

Novel Foods - Problems with Labelling, Testing and Technology for Processing



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2021/2022

Certificate of Originality

This is to certify that I am responsible for the work submitted in this thesis, that the original work is my own, except as specified in the acknowledgements and in references, and that neither the thesis nor the original work contained therein has been previously submitted to any institution for a degree.

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Abstract

Background

Novel foods are foods that have not been consumed to a significant amount or degree in the European Union and/or United Kingdom prior to 15 May 1997 (FSA, 2020). They are generally considered as unsafe until they are tested for toxicity and approved as safe for human consumption before they can be authorised to be placed in the EU or UK market.

Aim and Objectives

The main aim of this study is to understand the requirements for labelling, testing and processing of novel foods in the UK. This study further provides the background chronicle of the evolution of novel food in the UK with more searchlight beamed on the types of novel foods, technology used for processing and current consumer trends for this product category. It also examined the government regulation on novel foods, labelling requirements, testing and safety assessments of novel foods

Method

Systematic review approach was used to select and examine relevant research studies, and to extract and analyse the data from studies included in the review.

Results and Discussion

A total of 57 studies were filtered out for review from the 965 records obtained from the databases. Also, additional 31 studies from 56 records obtained from regulatory websites of EFSA, FSA, DHSC, UK government legislative websites, official government reports and publications were also included for the review. The studies revealed that compliance to labelling regulations and requirements, passing the testing regime for toxicity and safety assessment, and the technology used for processing the novel foods are critical to its acceptability and market growth/development.

Conclusion

The study revealed that the regulation, testing and processing of novel foods are different from conventional foods. The study also showed that novel foods are regulated within a regulatory framework specifically crafted to ensure that novel foods placement into the UK market are managed effectively by ensuring that they are safe for consumption and pose no risk to public health

List of Tables

Table 1: Factors influencing the acceptance or rejection of a novel food.....	25
Table 2: Categories of 3D printing technology.....	36
Table 3: Inclusion and Exclusion criteria for the selection of relevant studies for the review.....	39
Table 4: Distribution of the records extracted from the databases.....	41
Table 5: Number of publications per keyword strings used.....	41
Table 6: Records spreads across the years and the database.....	43
Table 7 : Excerpts from Union list of novel foods showing specific labelling requirements.....	45
Table 8: Regulatory frameworks for novel foods administration and regulation.....	46
Table 9 : Timeline for the novel food authorization process.....	48

List of Figures

Figure 1: Novel food categories as defined by the new Regulation (EU) 2015/2283.....	16
Figure 2: Sources, processes and materials involved in novel foods production.....	20
Figure 2: Sources, processes and materials involved in novel foods production.....	23
Figure 4: Market development phases of novel foods categories.....	23
Figure 5: Safety considerations as willingness to try novel alternative protein foods.....	24
Figure 6: Procedure for novel foods application and authorization.....	29
Figure 7: Steps involve in safety assessment of novel foods.....	31
Figure 8: Cultured meat production process.....	33
Figure 9: Various applications of nanotechnology in food science.....	34
Figure 10: Steps in a systematic review.....	
Figure 11: Method Flow Chart.....	38
Figure 12: Graphical display of the number publications per keyword strings used.....	41
Figure 13: PRISMA flow diagram for the studies systematic reviews.....	42
Figure 14: Records spreads across the years per each database.....	44
Figure 15: Distribution of the studies and sum total across each year of publication.....	44
Figure 16: Baskets of foods survey showing non-compliance result of food information standard test.....	47
Figure 17: Status of CBD products linked to novel foods applications.....	49

Table of Contents

Certificate of Originality.....	2
Acknowledgement.....	3
Abstract	4
List of Tables.....	5
List of Figures.....	6
Abbreviations.....	10
1.0 Introduction.....	11
1.1 Background of the study.....	11
1.2 Motivation.....	12
1.3 Research question and Hypothesis.....	13
1.4 Aims and Objectives.....	13
1.4.1 Aim of the study.....	13
1.4.2 Objectives.....	13
1.5 Importance of the study.....	13
1.6 Limitations and Delimitations.....	14
2.0 Literature Review.....	15
2.1 Global overview of novel foods.....	15
2.2 Novel foods, functional foods and Genetically Modified foods.....	17
2.3 Novel foods type and classification.....	18
2.3.1 Traditional foods (non-EU based foods).....	19
2.3.2 Alternative Protein foods.....	20
2.3.3 Novel Carbohydrates.....	20
2.3.4 Novel food supplements.....	21
2.4 Current consumer and market trends for novel foods.....	21
2.5 Consumer acceptance of novel foods.....	23

2.6	Novel foods development in the UK.....	25
2.7	Regulatory and legislative frameworks for novel foods in the UK....	25
2.7.1	Premarket approval of novel foods.....	26
2.7.2	Novel foods authorization requirements.....	27
2.7.3	Procedure for novel foods authorization.....	27
2.8	Labelling requirements and regulations for novel foods in the UK.....	28
2.9	Testing and safety evaluation of novel foods.....	29
2.10	Novel foods, allergy risk and control.....	31
2.11	Technologies for novel food processing.....	31
2.11.1	Cultured meat Technology.....	32
2.11.2	Nanotechnology.....	32
2.11.3	3D Food printing Technology.....	33
2.12	Background to the research method.....	35
3.0	Method.....	37
3.1	The study research method.....	37
3.2	Keywords creation.....	38
3.3	Identification and searching of databases.....	38
3.4	Inclusion/Exclusion criteria.....	38
3.5	Literature screening.....	39
3.6	Review of studies.....	39
4.0	Results and Discussion.....	40
4.1	Database report.....	40
4.2	Article screening report.....	41
4.3	Studies distribution.....	42

4.4 Novel foods compliance with general and specific labelling requirements.....	44
4.5 Novel foods labelling and consumer acceptance.....	46
4.6 Timeframe for testing and authorization of novel food products.....	47
4.7 Challenge with CBD novel food products.....	47
4.8 Challenge with technologies used for novel foods processing.....	49
5.0 Conclusions.....	50
6.0 Recommendations for future studies.....	52
References.....	53
Appendices.....	65

Abbreviations

ACNFP: Advisory Committee on Novel Food and Processes

CBD: Cannabidiol

DHSC: Department of Health and Social Care

EIT: European Institute of Innovation and Technology

EU: European Union

EC: European Council

FSA: Food Standards Agency

FSAI: Food Safety Authority of Ireland

FSS: Food Standards Scotland

FAP: Food Additive Petition

GM: Genetically Modified

GRAS: Generally Recognized as Safe

UK: United Kingdom

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

1.0 Introduction

1.1 Background of the study

Novel foods are described as foods which have not been consumed to a significant amount or degree in the European Union and/or United Kingdom prior to 15 May 1997 (FSA, 2020). Novel foods are foods that were produced using new technologies that were hardly or never used for conventional food products (Teagasc, 2013), or foods that were traditionally not consumed in the EU or UK but consumed in other countries (Tarja, 2015). They are also described as foods with no history of human consumption which were derived from plants, animal, microorganisms, mineral sources etc., (e.g., Chia seeds, Morinda fruit (noni juice), Algae, plant-based meat alternatives etc.), and as such were produced with technologies that have not been previously used for conventional food products e.g., nanotechnology, 3D food printing, etc. (Calabrese and Ferranti, 2018). This also include foods that have had their primary molecular structure or nutritional value modified and they are without historical records of safe food use (Sarkadi and Gal, 2012). They are generally considered as unsafe in their new geographical entity where such foods have not been previously consumed though they are traditional foods in the countries where they are widely consumed with no threat to public health. The foods that are now commonly eaten in Europe are once regarded as novel foods prior to their evaluation and approval/acceptance for safe use (EFSA, 2022). Foods such as maize, tomatoes, bananas etc are not traditionally consumed or domiciled in Europe but they find their way into the European market (EFSA, 2022) and they have evolved beyond the initial tag of being a novel food to more of a conventional food.

The “15 May 1997” date incorporated into novel food definition is significant, as this was the date European Union Regulation (EC) No 258/1997 was introduced to regulate non-traditional foods entry into the European market (Carla et al., 2020; Richard et al., 2017). This was the first attempt by the EU to regulate the placing of novel foods in the European market and its subsequent authorization (Carla et al., 2020). However, in order to eliminate potential food safety risk, and protect consumer interest, amendment was made to the earlier regulation. The new Regulation (EU) 2015/2283 was introduced to offer higher level of protection and public health safety (Carla et al., 2022) with the aim of addressing inadequacies of the previous regulation (Richard et al., 2017). The new regulation was also introduced to close the gap in national regulations for the safety assessment and authorization of novel foods among the members countries of the Union (Nada et al., 2021). It has also helped to clarify novel foods definition and categories, update the list of authorized novel foods allowed to be placed in the market, and define and establish the criteria for safety assessment of novel foods.

Novel foods are expected to go through premarket approval or authorisation before they can be allowed into the marketplace (Alie and Aalt, 2017; FSA, 2020). In seeking this approval, the detailed description of the novel food in terms of its history, source, identity, manufacturing process, compositional data, nutritional information, allergenicity, proposed used, etc. are to be provided to food safety authority (Nada et al., 2021) e.g., EFSA (European Food Safety Authority). They are tested for toxicity and their fitness for human consumption (Sarkadi and Gal, 2012). The approaches to how novel foods are regulated varied around the world, while some countries are open to it others are taking cautious approaches and have developed a regulatory framework around it to regulate its market placement (Campden BRI, 2021). In England, which is part of the UK, novel foods are regulated by the "[*The Novel Foods \(England\) Regulations 2018*](#)", a statutory instrument which came into force on the 8th of March 2018. In the EU, all novel foods that have been authorized and approved to be placed in the European market are included and maintained in the Union List of Novel Foods (Nada et al., 2021). The List contains information about the novel foods in terms of their condition of use, labelling requirements and specifications. This List is constantly updated once a new novel food product or ingredient is approved to be placed in the market. There are two approaches to how request can be made for any novel foods authorization, it is either by application or notification to the authorising bodies such as EFSA, FSA, etc. (Anu et al., 2021)

1.2 Motivation

Labelling, testing and technologies employed in the processing and production of novel foods have been identified as critical factors in the acceptance of novel food products (Feng et al, 2022; Boer and Bast, 2018). Novel foods labelling like any other food products are subject to rules and regulations which are expected to be complied with. As the labelling serves as important means of providing key information about the product to the consumers, failure to get it right within a regulatory requirement have its own implications both for the manufacturers and the consumers. Also, safety evaluation and testing of novel foods prior to being placed in the market is one of the major criteria for its authorization. And the main purpose for the testing is to guarantee novel food safety and safeguard public health (Richard et al., 2017). Concerns have been raised about the technology used for processing of novel foods with consumers expressing doubt about the safety and wholesomeness of novel food products (Sorenson and Henchion, 2009; Mona and Alexandra, 2012). It is therefore, important to appraise these key factors and the effect they can have on novel foods development and acceptance.

1.3 Research question and Hypothesis

This study will answer the research question as stated below.

- (i) Are regulation, testing, and processing of novel foods different from conventional foods?

This study also proposed three hypotheses in accordance with the novel foods current realities.

Hypothesis 1 (H1): Regulation, testing and processing of novel foods are different from conventional foods.

Hypothesis 2 (H2): Labelling requirement for novel foods are different from conventional or traditional foods

Hypothesis 3 (H3): Technology used for novel food processing can also be adopted for conventional food processing.

1.4 Aim and Objectives

1.4.1 Aim of the study

The main aim of this study is to understand the requirements for labelling, testing and processing of novel foods in the UK.

1.4.2 Objectives:

1. To provide a background on the history of development of novel food in the UK
2. To examine novel food types, processing and current consumer trends
3. To examine government regulation on novel foods and labelling requirements.
4. To examine testing and safety assessment of novel foods.

1.5 Importance of the study

This study will provide insight into regulatory frameworks, risk and safety assessment, and the emerging technologies that are being used to produce novel food ingredients or products.

It will examine challenges with consumer acceptance of novel foods and what have been done to sustain innovation and market presence of novel foods while also providing valuable information for future research on novel foods development in the UK.

1.6 Limitations and Delimitations

This study aims to examine and discuss the challenge with labelling, testing (risk and safety assessment), and technologies that were used in producing these novel foods. The findings will be limited to data and information extracted from the systematic review of various studies that have been done on novel foods, government regulatory websites and official publications, the limited time frame for this research, the selected databases and the key words used to search the databases. While administration of novel foods in European market and other non-EU markets will be briefly examined, the study will focus mainly on the UK market to answer the research question.

2.0 Literature Review

2.1 Global overview of novel foods

Generally, novel foods have been defined as food that have not been significantly consumed to be considered safe for human consumption (Calabrese and Ferranti, 2018). However, the use or adoption of this definition and foods that can be considered as novel depend on the regional or national regulations in place to regulate such foods (Hendrich, 2016).

In Europe, the European commission is the singular authorized body responsible for defining, authorising, assessing, evaluating, implementing, and managing information about the status of novel foods (Campden BRI, 2021). According to European Union Regulation (EC) No 258/1997, a novel food is defined as any food that was not used for human consumption to a significant degree within the continent before 15 May 1997 (FSA, 2020). Prior to introduction of this Regulation, no restriction was placed on what food can be placed or cannot be placed in the market as the consumption of traditional and new food products are generally regarded as safe for human consumption (Verhagen et al., 2009). This regulation was established to assured that the novel foods would not pose safety risk to the consumers, would not misinform, or mislead the consumers, and would not cause nutritional disorder (Verhagen et al., 2009). However, a gap was noticed in this Regulation which left out a grey area which was not addressed adequately. Verhagen et al. (2019) divided this grey area into two categories: the food products that can be subjected to different interpretations, and those food products that were erroneously not considered as novel due to gap and inadequacies in the Regulation. This gap has now been closed with the introduction of new Novel Foods Regulation (EU) 2015/2283 (Carla et al., 2020). This Regulation apart from defining what novel food is, which is not different from how it is defined in the Regulation (EC) No 258/1997, the Article 3, paragraph 2 of Regulation (EU) 2015/2283 went further to clearly state which foods can be qualified to be regarded as novel foods (Bresson et al., 2021). Food products or ingredients are thus considered to be novel if:

- i. The food has a new molecular structure, or the structure has been intentionally modified, and provided such structure was not in existence prior to 15 May 1997
- ii. The food consists of or has been isolated or produced from microbes, such as fungi or algae
- iii. The food consists of or has been isolated or produced from material of mineral origin
- iv. The food consists of or has been isolated or produced from plants or plant parts, except the food has been historically considered as safe and was produced through traditional propagating methods used prior to or non-traditional practices which have

not been used prior to 15 May 1997 and does not alter the composition or structure of the food.

- v. The food consists of or has been isolated or produced from animal or animal parts, except for animal that were breed with practices that has been in use prior to 15 May 1997 and known to have history of safe use.
- vi. The food consists of or has been isolated or produced from cell culture or tissue culture obtained from animals, plants, microbes, fungi, or algae.
- vii. Food produced using a production process which has not been used prior to 15 May 1997, giving rise to significant alteration of the food composition or structure which can affect its nutritional value, metabolism, or toxicity level.
- viii. The food consists of engineered nanomaterials or vitamins, minerals, and other substances that contain or consist of nanomaterials or a production process has been applied which has not been used prior to 15 May 1997.



Figure 1: Novel food categories as defined by the new Regulation (EU) 2015/2283 (EFSA, 2020)

Countries such as China, Canada, Australia, and New Zealand have also come up with Standard and Regulation to define and regulate novel foods.

In Australia and New Zealand, novel foods are regulated by the Food Standard 1.5.1 (Ryan et al., 2020), The Standard forbids the sale of novel foods unless they are authorised and listed in the Standard with full compliance to any special conditions that have been spelt out (Calabrese and Ferranti, 2018; Ryan et al., 2020). The Standard defines novel food as food

with no history of human consumption in Australia or New Zealand or derived from food or substances with no history of human consumption (Ryan et al., 2020).

