# Bio-Based Materials For Use In Food Contact Applications

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# Executive Summary

Bio-based food contact materials (BBFCMs) are derived from biological renewable resources (animal or plant biomass). They consist of polymers directly extracted or removed from biomass, produced by chemical synthesis using renewable bio-based monomers or produced by microorganisms or genetically modified bacteria. They are attractive alternatives to fossil-based polymers because they are derived from sustainable sources and are generally biodegradable or compostable. Substantial increases in the volume and range of BBFCMs available to food manufacturers are anticipated and combined with regulatory and consumer pressures, greater use of these materials by the food industry is predicted.

Food packaging provides a wide range of functions that extend beyond ensuring food safety and supply chain integrity, however, exposure to contaminants or the components of food contact materials due to migration into food poses a potential risk to human health. Depending on the nature of the migrant(s), and the overall exposure, the risk can be either negligible, acute or chronic. BBFCMs such as paper and board have been well studied, however, there was very limited information available for other types of BBFCMs.

A review of evidence relating to potential risks and other unintended consequences of replacing fossil based plastic food contact materials (FCMs) with BBFCMs was conducted. Data from a range of sources including scientific literature and grey literature (for example, Government, not-for-profit organisation, academic and industry reports) were reviewed. Specific significant or chronic risks were addressed by the review and these primarily related to the presence of allergens, biotoxins, nanomaterials and process contaminants. Few studies have been conducted that address these issues, with most recent research focussed on achieving performance characteristics that were at least comparable to those obtained from the use of fossil-based FCMs. This has been achieved through the inclusion of bioactive materials, often derived from agri-food by-products. The use of nanosized or nanostructured materials is also frequently reported as a means of obtaining enhanced barrier properties, anti-microbial or antioxidant capabilities or other active or intelligent packaging applications.

The properties of BBFCMs such as biodegradability combined with their manufacture from diverse biomass resources including agri-food by-products, may lead to additional sources of risk that are not observed with fossil-based plastics. This is due to the potential presence of co-extracted contaminants or allergenic materials. The exploitation of biomass for the production of BBFCMs, especially agri-food by-products, raises a range of issues such as the presence of inorganic contaminants, such as heavy metals, persistent organic chemical contaminants, residues (e.g. pesticides, veterinary medicines), allergens and natural toxins. The processing of these materials may also provide a source of non-intentionally added substances (NIAS), with potential to migrate upon food contact. Few data were available from the literature review; however, this is not a reflection of the relative risk of the contaminants but indicates the state of the art of the knowledge about them. The conversion of biomass into packaging, especially if subject to thermal processing, may also generate process contaminants more frequently associated with food such as acrylamide, although this has not been established.

Current analytical methods and risk assessment processes for establishing contaminant chemical transfer from fossil-based plastics to food are also expected to be appropriate for BBFCMs. However, the complex nature of BBFCMs, especially if nanosized or nanostructured components are present, suggests that *in vitro* screening methods based on cellular toxicity may be useful adjuncts to the accepted chemical analytical methods used to establish safety.

Other potential barriers to the adoption of BBFCMs, especially if derived from agri-food by-products, include variability in the availability and characteristics of the source materials. The authenticity of these source materials and the derived BBFCMs may need to be considered to ensure supply chain integrity. Consumer perception and acceptance may also be factors, for example, where animal-derived materials are used. Screening to determine authenticity as well as the presence of allergenic epitopes (the molecular regions that trigger an allergic response) appears desirable and the methods to detect allergenic epitopes might need to be considered. A declaration of the presence of allergens or materials that consumers may choose to avoid for religious or lifestyle reasons might be advantageous.

A proposal for consideration (although presently not Food Standards Agency policy) might be that, similar to food, the usable functional life of a BBFCM should also be established and stated to ensure that the expected shelf life of food products can be achieved. In addition to developing and standardising new analytical procedures for BBFCMs, surveillance of the materials in use within the supply chain should be considered as this would enable potential risks posed to consumer safety by BBFCMs to be evaluated.

Key findings from this study are:

1. Limited research has been undertaken into the development of BBFCMs derived from agri-food by-products, and the associated risks to the consumer.
2. BBFCMs can exhibit barrier properties similar to traditional fossil-based plastics enabling comparable shelf life performance and consumer protection.
3. Information on the presence of inorganic contaminants such as heavy metals, persistent organic contaminants and natural toxins in BBFCMs, and their capacity to transfer from biomass-derived BBFCMs into food, is required.
4. Polypeptide-based materials used for packaging may include substances that are known or suspected allergens or are extracted from matrices that contain allergens. The effects of processing to produce packaging materials may alter allergenicity in unpredictable ways, depending on whether the allergenic epitopes are destroyed or revealed, for example due to conformational changes of the polypeptides. Very limited information is available on the allergenicity of BBFCMs as well as the potential for transfer of allergens to food.
5. Current analytical methods and risk assessment processes for establishing contaminant chemical transfer from fossil-based plastics to food are expected to be appropriate for or adaptable to BBFCMs.

# Glossary

| | |
|---|---|
| **BBFCM** | bio-based food contact material |
| **Bio-PE** | bio-polyethylene |
| **Bio-PET** | bio-polyethylene terephthalate |
| **BPA** | bisphenol A |
| **Defra** | Department for Environment, Food and Rural Affairs |
| **EAC** | endocrine active chemical |
| **EFSA** | European Food Safety Authority |
| **FCM** | food contact material |
| **FSA** | Food Standards Agency |
| **HHP** | high hydrostatic pressure |
| **IAS** | intentionally added substances |
| **MEG** | monoethylene glycol |
| **NIAS** | non-intentionally added substances |
| **NP** | nanoparticle |
| **PAH** | polycyclic aromatic hydrocarbon |
| **PBAT** | polybutylene adipate terephthalate |
| **PBS** | polybutylene succinate |
| **PBSA** | polybutylene succinate adipate |
| **PCB** | polychlorinated biphenyl |
| **PCL** | polycaprolactone |
| **PET** | polyethylene terephthalate |
| **PHA** | polyhydroxyalkanoate |
| **PHB** | polyhydroxybutyrate |
| **PLA** | polylactic acid |
| **POP** | persistent organic pollutant |
| **ZnONP** | zinc oxide nanoparticle |

# 1. Introduction

## 1.1 Background to the study

The scope of this study includes materials and articles in contact with food such as packaging, food service and food preparation items. Packaging materials used for food or feed are primarily selected to provide a barrier function, preventing contamination with spoilage or pathogenic microorganisms, or chemicals present in the external environment during distribution or storage. The barrier function also helps regulate the internal environment and control growth of microorganisms or product deterioration. Additional roles include provision of consumer information and marketing display.

Much of the food and drink packaging in current use is based on materials derived from oil i.e. plastics. These fossil-based materials exhibit many of the properties required for effective food and drink packaging, however, there has been increasing concern about their behaviour and fate when discarded into the environment. In addition to food packaging, food contact articles used, for example to prepare and serve food, may also be made of plastic and so their disposal can also have an adverse impact on the environment. In 2018 the UK Government announced a 25 Year Environment Plan with the target of zero avoidable plastic waste by 2042 and this, along with various commitments by food sector industries, is expected to drive the development and use of alternative bio-based materials (NNFCC, 2018).

### 1.1.1 Food contact material risks

Any material or article that comes into contact with food has the potential to transfer its constituents into the foodstuff. These chemical constituents include the intentionally added substances (IAS) and the non-intentionally added substances (NIAS). The IAS are those used to produce packaging and for plastics are well defined and regulated. In contrast, the NIAS are unknowns and as well as impurities in starting substances, may include reaction and breakdown products generated during manufacture.

### 1.1.2 Legislation

The UK national Regulations of 2012 for Materials and Articles in Contact with Food provide a single point of reference for businesses and enforcement authorities by consolidating three main Statutory Instruments on materials and articles intended to come into contact with food into one set of Regulations. The consolidated Regulations ensure continuity of enforcement provisions for existing directly applicable European legislation on materials and articles intended to come into contact with food.

In European legislation, all materials and articles intended for contact with food must meet the requirements of the Framework Regulation (EC) No 1935/2004. This Regulation is the first step to harmonising the rules. The basic principle underlying this Regulation is detailed within Article 3 which states:

"Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

a) endanger human health;

b) bring about an unacceptable change in the composition of the food;

c) bring about a deterioration in the organoleptic characteristics thereof."

Thus, it defines both safety and inertness requirements that must be met by all materials and articles intended to come into contact with foodstuffs. It does not specify how compliance with these rules should be demonstrated rather it empowers the European Commission to allow specific measures to be set for different material types and specific substances. The material types are listed in Annex I of Regulation (EC) No 1935/2004 and includes BBFCM relevant groups and materials such as active and intelligent materials and articles; paper and board; plastics, regenerated cellulose and wood.

