TOX/2020/24

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

Scoping paper: alternatives to conventional plastics for food & drinks packaging

Introduction

Fossil-based plastics for food & drinks packaging

1. Packaging materials used for food and drinks are primarily required to provide a barrier function. This barrier prevents pathogenic microorganisms and chemicals getting inside and helps to regulate the internal environment and reduce microbial growth and product deterioration. Food packaging therefore extends shelf-life and reduces food waste. Extended shelf-life is essential for foods such as out-of-season fruit and vegetables which travel great distances to reach consumers. Packaging is also used to protect foods from physical damage and to display product information that is increasingly required by law.

2. Plastics have many properties that make them suitable materials for packaging food and drinks. These properties include gas and water vapour permeability, mechanical properties, sealing capability, thermoforming properties, resistance to water, grease, acid, UV, machinability on the packaging line, transparency, and anti-fogging.

3. The UK Government uses the following definition of plastic, taken from the EU Directive on Single-Use Plastics: “plastic means a material consisting of a polymer to which additives or other substances may have been added, and which can function as a main structural component of final products, with the exception of natural polymers that have not been chemically modified”[1].

4. The fossil-based plastic industry is an oil and gas-based industry - about 8 % of the world’s oil production is used to make plastic[2]. In volume terms, the global market in conventional plastics is dominated by four classes of polymer, synthesised primarily from fossil fuel sources: polypropylene (PP), polyethylene (PE), polyethylene terephthalate (PET), and polyvinyl chloride (PVC) (UNEP, 2018).

5. The production of conventional plastics generates greenhouse gases, and in addition to this environmental hazard, the majority of recyclable plastics are not recycled under current recycling systems. In the UK this is predominantly due to food-contaminated packaging and insufficient collection and processing infrastructure. In 2017, only 46.2% of UK plastic packaging from all sectors was

---

[1] http://www.legislation.gov.uk/eudr/2019/904/article/3/2019-10-31/data.xht?view=snippet&wrap=true

[2] https://www.nationalgeographic.com/news/2018/05/plastics-facts-infographics-ocean-pollution/

collected for recycling; of this, 34% was recycled in the UK and the rest was exported to other countries (RECOUP, 2018).

6. In the UK, plastic packaging which is not recycled is incinerated, landfilled (both of these outcomes produce further greenhouse gases) or creates litter which can persist in the natural environment for many years and can form microplastics. Oxo-degradable plastics contain additives to accelerate their degradation in heat and UV. This does not reduce the quantity of the polymer in the environment due to the microplastics formed, so the EU Single-use Plastics Directive will ban oxo-degradable plastics from 2021[3].

Initiatives to reduce plastic food & drinks packaging

7. Due to the adverse environmental impacts of fossil-based plastics described above, and owing to a large proportion of total plastic being used in packaging (40%[4]), there are many initiatives to reduce the amount of conventional plastic used within packaging. These initiatives include:

- an announcement from the UK Government in 2018 that “from April 2022 it would introduce a world-leading new tax on the production and import of plastic packaging with less than 30% recycled content” (DEFRA, 2019a).
- an announcement from the UK Government in 2018 of a *25* Year Environment Plan (25YEP) with the target of zero avoidable plastic waste by 2042.
- the UK Plastics Pact, launched by the Waste & Resources Action Programme (WRAP) charity in April 2018, which aims to ensure that by 2025, 100% of plastic packaging to be reusable, recyclable or compostable, of which 70% is effectively recycled or composted.
- UK Government and industry initiatives such as the Courtauld Commitment (an agreement between WRAP and major retailers which aims to eliminate packaging waste)
- Defra’s Waste and Recycling Strategy which plans to double resource productivity and eliminate avoidable waste of all kinds (including plastic waste) by 2050
- the proposed EU Directive prohibiting plastic cutlery, plates, stirrers and straws by 2021[5].

8. As a result of government initiatives such as these around the world, and in conjunction with pressure from environmentally-aware consumers, recent years have seen a major global increase in the development and use of biobased materials for food contact applications. Therefore, in 2004 the FSA conducted a literature review on the chemical composition and conditions of use of biodegradable polymers intended for food contact as well as their migration potential (Castle, 2004). Subsequently, in 2019, the UK FSA commissioned Fera Science Limited (Fera) to conduct a further literature review to better understand the potential health risks and other unintended consequences of replacing fossil-based plastic food contact materials (FCMs) with biobased food contact materials (BBFCMs) (Fera 2019). The review found that BBFCMs can exhibit properties similar to fossil-based plastics,

---

[3] https://ec.europa.eu/commission/presscorner/detail/en/IP_19_2631
[4] https://www.wrap.org.uk/content/plastic-packaging
[5] https://ec.europa.eu/commission/presscorner/detail/en/IP_19_2631

enabling comparable shelf-life and performance. It also suggested that current risk assessment processes for establishing transfer of contaminants from packaging to food would be appropriate for BBFCMs.

Bio-based materials for food & drinks packaging

9. Bio-based materials are derived from living matter (animal, plant or fungal biomass) and is partially or wholly made of substances that are naturally available or are synthesised from biomass, such as sugarcane, corn, and algae. This means that manufacturing biobased materials is more sustainable than fossil-based plastics because their production 1) uses biomass as a raw material which is renewable, 2) does not generate the same level of greenhouse gases. Furthermore, the finished material in some cases is biodegradable/ compostable. These terms are described below.

“Biodegradable” packaging

10. Biodegradable materials are generally accepted to mean those broken down by microorganisms into water, biomass and carbon dioxide (European Bioplastics, 2016). The carbon dioxide produced does not contribute to an increase in greenhouse gases because it is part of the biological carbon cycle (Song *et al.,* 2009).