While in Canada, novel foods are defined and regulated by the Food and Drug Regulations, which was set out in B.28.001 of the Regulations (Calabrese and Ferranti, 2018). It defines novel food as food or substances with no history of safe use, or food that has been produced by a new process or genetically modified food derived from animal, plant, or microbes.

In China, novel foods are regulated by the Administrative Measures of Novel Foods (2007) (Chun, 2014), which is a subset of China Food Hygiene Law (Juanjuan, 2015). Novel foods are regarded as animals, plants and microbes that are not traditionally consumed in China, or derived from animals, plants, and microbes with no history of consumption in China. New class of microorganisms used during food processing, and food material that have been structurally or compositionally modified by a new processing technology (Chun, 2014).

In the US, no special definition or recognition is given to any food which might be considered as novel, for example in the EU (Vapnek and Purnhagen, 2020; Calabrese and Ferranti, 2018). The food regulatory agency in the US, the Food and Drug Administration (FDA) has no formal definition for novel food and as such not recognised (Vapnek and Purnhagen, 2020). Therefore, the food considered as novel food in other clime is treated like any other foods in the US, and if any new substance is to be added to food, such food is subject to pre-market approval by the FDA through the Food Additive Petition (FAP) process unless it has been generally recognized (GRAS) as safe by a qualified expert (Calabrese and Ferranti, 2018). And once approval is given through FAP the food can access US market without any restriction (Vapnek and Purnhagen, 2020)

2.2 Novel foods, Functional foods and Genetically Modified foods

Novel foods, functional foods and genetically modified foods are the recent interventions into the agri-food system supply chain (Lezaun and Schneider, 2012). These interventions are necessary as part of the Agri-food industry contribution towards the achievement of United Nation (UN) Sustainable Development Goals (SDGs) 2.0 of ending hunger, achieving food security, improving nutrition and promoting sustainable agriculture (FAO, 2021).

Functional food concept originated from Japan in the mid-1980s in the face of increasing health cost and worsen health conditions of the aging population (FSAI, 2007; Clare, 2002), and they are conceptualized as Foods for Specified Health Use (FOSHU) (Ashwell, 2001). In response to this challenge, some foods with documented health benefits were designated and approved to be used as functional foods (Clare, 2002). Functional foods

have been generally regarded as foods that may offer health benefits beyond the inherent nutritional benefits (Steinberg and Grob-Steinberg, 2009). Unlike novel foods that require premarket approval and regulated by specific novel food regulations (e.g., Novel Foods Regulation (EU) 2015/2283), functional foods were only regulated in terms of health claims that can be made without misinforming the consumers. The health claims that can be made about a food in the UK are regulated by the Nutrition and Health Claims (England) Regulations 2007 as well as the labelling requirements for food products containing such functional food ingredients (DHSC, 2021). In the UK, there is a nutrition and claims register; *the Great Britain Health and Nutrition Claims Register*, the only health claims that can be made on the front of pack (FOP) of a food product must be claims that have been approved and listed in the register (DHSC, 2022).

Genetically modified foods have been defined as foods that are derived from plant or animal whose genetic material (DNA) has been altered or modified in a way that does not occur naturally (WHO; FSA, 2018). In most countries in which novel foods have been strictly defined, GM foods are not included as one of the categories of novel foods. However, in Canada GM foods are considered as novel foods as defined by the Food and Drug Regulations (Calabrese and Ferranti, 2018). In the UK, GM foods are regulated by the Genetically Modified Food (England) Regulation 2004, and they must be authorised before they can be placed on the market (FSA, 2022). This authorization only applies to GM foods made from organisms that are not live e.g., soybean oil, corn starch etc., and this authorization comes with a maximum validity of 10 years (FSA, 2022). The assessment for the safety of GM foods is done by the Food Standard Agency in conjunction with the Advisory Committee on Novel Foods and Processes (ACNFP). They are assessed for their toxicity, nutritional value and allergenicity and only authorised for market placement if they pose no health risk, will not mislead consumers and the GM foods will not be of less nutritional quality compared to non-GM foods (FSA,2018).

2.3 Novel foods type and classification

According to the EIT Food, introduction of novel foods into the food system could be the key to the transformation of the system and could contribute positively to the development of healthier and more sustainable diets. Novel foods can be classified into their types based on the categories they fall into by the novel food regulation definition. However, based on the current novel foods authorised to be placed in the market, the following novel foods types will be examined:

- i. Traditional foods
- ii. Alternative Protein foods

- iii. Novel Carbohydrate
- iv. Novel food supplements

Figure 2 below shows the sources of these novel foods categories and/or processes/materials involved in their production.

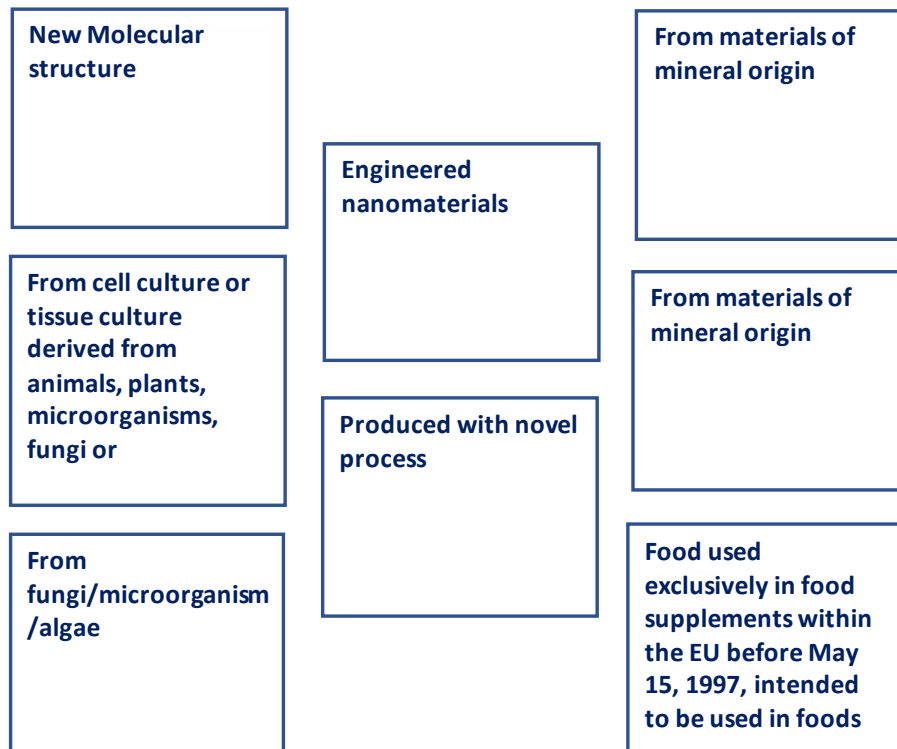


Figure 2: Sources, processes and materials involved in novel foods production (EFSA,2022)

2.3.1 Traditional foods (non-EU based foods)

Traditional foods are subset of novel foods, and these are foods that are traditionally consumed in countries outside the EU and/or UK as well as other countries in which such foods are being introduced newly (EFSA, 2021; Bresson et al., 2021). They are foods derived from primary production (Boer and Bast, 2018), typical example of such foods is, Chia seeds, insects, flax seeds, baobab fruits, etc. This also includes foods produced from animals, plants, microbes, algae, etc. It is expected that such food should have been consumed to a significant extent for a period of at least 25 years with evidence of safe use before it can be introduced into the EU or UK prior to being approved as a novel food (EFSA, 2021). Such food requires an official notification to be made according to article 14 of the European commission and with EFSA issuing an opinion of whether to accept or reject the food to be placed in the market.

2.3.2 Alternative Protein foods

These are foods that are derived from other novel protein sources aside from animal sources (Sawicka et al., 2020). They are classified based on the protein sources from which they are derived from (Marcin et al., 2022). They are either classified as insect-based, plant-based, or Lab-grown. Also included is the novel protein made from Algae, fungi etc.(Sexton et al., 2019). Plant-based alternative protein which are mostly meat analog or substitutes has attracted considerable attention from the consumer in recent years. This is due to increased awareness by the consumer of the health benefits of plant-based diets or products, animal welfare concerns and the need for sustainable food production (Marcin et al., 2022). Plant-based alternative are mainly derived from legumes (e.g., peas, lupins, lentils, chickpeas, faba bean etc.), Oilseeds (soybean, hemp seeds, flax seeds, chia seeds, rapeseeds, etc.), cereals and pseudo-cereals (e.g., wheat, rice, amaranthus, quinoa, etc.). Insects as a food have been consumed traditionally in many parts of the world and regarded to be very nutritious and appreciable source of quality protein (Marcin et al., 2022; Maurya and Kushwaha, 2019). Over 200 edible insect species have been identified and the species mostly consumed include Coleoptera Beetles, Lepidoptera Caterpillars, Hemiptera, etc.). Lab-grown meat or cultured meat are alternative protein food produced by a process called differentiation (Anu et al., 2021). This process involves feeding of cell issue taken from live animal into a bioreactor together with a growth medium that will allow it grow and divide. The production technology used for this process are regarded as novel with less environmental impact when compared to conventional meat production (Anu et al., 2021; Sexton et al., 2019). Algae is another protein source that is differentiated into microalgae and seaweed (Marcin et al., 2022). According to Novel Food Regulation (EU), any food produced with the addition of algae is regarded as novel food, example of such is their use in the formulation of meat analog. While fungus such as mushroom has been used as part of the ingredients in the production of meat analog because of their nutritional and organoleptic properties (Marcin et al., 2022).

2.3.3 Novel Carbohydrates

Novel carbohydrates are novel foods which comprises of novel fibre from new sources, human identical milk oligosaccharides and as well carbohydrates intended to be use as sugars replacer (EFSA, 2021). They were mostly derived from plant sources such as, carrot apple (pomace), seaweed, husk, bran, shells, peels, etc., (Sharma et al., 2015) animal sources such as crustaceans, microbes, algae or fungi. They are produced by means of enzymatic or chemical synthesis, hydrolysis of polysaccharides and fermentation process. They are produced to be source of dietary fibre and comprises of indigestible and non-

absorbable carbohydrate with a degree of polymerization of 3 or more (Sharma et al., 2015), e.g., Chitin, xanthan gum, hemicellulose, etc.

2.3.4 Novel food supplements

Novel food supplements comprises of novel food or ingredients such as plant extract, synthetic cannabidiol and engineered nanomaterials (EFSA, 2021). A supplement of great interest is that of cannabidiol (CBD), which can be produced synthetically or isolated from cannabis plant (e.g., *Cannabis sativa* L). The EC has determined that CBD can be considered as a novel food, and as of April 2022, EFSA reported that about 19 applications for CBD authorization are under consideration. Possible knowledge gap has been identified as regards to the safety of CBD as novel food. Therefore, due to ambiguity and gap in available safety data which makes it impossible to assure its safe use, EFSA concluded that safety of CBD as a novel food cannot be established for now (EFSA, 2022). Engineered nanomaterials are categorized into 3 main categories; (Sekhon, 2010) inorganic (silver, iron, selenium, silicates, etc.), surface functionalized materials, and organic engineered nanomaterials (e.g., benzoic acid, ascorbic acid, isoflavones, beta-carotene, etc.). They are designed and manufactured to have specific physical and chemical attributes with nanoparticle size of less than 100 nm (Bandala and Berli, 2018), and exhibit properties that are different from materials of similar chemical composition (Sekhon, 2010). The addition of engineered nanomaterials to a food product through the use of nanotechnology process produced a novel food termed as nanofood (Sekhon, 2010). The main aim of nanofood production is to enhance food safety, improve nutrition, flavour development, and cost reduction/optimization (Sekhon, 2010).

2.4 Current consumer and market trends for novel foods

In recent years, market for novel foods has grown considerably being part of a market segment of a larger health and wellness market (Southey, 2020). The key drivers for this market have been the increased awareness by the consumers about how production of food impact the environment and its adverse effects on climate change, concern about animal welfare and the need for healthy diets (Tuorila and Hartmann, 2020). Six market trends that are shaping the market have been identified (see figure 3 below), viz;

- I. Diet evolution as a result of migration and globalization
- II. Demand for sustainable food production with less impact on the environment
- III. Increased awareness about connection between health and food choices
- IV. Demand for value for money food products
- V. Demand for ready to cook (RTC) and ready to eat (RTE) foods

VI. Consumer demand for safe food and quality assurance

1 Demographic shifts and greater diversity in diets	2 Increase in sustainable and purpose-led alternatives	3 Bifurcation between healthy foods and indulgence	4 Premium specialty food vs low cost for basic food	5 Greater need for convenience and time savings	6 Growing importance of food safety and traceability
<ul style="list-style-type: none"> • Dispersion of diets as a result of globalization and migration. • New diets with low meat use, with flexitarians gaining popularity. 	<ul style="list-style-type: none"> • Increase public consciousness on sustainability. • Grocers expected to source and partner with more responsible Brands. 	<ul style="list-style-type: none"> • Greater concern on health impacts of dietary choices. 	<ul style="list-style-type: none"> • High demand for both price deals and premium goods. • Rise in private label with niched products for both ends. 	<ul style="list-style-type: none"> • Dietary changes come with faster and easier to prepare foods. • Emergence of dark kitchens and consolidation of delivery apps. 	<ul style="list-style-type: none"> • High level of transparency demanded by consumers and governments, with blockchain solutions gaining traction.

Figure 3: Six market trends shaping the novel foods market (Source: PWC, 2022)

This has led to demand for new food sources that will cater for these needs and development of new class of consumers such as vegans, flexitarians and vegetarians. While traditional foods such as chia seeds, flax seeds, noni fruit are gaining market traction as novel foods in the European market, the other novel foods categories are still in their early stages of development (see figure 4 below) in terms of their technological status and market visibility – consumers awareness and acceptability.