Specific measures have only been introduced for a small number of these materials with the rules for plastics, Commission Regulation (EU) No 10/2011 as amended and corrected, being the most comprehensive and so often used as a guide for the other material types. An overview of the existing EU legislation is provided in Figure 1.

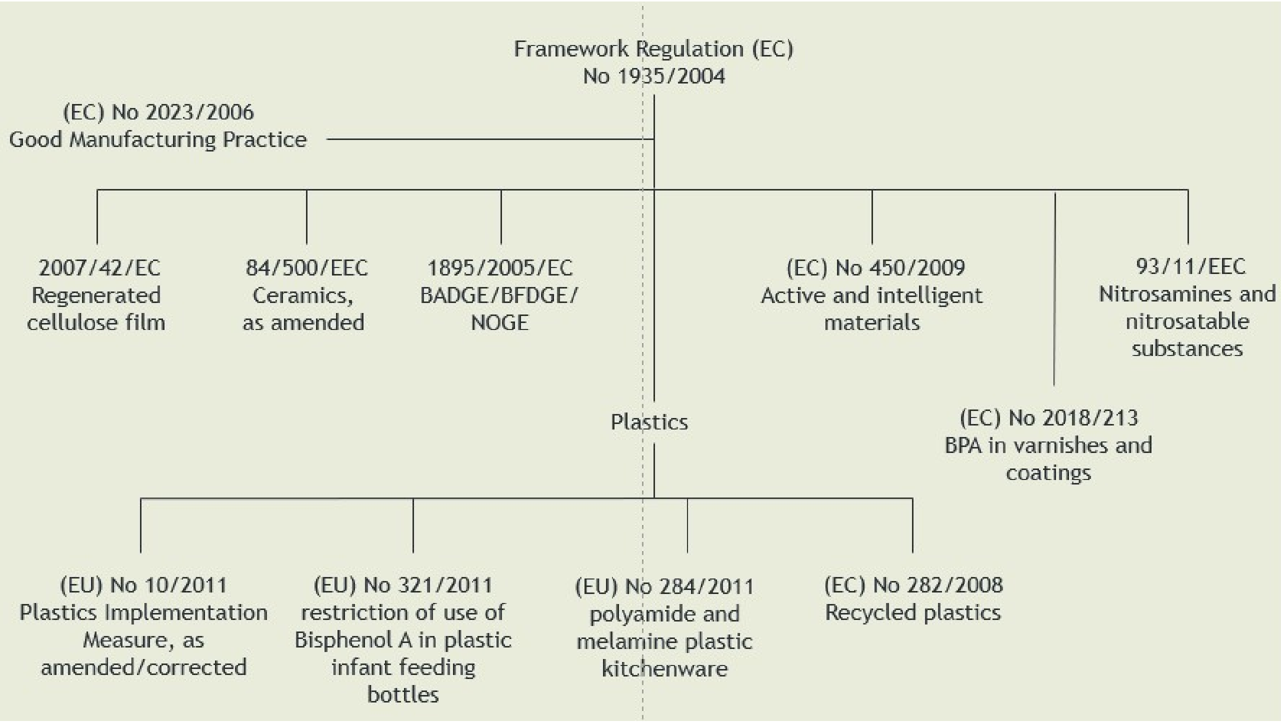


**Figure 1.** Overview of EU legislation on materials and articles intended for contact with food

The European Commission Joint Research Centre published a baseline study on the regulatory framework surrounding the non-harmonised (at EU level) material types. The study aimed to analyse the existing regulatory frameworks at national or sectorial level to demonstrate compliance with the general safety requirements for materials not harmonised at EU level. The full report can be found at:

https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/non-harmonised-food-contact-materials-eu-regulatory-and-market-situation-baseline-study

Traceability and labelling are also defined in the Framework Regulation. The traceability should be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility and labelling, advertising and presentation of food contact materials shall not mislead the consumer and instructions for safe use shall be provided.

The Framework Regulation also states that materials and articles shall (where specific rules are in place) be accompanied by a written declaration stating that they comply with the rules applicable to them and appropriate documentation shall be made available to the enforcement authorities to demonstrate such compliance on request. The rules on Good Manufacturing Practice Regulation (EC) No 2023/2006 are also overarching and so apply to all material types.

BBFCMs may be considered to fall within the scope of the plastics Regulation (EU) No 10/2011 as the definition given for plastics is:

"'plastic' means polymer to which additives or other substances may have been added, which is capable of functioning as a main structural component of final materials and articles;

'polymer' means any macromolecular substance obtained by:

a) a polymerisation process such as polyaddition or polycondensation, or by any other similar process of monomers and other starting substances; or
b) chemical modification of natural or synthetic macromolecules; or
c) microbial fermentation

'plastic multi-layer' means a material or article composed of two or more layers of plastic"

Where a BBFCM meets the definition of a plastic (as above) then the starting substances will need to be assessed. The rules for plastic materials and articles are well described and the authorisation process for these materials is published on the website of the European Commission:

https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/authorisations_en

In short, the process involves the authorisation of the substances (monomers and additives) used in the manufacture of the plastic. If a business operator wants to use a new substance, they must first get it approved for use. As an example, there is an increase in the use of bamboo in food contact articles such as re-usable cups. These articles are marketed as natural alternatives to plastics however in most cases the bamboo is added to a polymer (plastic) backbone. The European Commission is currently (March 2019) considering the use of such materials in contact with foods.

### 1.1.3 Bio-based food contact materials

In the UK, it was estimated that food packaging by households accounted for 525,000 tonnes of primarily fossil-based plastic packaging in 2018, of which the recycled proportion was 169,145 tonnes (32%) (Recoup, 2018). Increased recycling is expected in response to consumer pressure, government and industry initiatives such as the Courtauld Agreement, the Plastic Pact, the recently announced Defra Waste and Recycling Strategy and the potential introduction of deposit return schemes, a potential ban on single-use plastic drinking straws and stirrers, changes to the current producer responsibility system and a tax on plastics containing less than 30% recycled content. Current issues include the need for effective segregation of waste streams and transport of materials (Recoup, 2018). Factors such as consumer pressure and legislation are likely to increase demand for bio-based food contact materials. Despite the high level of awareness of the risks posed by plastic packaging within the environment and concerns about sustainability, the level of adoption of bio-based food contact materials (BBFCMs) by manufacturers is currently low. The global production volume of bio-based polymers (7.5 million tonnes) was only 2% of the fossil-based polymer production in 2018 (Nova Institute, 2019).

BBFCMs have and are being developed to provide a replacement for oil-derived plastics. These materials can aid with decarbonisation by acting as replacements ('drop ins') for current fossil-based plastics. For example, the use of partially or wholly bio-derived monomers can be used to produce biologically derived polyethylene terephthalate (bio-PET) or polyethylene (bio-PE). Despite their biological origin, these materials still exhibit the same end of life issues as the fossil-based counterparts.

The main advantages that many bio-based materials (excluding 'drop ins') have over fossil-based plastics are the use of renewable resources in their production, including agri-food by-products and in many cases, the biodegradability and/or compostability of the finished product which offers an alternative to disposal in landfill. This is particularly important when the product is designed to be disposable, as in the case of packaging (NNFCC, 2018).

Compostability is of particular advantage for food packaging, which is often not recycled because it is lightweight and food-contaminated. Furthermore, it can be disposed of in an environmentally-friendly way without separation from similar plastics. Bio-based plastics also offer an alternative renewable source to recycled plastic which, again, is particularly useful for food packaging due to the shortage of the high-quality feedstock required to produce food grade recycled plastic. However, a potential disadvantage arising from the use of BBFCMs is the need to ensure effective segregation from fossil-based materials to enable their effective recycling. For example, the presence of small quantities of polylactic acid (PLA) can prevent recycling of polyethylene terephthalate (PET) into a transparent product suitable for re-use in food and drink applications.

BBFCMs are derived from biological renewable resources (animal or plant biomass). The biomass need not be obtained at the expense of food crop production, either because agri-food waste may be exploited or because of the availability of non-food crops such as tobacco or hemp.

Petersen *et al.* (1999) defined three categories of bio-based materials with packaging applications:

- Polymers directly extracted/removed from biomass. Examples include polysaccharides (e.g. starch, cellulose) and proteins (e.g. chitin, collagen, casein, soy protein). Further modification of the polymers can produce additional valuable bio-based materials. For example, chitosan is derived from the chemical or enzymatic modification of chitin which is the major constituent in the exoskeleton of arthropods or crustaceans.
- Polymers produced by chemical synthesis using renewable bio-based monomers. For example, PLA, a bio-polyester polymerized from lactic acid monomers produced by fermentation of carbohydrate feedstock.
- Polymers produced by microorganisms or genetically modified bacteria. Examples include polyhydroxyalkonoate (PHA) and polyhydroxybutyrate (PHB).

Bio-based products contain mixtures of fossil-derived and biomass-derived bio-based materials (Petersen et al., 1999).