11. Although some packaging is “biodegradable”, this term generally has no specific timeframe or recognised standard. Products carrying ‘biodegradable’ claims may take years to fully break down. During this time-consuming process, these products may disintegrate into microplastics and release other environmental contaminants (Napper & Thompson, 2019). The rate of biodegradation depends on the type and thickness of the material, and the environment where biodegradation takes place, for example in compost, fresh water, or sea water.

“Compostable” packaging

12. Composting is the accelerated biodegradation of heterogeneous organic matter by a mixed microbial population in a moist, warm, aerobic environment under controlled conditions (Song et al*.,* 2009).

13. Vinçotte is a certification and standards agency based in Belgium which provides certification for compostable materials. Packaging certified as “OK compost” is designed to biodegrade in a certain time frame at elevated temperatures in an industrial composting facility when collected with food waste (POST, 2019). This allows for the processing of food-contaminated packaging which is otherwise problematic. Other materials certified by the “OK Compost Home” standard can be composted at home at ambient temperatures. To ensure that compostable packaging is correctly processed, the UK Government has proposed that from 2023, all local authorities in England should offer weekly separate food waste collections for households (DEFRA, 2019b). Vinçotte also provides certification for materials being biodegradable in soil (“OK soil”).

14. To comply with the EU harmonised standard (EN13432), industrially compostable materials undergo > 90% biodegradation within 6 months in an industrial facility in the presence of oxygen, microorganisms and temperatures of 50-60°C. On the other hand, home compostable materials undergo > 90% biodegradation within 12 months in a domestic composting unit in the presence of oxygen, microorganisms at temperature of 20-30°C. The 90% level set for biodegradation accounts for a 10% statistical variability in measurement tests, i.e. there is an expectation for a virtually complete biodegradation in the composting environment being tested.

15. Although certified compostable packaging biodegrades in industrial and in some cases domestic composting units, compostable packaging is not generally designed to biodegrade quickly in natural environments such as the ocean (POST, 2019).

Biobased Food Contact Materials

16. BBFCMs are diverse, and include paper/board, wheat-based, bamboo & rice-husk cups, wheat straws[6], beeswax wraps to replace clingfilm[7], and paper coffee cups[8]. Other BBFCMs made from chitin or seaweed have the advantage of not competing with food crops for land use.

17. Chitin can be made into a packaging material (UNEP, 2018). Chitin can be found in mushrooms and in the exoskeletons of insects and crustacea. It is estimated that >10,000 tonnes of chitin may be available each year from waste products of the global shellfish industry (Hamed et al*.,* 2016).

18. Seaweed is a renewable resource that has already been made into compostable food packaging, including pouches and sauce sachets (UNEP, 2018). Alginate can be extracted from species of brown algae, and Gao et al. (2017) developed plasticised alginate using glycerol as a plasticiser. Although these materials are still under development, the Skipping Rocks Lab start-up based at Imperial College London developed ‘Ooho’ - an edible, seaweed-based membrane made from sodium alginate and calcium chloride designed to contain water. Approximately 30,000 Ooho capsules were distributed to runners at the 2019 London marathon[9]. FCM made from edible materials may require additional consideration for additive content and allergenicity.

19. BBFCMs also include biobased polymers (also known as “bioplastics”). Whilst bioplastics based on naturally-occurring polymers such as starch or cellulose are generally biodegradable, bioplastics produced from biobased monomers (which include many conventional plastics such as polypropylene) can lose this property

---

[6] These straws may pose a risk to people with coeliac disease. In coeliac disease, eating gluten causes damage to the small intestine lining.

[7] https://www.beeswaxwraps.co.uk/

[8] TrioCup is a paper coffee cup designed on origami principles that removes the need for a plastic lid, and is suitable for industrial composting.

[9] https://www.telegraph.co.uk/news/2019/04/13/london-marathon-runners-given-edible-water-bottles-organisers/

during their manufacture through chemical modification. Therefore, not all bioplastics are biodegradable.

BBFCMs: bioplastics

20. Bioplastics can be produced from biomass, biobased monomers, or microorganisms. In the UK, commercial bioplastics are predominantly based on starch and cellulose, though PLA and PHAs are also emerging as major BBFCMs[10]. These BBFCMs are described below.

Bioplastics derived from biomass: starch

21. Starch is the major storage carbohydrate in plants. Thermoplastic starch (TPS) is made by processing native starch, where plasticisers such as glycerol and urea are added to reduce intermolecular hydrogen bonding and to stabilise the product. Although TPS can be processed into flexible or rigid plastics, its applications are limited due to its hydrophilicity and mechanical properties (Shen et al., 2009).

22. The properties of TPS or native starch can be improved by blending with other biobased materials to improve the properties of the finished product and increase the range of food packaging applications including wrap films, trays, boxes and tableware (La Mantia & Morreale, 2011). For example, addition of chitosan improves water vapour and oxygen barrier properties (Dang & Yosan, 2016), whilst addition of cellulose/lignin fibers reduces water solubility of TPS (Edhirej et al.*,* 2017). Durable polymers can also be produced by blending starch with bioplastics such as PLA (e.g. Cereplast Hybrid™) or fossil-based plastics such as polyurethane (e.g. Biopar® TPU).

Bioplastics derived from biomass: cellulose

23. Cellulose is the most abundant organic polymer on the planet and can be extracted by digesting wood pulp at high pressure. Like starch, cellulose is a polymer of glucose but with different linkages between the glucose units and a different configuration of the polymer chains. This configuration allows for stronger hydrogen bonds between polymer chains, and greater resistance to hydrolysis than starch. The most familiar application of cellulose-based packaging is paper and board.