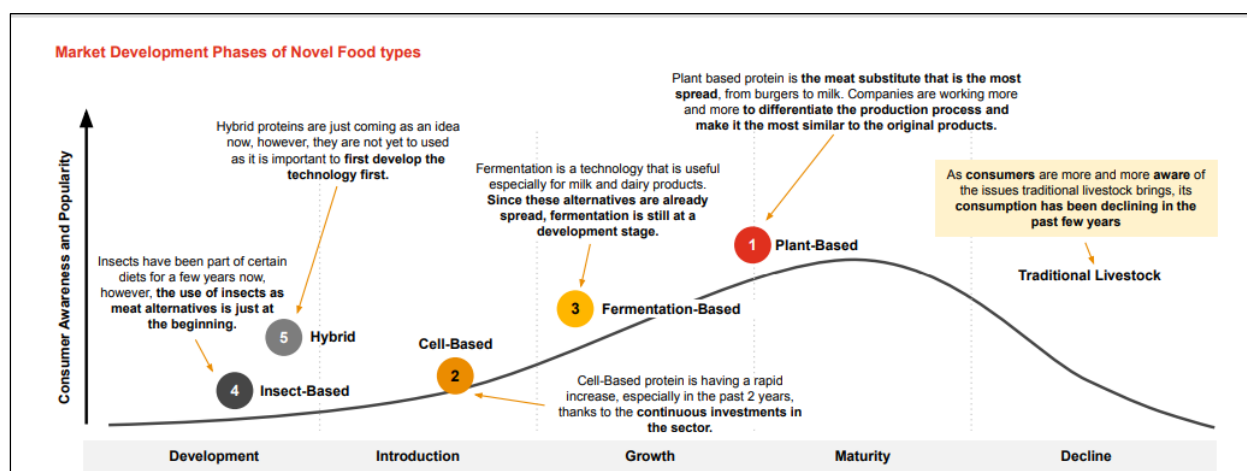


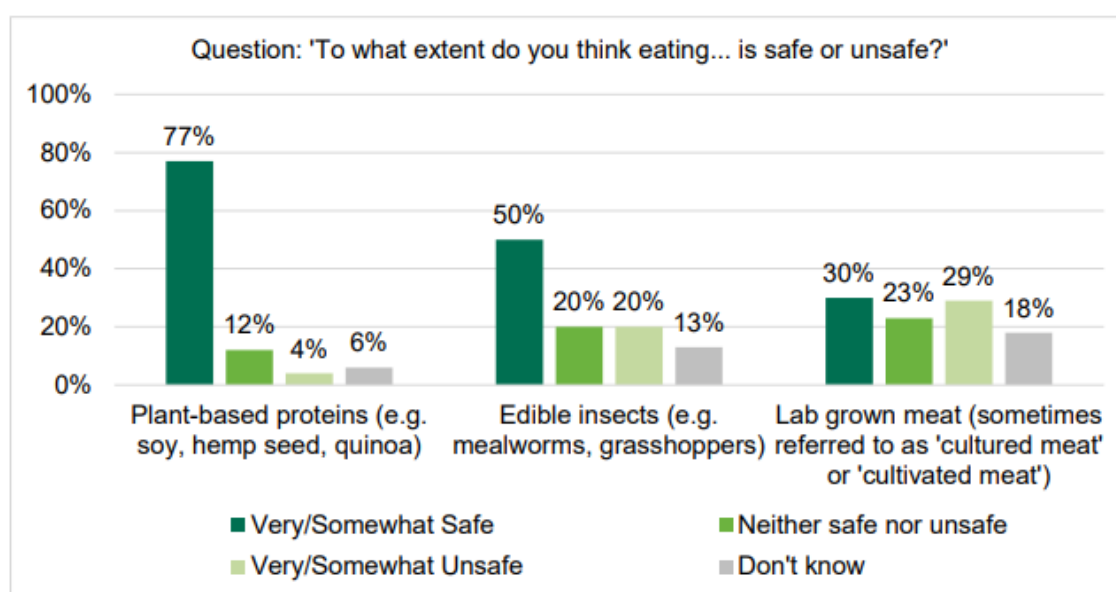
Figure 4: Market development phases of novel foods categories (Source: PWC, 2022)

However, in the UK plant-based novel food products have experienced appreciable growth and attained market maturity. For instance, plant-based meat alternatives recorded a growth of 40% from 2014 to 2019, and it has been predicted to achieve a market value of £1.1 billion by 2024 (Mintel, 2019). While as of 2019, the market value for plant-based milk

alternatives in the UK was put at £260 million and it has been projected to grow more than 50% by 2025 (Mintel, 2019).

2.5 Consumer acceptance of novel foods

Novel foods consumer acceptability is key to its continuous development and evolution (Fischer and Reinders, 2022), while cultural influences, unwillingness to try or eat new food (food neophobia) and safety concern has been identified as major barriers for acceptance of novel foods (Tuorila and Hartmann, 2020). Table 1 below according to Tuorila and Hartmann (2020), indicated those factors that may influence acceptance or rejection of a novel food. Also based on the survey conducted by Food Standards Agency (FSA) on the perception of novel sources of protein, 60% of the respondents indicated their willingness to try to plant-based proteins, 34% agreed to try out lab grown meat while only 26% of the respondents opted to try out edible insects. Based on this survey, safety of the food (as shown in figure 5 below), inherent health benefits, environmental and sustainability consideration have been identified as the major ground for their decision to opt-in and try it.



Base: 1,930 Online, adults 16-75 in England, Wales and Northern Ireland, 9-11th December 2021

Figure 5: Safety considerations as willingness to try novel alternative protein foods.(FSA, 2022)

Table 1: Factors influencing the acceptance or rejection of a novel food

Type of food	Definition	Acceptance	Rejection
Ethnic	Unfamiliar locally, known and 'safety tested' in another culture	Variety seeking Increased availability	Unfamiliar (weird) sensory properties Uncertainty Food neophobia
Nutritionally modified	Contains often more fiber or less fat, sodium, or sucrose than a conventional food	Health, nutrition and well-being	Sensory properties may differ from regular
Functional	Evidence based beneficial effect due to special ingredients	Health, nutrition and well-being	Price Perceived uselessness
Free from	An ingredient unfit for a part of population has been omitted (e.g., lactose, gluten, palm oil)	The absence of unhealthy or unfit ingredient	Sensory properties may differ from regular
Vegetarian and vegan	Free from meat and other animal-based material (different levels exist, fully free = vegan)	Meat avoidance Environmental concerns Moral views Health, nutrition and wellbeing Ethical value	Attached to meat Perceived inadequacy of nutritional value
Organic	Produced in traditional farming conditions without fertilizers or herbicides/pesticides	Naturalness Health, nutrition and well-being Ethical value	Price Quality defects
Plant based meat replacers	Products replacing the meat component from a dish or meal	Source of protein Ethical value	Attached to meat Sensory expectations hard to meet
Insect	Product containing whole or bruised insects	Source of protein Curiosity	Disgust Food neophobia
Artificial meat	Meat produced from stem cells without a living animal body	Sensory properties similar to meat Ethical value	Disgust Unnaturalness
3D-printed	Computer-assisted design combined with 3D food printer -> products in complex patterns and shapes	Personalized nutrition	Disgust Unnaturalness Food technology neophobia

2.6 Novel foods development in the UK

The market for novel foods in the UK has experienced appreciable growth since the exit of the UK from Europe (CHAP, 2021). This development was as a result of government revamped policy to promote innovation in the food sector of the economy and acknowledgement of the contribution of novel foods to food security, public health and sustainable agri-food system. According to paper published by the UK government titled; ***“The Benefits of Brexit: How the UK is taking advantage of leaving the EU”***, government promised to review novel foods regulation to support innovation and promote the sector (with more focus on the alternative protein categories). The key aspect of this support is to work with FSA to update the process of approving novel foods while creating a transparent and efficient system that will cater for the investors, innovators, and assured consumer protection with respect to safety of the novel food that will be authorised to be placed in the UK market (Home Office, 2014).

2.7 Regulatory and Legislative frameworks for novel foods in the UK

The regulatory and legislative frameworks that were in use for regulating novel food in the EU also applied to the UK. The UK did not try to re-invent the wheel but rather adopted the EU regulations on the administration of novel foods (FSA, 2020). Though there are reviews that are ongoing and amendments that have been proposed to promote innovations and protect public health.

There are two approaches to regulation of novel foods in the UK, which are process-related approach and product-related approach (Vapnek and Purnhagen, 2020). The process-related approach focuses on processes and methods used for the production of the food while product-related approach focuses on varying features of the food product. The other identified approaches to regulatory frameworks are those that focus on premarket approval and post-approval monitoring (Vapnek and Purnhagen, 2020). In the UK, there are four basic regulatory frameworks when it comes to novel foods regulation (FSA, 2020);

- i. **Regulation (EU) 2017/2469 which lays down administrative and scientific requirements for novel foods applications** (*Commission Implementing Regulation (EU) 2017/2469*)
- ii. **Regulation (EU) 2020/1824 which lays down administrative and scientific requirements for notification of traditional foods from third countries.** (*Commission Implementing Regulation (EU) 2020/1824*)
- iii. **Regulation (EU) 2017/2470 which regulates the establishment of the Union list of novel foods** (*Commission Implementing Regulation (EU) 2017/2470*)

iv. **Regulation (EU) 2015/2283 on novel foods** (*Regulation (EU) 2015/2283 of the European Parliament and of the Council*)

The regulatory frameworks are utilized to regulate and authorize novel food that can be placed in the UK market. There are two authorization routes as contained within the regulatory frameworks, traditional food notification and full application routes. Traditional food notification route is an easy to market route for traditional foods that have 25 years history of consistent consumption in a country outside UK. The data requirement for this route is lower than full application with a review period of maximum of four month prior to its authorization and market placement (FSA, 2020). However, those foods which by definition did not fall under the traditional food category are subjected to full application which takes between 9 – 12 months before authorization can be given (FSA, 2020).

2.7.1 Premarket approval of novel foods

In the UK, before a novel food can be authorised and allowed to be placed in the UK market such food must be subject to premarket approval. This requires the preparation of a dossier as a supporting document for the premarket approval (FSA, 2020). This is done by providing required data that will allow decision to be made about the application, this data includes the novel food description, process and/or technology used for its production/preparation, its composition, specification, intended use and usage level, and its anticipated intake level (Bresson et al., 2016; FSA, 2020). The dossier must also contain information such as history/source of the novel food, its absorption, metabolism, excretion, nutritional information, toxicity and allergenicity information, and in a situation where any of these information are not provided justification must be given (Bresson et al., 2021). This dossier is then submitted to FSA for safety assessment. While the main aim of this approval process is to protect the consumers and safeguard public health, this process has been faulted with believe that it is stifling innovation (Holle, 2018; Bernd et al., 2012). The process was regarded as high barrier to introduction of novel foods into the market with attendant negative impact on innovation and diversification of food sources (Holle, 2018). The key issues that have been identified includes;

- i. The timeframe required to make approval decision
- ii. Lack of scientific data protection submitted by the applicant
- iii. Transparency challenge with other not so clear approval factors

However, despite the repeal of the Regulation (EC) No 258/1997 because of the identified grey areas, the new Regulation (EU) 2015/2283 has not yet addressed the issue mentioned above.

2.7.2 Novel foods authorization requirements

For authorization to be granted for placement of novel foods in the UK market, application must be submitted through the Food Standard Agency (FSA) electronic-submission system which is accessible through the **regulated products application service** of the agency website (FSA,2021). Application is made by completing and submitting the e-form with all the required information. The information to be provided is in compliance to article 10 of Regulation (EU) 2015/2283, and once the submission is made, the applicant will receive an email with a secure link which is only valid for 7 days (FSA, 2020; Bresson et al, 2021). This link will allow the applicant to upload all the required documents needed for the authorization. The document to be uploaded includes;

Administrative information document – this document contains information about the applicant, the person(s) responsible for the product or process, and contact person(s) if further information is needed concerning the product. This may also include the information to be classified as confidential.

Technical Information document – This document provides more information about the product or process and its intended usage. This information includes the identity of the product, its functionality, nutritional benefits, usage levels in a food product (in case of a novel food ingredient), and consumption level. The document may also contain data that will assist in carrying out risk assessments of the product by the FSA risk management team. There is also allowance for certain information to be classified as confidential.

Safety Information document – This document contains scientific data that will allow for extensive safety assessment of the product to be carried out. And in a situation where the data provided is not sufficient, justification must be provided for the missing information.

2.7.3 Procedure for novel foods authorization

The procedure used by FSA is in accordance with the requirements contained in the Regulation (EU) 2015/2283, It allows for due diligence to be done while also ensuring that only safe food product is allowed to be placed in the UK market. The procedure is as follows (also see figure 6 below);

- i. Application must be submitted with all the requires documentation through the online e-submit system
- ii. Initial checks by FSA to ensure that all the necessary information have been provided
- iii. Safety assessments of the product and/or process. This is carried out by the Joint Expert Groups and/or Scientific Advisory Committee.

- iv. Formation of evidence package with consideration for other legitimate factors such as risks to the environment
- v. Possible risk management option is considered based on the evidence package
- vi. Recommendations are made to the ministers to decide if authorization can be granted. The authorization is dependent upon the novel food not posing a safety risk to the consumer, which is based on the scientific evidence, that the food will not mislead the consumer and nutritionally be disadvantageous to the consumer.

In the course of this process, there will be opportunity for the applicant to take part in consultation during the risk assessment process before final decision is made. If the approval decision is favourable, the legislation will be updated, and the food product will be included in the union list and be allowed to be placed in the UK market without any restriction. The timeframe for the authorization depends on the complexities of the application and may take a minimum of 12 months before authorization process can be completed.

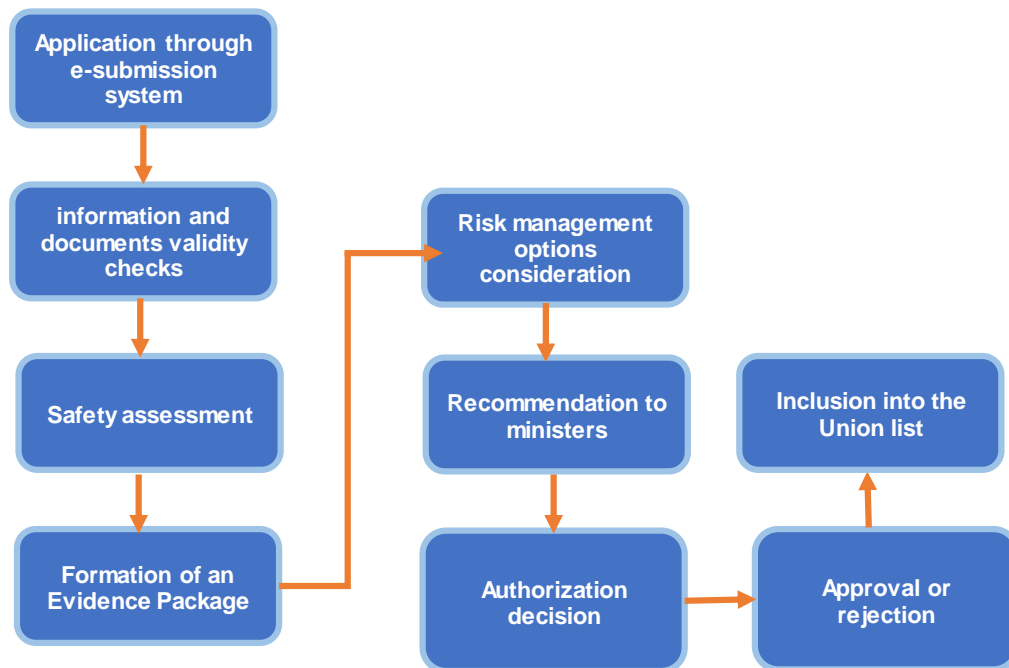


Figure 6: Procedure for novel foods application and authorization (FSA, 2020)

2.8 Labelling requirements and regulations for novel foods in the UK

Novel foods are subjected to the same general food labelling requirements as contained in the retained [Regulation \(EU\) 1169/2011](#) (FSA, 2021), and other relevant labelling

regulations. The regulation aids the consumer to make informed purchasing decision at the point-of-sale by providing quick information about the quality, nutritional component, ingredients etc. Novel foods like any other foods that are regulated under this legislation are required to have a food label that display certain information that are mandatory. This labelling information must be accurate without any intention or guise to mislead consumers. The mandatory information must be display on the pack of a novel food are as follows;

- i. Name of the food which must be clearly printed without misleading the consumer
- ii. Ingredients must be listed according to their order of weight, and ingredient with the highest weight contribution is listed first.
- iii. Declaration of allergens must be made for food that contains allergens in them. This must be boldly indicated on the front of pack (FOP) of the product using a different style, font, and background colour.
- iv. Quantitative declaration of ingredients (QUID) which enables consumers to know percentage of a particular ingredient that are in a product and this information must be visible without any encumbrance.
- v. Net quantity must be stated on the label in compliance to Food Information Regulations, provided the packaged food weighs above 5g but not applicable to foods that are sold by number or weighed in the presence of the buyer.
- vi. Storage conditions and labelling date such as 'best before', 'use by' and 'expiry' date must be stated on the label
- vii. Name and address of manufacturer of the product must be provided
- viii. Country of origin must be provided, and it is mandatory
- ix. Cooking or preparation instructions must be given on the label if they are needed
- x. The declaration of the nutritional component of the food is mandatory and must be clearly display is a specific format with energy values and six nutrients.