Many BBFCMs exhibit biodegradability which is generally considered advantageous in comparison to the fossil-based plastics which generally do not. A hydrolysable linkage is a common feature in most biodegradable polymers and most are polyesters. Biodegradable materials degrade to carbon dioxide, water and residual biomass due to microbial metabolism and other mechanisms. The process is influenced by environmental conditions and with variable outcomes. No internationally accepted standard currently exists.

Compostable materials are biodegradable under specific conditions as described in standards such as EN13432 (industrial composting of packaging) or equivalent (European Bioplastics, 2015). Biodegradability or compostability is not necessarily a feature of a bio-based material, for example bio-PE or bio-PET are indistinguishable from the fossil-based versions and so exhibit the same environmental behavior and fate.

The term 'bioplastic' is frequently used interchangeably with BBFCM, however, not all bioplastics are bio-based materials. Plastics can be categorised based on material origins (bio-based / fossil-based) and biodegradability (biodegradable / non-biodegradable) (WRAP, 2019). Bio-based non-biodegradable bioplastics include bio-PE and bio-PET.

Bio-PET is composed of purified terephthalic acid (70%) and monoethylene glycol (MEG; 30%). MEG is derived from sugars obtained from agri-food by-products such as bagasse or crops such as sugar beet. As described, bio-PET fails to meet the bio-based material definition given above due to only partial derivation from renewable biological sources; with the bulk derived from fossil sources. In contrast, bio-PE is considered a bio-based material as it is derived from bioethanol produced by fermentation of sugar cane. Similarly, the bio-based biodegradable bioplastics PLA, PHA, PHB and polybutylene succinate (PBS) fully meet the definition of bio-based materials.

### 1.1.4 Bio-based materials - natural polymers

The main examples of polymers directly extracted/removed from plant biomass include:

- Starch
- Cellulose
- Lignocellulose
- Gluten
- Zein
- Alginate
- Pectin
- Carrageenan

Examples of polymers derived from animal biomass include:

- Chitin / Chitosan
- Casein
- Gelatine

These materials from both animal and plant sources generally exhibit some degree of biodegradability. Modification of these natural polymers through chemical or enzymatic processes can be performed to improve packaging performance. The main examples are:

- Cellulose acetate
- Cellulose acetate butyrate
- Cellulose nitrate
- Regenerated cellulose
- Hydroxymethyl starch
- Hydroxypropyl starch
- Starch-acetate
- Starch-acrylamide

### 1.1.5 Bio-based materials - polymers derived from bio-based monomers

A diverse range of monomers can be obtained from biomass, especially if subject to microbial fermentation. Examples include terephthalic acid, succinic acid, butanediol, adipic acid, various amino acids, acetic acid, acetone, 2,3-butanediol, butyric acid, isopropanol, propionic acid, lactic acid, ethanol and a range of fatty acids. Derived polymers include:

- Polyvinyl alcohol / polyvinyl acetate

- Polyaspartic acid
- Polyester urethanes
- Poly(amide-esters)
- Poly(ester-urethanes)
- Polyanhydrides
- Polyethyleneglycol
- Polylactic acid
- Aliphatic / aromatic polyesters

#### 1.1.6 Polymers obtained from microorganisms or genetically-modified bacteria.

Some microorganisms synthesise polymers and store them as an energy source. These polymers may be extracted, isolated, purified and used as plastics. Examples include PHA, PHB and polyhydroxyvalerate.

#### 1.1.7 Most economically significant biodegradable BBFCMs

The uses of BBFCMs are diverse and include:

- Packaging barrier materials
- Surface coatings
- Food films

Of the various biodegradable BBFCMs, PLA currently has the greatest use as an FCM. PLA is obtained from the polymerization of lactic acid, which can be is derived from the fermentation of agri-food wastes that include sugar beet. PLA is compostable but not biodegradable. PLA exhibits barrier properties comparable to fossil-based plastics such as low-density polyethylene and PLA can frequently be used as a replacement.

Production volumes are expected to increase following several manufacturers bringing new plant on stream e.g. Total-Corbion®. Adoption by major retailers was previously limited by cost, especially in comparison to materials such as PET. Further limitations on the adoption of PLA are due to the commitment by manufacturers and retailers to single polymer plastic packaging and the introduction of PET recycling. Although the performance of PLA is comparable with PET, contamination of the PET waste stream by PLA at levels >0.01% results in loss of transparency, which may limit adoption in the absence of effective segregation.

#### 1.1.8 BBFCM risk

It was considered by Castle (2004) that the use of bio-based materials derived from natural sources is likely to extend the range of risk beyond the known components of the packaging materials. Considerable quantities of agri-food by-products are available and are attractive as a source of packaging materials. These may be contaminated with naturally produced contaminants e.g. mycotoxins and algal biotoxins, which can occur due to a range of factors including poor storage or climatic conditions. Global warming was considered likely to increase the incidence of fungal infestations of crops and thus the likelihood of mycotoxin contamination of biomass (Castle, 2004). Significant stimulation of aflatoxin B1 production by *Aspergillus flavus* both *in vitro* and *in vivo* in maize under conditions that replicate anticipated climate change conditions has since been observed (Battilani et al., 2016; Medina et al., 2017; Medina et al., 2015). Such observations may be considered to provide some support for the as yet unconfirmed proposition made by Castle (2004).

Organic compounds, e.g. dioxins and polychlorinated biphenyls (PCBs); and inorganic compounds, e.g. lead and arsenic, can be present as a result of environmental and geological conditions or the after effects of incidents such as fires. Other compounds such as nitrates, pesticide and veterinary medicines residues, and plant toxins, e.g. pyrrolizidine alkaloids, can arise due to horticultural or agricultural practices or misuse of agrochemicals or veterinary medicines.

Process contaminants such as acrylamide are formed due to Maillard reactions occurring when complex biomaterials such as food are heated. This suggests that depending on the conditions used and the feedstock, this may provide an additional route for chemical contaminant formation within the packaging.

#### 1.1.9 Migration from BBFCMs

Castle et al. (2004) highlighted the very extensive specifications placed on the copolymer 3-hydroxybutanoic acid-3-hydroxypentanoic acid, which is obtained by means of bacterial fermentation. It was suggested that other biodegradable polymers extracted from biomass should also have specifications placed on them to control the possibility of chemical migration to a food in contact (Castle, 2004).

Previous research (Bradley, 2010) examined the migration potential of low molecular weight materials (<1000 Daltons) from a broad range of BBFCMs (starch, cellulose, polylactic acid, cassava and bagasse-based) into food simulants, using protocols initially developed for fossil-based plastic packaging. This extensive study demonstrated that the methods of testing for migration, using food simulants, were likely to be directly applicable to testing most biodegradable polymers, albeit for the limited number of material/migrant/simulant/food combinations employed. Little measurable migration of toxicologically relevant low molecular weight volatile, polar and non-volatile substances chemicals was observed (Bradley, 2010).

Additional risk is potentially derived from the inclusion of nanosized (nanoparticles) or nanoscale materials (not nanosized in all dimensions, for example nanofibers or montmorillonite clay platelets) within bio-based packaging. This has been used to improve barrier function and to achieve similar or better shelf life than obtained from fossil-based plastic. Both hard nanomaterials such as metals and soft nanomaterials such as essential oil nanoemulsions have been incorporated to inhibit the growth of spoilage organisms or pathogens and slow lipid oxidation. These materials potentially pose an additional, much less well-defined risk to human health if they transfer to food and are then consumed. Furthermore, some BBFCMs are capable of being nanostructured, for example through use of electrospinning or electrospraying methods which generate nanofibers or nanoparticles. These exhibit anti-microbial activity and cytotoxicity through mechanisms such as membrane damage which indicates potential areas for concern if consumed (Almalik et al., 2018).

Further risks from BBFCMs may include the presence of allergens or allergenic epitopes (the regions or allergen molecules capable of stimulating an allergic response), especially if protein-based materials are used for construction of packaging or used as food films. These may be present in the initial feedstock or be generated during subsequent processing of the feedstock to produce the packaging. It is also possible that repeated exposure to allergenic materials may result in sensitization although the likelihood of this is uncertain.

Increased demands for BBFCMs may increase the value of agri-food by-products. Effective management of these resources will be required to avoid supply shortages and to maintain the integrity of the supply chain. Failure to control the quality of these feedstocks may result in greater risks to the food supply chain, either because of the greater likelihood of chemical or microbiological contaminants being present or because the performance of the derived packaging materials fails to meet specifications resulting in shelf life reduction. The use of biodegradable bio-based materials for packaging also suggests that a product shelf life may need to be specified to ensure that the required level of performance is achieved.