24. Cellulose films (cellophane™) are made from cellulose with glycerin added to increase flexibility. Cellophane is regulated by Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs. Because cellophane is heat-resistant it is used to wrap food for oven cooking. Cellophane also provides an effective barrier against bacteria, flavours, and aromas so it is used to package bread and cheese. Despite these advantageous properties, cellophane is highly permeable to water vapour, so it is usually coated with polymers such as PVC to improve barrier resistance (Benyathiar *et al.,* 2015). The use of polymer coatings such as PVC can slow down biodegradation of these films, because PVC biodegrades relatively slowly.

---

[10] Bioplastics can also be derived from proteins within biomass, but commercial food contact applications have not been identified due to their moisture sensitivity.

25. In addition to biomass, bioplastics can also be derived from biobased monomers, and microorganisms. Notable BBFCMs that are manufactured using these methods are described below.

Bioplastics produced biobased monomers: PLA

26. In the UK, polylactic acid (PLA) is the most common bioplastic synthesised from biobased monomers with food contact applications. The mechanical properties of PLA compare well with fossil-based plastics, for example high resistance to grease and oils. Therefore, PLA can replace several fossil-based plastics such as PET; indeed, PLA is used in the packaging of viscous, oily liquids in addition to dry products and those with short shelf-lives (Armentano *et al.,* 2013). Although PLA is suitable for serving beverages, it is not used for packaging carbonated drinks due to its poor vapour permeability.

27. PLA is obtained from the polymerisation of lactic acid (2-hydroxypropionic acid) with the addition of a plasticiser such as sorbitol or glycerine (Shanks & Kong, 2012). Lactic acid can be produced by bacterial fermentation of sugars derived from a variety of biomass sources including food and agricultural waste. PLA is safe to use for contact with food, and residual lactide in the polymer is not a food safety concern because PLA hydrolyses to form lactic acid, which occurs naturally in the body and in food (Auras *et al.,* 2004).

28. PLA is gaining popularity as a substitute for conventional plastics in the catering sector, where food waste and used PLA plates, cups and cutlery can be collected and the combined waste sent for industrial composting. This approach works well in a controlled closed-loop environment, such as institutional catering in companies and hospitals, to prevent cross-contamination of PLA plastics with conventional plastics.

29. Studies suggest that biodegradation of PLA in terrestrial and aquatic systems is limited (Karamanlioglu *et al.,* 2017), however PLA is fully biodegradable in industrial composting facilities. PLA can also be chemically converted back to lactic acid and recycled if appropriate facilities exist.

30. PLA can be blended with other polymers to extend its applications. For example, Ecovio® is a blend of PLA and the fossil-based polyester EcoFlex®.

Bioplastics produced by microorganisms: PHAs

31. Polyhydroxyalkanoates (PHAs) are a group of polymers produced in nature by numerous microorganisms, including through bacterial fermentation of sugars or lipids present in biomass such as food waste (Bugnicourt *et al.,* 2014). PHAs accumulate as granules within the cytoplasm of bacterial cells which are collected using enzymes or solvent extraction. The most common PHA is poly(3-hydroxybutyrate) (PHB) which is produced by the polymerisation of the 3-hydroxybutyrate monomer.

32. Biodegradation of PHAs in terrestrial and aquatic systems is limited, though they are fully biodegradable in industrial composting facilities (UNEP, 2018). PHAs are used for cutlery and packaging (bags, boxes and foams).

Bioplastics produced by microorganisms: cellulose

33. Cellulose can be produced by bacteria. *A.* xylinum and *A.* pasteurianus can produce an almost pure form of cellulose with a chemical and physical structure identical to cellulose found in plants. Bacterial cellulose is processed under ambient conditions, in contrast to higher temperatures required for the processing of plant cellulose. However, low yields and high costs are currently barriers to large scale production.

BBFCMs: microplastics from bioplastics

34. Many BBFCMs exhibit biodegradability. Given the fragmentation of larger pieces of bioplastics is inevitable and a fundamental route for degradation, it is possible for bioplastics to form fragments of various sizes and shapes in environments during degradation, including micro- and nanoplastics.

35. A first draft statement on the potential risks from exposure to microplastics (in respect of conventional plastics) was presented to the COT in March 2020[11]. In the corresponding minutes for this meeting, “Information was provided on toxicity to aquatic organisms. The Committee agreed that the focus should be limited to those studies that were of potential relevance to human health” (paragraph 32). “Overall, the Committee concluded that data were available on an insufficient range of foodstuffs” (paragraph 29).

36. Studies evidence that exposures of aquatic organisms to conventional and bioplastic-derived microplastics show similar adverse effects (Green, 2016; Straub *et al.*, 2017). However, impacts of microplastics on human health are largely uncharacterised (Shruti & Muniasamy, 2019). EFSA (2016b) noted that although “methods are available for identification and quantification of microplastics in food, including seafood, occurrence data are limited. In contrast to microplastics, no methods or occurrence data in food are available for nanoplastics”. Furthermore, “toxicity and toxicokinetic data are lacking for microplastics and nanoplastics which are required for a human risk assessment”.