2.9 Testing and safety evaluation of novel foods

The legal framework and risk management procedure put in place by the regulatory bodies like EFSA, FSA, FSS etc., have been used to manage potential risk from novel foods and possible negative impact on public health and safety of the consumer (Boer and Bast, 2018). Methodological difficulties have been identified as the major setbacks in safety assessment of novel ingredients and novel foods as a result of their complexities and high levels of dietary incorporation (Howlett et al., 2003). These identified difficulties have made checklist approach to risk assessment and safety evaluation of novel foods inadequate (Jonas et al., 1996). Instead, a case-by-case approach has been adopted by taking account of the peculiar characteristics of the individual novel food such as source of origin, compositional

data, intake level, dietary contribution and the intended target consumers (Edwards, 2005; Jonas et al., 2000). Novel foods have always been subjected to systematic safety assessments unlike their traditional food counterparts (Edwards, 2005; Howlett et al., 2003). While traditional foods are usually accepted based on their history of use, novel foods safety assessments are done by using traditional foods as reference points and then use the difference between the two food categories as the basis for assessment (Edwards, 2005). This approach is based on the concept that there might be substantial equivalence between the novel food and traditional foods whose safety status have been certified (Howlett et al., 2003). The following are the steps to safety assessment of novel foods (see figure 7 below);

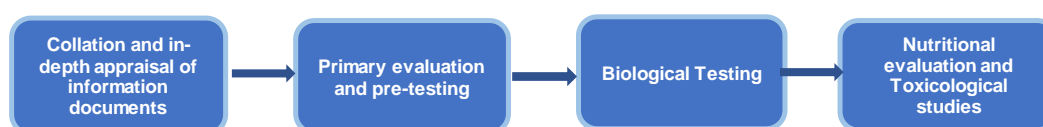


Figure 7; Steps involve in safety assessment of novel foods. (Howlett et al., 2003)

- i. Collation and in-depth appraisal of information on the origin, composition, production, compositional data, nutritional value, history of human use, and the intended use.
- ii. Primary evaluation and pre-testing – which in some cases might be enough to make a decision on the safety status of a novel food. This step will determine whether there will be need for additional studies and/or biological testing.
- iii. Biological testing – required if primary evaluation will not be enough for the safety assessment. Evaluation on the impact of novel foods on the diet of testing animal is also required at this stage. It is also important to give careful consideration to the formulations, storage and administration of test to assured of the validity of test result with respect to safety assessment of novel foods for human consumption.
- iv. Nutritional characteristics evaluation – assessment for potential impact on human diet and to identify any possible nutritional deficiencies or excesses. This is important for the conduct of toxicological studies (Edwards, 2005) This will also identify any possible knowledge gaps and determine whether further studies will be needed.

There are also post-safety assessments in case of any reported cases by the consumers after the novel foods have been approved and placed in the market to provide additional reassurance of their safety status (Jonas et al., 1996).

2.10 Novel foods, allergy risk and control

Introduction of novel foods into the food supply chain has initiated the need for special consideration for new allergen watch, and in particular the introduction of novel alternative proteins into the human diet may lead to new food allergy cases (Putten et al., 2005).

Allergens in food have been known to pose health risk to those that are susceptible to them (Abdelmoteleb et al., 2021), while allergen management of conventional food products have been achieved through the use of appropriate labelling by warning would be consumers that the food product contain allergens or may contain allergen (in case of cross contamination) that might put them at risk (Abdelmoteleb et al., 2021). It is important that allergen risk assessment as part of the overall safety assessment of novel food should be thoroughly carried out to prevent potential increase in prevalence of food allergy within the food chain system (Putten et al., 2011). Genomic and proteomic bioinformatics methods have been identified as major approaches for identification of proteins in a variety of food materials (Abdelmoteleb et al., 2021). These predicted proteins are then used against the allergen databases (<http://www.allergenonline.org>) to identify possible risk allergen factors for food safety assessment.

However, uncertainty still remains about the potential allergenicity of some approved novel foods, and this can be dealt with by evaluating the effectiveness of the risk management measures that have been put in place to manage novel food allergenicity (Putten et al., 2011). This can be achieved by carrying out post approval monitoring and market surveillance/monitoring for any potential allergic reactions to novel food that have been approved to be sold.

2.11 Technologies for novel food processing

One of the definitions given to food that can be regarded as a novel food, according to the Article 3, paragraph 2 of Regulation (EU) 2015/2283, is any food that has been produced using a production process or technology which has not been used prior to 15 May 1997, giving rise to significant alteration of the food composition or structure which can affect its nutritional value, metabolism, or toxicity level. Most of these technologies came about as a result of response to consumer needs and the quest to meet these needs through innovation and technological advancement. These novel food technologies are essential for food security, safety and sustainability (Siegrist and Hartmann, 2020)

2.11.1 Cultured meat technology

This is a technology used to produce meat from animal cells without slaughtering the animal (Goodwin and Shoulders, 2013). The culture meat produced from this technological process are also referred to as lab grown meat or in-vitro meat (Chriki and Hocquette, 2020; . Goodwin and Shoulders, 2013). This technology involves recreation of livestock muscles from few cells taken from a live animal which are then allowed to grow into muscle and fat cells with similar physiological characteristics (e.g., juiciness, tenderness, and flavour) as meat produced from normal slaughtering process. The cells are grown in a culture medium that have been enriched with nutrients (e.g., amino acid, glucose, vitamins, inorganic salt, etc.), hormones and growth factors (Kazuko, 2020). This process is carried out in a controlled and monitored environment that will support the growth of the seed cells (Chriki and Hocquette, 2020).

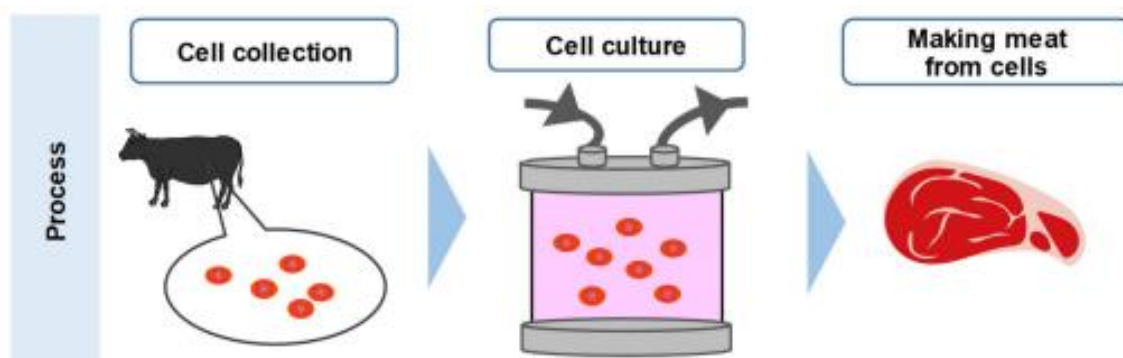


Figure 8: Cultured meat production process (Source: MGSSI; Kazuko, 2020)

However, some challenges have been identified with this technology, this includes technological limitation in the area of developing and mass-producing culture medium that will allow for the scaling up of the culture meat, as well as safety concern and consumer acceptability (Kazuko, 2020; Chriki and Hocquette, 2020; Bryant and Barnett, 2018). Despite these challenges, the technology has the potential to address the ethical, environmental and health concern associated with conventional meat production (Bryant, 2020).

2.11.2 Nanotechnology

Nanotechnology is an emerging technology that are deployed in the manipulation of nanomaterials for numerous purposes (Nile et al., 2020; Ravichandran, 2010). This technology plays an important role in agri-food system by contributing to crop improvement, enhancing food safety and quality, and promotion of human health through novel and innovative approach (Nile et al., 2020). The technology has been deployed in the various aspect of food processing and packaging effectively (see figure 9 below) to enhances food nutrient bioavailability, taste and texture improvement, removal of unpleasant odour, particle size modification and increased shelf-stability of food (Chellaram et al., 2014). Foods

produced using this technology are referred to as nanofoods (Nile et al., 2020; Ravichandran, 2010).

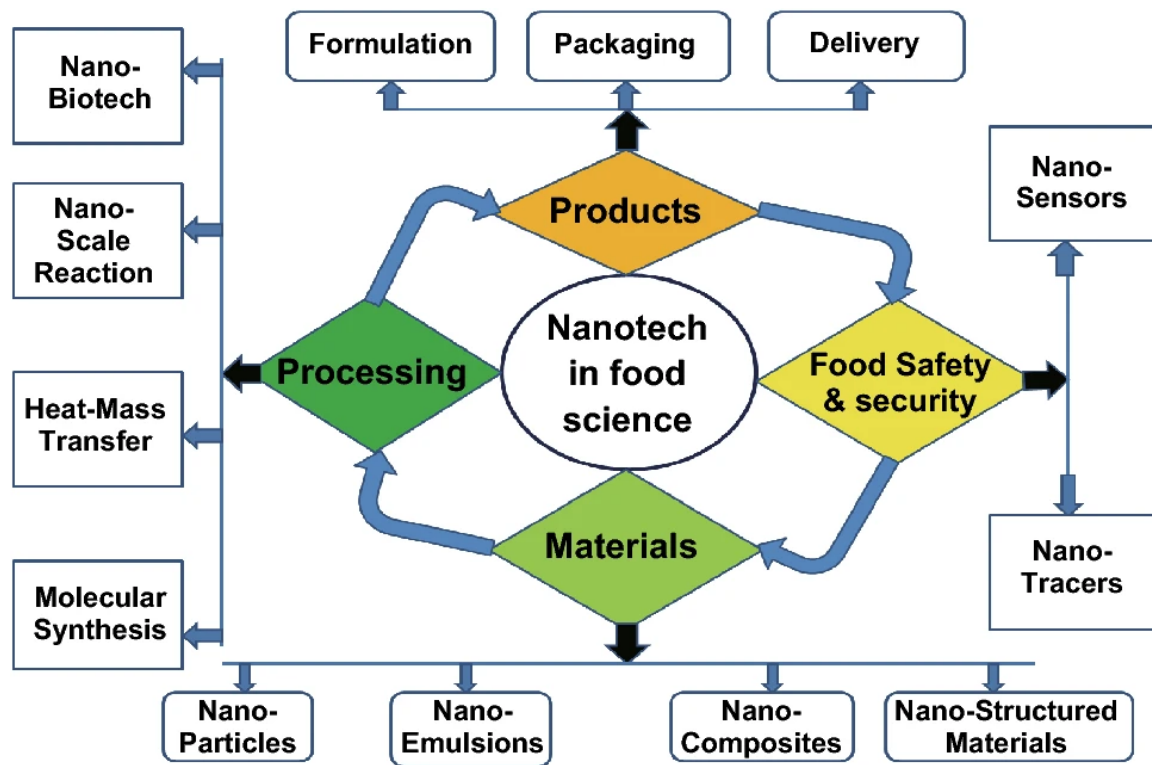


Figure 9: Various applications of nanotechnology in food science (Nile et al., 2020)

The nanomaterials used for this technology have been categorized into 3 main categories; (Sekhon, 2010) inorganic (silver, iron, selenium, silicates, etc.), surface functionalized materials, and organic engineered nanomaterials (e.g., benzoic acid, ascorbic acid, isoflavones, beta-carotene, etc.). They are designed and manufactured to have specific physical and chemical attributes with nanoparticle size of less than 100 nm (Bandala and Berli, 2018), and exhibit properties that are different from materials of similar chemical composition (Sekhon, 2010). The main aim of nanofood production is to enhance food safety, improve nutrition, flavour development, and cost reduction/optimization (Sekhon, 2010).

2.11.3 3D Food printing Technology

3D food printing technology is an additive manufacturing technique used for creating a unique novel textured food in attractive format (Prakash et al., 2019; Pitayachaval et al., 2018). This technology has been used in several industries including food industry to create amazing food design. It is a print and eat technology that can be used to produce healthy foods, and smooth and easy to swallow foods (Prakash et al., 2019). It allows for food

customization and ability to control certain food properties such as rheological or nutritional properties (Dianez et al., 2022)

The 3D food printing technique used in food design creation has been classified into 3 categories, namely; Extrusion-based printing, Inkjet printing, and Binder printing (see table 2 below).

	Category		
	Extrusion-based printing	Binder jetting	Inkjet printing
Principle	Extrusion and deposition	Powder binding and binder drop-on demand deposition	Drop-on-demand deposition and continuous jet printing
Materials	Solid-based, Paste material	Liquid-based, Powder-based	Liquid-based, low viscosity material
Processing factor	-Printing head height -Nozzle diameter -Printing rate -Nozzle movement rate	-Printing head types -Printing rate -Nozzle diameter -Layer thickness	-Temperature in print head -Nozzle diameter -Printing head height -Printing rate
Advantage	-Low cost of the entry - level machines -A variety of raw materials are available -Easy to customize	-Large number of potential materials -Very high production speed -Support structure are included automatically in layer fabrication -Low-imaging specific energy -Complex 3D food fabrication	-No waste of model material -High resolution and accuracy -Multiple materials and multiple colors -Fast fabrication
Disadvantage	-Low level of precision and long build time -Unable to build sharp external corners -Anisotropic nature of a printed part -Difficult to hold 3D structures in post processing	-Rough or grainy appearance -Post-processing required to remove moisture or improve strength -Limited material -Less nutritious products	-Post-processing may damage thin and small features -Support materials cannot be recycled thus wasted -Simple food design -Only for surface filling or image decoration
Application	Chocolate, Confection, Decorations made of sugar, Candies	Chocolate, Pizza (Powder form), Fake food	Chocolate, Liquid dough, sugar icing, meat paste, cheese, jams, gels

Table 2: Categories of 3D printing technology (Pitayachaval et al., 2018)

The **extrusion-based printing** allows food to be printed/created by extruding or forcing a food material through a die opening or nozzle under sustained pressure. The food material being extruded can be a solid and/or slurry with low viscosity with the extruder allowing layer by layer of food to be printed utilizing Fuse Deposition Modelling (FDM) (Pitayachaval et al., 2018; Yang et al., 2017). Dough meat paste and cheese are examples of food that have been produced using this technique. The **inkjet printing** technique uses a system where the electrically heated print head is allowed to dispense a stream of food material droplets as a coating or decoration on a food surface such as cookies, cakes, pizza etc. The **binder printing** uses a technique that allows food materials to be deposited on to a power bed surface through a die. This is mainly use for liquid or fine particulate materials.

2.12 Background to the research method

A systematic review approach was used for this research to appraise scientific studies that have been conducted previously. It allows relevant studies to be identified and logically appraised for the purpose of extracting and examining data from such studies (Clarke, 2011). This research being a desktop research requires that appropriate data and information from the relevant studies must be fitly explored and harnessed to answer the research question.

Therefore, using this systematic review approach enables the use of reproducible and repeatable method to search, identify, select and integrate information from various primary sources. It follows a systematic steps of formulating a research question, identification of databases, setting up of an inclusion and exclusion criteria, using of keywords to search databases for relevant studies, selection of relevant studies based on the inclusion criteria, extraction of data from the studies and presentation of the results. Figure 10 below shows the typical steps in a systematic review. This method is mostly used by researchers when seeking answer to a specific question by conducting evidence-based research through the methodical review of existing relevant studies (Gopalakrishnan and Ganeshkumar, 2013)

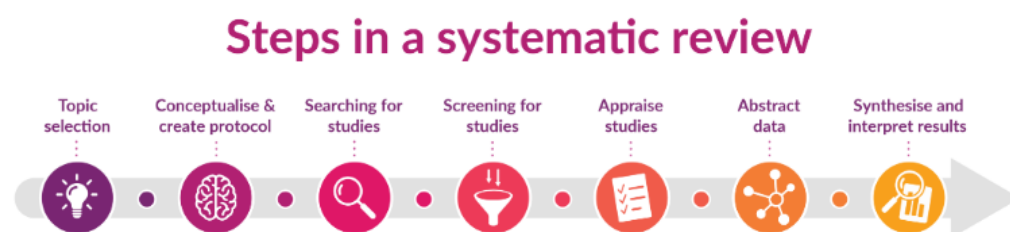


Figure 10: Steps in a systematic review (Karolinska, 2022)

The merits of using systematic review for a desktop-based research cannot be overemphasised as it helps in reducing research prejudice, it allows for use of unambiguous and easy to follow methods, and also enables information from different sources to be synthesised (Shaun, 2022). However, the major limitation of this method is the time required to conduct the research and its narrow scope as it only answers the specific research questions (Shaun, 2022).