#### 1.1.10 Emerging issues

The impacts of climate change as a result of increasing average temperatures can include more variable rainfall, rising sea levels, warmer oceans, more forest fires and more extreme events such as floods, storms, cyclones, droughts and landslips (Environment Agency, 2018). These events may mobilise contaminants within the environment which may lead to increased levels in crops and animals and thus derived biomaterials used for packaging. Suggested outcomes range from elevated levels of heavy metals and persistent organic contaminants such as polycyclic aromatic hydrocarbons (PAHs), dioxins and mercury as well as mycotoxins such as aflatoxin $B_1$ (Battilani et al., 2016; Thomson & Rose, 2011). Another consideration is the potential impact from the proposed EU ban of certain plant protection products. A reduction in use of fungicides on cereals could result in more contamination from mycotoxins, some of which are endocrine disrupting (Kwon et al., 2018). However, the it is most likely that the greatest risk to the consumer will arise from the consumption of contaminated foods rather than from food contact materials.

## 1.2 Aims

Although the current use of BBFCMs is low, it is anticipated to rise significantly in response to consumer pressure, manufacturer demand and increased levels of industrial production. This review has been conducted to support the work of the Food Standards Agency in ensuring that the risk to the food supply chain and the consumer posed by the introduction of novel BBFCMs is better understood.

The aim of this study is to better understand any potential risks and other unintended consequences of replacing fossil-based food contact materials with bio-based or other novel alternative packaging materials. The scope was limited to newer biodegradable BBFCMs and did not consider paper or board as these materials have been used extensively and the risks previously studied. The review aims to highlight current and emerging risks and evidence gaps for prioritisation through future research and surveillance programmes. This review will help the Food Standards Agency (FSA) ensure that effective regulation of novel BBFCMs and protection of consumer health is based on the most up to date, expert scientific evidence and that advice, guidance and research is effectively targeted to the areas of risk which are of most significance to the UK.

# 2. Methodology

## 2.1 Approach

The review focusses on those materials already marketed for food contact use as well as any scientific literature which reports on the developments of new materials and articles.

It covers the presence of chemical contaminants (whether IAS or NIAS), microorganisms, allergens, nanomaterials and their transfer through contact to food. The effect on shelf life performance and evaluation of the toxicity of the BBFCM are also examined.

The chemical contaminants include naturally occurring organic chemical contaminants e.g. mycotoxins, plant toxins, industrial organic pollutants e.g. dioxins, PCBs; inorganic heavy metals e.g. lead, arsenic, mercury; and process contaminants e.g. furan and acrylamide.

The work of UK academic institutions actively involved in this area will be identified and their research programmes will be summarised. As well as identifying any materials used, the stage of development, any additional work required to take the products to market and any work carried out to assess their suitability for contact with food will be considered.

## 2.2 Literature search

Fera Information Centre (FIC) has access to commercial databases – especially those of the Dialog, Web of Science and OVID hosts - covering all scientific disciplines through the Athens IP access, as well as the use of open access databases such as PubMed, ScienceDirect and various government hosted databases. The FIC also subscribes to *circa* 150 current journals.

Using these resources, literature searches were conducted for information on bio-based materials used as food contact materials. Search terms including Boolean operators were drawn up by the project team and sent to FSA for comment and approval. Some additional terms were added and the final list was agreed.

In addition to the peer-reviewed literature 'grey literature' sources were searched. These include reports (annual, technical), working and white papers from government and non-governmental organisations including academic institutions and private industry.

### 2.2.1 Literature review search terms

A general search for the main economically significant biodegradable BBFCMs was performed using Google Scholar. This generated a large number of publications even when limited to the period 2013-19. For the same reason the more refined search was limited to a 5-year period. A copy of the search terms used is given in Appendix 1.

# 3. Results

## 3.1 Scientific literature review results

Total publications and patents that refer to the main economically significant bio-plastics for the years 2013-2019 are shown in Figure 2.

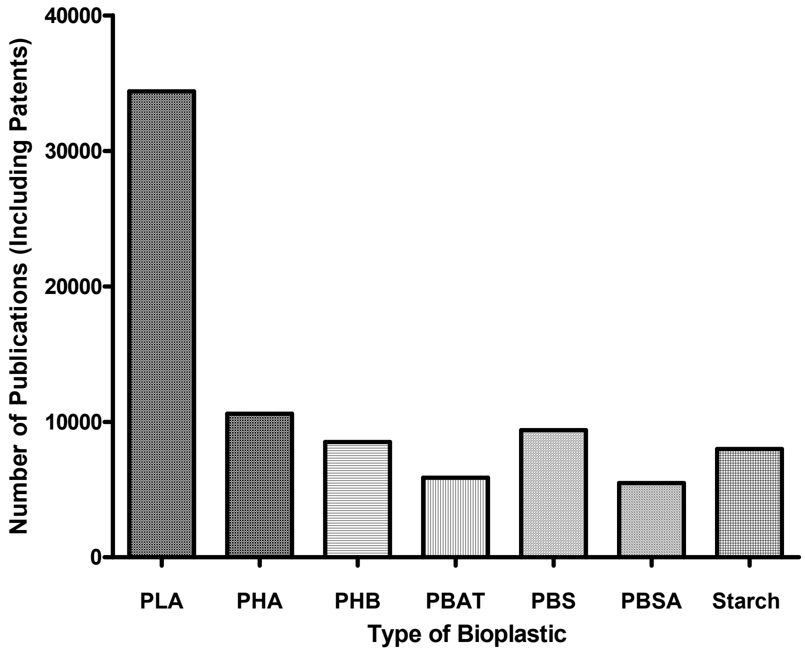


**Figure 2.** Publications and patents for bio-plastic food packaging (2013-2019)

*Polylactic acid (PLA), polyhydroxyalkanoate (PHA), polyhydroxybutyrate (PHB), polybutylene adipate terephthalate (PBAT), polybutylene succinate (PBS), polybutylene succinate adipate (PBSA).*

The most frequent citation obtained from the general literature search during the period 2013-19 was for PLA, with in excess of 30,000 publications recorded.

Several searches were performed to refine the search terms. Once the search criteria had been finalised and duplicates removed, the results were saved in EndNote libraries. These files were reviewed by Fera experts to remove any results that were not relevant, or that fell outside the scope of this review.

In total, 1,267 results were obtained from the peer reviewed literature sources.

## 3.2 Grey literature review results

The grey literature search resulted initially in many thousands of results. Considerable duplication was found and after re-processing the data, a file was generated with 89 relevant results. Most of these articles were directed towards the use of PLA and chitosan as replacements for fossil-based plastics. The production and performance of bio-nanocomposite films, especially with the inclusion of nanosized metals, cellulose nanofibers and essential oils, was frequently reported.

## 3.3 Economically significant biodegradable BBFCMs

Global production of bioplastics (both biodegradable and non-biodegradable) reached 2.112 million tonnes (Mt) in 2018, approximately 1% of all plastics produced. Food packaging applications were the second largest application with 516 Mt used in 2018. A projected increase to 2.616 Mt is anticipated by 2023. Biodegradable materials accounted for 0.912 Mt in 2018 and this is projected to increase to 1.288 Mt by 2023. The primary biodegradable BBFCMs materials in commercial use in 2018 were:

- Starches (18.2% of global BBFCM production)
- Polylactic acid (PLA; 10.3%)
- Polybutylene adipate terephthalate (PBAT; 7.2%)
- Polybutylene succinate (PBS; 4.6%)
- Polyhydroxyalkanoate (PHA; 1.4%)
- Other biodegradable biopolymers (1.5%).

Further increases in PLA and PHA production are predicted (>60% for PLA by 2023), with the bulk of global production concentrated in Asia (Nova Institute, 2019) .

## 3.4 Composite materials

From the literature search, few data were obtained for single component BBFCMs; most research seeking to achieve extended shelf life through enhanced barrier performance (oxygen/water), to improve physical characteristics such as tensile strength, rigidity or flexibility and additional functionality such as anti-oxidant, anti-microbial performance (active packaging) or inclusion of sensors (intelligent packaging). Consequently, the bulk of published research addresses the development of composite materials, frequently employing both hard and soft or natural nanomaterials.

## 3.5 BBFCM contaminant issues overview

The nature and the source of the BBFCM determines the possible contaminant migrants (Castle, 2004). In general, biodegradable polymers built-up by polymerisation of monomers (from either natural or synthetic sources) have a more defined composition than biodegradable polymers obtained as such from biopolymers. This is because the processes available to purify monomers (e.g. distillation, recrystallisation) are more efficient than the processes available to purify polymers (e.g. washing).

### 3.5.1 Heavy metals and trace elements

Heavy metals as environmental and food contaminants are a known issue and can arise in biomass as a result of the geology of the area in which it is produced, or as a result of human activity. The heavy metals usually considered as a primary toxic risk include those with potential to bioaccumulate such as lead, cadmium and mercury and it is recommended that exposure should be minimised. Similar considerations exist for some toxic metalloids such as arsenic.