37. The United Nations Environment Programme (UNEP) is the leading global environmental authority that sets the global environmental agenda, promotes the coherent implementation of the environmental dimension of sustainable development within the United Nations system, and serves as an authoritative advocate for the global environment. UNEP (2018) stated that “interaction with microplastics could cause direct physical damage or indirect damage through an inflammatory response to an ingested particle…In addition, there is the potential for harm due to the leaching of chemicals from the polymer”. UNEP (2018) described several possible sources of chemical contamination:

---

[11] https://cot.food.gov.uk/sites/default/files/tox202015microplasticsfirststatementannexa.pdf

- Monomers that make up the polymer (though starch and cellulose comprise of non-hazardous glucose molecules).
- Chemicals added to adjust the properties of the polymer. In many cases these chemicals, such as plasticisers, are not strongly bound within the plastic matrix so will tend to leach into the surrounding environment.
- Absorbed contaminants, particularly persistent organic pollutants already present in the environment such as PCBs are preferentially absorbed by plastics, with the potential for being desorbed into organisms after ingestion.

38. Although humans may be exposed to microplastics by ingesting seafood, Lusher et al*.* (2017) concluded that the corresponding risk to human health from chemical exposure to additive and absorbed chemicals is low. Furthermore, EFSA (2016) concluded that “based on a conservative estimate the presence of microplastics in seafood would have a small effect on the overall exposure to additives or contaminants.

39. Zuo et al*.* (2019) investigated the sorption characteristics of biodegradable microplastics. In this study, the sorption and desorption behaviours of phenanthrene (an organic pollutant) on biodegradable polybutylene adipate terephthalate (PBAT) were investigated and compared with two types of conventional plastics (polyethylene and polystyrene). The authors found that the sorption and desorption capacities of PBAT were higher than those of the other types of microplastics.

40. Another possible route of human exposure to microplastics is through the consumption of and food and drinks packaged with bioplastics such as PLA, though data are lacking.

BBFCMs: chemical migration

41. Any material that comes into contact with food has the potential to transfer its constituents into it. Various factors require consideration when evaluating the potential extent of chemical migration. For example, if there is insubstantial direct contact between food and its packaging, then for such applications it may be expected that only low levels of migration will occur. However, in other cases such as the use of disposable cups in continuous contact with hot beverages, elevated levels of migration may be expected.

42. In European legislation, all materials and articles intended for contact with food must therefore meet the requirements of the Framework Regulation (EC) No 1935/2004. The basic principle underlying this Regulation is detailed in 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.”

43. It can be challenging for BBFCMs to meet these criteria because biodegradable packaging materials are generally inferior to fossil-based plastic in terms of providing an adequate gas and moisture barrier. Subsequently, it has been proposed that BBFCMs are used exclusively for dry foods which do not place high demands in terms of these barrier properties on the polymers, or as secondary packaging to provide indirect contact and rigidity (Weber *et al*., 2002). Foodstuffs most commonly packaged in bioplastics include fruit and vegetables, confectionary, cereals, tea, bakery products and pasta where this is the case.

IAS and NIAS

44. Intentionally added substances (IAS) used in the manufacture of biobased packaging may migrate into food. In respect of bioplastics, IAS include biobased monomers and plasticisers such as glycerol, sorbitol, and urea.

45. IAS used to produce food packaging made from conventional plastics are well defined and regulated. The Plastics Regulation (EU 10/2011)[12] provides a list of authorised substances for conventional plastics, and sets an overall migration limit and includes a list of authorised substances for the manufacture of plastic food contact materials with their corresponding specific migration limits:

- Overall Migration Limit: 10 mg of substances/dm^2 (square decimetre) of the food contact surface for all substances that can migrate from food contact materials to food. In some cases this limit is expressed as 60 mg/kg of packaged food.
- Specific Migration Limit (SML) for individual authorised substances fixed on the basis of a toxicological evaluation and a default exposure assumption.

These limits assume daily exposure throughout a lifetime for a person weighing 60 kg, to 1 kg of food packed in plastics containing the substance in the maximum permitted quantity. The Plastics Regulation also covers biobased and biodegradable plastics (i.e., those that are manufactured with synthetic polymers, chemically modified natural or synthetic polymers or polymers manufactured by microbial fermentation), and provides additional requirements that these plastics should adhere to (above the main Framework Regulation Article 3 requirements).

46. Directive 2007/19/EC states a general requirement to assess the safety of all potential migrants, including impurities, reaction and breakdown products. Starch, cellulose and lactic acid are authorised as starting substances for use in the manufacture of BBFCMs. However, these compounds have not been assigned a SML, thus their migration is controlled by the overall migration limit of 60 mg/kg of packaged food.

47. Chemicals in packaging which may migrate into food also includes non-intentionally added substances (NIAS). These include chemical impurities, reaction and breakdown products, and possibly contaminants of the biobased source material that could remain in the finished bioplastic such as mycotoxins, phytotoxins and algal toxins. In addition, food crops treated with pesticides can exhibit pesticide residues,

---

[12] https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_plastic-guidance_201110_en.pdf

and their subsequent processing may decrease or increase residue concentrations (Bajwa & Sandhu, 2014). However, no data were identified concerning the transfer of pesticide residues from BBFCMs to food.

Chemical migration: scientific studies

48. Bradley (2010) examined the migration potential of low molecular weight materials (<1000 Da) from a broad range of BBFCMs into food. Thirteen samples covering a range of biobased material types including starch, cellulose and PLA were analysed. Little measurable migration of toxicologically relevant low molecular weight volatile, polar and non-volatile substances chemicals was observed.

Migration from cellulose-based materials

49. Chemical migration from cellulose-based packaging is well characterised (Cwiek-Ludwicka & Ludwicki, 2014). Castle *et al*. (1988a,b) reported on the migration of plasticisers (propylene glycol, mono-, di-, and tri-ethylene glycol) from cellulose film. Mono-ethylene glycol and di-ethylene glycol were withdrawn from this specific use in 1985 and in some cases have been replaced by other plasticisers such glycerol and urea.