3.0 Method

3.1 The study research method

For the method used for this study, the aim is to ensure that relevant academic studies and/or articles are harnessed and reviewed to effectively answer the research question. The research topic was duly evaluated which allowed the keywords to be defined and created. Databases were also identified and searched using the created keywords based on set eligibility criteria. The resulting scientific research documents are imported into the Rayyan software for screening. The documents were screened for their titles and abstract to select those that were relevant/unique to the study. The selected studies coupled with other additional documents were reviewed to extract the required information that will answer the research question and address the main aim of this study. Figure 11 below is the flow chart of the method used for this study.

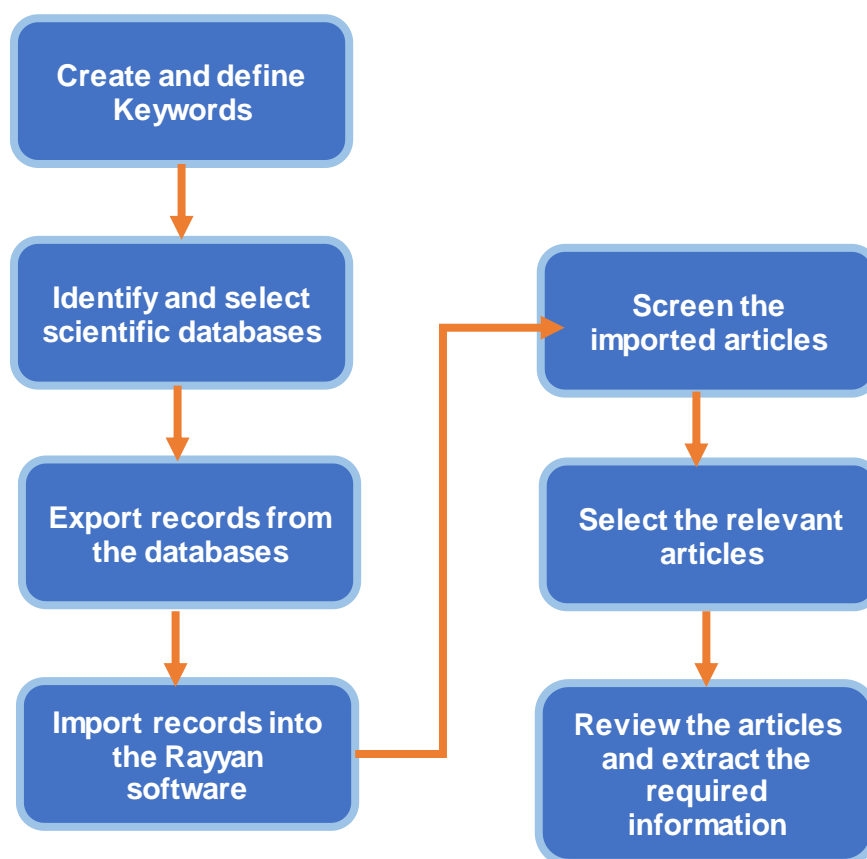


Figure 11: Method Flow Chart

3.2 Keywords creation

The key words identified for this study includes novel foods, novel food labelling, novel food technologies, functional foods, GM foods, novel food regulations, consumer acceptance. A Boolean search approach was used to search the identified databases (such as ‘Scopus’, ‘PubMed’, ‘ScienceDirect’, ‘ResearchGate’, ‘JSTOR’, ‘MDPI’, ‘Google Scholar’) using operators such as ‘AND’, ‘OR’, and ‘NOT’ to combine the keywords and to define, organise and sift through the databases for relevant results.

3.3 Identification and searching of databases

The following databases of Scopus, PubMed, Google Scholar, ScienceDirect, JSTOR and MDPI were identified and searched for the relevant records. The databases were searched in June 2022

Additionally, Food Standard Agency (FSA) websites, European Union (EU) website, UK government publications, UK legislative websites and other relevant sources were also checked and reviewed for necessary information.

3.4 Inclusion/Exclusion criteria

The criteria were set to ensure that only relevant studies from the databases were selected and included for the review. The following inclusion and exclusion criteria were used during the screening for the relevant studies;

Table 3: Inclusion and Exclusion criteria for the selection of relevant studies for the review

Inclusion criteria	Exclusion criteria
I The search was limited to studies published between 1997 and 2022. The 1997 was used as the start date to coincide with the year novel food regulation was introduced by the EU	I Studies published before 1997 not considered
II Studies that focused on the concept of novel foods	II Studies not written in English
III Studies that focused on novel foods labelling requirements and regulations	III Non-peer reviewed literature excluding grey literature (technical report and web based guidelines)
IV Studies that focused on novel foods safety assessment and approval process	
V Studies that focused on technology for novel foods processing	
VI Studies that were written in English only	

The final studies selected for the review were those that fulfilled the inclusion/exclusion criteria set above in table 3.

3.5 Literature screening

The extracted records were imported into the Rayyan software for screening and selection of relevant studies using the set eligibility criteria. The screening was conducted between 26 June to 02 July 2022. The following workflow was used for the screening process:

- I. Removal of duplicate articles from the records which was automatically detected by Rayyan
- II. Titles and abstracts were examined to excludes articles that failed the inclusion criteria
- III. The full text of relevant articles was searched for
- IV. Reports referring to the same study were kept together
- V. Full-text articles were screened against criteria for inclusion
- VI. Final decisions on the study inclusion were then made

3.6 Review of studies

The studies that passed the screening process were reviewed together with the other information obtained from regulatory websites of EFSA, FSA, DHSC, UK government legislative websites, official government reports and publications.

4.0 Results and Discussion

4.1 Database report

A total of 965 records were filtered out from the databases. Below is the distribution of the records extracted from each database and presented in table 4, 5, and figure 12;

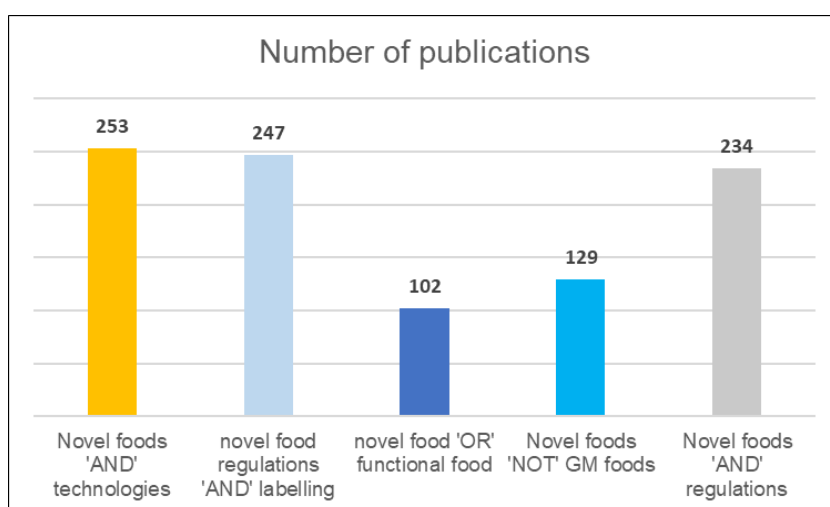
Database	No of records extracted
Scopus	675
Google Scholar	105
ScienceDirect	35
PubMed	125
JSTOR	13
MDPI	12

Table 4: Distribution of the records extracted from the databases

Keyword strings	Number of publications
Novel foods 'AND' technologies	253
novel food regulations 'AND' labelling	247
novel food 'OR' functional food	102
Novel foods 'NOT' GM foods	129
Novel foods 'AND' regulations	234

Table 5: Number of publications per keyword strings used

Figure 12: Graphical display of the number publications per keyword strings used

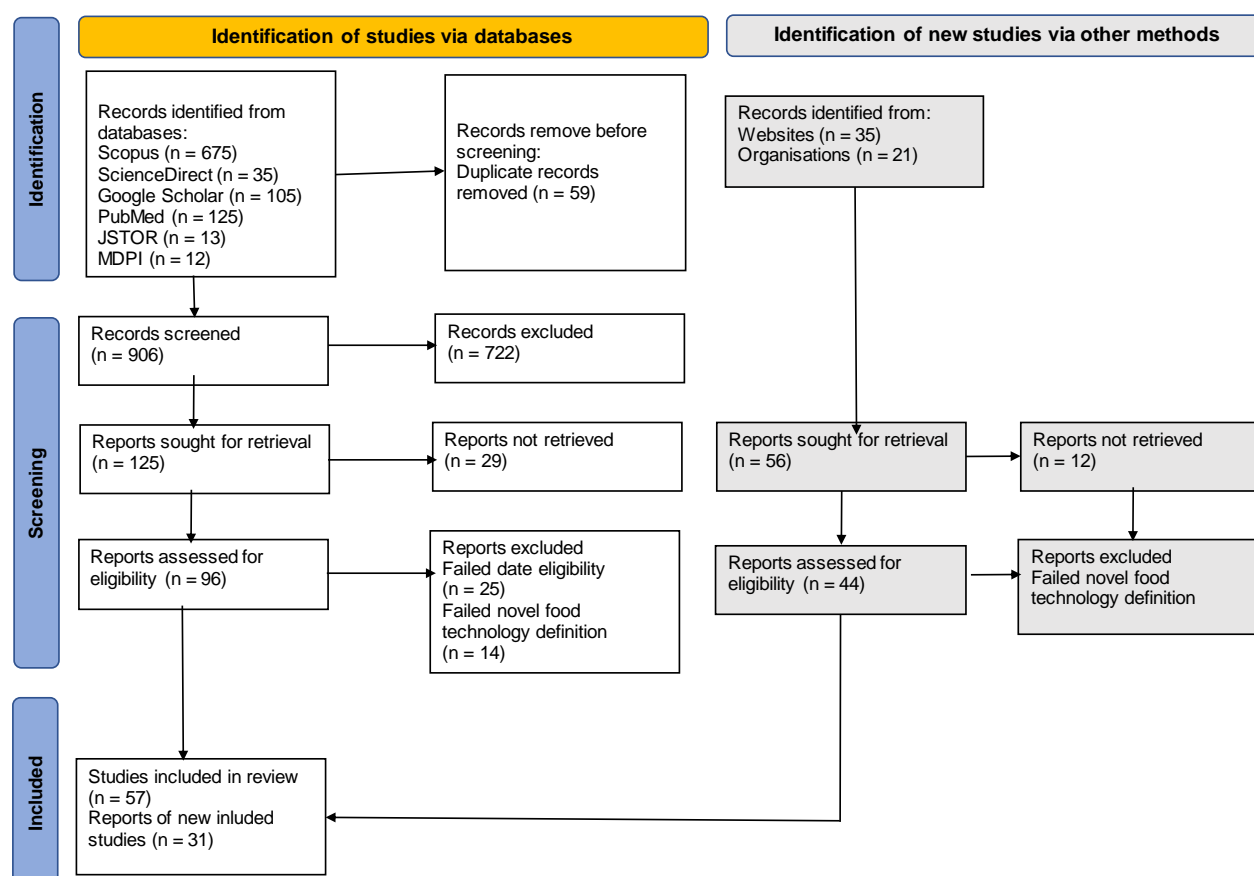


The bulk of the studies for the review were extracted from the Scopus database which accounted for 70% of the records.

4.2 Article screening report

A total of 57 studies from the 965 records filtered out from the databases were included for review after screening. Also, additional 31 studies from 56 records obtained from regulatory websites of EFSA, FSA, DHSC, UK government legislative websites, official government reports and publications were also included for the review (see figure 13 below).

Figure 13: PRISMA flow diagram for the studies systematic reviews (PRISMA 2020)



4.3 Studies distribution

Data extracted and the information sourced from the identified records obtained from the databases are spread across studies published between 1997 to 2022. The analysis of the data shows that there were more published studies between 2020 and 2021. See table 6, figures 14 and 15 below for the analysis of the spread of the records across years of publication and the databases.

Year of Publication	Database						Total Records
	Scopus	Google Scholar	ScienceDirect	PubMed	JSTOR	MDPI	
1997	0	0	3	7	2	4	16
1998	0	0	2	13	1	1	17
1999	0	0	2	9	0	0	11
2000	0	0	1	7	2	0	10
2001	0	0	4	5	2	3	14
2002	0	0	5	7	1	2	15
2003	0	0	3	7	0	0	10
2004	12	5	1	2	0	0	20
2005	15	10	0	4	0	0	29
2006	17	10	0	0	2	0	29
2007	25	7	1	5	0	0	38
2008	31	12	1	8	0	0	52
2009	21	9	0	4	1	0	35
2010	35	10	0	0	0	0	45
2011	20	5	3	0	0	0	28
2012	40	6	0	0	0	0	46
2013	35	10	2	3	0	0	50
2014	29	11	1	10	1	1	53
2015	44	2	1	5	0	0	52
2016	30	2	1	1	0	1	35
2017	59	1	1	4	0	0	65
2018	54	1	1	3	0	0	59
2019	50	1	1	1	1	0	54
2020	62	1	1	1	0	0	65
2021	79	1	0	10	0	0	90
2022	17	1	0	9	0	0	27
	675	105	35	125	13	12	

Table 6: Records spreads across the years and the database

Figure 14 : Records spreads across the years per each database

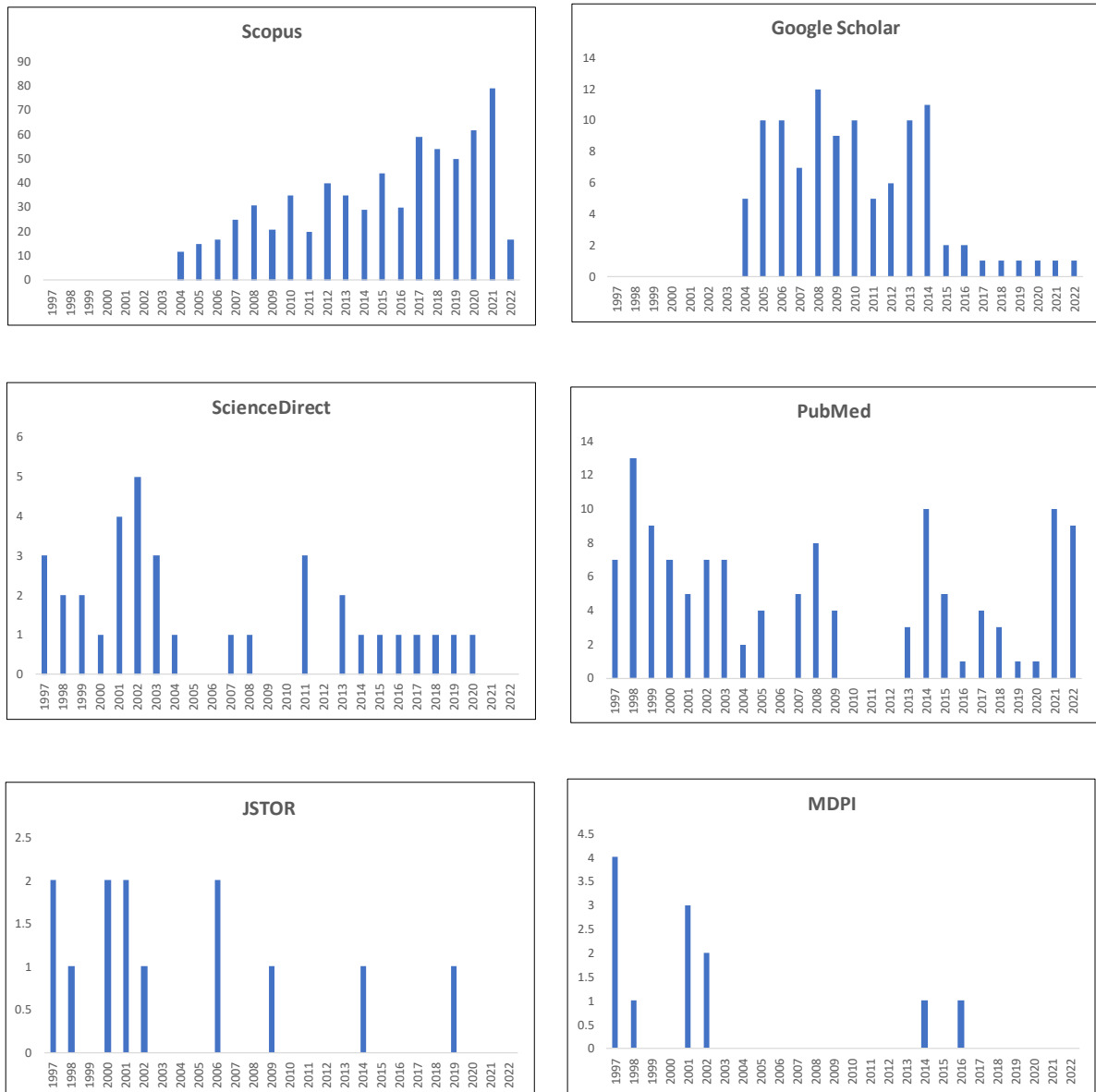
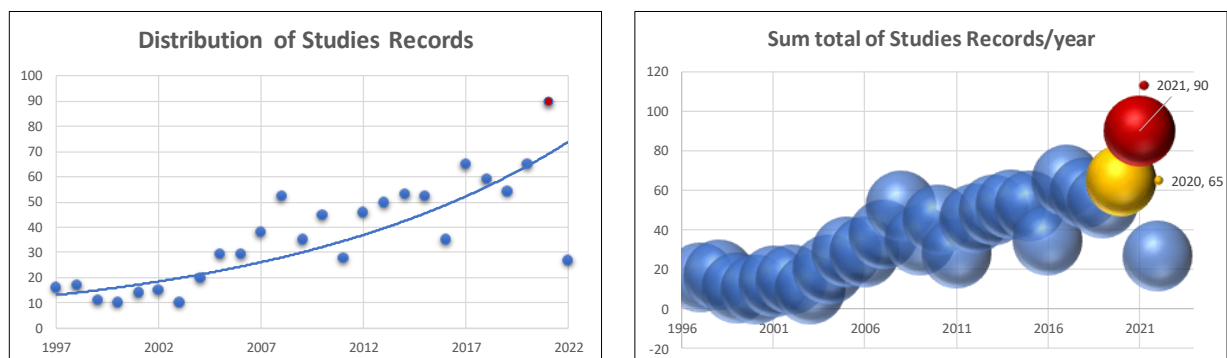