Heavy metals such as lead have been demonstrated in biomaterials such as recycled paper and board and subsequently found to migrate into food (Mohammadpour et al., 2016). The main source of heavy metals are colourants, mainly consisting of conventional paint and pigments, as well as spot and Pantone Matching System colourants (Mertoglu-Elmas, 2017). The migration of printing inks and other colourant materials from many newer BBFCMs such as those derived from agri-food waste has not been reported.

In a Korean study, a variety of polylactide (PLA) articles (n = 211) were tested for migration of lead (Pb), cadmium (Cd) and arsenic (As) into the food simulant (4% v/v acetic acid). Migration tests were performed at 70°C and 100°C for 30 minutes. The amounts of Pb, Cd, and As increased at 100°C for 30 minutes compared with levels at 70°C. However, the migration at both conditions was very low. The maximum level of Pb at 100°C for 30 min corresponded to 1% of the migration limit (김미혜 et al., 2018)

Evidence of heavy metal migration has primarily been reported in relation to the inclusion of metallic nanoparticles within composite BBFCMs. This is addressed in more detail below.

### 3.5.2 Persistent organic pollutants

The persistent organic pollutants (POPs) are characterized by a potential to bioaccumulate, to exhibit environmental mobility, persistence and toxicity. Examples include PAHs, PCBs and dioxins. No data were obtained regarding the presence of POPs in BBFCMs and their transfer to food.

### 3.5.3 Residues

Food crops treated with pesticides frequently exhibit residues and subsequent processing may decrease or increase their concentrations (Bajwa & Sandhu, 2014). Similarly, the treatment of animals with veterinary medicines can result in the presence of the parent compounds or their metabolites in tissues. No data were found concerning the transfer of pesticide or veterinary medicines residues from BBFCMs to food.

### 3.5.4 Natural toxins

These are toxins that occur naturally in food or feed and include mycotoxins (fungal toxins), phytotoxins (plant toxins) and algal toxins.

Mycotoxins are produced by moulds growing on food commodities under certain conditions. They can be formed pre-harvest (i.e. in the field during the growth of the food), or they can occur post-harvest, as a result of poor storage conditions e.g. storing cereals with too high-water content; lack of control in drying processes. Some mycotoxins are more likely to be formed in tropical, warmer climates e.g. aflatoxins and fumonisins and these pose a greater hazard in imported foods.

No data were found concerning the occurrence and transfer of natural toxins from BBFCMs to food.

### 3.5.5 Process contaminants

Process contaminants are chemicals that are formed in foods often due to heat treatment or fermentation. Examples of process contaminants include acrylamide, 3-monochloropropanediol, glycidyl esters, furan and ethyl carbamate. PAHs may occur as a consequence of drying or smoking food.

Acrylamide was classified as probably carcinogenic to humans in 1994 (group 2A) by the International Agency for Research on Cancer. It is also a known neurotoxin. Acrylamide is a contaminant naturally generated when sugars and the amino acid asparagine react during the heat treatment of carbohydrate rich foods (European Food Safety Authority (EFSA), 2015).

No data were found concerning the occurrence and transfer of process contaminants from BBFCMs to food.

## 3.6 Nanomaterials

Nanotechnology has great application potential in the food industry. In packaging development, it can provide several alternatives, such as the formation of nanoparticles (NPs), nanodispersions, nanolayers and nanotubes, which, associated with polymers, can provide multiple functions. For example, by embedding NPs with antimicrobial properties; nanosensors capable of detecting chemicals products, pathogens and toxins in food; bioactive NPs capable of maintaining compounds at optimal conditions until their migration to the food product and nanocomposites, which improve the properties of flexibility, gas and humidity barrier and UV irradiation absorption of the materials to which they are incorporated, as well as resistance to temperature fluctuation (Bumbudsanpharoke et al., 2015; Sergio Almeida et al., 2015). For these reasons, a significant proportion of recent scientific publications have reported the production of BBFCMs with the incorporation of nanomaterials.

Addition of metal oxide NPs into polymers allows for the production of nanocomposites with increased mechanical strength and water and oxygen barrier properties and can also confer other benefits including antimicrobial activity and light-blocking properties (Garcia et al., 2018). Most nanotechnology applications reported for food packaging applications involve the use of nanometals such as silver, zinc or copper NPs or Montmorillonite clay (nanoclay). At least 50% of all reported nanofillers constitute nanoclays of either natural or synthetic origin (Bandyopadhyay & Ray, 2019).

Migration of NPs from packaging could be of concern because of their potential toxicity (Garcia et al., 2018) It has been recognised that migration studies must be conducted to determine the amounts of nanomaterials released into food matrices (Honarvar et al., 2016). Compliance with the current specific migration limit, in combination with the dietary exposure from other sources, is required. The upper level for nanometals such as zinc has been set at 25 mg/person per day (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids, 2016).

Numerous studies into the development of nanocomposite BBFCMs have been reported during the period 2013-2019. Recently, these have begun to address the potential for migration into food. Most of the studies have addressed migration from PLA. PLA containing functionalized cellulose nanocrystals formates was examined and the migration levels were below the permitted limits in both non-polar and polar food simulants (Yu et al., 2016).

PLA with embedded copper-doped zinc oxide powder functionalized with silver NPs were prepared by melt blending processing technique. The overall migration from these materials into three food simulants was below 10 mg.dm$^{-2}$, the accepted value according to Regulation (EC) No10/2011 for plastic materials and articles intended to come into contact with food (Vasile et al., 2017).

PLA with embedded titanium dioxide or silver NPs was prepared and cheese packed and stored at 51°C for 25 days. Migration of titanium and silver NPs was reported to be lower than the limit of 10 mg/kg as defined by EFSA for food contact materials (Li et al., 2018). Migration of nanoclay from PLA into salmon was detected after 8 days of storage. The evidence was obtained indirectly through the detection of elevated magnesium and silicon concentrations in the tissues (Dias et al., 2019).

PHB-based bionanocomposites incorporating different contents of zinc oxide NPs were prepared by Diez-Pascual & Diez-Vicente. The migration levels of the NPs into non-polar and polar simulants decreased with increasing NP content. The levels recorded were below the legislative limits for food packaging materials (Diez-Pascual & Diez-Vicente, 2014).

Montmorillonite nanoclays are frequently described as components of composite BBFCMs with 33 studies reported since 2014. The majority have focussed on PLA and the achievement of effective barrier properties. Few have addressed the potential toxicity of these materials. The *in vivo* toxicity of migration extracts from nanoclay-PLA composites was examined by Maisanaba et al. In this study, Wistar rats were fed the migration extract for up to 90 days and no evidence of damage was found. These data indicated that this type of nanocomposite might be considered safe for food packaging (Maisanaba et al., 2014).

Nanoclays modified with a quaternary ammonium salt/starch nanocomposite, silver NP/starch nanocomposite and both silver NP/quaternary ammonium salt/starch nanocomposites were reported (Abreu et al., 2015). The migration of the components from the nanostructured starch films, assessed by food contact tests, was minor and under the legal limits. Similarly, migration of nanoclay from a multilayer PLA film into 50% ethanol was also found to be below the EU overall migration limit (Scarfato et al., 2017).

High toxicity was observed when composite materials based on organically modified nanoclays in a polycaprolactone (PCL) matrix were evaluated for cytotoxicity towards epithelial cells and osteoblasts. This was due to leachable materials and it was determined that these materials were not suitable for food packaging applications (Kumar et al., 2014).

These limited data suggest that, for the composite BBFCMs based on ‘hard’ nanomaterials examined, migration into food matrices was low and often within current legal limits. Data on the toxicity of leachables from BBFCMs, and thus potential food contaminants, is restricted and further studies are required.

Numerous ‘soft’ or natural nanomaterials have been reported being used as components of bionanocomposite films or as surface coatings for food packaging (Youssef & El-Sayed, 2018). These attract interest because they provide a means of obtaining additional functionality such as anti-microbial or anti-oxidant activity (Vasile, 2018), mechanical strength (Sun, J. et al., 2018) and ethylene scavenging to control ripening (Siripatrawan & Kaewklin, 2018). The range of materials used is diverse and has included chitosan nanoparticles (E. Medina et al., 2019), cellulose nanocrystals (Xu et al., 2018) and essential oils (Tampau et al/, 2018).

Nanostructured chitosan, alone or in combination with other nanomaterials, attracts considerable interest because it is considered non-allergenic and non-toxic, produced from agricultural by-products, whilst its anti-microbial activity has been reported to extend shelf-life (Perinelli et al., 2018). The anti-microbial activity exhibited by biomaterials such as gelatine and alginate when produced as nanoparticles or fibres has attracted interest due to the ability to manufacture these materials using relatively simple techniques such as electrospraying or electrospinning (Liu et al.2018). The functionality of electrospun nanofibers can be extended to allow controlled release of anti-microbials, anti-oxidants or as the basis of sensors for food safety or quality (Fonseca et al., 2018; Kuntzler et al., 2018; Lin et al., 2017; Moreira et al., 2018; Soares et al., 2018; Xiao & Lim, 2018; Zheng et al., 2018).