Migration from starch-based materials

50. Avella et al. (2005) determined the extent of migration of minerals from biodegradable starch/clay nanocomposite films developed for use in food packaging. The experimental work involved putting vegetable samples into bags made from either potato starch or potato starch-polyester blend, and their respective composites with nano-clay. The bags were heated at 40°C for 10 days, and migration of minerals determined by atomic absorption after digestion of the vegetables. The results indicated an insignificant trend in the levels of iron and magnesium in the vegetables, but a consistent increase in the amount of silicon (the main component of nano-clay). The concentrations of silicon detected in the vegetables were 16-19 ppm in the case of nano-clay composites of potato starch and potato starch-polyester blend, compared to 13 ppm for the same polymers without nano-clay, and around 3 ppm in control vegetables. The migrants determined were all associated with the nano-clay.

Migration from PLA

51. Conn et al. (1995) demonstrated that the level of lactic acid monomer that migrates to food from PLA packaging under intended use is substantially lower than the amount used in food as a common ingredient. When PLA was tested for migration into 8% ethanol solution and olive oil, under test conditions of 10 days at 43°C, the overall migration was 0.85 and 0.15 mg/ dm^2 into the two simulants, respectively. The migration studies were conducted on samples of PLA following guidelines issued by the Food and Drug Administration. The migrate comprised of lactic acid, lactoyl lactic acid (acyclic dimer), trimer, and lactide (cyclic dimer). Conn et al. noted that these dimers and oligomers hydrolyse in aqueous systems (i.e. *in vivo*) to lactic acid.

52. Mutsuga et al. (2008) subjected different types of PLA sheet to migration tests under various conditions and the lactic acid, lactide and oligomers content of the migration solutions were determined using LC/MS. PLA was found to be stable at 40°C for 180 days, and the total migration level of lactic acid, lactide and oligomers was 0.028 - 1.5 mg/ dm^2. When stored at 60°C for 10 days, PLA decomposed and the total migration level increased to 0.073 - 284 mg/ dm^2.

BBFCMs: active/ intelligent packaging

53. Recent research has addressed the development of composite films for food packaging which consist of antimicrobial agents such as organic acids, bacteriocins, enzymes, essential oils and phenolic compounds (Sung et al., 2013; Marra et al., 2016). For example, Priyadarshi et al. (2018) developed a chitosan film enhanced with apricot kernel essential oil. The antimicrobial properties of the film were assessed against B. subtilis and E. 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.

54. The use and authorisation of these 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. National rules and requirements of Regulation 1935/2004 still apply as the EU has not published the ‘positive’ list of substances following EFSA’s evaluations.

BBFCMs: heavy metals

55. 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. The heavy metals usually considered to pose a risk include those with the potential to bioaccumulate such as lead, cadmium and mercury. Heavy metals such as lead have been demonstrated in BBFCMs such as recycled paper and board and subsequently found to migrate into food (Mohammadpour et al., 2016). The main source of heavy metals is colourants (Mertoglu-Elmas, 2017).

56. Kim et al. (2018) studies a variety of polylactide (PLA) articles (n = 211) for migration of lead (Pb), cadmium (Cd) and arsenic (As) into a 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.

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

BBFCMs: nanomaterials

58. The Plastics Regulation (EU 10/2011) states that “substances in nanoform shall only be used if explicitly authorised and mentioned in the specifications in Annex I”. Biobased materials that come under the scope of materials in this regulation should also meet this requirement.

59. Numerous natural nanomaterials have been reported being used as components of nanocomposite films for food packaging (Youssef & El-Sayed, 2018). These nanomaterials attract interest because they provide antimicrobial or antioxidant activity (Vasile, 2018), mechanical strength (Sun *et al*., 2018) and ethylene scavenging to control ripening (Siripatrawan & Kaewklin, 2018). These properties may improve barrier function and achieve similar or better shelf-life than obtained from fossil-based plastic. The range of materials used is diverse and has included cellulose nanocrystals (Xu *et al*., 2018) and chitosan nanoparticles (Medina *et al*., 2019).

60. Nanostructured chitosan, alone or in combination with other nanomaterials, attracts interest because it is considered to be non-allergenic and non-toxic, is produced from agricultural byproducts, and its antimicrobial activity has been reported to extend shelf-life (Perinelli *et al*., 2018).

61. The antimicrobial 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).

62. Nanomaterials generally pose an ill-defined risk to human health if they are transferred to food and consumed (Almalik et al., 2018; Garcia et al., 2018). Therefore, EFSA recently opened a public consultation on its draft guidance for the risk assessment of nanoscience and nanotechnology applications in the food chain (EFSA, 2018). The guidance covers food contact materials and 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. Compliance with the current specific migration limit, in combination with the dietary exposure from other sources, is required. For example, the upper level for nanometals such as zinc has been set at 25 mg/person per day (EFSA, 2016a).

63. Abreu et al. (2015) examined a silver nanoparticle/starch composite and a silver nanoparticle/ammonium salt/starch composite for migration. The migration of the components from the nanostructured starch films was below the permitted limit of 60 mg/ kg.

64. Most migration studies with nanocomposites intended as BBFCMs have focused on PLA. For example:

- Migration levels of PLA containing cellulose nanocrystals and silver nanoparticles were examined. Migration levels were below the permitted limit of 60 mg/ kg (equivalent to 10 mg/ dm^2) in two food simulants (ethanol 10% (v/v) and isooctane) (Yu *et al.,* 2016).

- The overall migration from PLA with embedded copper-doped zinc oxide powder functionalised with silver nanoparticles into three food simulants was <10 mg/ dm^2 (Vasile *et al.*, 2017).
- PLA with embedded titanium dioxide or silver nanoparticles was prepared and cheese packed and stored at 51°C for 25 days. Migration of titanium and silver nanoparticles was <10 mg/ dm^2 (Li *et al.,* 2018).