Figure 15: Distribution of the studies and sum total across each year of publication



The review done so far, and the data extracted from the studies have shown that compliance to labelling requirements, passing the testing regime for toxicity and safety assessment, and the technology used for processing the novel foods are critical to its market growth/development. These 3 elements will bring about either positive or negative consequences depending on how effectively they are managed.

4.4 Novel food compliance with general and specific labelling requirements

Novel foods like any other foods are expected to comply with all the labelling requirements that a conventional food will be subjected to. And aside from the general labelling requirements, they are also required to comply with specific labelling requirements as contained in the Union list of novel foods. Table 7 below is a typical example of specific labelling requirements for certain novel food products/ingredients. This Union list of novel foods is regulated by the Regulation (EU) 2017/2470 which is one of the regulatory frameworks for novel foods regulation (See Table 8 below)

Table 7 : Excerpts from Union list of novel foods showing specific labelling requirements (Commission Implementing Regulation (EU) 2017/2470)

Low fat cocoa extract	Specified food category	Maximum levels	Consumers shall be instructed not to consume more than 600 mg of cocoa flavanols per day
	Foods including food supplements as defined in Directive 2002/46/EC	730 mg per serving and around 1.2g/day	
Coriander seed oil from <i>Coriandrum sativum</i>	Specified food category	Maximum levels	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Coriander seed oil'
	Foods including food supplements as defined in Directive 2002/46/EC	600 mg/day	
<i>Crataegus pinnatifida</i> dried fruit	Specified food category	Maximum levels	The designation of the novel food on the labelling of the foodstuffs containing it shall be ' <i>Crataegus pinnatifida</i> dried fruit'
	Herbal infusions		
	Foods including food supplements as defined in Directive 2002/46/EC	In line with normal food use of <i>Crataegus laevigata</i>	
	Compotes		
α -cyclodextrin	Not specified		The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Alpha-cyclodextrin' or ' α -cyclodextrin'

Table 8: Regulatory frameworks for novel foods administration and regulation

Novel Foods Regulatory Framework	Application/Uses
Regulation (EU) 2017/2469	Provides framework for administrative and scientific requirements for novel foods application
Regulation (EU) 2020/1824	Provides framework for administrative and scientific requirements for notification of traditional foods from third world countries
Regulation (EU) 2017/2470	Provides framework for the establishment of the Union list of novel foods and specific labelling requirements
Regulation (EU) 2015/2283	Provides framework for definition and regulation of novel foods

Labelling of food play an important role in assisting consumers to make informed decisions about their food choices with respect to their health and dietary needs (FSA, 2022). It is important for the information provided on the label to be clear and accurate in full compliance with all the labelling requirements, as any deviation from this will have dire consequences for the manufacturers and the consumers. In the UK, FSA and FSS are responsible for ensuring that food information standards are complied with. They both undertake regular sampling activity to check that food products (novel food inclusive) meet safety, authenticity and food information requirements. In the recent Baskets of foods survey (2021) done to check this compliance, the results showed that 89% of the sample surveyed complied with specific standard set for the test. The test checked compliance for labelling, authenticity, allergens, composition, containment and adulteration. The figure 16 below showing non-compliance result indicated higher non-compliance in composition (9%), labelling (7%), and allergens declaration (5%). These 3 test variables are some of the key components of information that are required to be provided on a label of any novel food product.

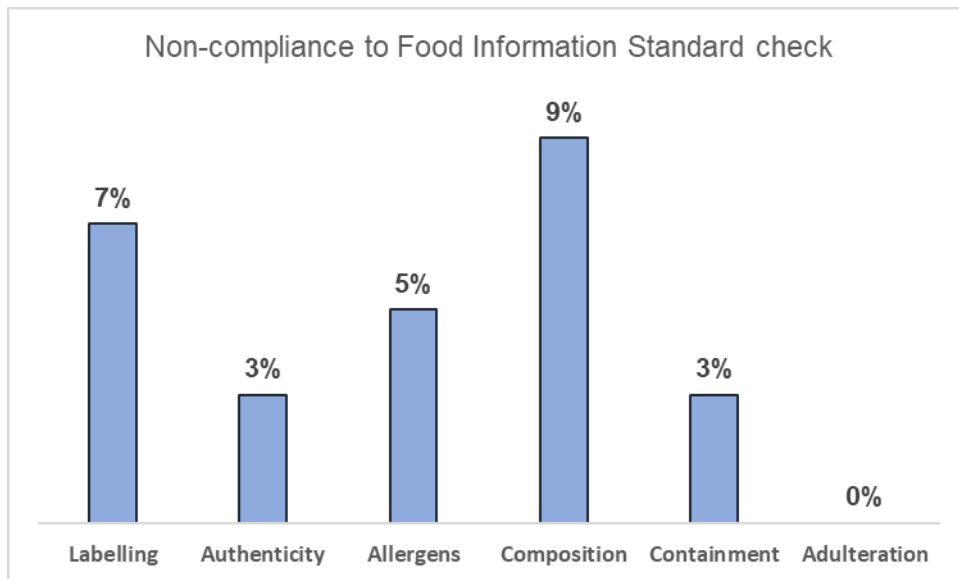


Figure 16: Baskets of foods survey showing non-compliance result of food information standard test (FSA, 2022).

The result shows that there are still some challenges with accuracy and clarity of information being provided on some novel food products. It is important to get this right first time, notably failure to declare information such as allergens can be harmful to the consumer and can increase rejection level of novel foods (food neophobia).

4.5 Novel foods labelling and consumer acceptance

The importance of information provided on a label of a food pack cannot be overemphasized, and this is even more critical for novel food products because of some intrinsic factors such as food neophobia, disgust sensitivity, variety seeking tendency, etc., which can influence consumer acceptance of a novel food product. However, based on the general labelling requirements and specific labelling requirements for novel foods it is mandatory that designation of the novel foods must bear the name of the food source with ingredients clearly listed. This is one of the labelling challenge with novel foods with respect to its acceptance by the consumer – typical example is that of insect-based novel food products. According to studies carried out by Modlinska et al. (2020), and Mancini et al.

(2019), the studies showed that novel food products labelled as containing insects are reluctantly consumed and in lower quantities despite their pleasing appearance. The study was able to establish that prior disgust and food neophobia for a novel food ingredient can further be exacerbated by the labelling information on the product irrespective of the organoleptic quality of the novel food product.

4.6 Timeframe for testing and authorization of novel food products

The major issues that have been identified with novel foods testing and authorization are the cost of putting a dossier together and the time frame required before approval could be given for novel food market placement. While application for authorization is free (FSA, 2022) but the cost of putting a dossier together has been estimated to be around £100,000 and can be more for a complex product that requires extensive assessment (FoodNavigator, 2022). The timeframe required for a full novel food application has been highlighted as a major barrier for novel foods development and growth. It takes a total of 17 months (see table 8) before approval can be given for a novel food product provided there is no case of any process paucity within the legislative timeline (FSA, 2022). However, getting this done within the set timeframe will depend on the quality of the dossier submitted and the information provided (FSA, 2020).

Key steps in Authorization process	Time frame
Validation process	1 month
Risk and safety assessment	9 months
Risk management consideration & authorization decision	7 months

Table 9 : Timeline for the novel food authorization process (FSA, 2022)

It is noteworthy to state here that for novel foods that have been authorized by the European Commission before 1 January 2021 will remain valid in UK and are not required to go through new authorization application to be placed in the UK market.

4.7 Challenge with CBD novel food products

The status of CBD extracts as novel food was confirmed in January 2019, and therefore required to be authorised before it can be placed in the UK market (FSA, 2022). Before its status was confirmed as novel food product, CBD product has been on sale in the UK market but unregulated and this present a potential public health risk. And to eliminate this risk and assure the safety of this novel product, FSA intervened by ensuring that all CBD novel food products in the UK market are subjected to full novel food application. A deadline of 31 March 2021 was given for all CBD products to be put forward for authorization applications. After which all the products that fail to meet this deadline are ordered to be removed from the market. According to FSA there are currently no authorised CBD products in the UK market while those that have applied for full application and have status of either awaiting evidence or validated are allowed to remain in the market pending their authorization.

Status of CBD products linked to novel foods applications

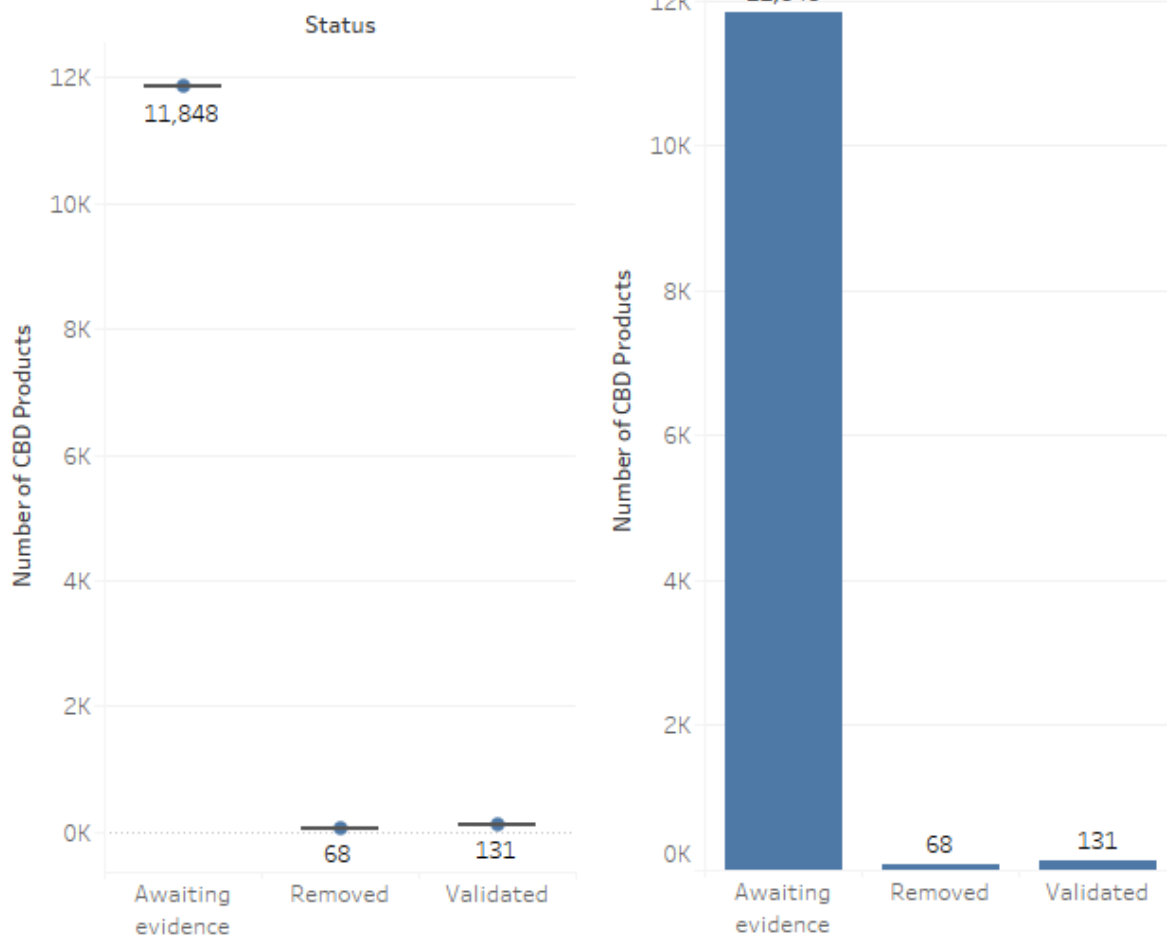


Figure 17: Status of CBD products linked to novel foods applications (FSA, 2022)

Based on the FSA publication there are currently about 12,047 CBD products awaiting authorization as of 03 August 2022, as contained in the [register of CBD products linked to credible novel food applications](#). The breakdown and analysis of the register shows that a total of 11,848 CBD products are awaiting further evidence, 131 CBD products with validated status (i.e., full information have been provided) while 68 CBD products have been ordered to be removed from the market (See figure 17 above). The following issues have been identified as the major factors affecting authorization of CBD products;

- Several data gaps in literature on toxicological information available for CBD products, especially in the areas of reproduction and immunology
- Inadmissibility of literature only to evidence safety of a CBD novel ingredient
- Difficulty in establishing the safety of CBD due to conflicting genotoxicity data

- Difficulty in identifying a safe upper intake level of CBD

The fact that no CBD products in the market are authorized and their safety yet to be established calls for concern with UK CBD market that was estimated to be worth £690 million as at 2021 and second largest in the world after US (ACI, 2021).

4.8 Challenge with technologies used for novel foods processing

The technologies used for processing novel foods have been identified as an important critical factor in promoting food security, food safety and sustainability (Siegrist and Hartmann, 2020). However, despite the importance of these technologies they are often being met with hesitation or resistance by the consumers because of the perceived unnaturalness of the food made from them (e.g., 3D printed foods) safety concern (e.g., nanofoods) consumers' refusal to accept new food technologies (food technology neophobia), and cultural factors (e.g., cultured meat versus natural meat). And one notable feature of technologies utilized in food industry is that they hardly go out of use unlike technological development in other non-food industries. Therefore, new technology does not often replace the existing technology in its entirety, but it is rather built upon as an additional technological improvement. As a result of this, there's little or no pressure on consumers to accept new innovation or technology or new food (Siegrist and Hartmann, 2020). For novel food technologies such as Nanotechnology, Cultured meat technology and 3D food printing technology how they are described and labelled have been known to influence how novel food products produced from such technologies will be accepted either negatively or positively (Runge et al., 2018). Application of technology to food and the unnaturalness tag given to product of such technology is often viewed in a negative way when compared to food produced with less technological intervention which is more acceptable and viewed in a positive way of being healthier, safer and natural. But is just all about perception as novel foods are as safe as any conventional foods that are out there in the market.