The potential risks to human health from nanomaterials in food packaging have been recognised, especially in relation to the migration of hard nanomaterials (Sharma et al., 2017). From a review of the available literature, there appears to be an assumption that these materials are inherently safe because of their biological origin. However, no information concerning migration or toxicity of these ‘soft’ or ‘natural’ nanomaterials was obtained.

### 3.6.1 Effect of processing on the migration of NPs

The impact of high hydrostatic pressure (HHP) treatment on microstructure, water vapour and gas barrier, antibacterial and mechanical properties of polyvinyl alcohol-chitosan biodegradable films containing nanotitanium dioxide was reported (Zixuan et al., 2016). The migration of titanium dioxide from the films was investigated using food simulants that included distilled water, acetic acid, ethanol and olive oil. Trace quantities of titanium dioxide were detected in olive oil. HHP treatment at 200-400 MPa significantly reduced migration of titanium dioxide NPs from the films and it was considered that this form of processing when applied to these materials presented limited risk.

The impact of NPs present in food is an area of potential public health concern. EFSA has recently opened a public consultation on its draft guidance for the risk assessment of nanoscience and nanotechnology applications in the food and feed chain (EFSA, 2018). The guidance covers food contact materials and also considers appropriate toxicological testing. Given the potential risks of nanomaterial exposure, it is essential that all nanocomposite BBFCMs should be tested for migration prior to approval for use.

## 3.7 Endocrine active chemicals

Endocrine active chemicals (EAC) show structural similarities to natural hormones and are suspected to affect the human endocrine system by inducing hormone dependent effects (Mertl et al., 2014). Implicated chemicals include bisphenol A (BPA), alkylphenols, phthalate esters, nonyl phenols and perfluorinated compounds, which are chemicals used in the production of everyday commodities and may be present in food packaging materials. Sources include plasticisers, inks and adhesives (Nakazawa et al., 2014; Vandermarken et al., 2019).

FCMs such as paperboard have been previously reported to be a major source of endocrine active chemical substances, thus forming an important part of human exposure to these compounds (Cwiek-Ludwicka & Ludwicki, 2014). More stringent measures have since been introduced by the EC to control exposure to compounds such as BPA.

FCMs may transfer their constituents to foods, but at levels not always detected by analytical chemistry, resulting in low but measurable human exposure. Testing FCM extracts with bioassays is considered a useful, complimentary approach to chemical analysis (Severin et al., 2017; Veyrand et al., 2017). Use of the ERE-CALUX bioassay as a bioanalytical tool demonstrated migration of EACs from recycled paperboard to dry foods, whilst estrogenic activity was related to the recycling rate of the paperboard (Vandermarken et al., 2019).

A review of the literature has not demonstrated either the presence or migration of EACs from BBFCMs to food.

## 3.8 Genetically modified materials

Genetically modified materials may be present in the biomass used for the production of BBFCMs. To date no studies have addressed this issue. There is no information concerning migration from BBFCMs to food.

## 3.9 Allergenicity potential of bio-based materials

Materials used or under development as primary food packaging include polysaccharides such as starch and cellulose, proteins like casein and gluten and polymers produced either by microorganisms or by chemical synthesis from renewable bio-based monomers. In addition, polymers and proteins including milk, gelatine, gluten, soya, are used to produce edible films and coatings. Frequently, other components of biological origin are added to these films to provide the desired structural or functional properties. Examples of these include plant seed oils, essential oils, alginate and chitosan.

Given the animal or plant origin of bio-based materials, there is an intrinsic risk of allergenicity associated with them. When these materials are used for food contact application, their potential role as a food allergen needs to be considered. This is particularly important in the case of protein-based materials, but other polymers directly extracted from biomass should also be assessed as they may be contaminated with allergenic proteins. Furthermore, contact allergy induced by other bio-based molecules may also be possible.

This literature review has revealed the scarcity of studies investigating the allergy risks of biomaterials used in food packaging. More information is available concerning the immunogenicity of some of these materials in relation to their medical applications (Bedian et al., 2017). Numerous studies on materials based on PHAs, alginate, chitin/chitosan and others have described their use in tissue engineering and other clinical applications and reported their general biocompatibility and lack of toxicity and immunogenicity (Edgar et al., 2016). Chitosan has been studied extensively and it is considered to be non-allergenic. Chitins and chitosan extracted from shellfish, if purified correctly, will be totally isolated from proteins and other contaminants, and there is no evidence of their allergenicity (Muzzarelli, 2010). Incomplete purification, however, may lead to the presence of contaminating tropomyosin, which is the main allergenic protein in sea food.

Despite the low antigenicity of biomaterials reported for clinical applications, their allergenic properties in food applications must be investigated. Several aspects need to be considered including allergenicity of the initial material, processing method, combination with other materials, food to be in contact with and potential migration into foodstuff. Some of the proteins used to produce packaging materials, edible films and coatings are known food allergens (milk and egg proteins, soya, corn, gluten) and therefore, it is important to understand if their allergenic potential remains in the final product.

The processing of proteins to produce packaging materials involves physical, chemical and enzymatic treatments that induce denaturation, cross-linking and other chemical modifications that may alter the allergenic properties of the natural protein. Some of the methods that are being used to reduce the allergenicity of foods are also applied during production of bio-based packaging. For example, transglutaminase-mediated cross-linking of proteins, which has been used to produced gelatine and casein edible films (Chambi & Grosso, 2006), has also been extensively studied for the improvement of the functional properties of proteins, and it has been reported to reduce or eliminate the allergenicity of food proteins including whey protein isolate, soy protein isolate and casein (Damodaran & Li, 2017; Li & Damodaran, 2017; Quintieri et al., 2017).

The reduction in immunoreactivity of proteins following these treatments may be partly caused by the destruction of structure-dependent epitopes upon denaturation or by loss of accessibility to the epitope caused by cross-linking. Nevertheless, it is also possible that certain epitopes may be exposed as a result of the treatments, increasing allergenicity. Therefore, an allergenicity evaluation of protein-derived food packaging materials would be appropriate.

In addition to the primary packaging, the allergenic potential of other components such as coatings and fillers need to be considered. Edible films are often coated with seed oils or plant essential oils such as rosemary, oregano, tea tree and others. Some of these are known to be able to elicit allergic reactions by oral or skin contact (Avonto et al., 2016; Damiani et al., 2012; Mortimer & Reeder, 2016).

At present there is no evidence to indicate that BBFCMs pose an allergenic risk to consumers. However, it might be considered prudent for manufacturers to review the use of potentially allergenic materials as components of BBFCMs.

## 3.10 Performance of bio-based packaging – shelf life

One of the main functions of food product packaging is to maintain the integrity, quality and safety of the product. From a microbiological viewpoint, packaging has the function of protecting from environmental contamination as well as extending the shelf life of the product by preventing or controlling the growth of spoilage organisms or pathogens.

One approach to enhance packaging for prevention of microbiological proliferation is by the application of antimicrobial packaging films (active packaging). The use and authorization of active and intelligent materials and articles intended to come into contact with food is regulated under Commission Regulation (EC) No 450/2009. The regulation also establishes an EU-wide list of substances that can be used in the manufacture of these materials: substances may only be added to the list once their safety has been evaluated by EFSA. Previously, these have been prepared by blending agents with antimicrobial properties. These agents can include but are not limited to: organic acids, bacteriocins, enzymes, essential oils and phenolic compounds (Sung et al., 2013). For these reasons, much recent research has addressed the development composite films for food packaging (Marra et al., 2016).

Priyadarshi and co-workers proposed a chitosan film enhanced with apricot kernel essential oil. The antimicrobial properties of the film were assessed against *Bacillus subtilis* and *Escherichia coli in vitro*. In addition, the antifungal properties of the film were tested on samples of bread over a 10-day shelf life. The proposed film showed promising results to maintain the safety of bread over its shelf life (Priyadarshi et al., 2018). The possibility of extending shelf life requires further investigation as well as the applicability of the material for large scale production.

A novel melanin-stabilised zinc oxide nanoparticle (ZnONP) biopolymer-based nanocomposite film has been described based on carrageen (Roy et al., 2019). In their work, the authors describe the preparation of their material through treatment of squid ink and its subsequent incorporation into the zinc acetate and potassium hydroxide synthesised materials. Carrageenan, a linear sulfacted polysaccharide extracted from marine red algae, was mixed with water, glycerol and the melanin-stabilised ZnONPs. The products were analysed for their antimicrobial properties against *E. coli*, *Listeria monocytogenes* and total viable count. The results indicated a decreased viability of all organisms analysed over a 12-hour period. The study suggests that the proposed bio-based packaging could present a viable alternative to some plastic based compositions in the food industry.