BBFCMs: allergens

65. In the literature review of Fera (2019), it was noted that:

- "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", and
- "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)".

Despite these observations, this review revealed a scarcity of studies investigating the allergy risks of biomaterials used in food packaging. 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).

66. In respect of labelling, any advice would be directly applicable to allergy (via food contact material legislation). Labelling would be in accordance with the general food contact materials legislation (specifically Article 15 of Regulation 1935/2004 which states, with regards to necessary labelling, that "special instructions to be observed for safe and appropriate use"). This should provide adequate advice to manufacturers that they should be providing clear warning labels on their products if there is still a potential allergenicity and/or intolerance risk.

BBFCMs: endocrine active chemicals

67. Endocrine active chemicals (EAC) show structural similarities to natural hormones and are suspected to affect the human endocrine system. BBFCMs such as paperboard have been reported to be a major source of EACs (Cwiek-Ludwicka & Ludwicki, 2014; Vandermarken et al., 2019). Sources of EACs include plasticisers, inks and adhesives (Nakazawa et al., 2014; Vandermarken et al., 2019). However, the migration of printing inks from many BBFCMs has not been reported. Stringent measures have been introduced by the European Commission to control exposure to EACs such as the plasticiser bisphenol A.

Summary - usage

68. BBFCMs have the potential to contribute to material recovery, reduction of landfill and use of renewable resources. However, there are two key caveats to promoting their use: 1) they should be excluded from the recycling stream, to avoid compromising the quality of recycled conventional plastics, and, 2) bioplastics such as PLA and PHA behave like conventional plastics in aquatic environments, and contribute to an increase in ocean plastics if not disposed of correctly. Therefore, widespread public awareness of these materials and effective infrastructure for their certification, collection, separation and composting is necessary to obtain their benefits in full.

69. The majority of BBFCMs have undergone limited analysis under laboratory conditions with respect to their ability to provide effective packaging solutions for specific types of food commodities. For example, 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, on complex foods, and over extended product shelf lives. Additionally, limited information is available regarding the ability of the proposed packaging alternatives to behave under unexpected or adverse storage conditions such as temperature abuse and whether under these conditions they could still maintain their properties, particularly gas and moisture permeabilities.

Summary- potential health effects

70. BBFCMs entail a number of potential risks to human health, namely migration of chemicals, heavy metals and nanomaterials into food, in addition to allergy and formation of microplastics.

Questions for the Committee

71. The Committee are asked to consider the following:

- This paper has introduced various toxicological hazards associated with the use of plastic alternatives, namely migration of chemicals, heavy metals and nanomaterials into food, in addition to allergy and formation of microplastics; What further information is necessary on these aspects to provide guidance on the corresponding risks?

- In the UK, commercial bioplastics are predominantly based on starch (e.g. TPS) and cellulose (e.g. cellophane), though PLA and PHAs are also emerging as major BBFCMs. Which BBFCMs need to be considered in further detail?

- Any other comments on this discussion paper?

Secretariat
April 2020

References

Abreu A.S., Oliveira M., de Sá A., et al. (2015). Antimicrobial nanostructured starch based films for packaging. Carbohydrate Polymers **129:** 127-134

Almalik A., Alradwan I., Majrashi M., et al. (2018). Cellular responses of hyaluronic acid-coated chitosan nanoparticles. Toxicology Research ***7*:** 942-950

Armentano I., Bitinis N., Fortunati E., et al. (2013). Multifunctional nanostructured PLA materials for packaging and tissue engineering. Progress in Polymer Science **38(10):** 1720-1747

Auras R., Harte B., & Selke S. (2004). An overview of polylactides as packaging materials. Macromolecular Bioscience **4(9):** 835-864

Avella M., de Vlieger J.J., Errico M.E., et al. (2005) Biodegradable starch/clay nanocomposite films for food packaging applications. Food Chemistry **93:** 467-474

Avonto C., Chittiboyina A.G., Wang M., et al. (2016). In Chemico Evaluation of Tea Tree Essential Oils as Skin Sensitizers: Impact of the Chemical Composition on Aging and Generation of Reactive Species. Chem Res Toxicol **29(7):** 1108-1117

Bajwa U. & Sandhu K.S. (2014). Effect of handling and processing on pesticide residues in food-a review. Journal of Food Science and Technology **51(2):** 201-220

Benyathiar P., Selke S., & Auras R. (2015). Effect of Irradiation on the Biodegradation of Cellophane Films. Journal of Polymers and the Environment **23(4):** 449-458

Bradley E.L. (2010). FSA Project A03070: Biobased materials used in food contact applications: an assessment of the migration potential. Available at: https://www.food.gov.uk/sites/default/files/media/document/a03070.pdf

Bugnicourt E., Cinelli P., Lazzeri A., et al. *(*2014). Polyhydroxyalkanoate (PHA): Review of synthesis, characteristics, processing and potential applications in packaging. eXPRESS Polymer Letters **8(11):** 791-808

Castle L., Cloke H.R., Startin J.R., et al. (1988a) Gas chromatographic determination of monoethylene glycol and diethylene glycol in chocolate packaged in regenerated cellulose films. Journal of the Association of Official Analytical Chemists **71:** 499-502

Castle L., Cloke H.R., Crews C., *et al*. (1988b) The migration of propylene glycol, mono-, di-and triethylene glycols from regenerated cellulose film into food. *Z* Lebensm Unters Forsch. **187:** 463-467

Castle L. (2004). Food Standards Agency Report A03040 Investigation of the nature and extent of biodegradable polymers used in direct food contact applications. Available at: https://www.food.gov.uk/sites/default/files/media/document/a03040.pdf

Conn R.E., Kolstad I.J., Borzelleca J.F., *et al*. (1995) Safety assessment of polylactide (PLA) for use as a food contact material. Food and Chemical Toxicology **33:** 273-283.

