in Article 14 (5) GFL to deem food unfit. Thus, the food business operator cannot be sure that only the criteria defined in the concept itself will be applied by the enforcement authorities. If fixed categories of criteria that render food unfit were defined, the food business operator would be given more legal safety on the applied criteria. Such definition erases the risk for the operator that criteria could be applied which are not expressed in Article 14 (5) GFL or national legislation. Furthermore, the increased legal safety would give the food business operator the opportunity to focus on the relevant factors to ensure a food's fitness for consumption in the daily business.

Due to clarification of procedures to be followed when a public warning or recall of unfit food is required, the food business operator would also be better informed about the consequences that arise when unfit food is placed on the market. This enables operators to immediately initiate the required measures if necessary. The increased transparency about which measures apply may also reduce the risk of conflicts between authorities and food

[282] Because they are not considered to be of relevance for the purpose of the concept.

[283] Unless there is reason to believe that it might even be injurious to health.

[284] Recital 30 GFL.

business operators concerning the actions demanded or taken. Side benefits are likely to be the comparable and equal consequences for all EU food business operators if they market unfit food. Currently, these may differ among regions and countries.

Consumers

It is likely that the redefinition and revision of the unfitness concept would not have a direct impact on consumers. The redefinition of the unfitness concept mainly covers already applied criteria among the MSs and is unlikely to have a major impact on food diversity and security.

From a general point of view, consumers' trust in EU food law may increase as the same level of fitness for consumption would prevail throughout the EU. Increased transparency for consumers when a public warning or recall of unfit food must be issued may also have a positive effect on their trust in the food supply. It is likely that consumer's trust in EU food law would be strengthened if they could be sure about food being recalled if its unfitness is not visible.

In summary, the impact assessment indicates increasing transparency of the unfitness concept due to fixed categories and clarification of measures to be taken if food is unfit. This would have a direct influence on the daily business of food business operators and enforcement authorities. In addition, the clarity and arising common 'language' on unfit food is likely to positively affect the functioning of the internal market as all actors 'speak' the same language. Consumers are not directly affected by the recommendations, but their trust in EU food law might be strengthened.

A major drawback of the recommended measures seems to be the advice to rename the current term of unsafe food. This would require the change of further legislative documents referring to unsafe food or food safety. Given this high impact, the renaming the term 'unsafe' is unlikely. In comparison, the redefinition of the concept 'unfit for human consumption' in Article 14 (5) GFL appears to be feasible and would be accompanied by various advantages.[285] Given the relevance of the unfitness concept within EU food law, it is therefore recommended to implement a definition on unfit food with fixed categories and to clarify when a recall or public warning on unfit food is required. This approach would successfully meet the GFL objective to establish common definitions and comprehensive guiding principles in order to harmonize general food law principles throughout the EU. The accompanied transparency would be to the benefit of all, from food business operators to enforcement authorities and the final consumer.

[285] The same is applicable for increased guidance on when to recall unfit food or to issue a public warning.

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Appendix

Questionnaire 'Unfit for human consumption'

National interpretation and application of the concept '*unfit for human consumption*' according to Art. 14 (2) (b) Regulation (EC) No 178/2002

According to Art. 14 (1) Regulation (EC) No 178/2002 food is not allowed to be placed on the market if it is unsafe. In order to be deemed as unsafe the food has to be considered as injurious to health or unfit for human consumption.[286]
In order to support the determination whether food is considered to be unfit for human consumption *'(…) regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.'* [287]
Although this paragraph provides a first explanation of the concept of *'unfit for human consumption'*, it is still very vague. Therefore, the aim of this questionnaire constitutes to research how the concept of '*unfit for human consumption'* is applied and interpreted in the Member States of the European Union, including the legal consequences in case food is deemed to be unfit for human consumption.

Preferably the questions will be part of a personal interview via telephone or Skype. A personal interview will increase the quality of the research and also provides the possibility to exchange more detailed information. Of course the questions can also be answered in written form.

National legislation and guidance documents

1. Is national legislation in force that further elaborates the concept of *'unfit human consumption'*?

   1.1. If so, which national law(s)? Please indicate the relevant article.

   1.2. How is the concept of *'unfit for human consumption'* defined according to national legislation?

   1.3. Which criteria have to be fulfilled in order to be deemed as unfit for human consumption according to national legislation?

   1.4. Can food be categorized as injurious to health and unfit for human consumption at the same time according to national legislation?

[286] Art. 14 (2) (a) (b) Regulation (EC) No 178/2002.
[287] Art. 14 (5) Regulation (EC) No 178/2002.

2. If national legislation is in place but does not elaborate the concept of *'unfit for human consumption'* further, how is food safety defined in national legislation additionally to the Regulation (EC) No 178/2002? Please indicate the relevant legislation and article.

3. Is there a national guidance document on the interpretation of the concept *'unfit for human consumption'*?

   3.1. If yes, which?

   3.2. How does it elaborate and explain the concept *'unfit for human consumption'*?

Historical background

(*Question 4. may be skipped if question 1. – 2. refer to the same national legislation and may have already been answered)*

4. The concept of *'unfit for human consumption'* is part of the food safety requirements which are laid down in Regulation (EC) No 178/2002[1] which entered into force in the Member States of the European Union in 2002.

   4.1. How was food safety defined in the former national legislation? Please also add the concerning legislation and article.

   4.2. Was there a similar concept that can be compared to the concept of *'unfit for human consumption*'? Please elaborate.

Application of the concept '*unfit for human consumption'*

5. Is there national case law which is related to the concept of *'unfit for human consumption'*?

   5.1. If yes, which?

6. Are there (further) national examples of food that has been considered to be *'unfit for human consumption'* in the past? Please elaborate.

7. If a product does not meet legal requirements, is the concerned food considered as unfit for human consumption?

8. What determines the difference between injurious to health and unfit for human consumption in the practical application?

9. Can food be deemed to be unfit for human consumption and injurious to human health at the same time?

[1] Art. 14 Regulation (EC) No 178/2002.

10. According to the guidance document on the implementation of Regulation (EC) No 178/2002 the central concept of unfitness for human consumption is unacceptability.[2]

    10.1. How is unacceptability of food determined in your country? Is there any guidance for the interpretation of unacceptability?

11. In the following section example cases will be provided. Please indicate whether or not the food would be considered as unfit for human consumption.

    11.1. Traceability of the food is not provided.

    11.2. The food contains pesticides above the maximum residue level.

    11.3. Horse meat is sold as beef.

    11.4. Meat of an animal, that has not been controlled before slaughtering.

Legal consequences

12. What are the legal consequences in case food is deemed to be unfit for human consumption (i.e. recall[3])?

    12.1. Do legal consequences differ depending on whether the food is deemed to be unfit for human consumption or injurious to health? Please elaborate.

    12.2. Are there examples of recalls of food that was not deemed to be injurious to health?

Thank you very much for your cooperation!

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[2] Guidance on the implementation of articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on General Food Law (2010), as available in the internet at http://ec.europa.eu/food/safety/docs/gfl_req_guidance_rev_8_en.pdf.

[3] Art. 19 (1) Regulation (EC) No 178/2002.