Prabhawathi and colleagues proposed the use of a polycaprolactam, biodegradable polymer, which was covalently linked to papain, a protease from the papaya fruit with antimicrobial properties towards *E. coli*. The study used the proposed wrap on processed cottage cheese samples and found that the long-term antimicrobial effect of the polycaprolactam / papain film had significantly reduced the microbial activity of *E. coli* within the cheese over the period of one month when stored at 4°C. In addition, papain is already widely used within the food industry as part of the cheese ripening process and its food safety has previously been established not to cause unwanted by-products (Prabhawathi et al., 2014).

A study by Correa et al. investigated the effectiveness of nisin-PHB / PCL separating films on extending the shelf life of packaged cooked ham. The proposed material was composed of PHB, a renewable thermoplastic material, PCL, organo-clays nanofillers and nisin (a commercially available bacteriocin which has approval for food application). The data demonstrated that the packaging reduced the microbiological load of the ham and extended its regular 7 day shelf-life to one month (Correa et al., 2017). However, due to potential concerns over the safety of nanoclays when in direct contact with a food product further investigation is required to understand safe levels of nanomaterials in packaging.

A cellulose film covalently bonded with nisin was investigated in 2018 by Wu et al. and its antimicrobial activity over a three month period was evaluated (Wu et al., 2018). The proposed material was a cotton linter cellulose was formed into a membrane and nisin was bonded to the material and tested against *Alicyclobacillus acidoterrestris in vitro* over prolonged storage of the material. Analysis showed the material retained its antimicrobial activity over a three-month period. Further investigation into the applicability and safety of the material are required.

Valerini and co-workers described a coating based on treating PLA films, a linear aliphatic nature-derived polyester approved for food safety, with nanostructured aluminium-doped zinc oxide. Antimicrobial properties were investigated against *E. coli* (Valerini et al., 2018). The proposed coating and film demonstrated the ability to inhibit *E. coli* growth over a 48-hour period *in vitro*. However, simultaneous analysis of the degradation of the coating over a three-week period demonstrated some release of the materials on films not coated uniformly. The effect as a packaging migrant on the safety of the product remains to be investigated as well as its applicability to large scale productions.

A study by Woraprayote and colleagues described a polylactic acid/sawdust particle biocomposite film coated with Bacteriocin 7293, a bacteriocin obtained from *Weissella hellenica.* The film was tested as a packaging for *Pangasius sp*. fish fillets for its ability to inhibit the growth of *E. coli, L. monocytogenes*, *Salmonella typhimurium*, *Staphyllococcus aureus*, *Aeromonas hydrophila* B1 and *Pseudomonas aeruginosa* under refrigerated conditions. The analysis conducted on inoculated fish samples with the above cocktails showed an antimicrobial effect of the proposed packaging film over a 7-day shelf life. In the same study, the authors analysed the migration of the packaging film components into the fish. The results indicated that migration was occurring over the 7-day storage time due to changes in the packaging structure but the overall migration in $mg/dm^2$ was below the migration limit set out in EU standards. The analysis of the novel film suggests it may be suitable for use as a food packaging material (Woraprayote et al., 2018).

Chitosan and gelatin were combined with silver NPs in a nanocomposite film for the packaging of fresh red grapes and was investigated by Kumar et al. The grapes were wrapped directly in the film and stored over a 14-day period. In this study, film composition was analysed and the microbiological quality was assessed visually. Compared to the controls, which included standard plastic wrapping, there was no putrefaction or change in appearance of the grapes when wrapped in the biopolymer film (Kumar et al., 2018). Although the study showed promising results for the application in food, further investigations into the migration of nanomaterials and life cycle behaviour are required.

Salari et al., (2018) examined a chitosan-based nanocomposite film, with bacterial cellulose nanocrystals and silver nanoparticles for use as an antimicrobial packaging film. The *in vitro* analysis demonstrated growth inhibition for *S. aureus*, *B. cereus, E. coli* O157, *P. aeruginosa* and fungi.

A packaging film based on cassava starch and pumpkin peel obtained from industry waste was reported by dos Santos Caetano et al. Oregano essential oil was added to the film to promote antimicrobial activity. The *in vitro* analysis of the film demonstrated an antimicrobial effect against *E. coli*, *S. aureus* and *L. monocytogenes* (dos Santos Caetano et al., 2018). However, further investigation into the durability of the material is required, as well as its ability to retain its antimicrobial functionality when applied to different food matrices.

A novel packaging film based on cassava starch and blueberry pomace, both obtained from waste by-products from the food manufacturing industry, was reported by Luchese et al. The material was assessed for its physiochemical properties as well as ability to extend food shelf life by providing an effective UV barrier for water rich food products *in vitro* (Luchese et al., 2018). The results showed that the material had desired properties, however further optimization of the material is required.

ZnONPs are of particular interest due to their antifungal and mycotoxin syntheses inhibition abilities (Sun, Q. et al., 2018). The European Food Safety Authority (EFSA Panel on Food Contact

Materials, Enzymes & Processing Aids, 2016) concluded that ZnONPs in their current analysis are safe to use in a food contact material.

Edible coatings or films are of great interest due to their ability to create additional barriers directly on the surface of the food product to support quality, safety and shelf life (Dehghani et al., 2018). For example, protein/chitosan edible films have been investigated for their antimicrobial properties and to coat packaging or food products. A quinoa flour/chitosan film has been described by Medina et al. and its antimicrobial activity *in vitro* was discussed. In their work, the authors described how the preparation of a quinoa flour/ NP thymol chitosan composition exhibited antimicrobial activity against *S. aureus, S. typhimurium* and *Listeria innocua in vitro*. The results obtained indicated that the NP with thymol had significant antimicrobial properties in comparison to controls (Medina et al., 2019). Whilst use as an edible film is outside the scope of this report, the authors also proposed using this nanocomposite material as a coating for plastic-based containers to reduce the water loss of fresh produce (blueberries and cherry tomatoes). In addition, the proposed coating could be applied to other bio-based or even non-bio-based packaging materials to enhance their antimicrobial properties to extend shelf life.

Antimicrobial substances are prevalent in current research for the enhancement of novel packaging materials due to their ability to potentially support food safety and shelf life of food products. However, the proposed substances in combination with the materials require further investigation into their properties and a risk assessment before considering their use on a larger scale. Particularly, when considering the increasingly observed antimicrobial resistance of microorganism in food and non-food (Pellerito et al., 2018).

Applications of nanomaterials in the food systems are of great interest due to their antimicrobial properties and abilities to enhance packaging materials food safety and shelf life. It has been reported that some nanomaterials (especially 'hard' or 'engineered' nanomaterials) may pose a potential risk to the consumer, either via direct contact or through secondary contact as a result of migration into food (Huang et al., 2018).

Chitosan-based films are amongst the most promising candidates to provide the base for novel packaging materials. Whilst *in vitro* and small-scale studies focusing on physiochemical properties and antimicrobial properties have produced promising results further intensive investigations are required to assess the suitability of the proposed composites to a variety of food products and the possibility of combining several technologies as well as their applicability to mass production. Additionally, toxicity studies are required to investigate the food safety of the chitosan composites as well as the realistic environmental impact of their production and degradation (Wang et al., 2018).

Although BBFCMs have been suggested as being useful for long shelf life food products (Peelman et al., 2016), one of the biggest potential hurdles is their ability to be deployed on a large scale. The majority of BBFCMs having undergone only limited analysis under laboratory conditions with respect to their ability to provide effective packaging solutions for specific types of food commodities or *in vitro* studies. Whilst these materials prove to be efficient in reducing microbiological activity and thereby supporting an extended shelf life, it remains unknown whether these attributes remain present in large scale packaging productions and on complex foods. Additionally, very limited information is available regarding the ability of the proposed packaging alternatives to behave under unexpected or adverse storage conditions, e.g. temperature abuse and whether under these conditions they could still maintain their properties. In addition, limited information is available on how the materials would behave over extended product shelf life. Depending on the type of proposed material and the required manufacturing methods it remains unclear if the cost of large scale production would be feasible or if the impact on the environment from the novel technologies such as the bioactive ingredients or nanomaterials would have an equal negative impact as the plastic manufacture from production point to the waste stream (Werner et al., 2017).

In case of complex food products or composite products, packaging may require a combination of several technologies to provide the desired functions of safety, quality and shelf life. It needs to be highlighted that most of the available analysis to date on proposed bio-based packaging materials have not been tested with multiple technologies and have focused on one composition and one food type or *in vitro* analysis. Additionally, investigations looking at negative impacts on the food during trial phases have not been considered (Vilela et al., 2018).

Key factors for the development of plastic alternative packaging need to take into consideration their intended use on the product and their capability to maintain their structure and properties during their entire cycle.