Cwiek-Ludwicka K. & Ludwicki J.K. (2014). Endocrine disruptors in food contact materials; is there a health threat? Roczniki Panstwowego Zakladu Higieny **65(3):** 169-177

Damiani E., Aloia A.M., Priore M.G., et al. (2012). Allergy to mint (Mentha spicata). *J I*nvestig Allergol Clin Immunol **22(4):** 309-310

Dang K.M. & Yoksan R. (2016). Morphological characteristics and barrier properties of thermoplastic starch/chitosan blown film. Carbohydrate Polymers **150:** 40-47

DEFRA (2019a) Plastic Packaging Tax Consultations. Available at: https://consult.defra.gov.uk/environmental-quality/resource-and-waste-and-plastic-packaging-tax-consu-1/

DEFRA (2019b) Consultation on consistency in household and business recycling collections in England. Available at: https://consult.defra.gov.uk/environmental-quality/consultation-on-consistency-in-household-and-busin/supporting_documents/recycleconsistencyconsultdoc.pdf

Edgar L., McNamara K., Wong T., et al. (2016). Heterogeneity of Scaffold Biomaterials in Tissue Engineering. Materials (Basel), 9(5). doi:10.3390/ma9050332

Edhirej A., Sapuan S.M., Jawaid M., et al. (2017). Preparation and characterization of cassava bagasse reinforced thermoplastic cassava starch. *Fibers and Polymers* **18(1):** 162-171

EFSA (2016a) Safety assessment of the substance zinc oxide, nanoparticles, for use in food contact materials. EFSA J **14(3):** 4408. doi:10.2903/j.efsa.2016.4408

EFSA (2016b) Panel on Contaminants in the Food Chain. Presence of microplastics and nanoplastics in food, with particular focus on seafood. *EFSA J* **14(6):** 4501 doi: 10.2903/j.efsa.2016.4501

EFSA (2018). Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health. *EFSA J* **16(7):** 5327 doi:10.2903/j.efsa.2018.5327Environment Agency. (2018).

European Bioplastics (2016) Bioplastics – Industry standards & labels, Fact Sheet. Available at: https://docs.european-bioplastics.org/2016/publications/fs/EUBP_fs_standards.pdf

Fera (2019) Bio-Based Materials For Use In Food Contact Applications.
Fera project number FR/001658. Report to the Food Standards Agency. Available at: https://www.food.gov.uk/sites/default/files/media/document/bio-based-materials-for-use-in-food-contact-applications.pdf

Gao C., Pollet E., & Avérous L. (2017). Innovative plasticized alginate obtained by thermo-mechanical mixing: Effect of different biobased polyols systems. Carbohydrate polymers **157:** 669-676

Garcia C.V., Shin G.H., & Kim J.T. (2018). Metal oxide-based nanocomposites in food packaging: Applications, migration, and regulations. Trends in Food Science & Technology **82:** 21-31

Green D.S. (2016) Effects of microplastics on European flat oysters, Ostrea edulis and their associated benthic communities. Environ. Poll. **216:** 95-103

Hamed I., Özogul F., & Regenstein J.M. (2016). Industrial applications of crustacean by-products (chitin, chitosan, and chitooligosaccharides): A review. *Trends in Food Science & Technology* **48:** 40-50

Karamanlioglu M., Preziosi R., & Robson G.D. (2017). Abiotic and biotic environmental degradation of the bioplastic polymer poly(lactic acid): A review. Polymer Degradation and Stability **137:** 122-130

Kim H., Park S.Y., YE Jo, et al. (2018) Monitoring of Heavy Metals Migrated from Polylactide (PLA) Food Contact Materials in Korea. Journal of Food Hygiene and Safety **33(2):** 102-109

La Mantia F.P. & Morreale M. (2011). Green composites: A brief review. Composites Part A: Applied Science and Manufacturing **42(6):** 579-588

Li W., Li L., Zhang H., *et al.* (2018). Evaluation of PLA nanocomposite films on physicochemical and microbiological properties of refrigerated cottage cheese. Journal of Food Processing and Preservation 42(1)

Liu Y., Liang X., Wang S., *et al*. (2018). Electrospun Antimicrobial Polylactic Acid/Tea Polyphenol Nanofibers for Food-Packaging Applications. Polymers **10(5):** 561

Lusher A., Hollman P., & Mendoza-Hill J. (2017). Microplastics in Fisheries and Aquaculture: Status of Knowledge on their Occurrence and Implications for Aquatic Organisms and Food Safety. FAO Fisheries and Aquaculture Technical Paper. No. 615. Rome: Food and Agriculture Organization of the United Nations. http:// www.fao.org/3/a-i7677e.pdf.