5.0 Conclusions

The main purpose of this study is to answer the research question:

- i. Are regulation, testing, and processing of novel foods different from conventional foods?*

In doing this, systematic review of relevant studies about novel foods have been done with additional review of information from other sources to answer the research question and test the research hypothesis. The background on the history of development of novel food in the UK has been review with critical examination of novel food types, processing and current consumer trends. In addition, government regulation on novel foods and labelling requirements (both general and specific requirements) were examined together with testing, risk and safety assessment of novel foods as well.

The study has revealed that the regulation, testing and processing of novel foods are different from conventional foods. The study has shown that novel foods are regulated within a regulatory framework specifically crafted to ensure that novel foods introduction into the market are managed effectively by ensuring that they are safe for consumption and pose no risk to public health. While both novel and conventional foods are expected to comply with all the standards and general food regulations, there is additional regulatory requirements that all novel foods must comply with before they can be allowed to be sold in the UK market. They must be subjected to premarket approval process before they can be placed in the market. Novel foods are expected to go through testing and safety assessments evaluation which are not required for conventional foods. There are some processing techniques that are applicable to both conventional and novel foods, however, novel processing techniques such as 3D printing, culture meat technology, nanotechnology, etc., cannot be applied to conventional food processing without changing its conventional status.

Aside from the general labelling requirements that are applicable to both novel and conventional foods, there are additional specific labelling requirements that novel foods must comply with as part of the regulatory requirements as stated in the Union list of novel foods. This is done to protect the consumers and enabled them to make informed decisions.

The novel food Regulation (EU) 2015/2283 has strictly defined food that can be termed as novel with respect to applied processing technology. A food can be termed as novel if the processing technology applied to it is capable of altering or modifying its molecular structure, nutritional value, metabolism or toxicity level. Processing technologies such as high-pressure processing (HPP), pulse electric field (PEF), cold plasma (CP), ohmic heating (OH), hydrodynamic cavitation, etc., in several literatures have been regarded as novel

technologies but why in actual sense they are only used for decontamination and foods produced from such processing techniques cannot be regarded as novel based on the novel food Regulation (EU) 2015/2283 definition. While such technologies can be applied to both the conventional and novel foods for the purpose of decontamination and extended shelf-stability, novel processing technology such as 3D printing, cultured meat technology and nanotechnology cannot be applied to or adopted for conventional food processing without altering its properties such as molecular structure, nutritional value and its toxicity level.

6.0 Recommendations for future studies

This research study has revealed how wide the concept of novel foods is and inexhaustible nature of the study area. There are a lot of aspect of novel foods that need to be studied which ranges from research into innovation acceleration, consumer acceptability, accelerated premarket approval and gaps in safety assessment. Therefore, I would like to suggest the following for future studies;

1. Novel foods authorization: challenges and solutions to quicker approval process

The delays in authorization of novel foods have been regarded as one of the factors stifling innovation when it comes to novel food development. Therefore, quicker approval process will lead to accelerated novel product development and innovation.

2. Investigation into safety of CBD novel food products and how to close the data gaps in safety assessment.

The major challenge with CBD novel food products is the inability to assure its safety due to data gaps in literature with respect to safety and toxicological assessment. However, despite this challenge CBD novel food products are still being allowed to be placed in the market once the submitted information about the products have been validated. This I considered as a threat to public health and consumer safety.

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Appendices

Appendix A

FSA Electronic submission page for Novel Food Application

Application form

Submit the form to receive an email with your application number and a secure link where you can upload your supporting documents. You will have 7 days to submit your application documents before the link expires. Please allow up to 30 minutes for the email to arrive and check your spam folder.

Contact details

Enter the contact details for the person who is the main point of contact for this application.

First name(required)

Last name(required)

Email address(required)

We'll only use this to contact you about your application.

Confirm email address(required)

Product details

Tell us about the product or process you are requesting authorisation for

Product owner(required)

Product type(required)

Name of the product(required)

This can be an internal name you are using or the final product name.

Product summary (required)

Tell us a bit more about the product or process you are requesting authorisation for.

You have 500 characters remaining.

Have you previously submitted this application for approval in the European Union?(required)

Appendix B

Screening of relevant studies using Rayyan software

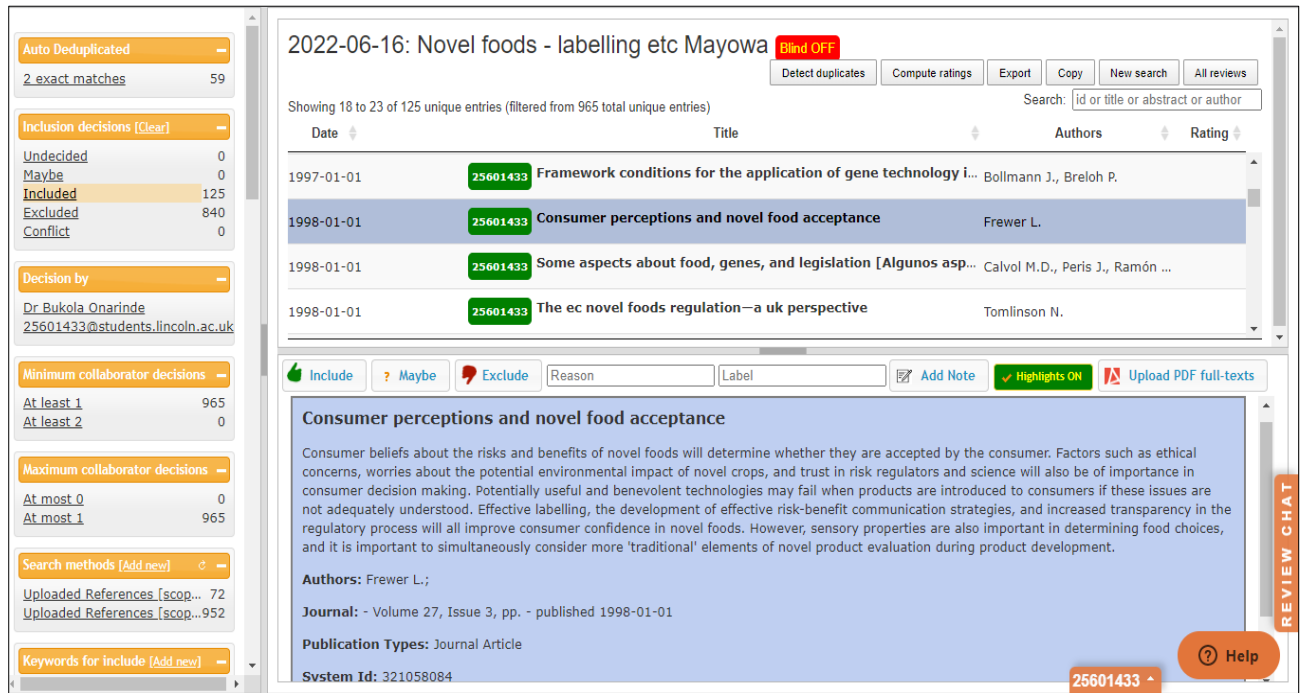


Figure A1: Rayyan software interface for active screening of relevant studies.

Active review of articles that passed inclusion criteria

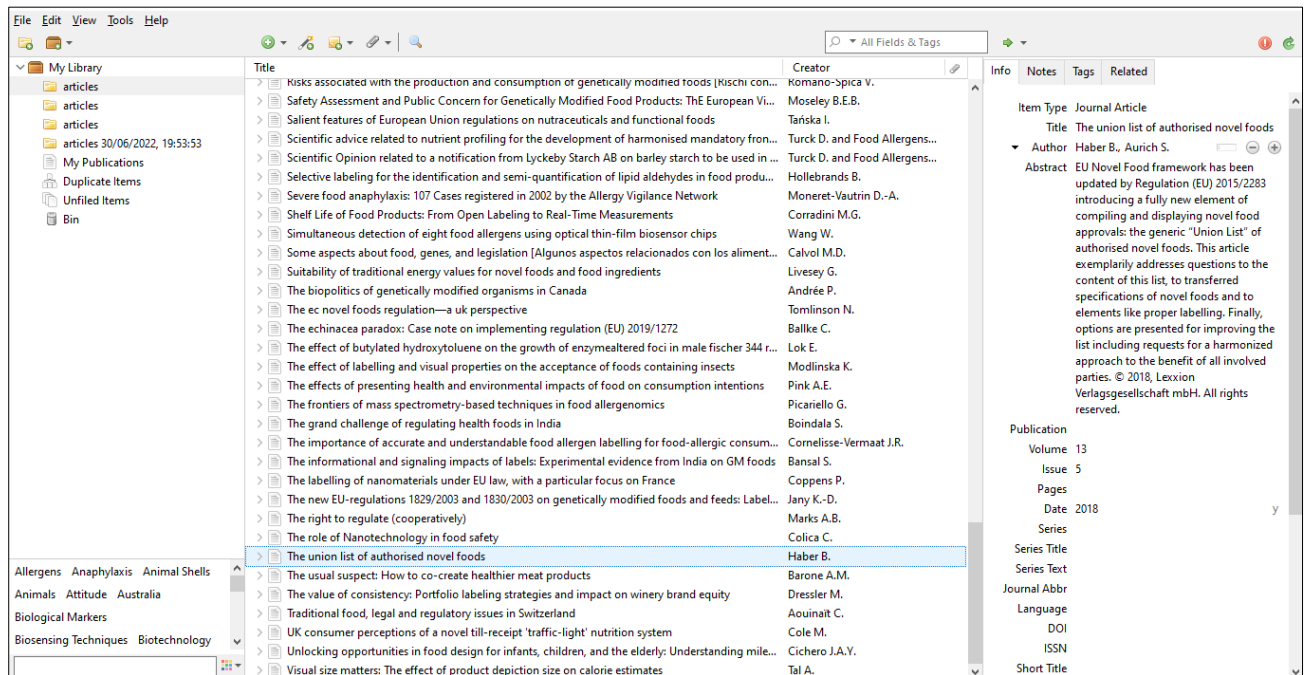


Figure A2: The active review of articles that met the inclusion criteria.

Appendix C

Guidance on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries

Organisation and content of the dossier

The following information should be provided in the notification and the application, and the structure should follow a common format. Data provided in the dossier should be organised into three parts:

- Part 1 contains the administrative data, such as information related to the applicant.
- Part 2 contains information related to the introduction (Section 2.1), identity (Section 2.2), production process (Section 2.3), compositional data (Section 2.4), specifications (Section 2.5), experience of continued use (Section 2.6) and proposed conditions of use (Section 2.7). It includes a list of all references.
- Part 3 comprises the glossary or abbreviations of terms quoted throughout the dossier, the certificates (on the accreditation of laboratories, certificates of analyses) and contains full copies/reprints of all pertinent scientific data (published and unpublished), full study reports, and scientific opinions of national/international regulatory bodies. It should also contain the full texts of all cited non-scientific references ('grey literature').

1. Part 1: Administrative data

1.1. Comprehensive table of contents of the dossier

1.2. Applicant

1.2.1. Company/organisation

Provide the name and address of the company or organisation.⁴

1.2.2. Contact person

Indicate the contact person authorised to communicate with EFSA on behalf of the applicant.⁵

1.3. Specifications

Please select one of the options below:

- ☐ a notification for authorisation of traditional foods from a third country which fall under Article 14 of Regulation (EU) 2015/2283;
- ☐ an application for the authorisation of traditional foods from a third country under Article 16 of Regulation (EU) 2015/2283 concerning the data on the history of safe use in a third country.

1.4. Regulatory status outside the European Union

If the traditional food has been submitted by the applicant to a regulatory body for authorisation outside the EU, please indicate the status of the evaluation by each regulatory body (if more than one), as appropriate:

- ☐ Under consideration

Specify the proposed conditions of use (if they are different), the date of submission, and the recipient regulatory body.

- ☐ Withdrawn

Specify the conditions of use (if they are different) of the traditional food which was withdrawn, the date of withdrawal, the reasons for withdrawal. Indicate the regulatory body at the time of withdrawal.

- ☐ Authorised

Specify the conditions of use (if they are different) of the traditional food which has been approved, the date of approval. Indicate the authorising regulatory body, and if available, provide a copy of the scientific opinion of the regulatory body which authorised the traditional food (in Part 3).

- ☐ Rejected

Specify the date and the reasons of rejection. Indicate the regulatory body which rejected the traditional food, and if available, provide a copy of the scientific opinion of the regulatory body which rejected the traditional food (in Part 3).

2. Part 2: Characterisation of the traditional food, technical and scientific data

2.1. Introduction

The traditional food should be briefly described in an introductory paragraph, including the source, the principle of the production process and typical compositional features. Its purpose and intended use should be described.

2.2. Identity of the traditional food

Information on the identity of the traditional food should be provided, depending on the class(es) under which the traditional food falls. The Panel notes that the proposed classification is based on the chemistry, production process and source of traditional foods, for the purpose of the scientific assessment, and is not meant to reflect the regulatory categories outlined in Article 3(2)a of the Regulation. There may be cases where a traditional food could be allocated to two or more classes (e.g. 'chemical substances' and 'food produced by a microorganism'). In such cases, the relevant information for all applicable classes should be provided.

2.2.1. Chemical substances

- Chemical name, when appropriate, according to IUPAC nomenclature rules
- CAS number (if this has been attributed) and other identification numbers
- Synonyms, trade names, abbreviations
- Molecular and structural formulae; stereochemistry
- Molecular mass (Da).

2.2.2. Foods consisting of, isolated from or produced from microorganisms, fungi or algae

- Scientific (Latin) name (family, genus, species, strain) according to the international codes of nomenclature
- Synonyms that may be used interchangeably with the preferred scientific name
- For algae⁶ and fungi,⁷ verification of the identity according to internationally recognised databases and methodology
- For bacteria and yeasts (unicellular organisms), verification of the species and strain identity according to internationally accepted methods; Information on applicable methods for the characterisation of bacteria and yeasts are provided in the EFSA Health Claim guidance (EFSA NDA Panel, 2016b). Molecular methods allow predictions of genes encoding for toxins, antimicrobial resistance and other pathogenic factors
- Origin of the organism
- If available deposition in an officially recognised culture collection with access number

2.2.3. Food consisting of, isolated from or produced from plants or their parts⁸

- Scientific (Latin) name (botanical family, genus, species, subspecies, variety with author's name, chemotype, if applicable) according to the international codes of nomenclature
- Synonyms (botanical name) that may be used interchangeably with the preferred scientific name
- For plants,⁹ verification of the identity should be according to internationally recognised databases and methodology
- Common names (if a trivial or a common name is used, it should be linked to the scientific name and part used)

- Part(s) used (e.g. root, leaf, seed, etc.)
- Geographical origin (continent, country, region)

2.2.4. Food consisting of, isolated from or produced from animals or their parts

- Scientific (Latin) name (zoological family, genus, species, subspecies, breed, if applicable)
- Synonyms that may be used interchangeably with the preferred scientific name
- Common names (if a trivial or a common name is used, it should be linked to the scientific name and part used)
- Part(s) used
- Geographical origin (continent, country, region).

2.2.5. Food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, fungi or algae

This section concerns cultures derived from multicellular origin (animals, plants, multicellular algae and mushrooms). Foods originated from cultures of unicellular origin should be addressed under Section 2.2.2.

- Biological source (taxonomic information on family, genus, species, subspecies, variety)
- For plants,⁹ algae⁶ and fungi,⁷ verification of the identity according to internationally recognised databases and methodology
- Organ and tissue or part of the organism sourced
- Laboratory or culture collection sourced
- Information on the identity of cells
- Cell or tissue substrate used as a traditional food
- Type of cultures.