Thermoplastic starches which have been converted from agri-food by-products through casting, extrusion, compression or moulding into films or packaging material, are promising candidates for use as food contact materials. However, thermoplastic starch has been shown to have a limited shelf life as it is easily biodegraded. The lack of durability is a significant drawback and further work is required to develop a material composite which retains its quality for extended periods of time before degrading. Currently, the large scale production of this type of material is not economical and consumer reluctance due to its relatively higher cost outweighs the environmental benefit (Prabhu & Prashantha, 2018).

Biomaterials such as alginate and chitosan have been assessed for their suitability as coatings when applied to paper-based packaging products in a study by Kopacic et al., (2018). The results demonstrated a reduction of permeability, migration and transmission when compared to traditional paper-based packaging and control paper. These biopolymers have the potential to be a beneficial additive to existing packaging and enhance food material shelf life. Similarly, wrapping paper prepared from a carbohydrate blend of alginate, cellulose, carrageenan with the addition of grapefruit extract enhanced the antimicrobial properties when compared to traditional wrapping papers. The analysis showed activity against *L. monocytogenes* and *E. coli* over a shelf life of 9 days when wrapped around fish paste stored under refrigerated conditions (Shankar & Rhim, 2018).

Zhang et al discussed steps to achieve commercial production of novel BBFCM packaging materials (Zhang et al., 2018). In particular, techniques such as electrospinning of biopolymers were reviewed and difficulties in up-scaling were identified. Despite these issues, nanotechnologies were considered likely to have a positive impact on future food packaging, enhancing its performance and also food safety, quality and shelf-life (Mihindukulasuriya & Lim, 2014).

## 3.11 Kitchenware and tableware

Whilst much attention has been focussed on the use of BBFCMs for food packaging, the production of food service items such bowls, plates, cups and cutlery based on composites containing plant fibres has increased significantly. This is also perceived as a more sustainable solution, generating both lighter and stronger products. These materials are also promoted by industry as a more acceptable alternative to conventional plastic FCMs. In these items, the composites consist of a resin reinforced with lignocellulosic fibres and powders derived from crop by-products such as bamboo, banana, coir, peanut shells, bagasse or rice straw. The plant-derived fibres and/or powders are mixed with materials such as phenol-formaldehyde resins or polypropylene. Mechanical and chemical processing of the plant fibres to reduce the lignin content is frequently performed, in association with the addition of agents to the resin to enhance mixing, wetting and interfacial adhesion between the components. The composite mixture is subjected to a combination of high pressure and temperature for varying time periods to generate a thermoset plastic item of kitchenware or tableware (Abd-El Salam, 2014; Naik et al., 2015; Shah et al., 2016).

This is analogous to the use of sizing agents in the production of glass fibre food contact materials as described in the Scientific Opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (EFSA, 2015). Regulation (EU) No 10/2011 stipulates that IAS used in the manufacture of the composite food contact material must be listed in the Union List. Similarly, the IAS used to produce the food service items must comply with the positive list of chemicals permitted through regulations such as Commission Regulation (EU) No10/2011 for plastic materials and articles in contact with food. Any NIAS developed during processing of the materials also need to be identified to ensure safety. A frequently reported issue with the thermoset food service items based on phenol formaldehyde resins is the release of formaldehyde with potential for migration into food matrices. In response to the continuing rapid growth in demand by consumers for these ‘sustainable’ tableware and kitchenware items and the widening range of agri-food by-products used in their manufacture, greater surveillance of both IAS and NIAS chemical migrants may be required to ensure consumer protection.

# 4. Conclusions

Based on the literature review, the following conclusions can be made:

1. Limited research into the development of BBFCMs derived from agri-food by-products, and the associated risks to the consumer, has been undertaken.
2. BBFCMs can exhibit barrier properties similar to traditional, fossil-based plastics enabling comparable shelf life performance and consumer protection.
3. Information on the presence of contaminants such as heavy metals, persistent organic contaminants and natural toxins in BBFCMs and their capacity to transfer from biomass-derived BBFCMs is required.
4. Polypeptide-based materials used for packaging include substances that are known allergens or are extracted from matrices that contain allergens. The effects of processing to produce packaging materials may alter allergenicity in unpredictable ways, depending on whether the allergenic epitopes are destroyed or revealed, for example due to conformational changes of the polypeptides. Very limited information is available on the allergenicity of BBFCMs as well as the potential for transfer of allergens to food.
5. Current analytical methods and risk assessment processes for establishing contaminant chemical transfer from fossil-based plastics to food are expected to be appropriate for BBFCMs.

Although the current analytical methods for determining the migration of IAS and NIAS from FCMs are expected to be applicable to BBFCMs, there is some scope for further method development e.g. high resolution mass spectrometry for allergen epitopes.

Migration studies have demonstrated that only a negligible amount of nanomaterial migrates from packaging into food simulants or foods, suggesting that consumer exposure to these nanomaterials would be low. However, the regulatory framework for nanomaterials in packaging is still underdeveloped even in major economies (Garcia et al., 2018).

The majority of BBFCMs are currently imported into the UK. Extended supply chains may present additional risks around integrity that might need to be addressed.

Overall, the results of this study indicate that in response to the ongoing innovation and growing use of BBFCMs as an alternative to fossil-based packaging, additional studies or actions may be required to help contribute towards ensuring future food safety and consumer protection.

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# Appendix 1: Search term criteria used for literature searches

Search terms used were:

- Allergens
- Bio-based
- Bioplastic
- Biopolymer
- Contaminants
- Food contact materials
- Non-fossil fuel
- Renewable
- Packaging
- Plant-based
- Regulation
- Risk
- Safety
- Toxicity

# Appendix 2: Regulations relevant to BBFCMs

**UK National Regulations**

The national regulations are The Materials and Articles in Contact with Food Regulations 2012.

Links to the regulations for England, Wales and Northern Ireland can be found at:

https://www.food.gov.uk/business-guidance/food-contact-materials

For Scotland, the Materials and Articles in Contact with Food (Scotland) Amendment Regulations 2019 can be found at:

http://www.legislation.gov.uk/ssi/2019/32/contents/made

**European Regulations, Directives and Recommendations**

Copies of the Regulations are available online on the Eur-Lex website:

https://eur-lex.europa.eu/homepage.html

**General**

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.

**Food Contact Materials**

The regulations relating to food contact materials can be obtained from the European Commission at:

https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/legislation_en

These include (but not limited to):

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

# Appendix 3: Current BBFCM Research in the UK

A combination of literature review and web search was undertaken to determine active research into BBFCMs. The results are summarized below:

**Bangor University**

The Biocomposites Centre is a designated Centre of Excellence that undertakes world leading fundamental and applied research into products and processes based on wood, industrial crops, recycled materials and industrial residues. Work includes preparation and evaluation of BBFCMs.

(Graham Ormondroyd – Head of Materials Research)

**Biorenewables Development Centre**

Process optimisation and valorisation of agri-food waste.

(Joe Bennett, Gail Shuttleworth)

**CuanTec Ltd**

Expertise in the biological extraction of chitin and formulation of chitosan biopolymer mixtures to provide film and other packaging materials.

(Ryan Taylor – Chief Scientific Officer)

**Fera Science Ltd**

Production and characterization of chitosan from agri-food waste for use in food contact applications. Chemical safety of BBFCMs.

(Emma Bradley, Adrian Charlton, Sean Mason, Maureen Wakefield)

**Newcastle University**

Established the Institute for Agri-food Research & Innovation joint venture with Fera Science Ltd. Supports a range of pure and applied research projects including BBFCMs.

Development and evaluation of nanofiber films from agri-food waste. Production and characterization of active nanocomposite BBFCMs. Evaluation of novel food packaging performance (shelf life, physical, chemical & sensory analysis).

(Catherine Birch, Graham Bonwick – NU-Food Centre, School of Natural & Environmental Sciences)

Production and biochemical characterization of biopolymers derived from agri-food waste.

(Catherine Tetard-Jones, William Willats, School of Natural & Environmental Sciences)

Development of PHA production through use of microbial fuel cells / molecular engineering.

(Eileen Yu, Thomas Howard – School of Natural & Environmental Sciences)

Design and evaluation of PLA packaging solutions.

(Katerina Novakovich – School of Engineering)

**Northumbria University**

Biotechnology applications for optimization of agri-food waste processing for BBFCM production.

(Gary Black, Justin Perry – Department of Applied Sciences)

Bionanomaterials for food packaging applications. Green bio-composite fabrication processes for food packaging.

(Raymond Oliver – Northumbria School of Design)

**University of Bath**

Novel bio-based plastics based on agri-food waste.

(Matthew Davidson – Centre for Sustainable Chemical Technologies)

**University of Leeds**

Soft bio-inspired nanostructured biomaterials derived from natural polymers. Exploitation of agri-food waste for packaging applications.

(Francisco Goycoolea – School of Food Science & Nutrition)

**University of York**

Exploitation of lignocellulosic biomass for biorefinery and packaging applications.

(Neil Bruce, Simon McQueen-Mason - Centre for Novel Agricultural Products)