2.3. Production process

2.3.1. Detailed description of the production process

The process(es) employed to produce the traditional food (e.g. chemical synthesis, enzyme-catalysis, fermentation or isolation from a natural source, etc.) should be described. The description of the production process should be detailed enough to provide the information that will form the basis for the evaluation of the bioavailability, nutritional value and safety, which should be addressed in the respective sections. With regard to safety, the description should include information on potential by-products, impurities or contaminants.

Information should also be provided on the handling of the sources, for example, the propagation, growth and harvesting conditions for plants and fungi (e.g. wild or cultivated, cultivation practices, time of harvest in relation to both season and stage of the plant growth); the breeding, rearing, feeding and farming conditions for farmed animals or the hunting, catching or collecting and killing of wild living animals; the culture conditions for microorganisms and algae, and cell culture or tissue culture from plants and animals. The description of the cultivation of plants, fungi, algae and microorganisms, and the rearing of animals should also include information on the use of pesticides, antimicrobials and antiparasitic agents.

Post-harvest handling, e.g. transport, drying techniques and storage conditions (duration, light, moisture and temperature) of unprocessed foods and the raw materials for further processing should be described. The parts of the organism used as a raw material should be specified and information on other starting substances or materials should be provided.

For traditional foods consisting of, isolated from or produced from plant, animal or microbiological sources, the applicant should describe in detail the process by which the raw material is converted into an ingredient or a preparation intended for a food product. Examples may include heat treatment, extraction, distillation, squeezing, fractionation, purification, concentration, fermentation, or other procedure(s). Information on substances used in the manufacturing process, e.g. identity of the extraction solvents, ratio of extraction solvent to the material, reagents, residues remaining in the final product, and any special precautions (light and temperature) should be provided.

Operational limits and key parameters of the production process should be given. Measures implemented for production control and quality and safety assurance should be described (e.g. HACCP,

GMP, ISO). A production flow chart should be provided, including quality and safety control checks. Standardisation criteria (e.g. chemical markers for the traditional food) should be provided.

For traditional foods consisting of, isolated from or produced from plants specific considerations and complementary information is provided in the EFSA guidance on safety assessment of botanicals and botanical preparations (EFSA Scientific Committee, 2009).

The applicant should consider and address how changes from traditional production processes to industrial (large scale) production will affect the composition, nutritional value and safety of the traditional food.

2.3.2. Non-confidential description of the production process

If the detailed description on the production process (Section 2.3.1) contains confidential elements, the applicant is asked to provide a non-confidential summary of the production process of between half to a maximum of a page in length.

2.4. Compositional data

The information should include qualitative and quantitative data on the composition as well as physicochemical and biochemical properties and microbiological characterisation of the traditional food.

Section 2.4.1 outlines general data requirements applicable to all traditional foods. Sections 2.4.2 and 2.4.3 set specific requirements depending on whether the traditional food is a single substance or a simple mixture thereof, a complex mixture or a whole food.¹⁰

Validated methods should be used for the analyses, preferably applying nationally or internationally recognised methods (e.g. Association of Analytical Communities, American Chemical Society, European Pharmacopoeia). The respective methods of analysis should be described together with relevant references. The information on analyses for substances of toxicological concern should also include their limit of detection and limit of quantification. Certificates of analyses and information on the accreditation of laboratories should be provided. If in-house methods are employed, they should be fully described and the results of the respective validation procedures should be provided. If the analyses are not performed in accredited laboratories, justification should be provided. Analytical data from publications can also be used if the publications provide sufficient information on the laboratory where analyses have been carried out, the methods utilised, and if the studies were performed on representative samples of the notified traditional food. Available published data can also provide information on the variability of the composition of the traditional food.

Compositional data and their variability should support the setting of specifications of the traditional food how it is intended to be placed on the market (Section 2.5). The analytical information should be provided on preferably at least five representative batches of the traditional food that have been independently produced (i.e. with independent batches of raw materials). When several production processes are proposed, such data should be provided for each given process.

2.4.1. General requirements

Information on the identities and the quantities of impurities or by-products, residues and chemical and microbiological contaminants should be provided (e.g. heavy metals, mycotoxins, PCBs/dioxins, pesticides). The type and spectrum of potential target analytes should be considered in the light of the sources and the production process. For example, for substances produced by microbial fermentation, the presence of undesirable metabolites should be investigated; for substances isolated by extraction, data on residues of the solvent used should be provided.

2.4.2. Single substances and simple mixtures thereof

Simple mixtures are mixtures whose components can be fully chemically characterised. For simple mixtures of defined substances, information on the identities and the relative ratios of all components should be provided. This should allow the elaboration of a mass balance.

For single substances, the following data should be provided:

- Identity tests (e.g. UV-VIS, IR, NMR, GC-MS, LC-MS)
- Physicochemical properties (e.g. appearance, melting point, boiling point)

- Solubility data in water and other common solvents
- Particle size, shape and distribution
- Minimum purity value
- Density and/or viscosity for liquid preparations

For single substances and their mixtures produced with genetically modified microorganisms (GMMs), applicants are referred to the requirements for GMMs Category 1 (i.e. chemically defined purified compounds and their mixtures in which both GMMs and newly introduced genes have been removed, e.g. amino acids, vitamins) as laid down by the EFSA guidance on the risk assessment of GMMs and their products intended for food and feed use (EFSA GMO Panel, 2011).

2.4.3. Complex mixtures and whole foods

Complex mixtures (e.g. extracts, protein hydrolysates) and whole foods (e.g. milk, meat, fruits, seeds) are defined as those where all constituents cannot be fully chemically characterised and/or identified.

A qualitative and quantitative characterisation of the main constituents should be performed, at least via sum parameters. For whole foods, this should include proximate analyses (i.e. ash, moisture, protein, fat, carbohydrates). On the basis of these data, a mass balance should be calculated. The amount of unidentified components should be indicated and should be as low as possible.

For the classes of naturally or chemically derived components, which characterise the nature of the traditional food (e.g. peptides, phospholipids, carotenoids, phenolics, sterols), comprehensive qualitative and quantitative data should be provided.

Qualitative and quantitative data on nutritionally relevant inherent constituents (e.g. micronutrients) should also be given.

Taking into account the source of the traditional food, qualitative and quantitative data on inherent substances of possible concern to human health (e.g. toxic, addictive, psychotropic, allergenic) should be provided.

In addition to analytical data on composition, a literature search should be performed according to the methodology developed by EFSA (EFSA, 2010; section 3.2) to retrieve published compositional data for the source and the part used in/as traditional food. Information on the used keywords and applied inclusion/exclusion criteria for the literature search should be provided.

Any substances of concern derived from plants should be classified according to their chemical structure. Levels at which the constituents are present in the respective part of the botanical or botanical preparation should be given where available. It is recommended that chemical fingerprinting of the botanical material is undertaken for this purpose.

Particular attention should be given to the possible presence of genotoxic and/or carcinogenic substances.

The following non-exhaustive tools can help identifying the possible substances of concern in a botanical material:

- The EFSA Compendium of Botanicals which provides information on naturally occurring substances that may be of concern for human health (EFSA, 2012),¹¹
- The EFSA Chemical Hazard Database (S-IN, 2015).

For complex mixtures produced with GMMs, applicants are referred to the requirements for GMMs Category 2 (i.e. complex products in which both GMMs and newly introduced genes are no longer present, e.g. cell extracts, most enzyme preparations) as laid down by the EFSA guidance on the risk assessment of GMMs and their products intended for food and feed use (EFSA GMO Panel, 2011).

2.4.4. Stability

The stability of the traditional food should be evaluated in order to identify hazards which might arise during storage and transport. The nature of degradation products should be characterised.

Stability tests should therefore focus on those compounds and parameters of the traditional food which may be susceptible to changes during storage and which may directly affect its safety or serve as indicators for alterations which could have an impact on the safety of the food.

Depending on the nature and type of the traditional food, the stability testing should address the physicochemical, biochemical and microbiological stability of the traditional food under normal conditions of storage, including the effects of packaging, the storage temperature and the environment (light, oxygen, moisture, relative humidity). Information on the normal storage conditions of traditional food should be provided as well as on the storage conditions under which the stability testing was performed. The stability testing should be provided on preferably at least five representative batches of the traditional food that have been independently produced (i.e. with independent batches of raw materials).

The duration of the stability testing may depend on the type of the traditional food and its proposed uses and should cover at least the end of the shelf-life. Accelerated conditions (usually at higher temperature) may be used as an alternative to stability testing under normal conditions.

Information on ingredients added to the traditional food to improve its stability should be provided.

2.5. Specifications

The specifications define the key parameters which characterise and substantiate the identity of the traditional food, as well as limits for these parameters and for other relevant physicochemical, biochemical and microbiological properties. The specifications will be used as key parameters, among other compositional data, to evaluate whether the data provided to substantiate the 'history of safe food use' are relevant to the traditional food intended to be placed on the EU market. In addition, the limits set in the specifications for toxicologically and/or nutritionally relevant components will be considered in the risk assessment.

On the basis of the analytical data on the traditional food provided in Sections 2.2–2.4, the applicant should propose specifications, in the form of a table, which should include the limits and information on the exact method for each of the selected parameter.

The specifications should include nutritional or biologically active components or, when these are not known, on selected chemical markers. The specifications should also include concentrations of the major groups of constituents present in the food including, for example, amino acids and proteins, lipids, carbohydrates, inorganic ions, polyphenols, alkaloids, terpenes, alkenylbenzenes, lignin, saponins, chitin, as well as the main substances within these classes.

A rationale for the selected parameters should be provided. As a minimum, the specification should include contents and/or limits for the parameters on the identity of the product; the minimal purity; limits acceptable for impurities and degradation products, in particular those of toxicological or nutritional relevance. In the absence of legal requirements in the EU, maximum levels of contaminants (e.g. microorganisms, mycotoxins, heavy metals, pesticide residues, polycyclic aromatic hydrocarbons) should be included.

2.6. Data from experience of continued use

This section should provide all data from the experience of continued use which are pertinent to the safety assessment of the traditional food.

The type of references could include scientific publications, scientific expert opinions, monographs, information from international or national organisations, governmental documentation, figures on cultivation/harvesting, and sales and trade. Further information might be obtained from cookbooks, recipes and anecdotal data. The reliability and weight of the data will be assessed in the light of their source, qualitative and quantitative nature.

It is important to characterise as much as possible the traditional modalities of use in terms of preparation type, extent of use and duration of the exposure. A food traditionally consumed only at special occasions, or exclusively in combination with another food/substance, may cause health concerns/adverse effects when consumed in larger quantities, for longer duration or in a different combination or context. It is possible that the food could be used, cooked and consumed differently by consumers in the EU, as compared to that in the third country.

2.6.1. Experience of continued food use in the third country

The supporting documentation on the experience of the continued food use should provide a description of the extent of use of the traditional food, the population group for which the traditional food has been a part of their diet, information on its preparation and handling, its role in the diet, information on precautions. A comprehensive literature review of human studies related to the

consumption of the traditional food should be performed. Information on the search strategy, including the sources used to retrieve pertinent data (databases, other sources), the terms and limits used (e.g. publication dates, publication types, languages, population, default tags) should be reported. Where applicable, the published literature should be reviewed by taking into account systematic review principles (EFSA, 2010). Information on the search strategy for data in the non-peer reviewed literature ('grey literature') should also be provided. Full study reports should be provided if available.

The documentation provided should relate to the traditional food as it is intended to be placed on the EU market.

2.6.1.1. Extent of use

The applicant should characterise the extent of use of the traditional food by documenting:

- the place of production and volume of the traditional food produced per year in the third country or countries;
- the geographical areas (e.g. region, country, continent) where it has been consumed;
- the quantity of consumption, information on the serving size(s), average, high and if available maximum intake levels per person should be provided. If available, intake estimates based on food consumption surveys or other estimates should be provided;
- clear distinction should be made between the intakes of a part of a botanical as such, preparations made of it (e.g. tea), or e.g. an intake of essential oil;
- the length and continuity of its use over time.

2.6.1.2. Characteristics of the population group(s) of consumers

Documentation should be provided on whether a food has been consumed by the general population or whether its consumption was rather or entirely limited to specific subpopulations defined by, for example, their age, sex, ethnic background, physiological and/or disease conditions. Information on the size of the population or population groups which have consumed the traditional food should be provided.

2.6.1.3. Role in the diet

Documentation should be provided on the consumption pattern including the frequency, the context and pattern of the consumption (e.g. for specific purposes, ceremonies, combined consumption with other foods), the type of dish or meal for which the food is used (e.g. as a snack, main dish, ingredient or spice for specified foods or meals). Information on the contribution of the food to the overall macro- and micronutrient intake of the population may be helpful.

2.6.1.4. Information on the handling and preparation of the food

This section should provide documentation concerning the handling, including storage, and the preparation of the food prior to its consumption, e.g. breakup or milling, peeling, removing or making use of only specific parts of the food, any kind of heat treatment (cooking method), or any other type of treatment.

2.6.1.5. Precautions for the preparation and restrictions of use

Information on any prohibition or restrictions imposed in respect of the food in the third countries, precautions to be taken during its preparation, any kind of treatment or methods to reduce levels of toxic, allergenic or antinutritional substances or to improve digestibility, should be provided, as well as information on reported limitations and restrictions for sensitive/specific population groups.

2.6.1.6. Human data

The applicant should document their comprehensive literature search for available human data related to the safety of the traditional food (e.g. kinetic data, toxicological, nutritional, microbiological, allergenic, tolerability, interaction with medicines). These could include human intervention and observational studies, case reports and information from surveillance reports.

The applicant should not only consider and limit their literature search to the traditional food itself, but should also consider searching for studies with specific and typical components of the traditional food and for studies with similar foods from the same or other closely related sources (e.g. other varieties or subspecies or related species of the same genus or family).

2.6.2. Other information

All other available information relevant for the safety assessment of the traditional food should be provided. This could include non-food uses (e.g. cosmetic, medical, feed) and animal studies (e.g. toxicity studies).

2.7. Proposed conditions of use for the EU market

A rationale for the target population, proposed uses and use levels, precautions and restrictions of use should be provided with cross-referencing to relevant data on the 'history of safe food use'.

2.7.1. Target population

The applicant should unambiguously specify the intended target population, e.g. the general population or certain defined population subgroups.

2.7.2. Proposed uses and use levels

It is of utmost importance that the information provided in this section is precise, complete and free of ambiguity. When proposing uses and use levels, all available information on safety should be taken into consideration.

The applicant should specify:

- the form of uses (e.g. as whole food, ingredient);
- the food categories¹² in which the traditional food (if an ingredient) is proposed to be used;
- whether the traditional food is intended to replace another food;
- the proposed maximum use level(s) and concentration(s) in final product(s);
- the proposed daily intakes for different age/gender groups as appropriate.

2.7.3. Intended role in the diet

Where a traditional food is intended to replace another food, the applicant should demonstrate that it does not differ from that food in a way that it would be nutritionally disadvantageous for the consumer.

2.7.4. Precautions and restrictions of use

When proposing precautions and restrictions of use, all available information on safety should be taken into consideration.

The applicant should specify the population (sub)groups (including population groups with certain physiological conditions) which should avoid consumption of the traditional food and include the rationale. The applicant should also indicate any other restrictions of use and precautions related to the handling, preparation and consumption of the traditional food.

Any effect(s) of potential overconsumption on population or subgroups of population should be described.

2.8. Concluding remarks

The applicant should integrate the information on the composition and the experience of use and provide a concise overall consideration on how this substantiates the history of safe use of the traditional food and how this relates to the proposed conditions of use for the EU market. Where potential health hazards have been identified on the basis of the composition and/or data from the experience of use, they should be discussed.

3. Part 3: Annexes to the dossier

- The glossary or abbreviations of terms quoted throughout the dossier
- The certificates (on the accreditation of laboratories, certificates of analyses)
- Full copies/reprints of all pertinent scientific data (published and unpublished)
- Full study reports