Medina E., Caro N., Abugoch L., *et al*. (2019). Chitosan thymol nanoparticles improve the antimicrobial effect and the water vapour barrier of chitosan-quinoa protein films. Journal of Food Engineering **240:** 191-198

Mertoglu-Elmas G. (2017). The Effect of Colorants on the Content of Heavy Metals in Recycled Corrugated Board Papers. Bioresources **12(2):** 2690-2698

Mohammadpour I., Ahmadkhaniha R., Jeddi M.Z., *et al*. (2016). Heavy Metals in Recycled Pastry Packages and Pastries. Acta Alimentaria **45(4):** 509-514

Mortimer S. & Reeder M. (2016). Botanicals in Dermatology: Essential Oils, Botanical Allergens, and Current Regulatory Practices. Dermatitis **27(6):** 317-324

Mutsuga M., Kawamura Y., & Tanamoto K. (2008) Migration of lactic acid, lactide and oligimers from polylactide food-contact materials. Food Additives and Contaminants *Part A* **25:** 1283-1290

Nakazawa H., Iwasaki Y., & Ito R. (2014). Analytical Methods for the Quantification of Bisphenol A, Alkylphenols, Phthalate Esters, and Perfluoronated Chemicals in Biological Samples. Analytical Sciences **30(1):** 25-34

Napper I.E. & Thompson R.C. (2019) Environmental Deterioration of Biodegradable, Oxo-biodegradable, Compostable, and Conventional Plastic Carrier Bags in the Sea, Soil, and Open-Air Over a 3-Year Period. Environ. Sci. Technol*.* **9:** 4775-4783

Perinelli D.R., Fagioli L., Campana R., et al. (2018). Chitosan-based nanosystems and their exploited antimicrobial activity. European Journal of Pharmaceutical Sciences **117:** 8-20

POST (2019) The Parliamentary Office of Science and Technology. Postnote 606: Compostable Food Packaging. Available at: https://post.parliament.uk/research-briefings/post-pn-0606/

Priyadarshi R., Sauraj, Kumar B., et al*.* (2018). Chitosan films incorporated with Apricot (Prunus armeniaca) kernel essential oil as active food packaging material. Food Hydrocolloids **85:** 158-166

RECOUP (2018) RECycling of Used Plastics Limited. UK household plastics collection survey 2018. Available at:
http://www.bpf.co.uk/media/Download.aspx?MediaId=3061

Shanks R. & Kong I. (2012). Thermoplastic starch. In Thermoplastic Elastomers. El-Sonbati, A.Z. (ed.). Intech. chapter 6. https://cdn.intechopen.com/pdfs-wm/34063.pdf.

Shen L., Haufe J., & Patel M.K. (2009) Product Overview and Market Projection of Emerging Bio-Based Plastics -PRO-BIP 2009 – Final Report. http://www.epnoe.eu/content/download/7670/109501/file/PROBIP2009%20Final%20June%202009.pdf

Shruti V.C. & Muniasamy G.K. (2019) Bioplastics: Missing link in the era of Microplastics. *Science of the Total Environment* **697:** 134139

Siripatrawan U. & Kaewklin P. (2018). Fabrication and characterization of chitosan-titanium dioxide nanocomposite film as ethylene scavenging and antimicrobial active food packaging. Food Hydrocolloids **84:** 125-134

Straub S., Hirsch P.E., & Burkhardt-Holm, P. (2017) Biodegradable and petroleum-based microplastics do not differ in their ingestion and excretion but in their biological effects in a freshwater invertebrate Gammarus fossarum. Int. J. Environ. Res. Public Health **14:** 774.

Song J.H., Murphy R.J., Narayan R., et al. (2009) Biodegradable and compostable alternatives to conventional plastics. Phil. Trans. R. Soc. B **364:** 2127-2139

Sun J., Shen J., Chen S., et al. (2018). Nanofiller Reinforced Biodegradable PLA/PHA Composites: Current Status and Future Trends. Polymers **10(5):** 505

UNEP (2018) United Nations Environment Programme (2017). Exploring the potential for adopting alternative materials to reduce marine plastic litter. Available at: http://wedocs.unep.org/bitstream/handle/20.500.11822/25485/plastic_alternative.pdf?sequence=1&isAllowed=y

Vandermarken T., Boonen I., Gryspeirt C., et al. (2019). Assessment of estrogenic compounds in paperboard for dry food packaging with the ERE-CALUX bioassay. Chemosphere **221:** 99-106

Vasile C. (2018). Polymeric Nanocomposites and Nanocoatings for Food Packaging: A Review. Materials **11(10)**: 1834

Weber C.J., Haugaard V., Festersen R., *et al*. (2002) Production and applications of biobased packaging materials for the food industry. Food Additives and Contaminants **19**: 172-177

Xu Y., Rehmani N., Alsubaie L., *et al*. (2018). Tapioca starch active nanocomposite films and their antimicrobial effectiveness on ready-to-eat chicken meat. Food Packaging and Shelf Life **16:** 86-91

Youssef A. M., & El-Sayed S. M. (2018). Bionanocomposites materials for food packaging applications: Concepts and future outlook. Carbohydrate Polymers **193**: 19-27

Yu H.Y., Yang X.Y., Lu F.F., *et al.* (2016). Fabrication of multifunctional cellulose nanocrystals/poly(lactic acid) nanocomposites with silver nanoparticles by spraying method. Carbohydrate Polymers **140:** 209-219

Zuo L.Z., Li H.X., Lin L., *et al*. (2019). Sorption and desorption of phenanthrene on biodegradable poly(butylene adipate coterephtalate) microplastics. *Chemosphere* **215**: 25-32

List of abbreviations

BBFCM - biobased food contact materials
EAC - endocrine active chemical
EFSA - European Food Safety Authority
FCM - food contact materials
IAS - intentionally added substances
NIAS - non-intentionally added substances

LC/MS – liquid chromatography/mass spectrometry
PBAT - polybutylene adipate terephthalate
PCB - polychlorinated biphenyl
PET - polyethylene terephthalate
PHAs – polyhydroxyalkanoates
PHB - poly(3-hydroxybutyrate)
PLA - polylactic acid
PVC - polyvinyl chloride
SML - specific migration limit
TPS - thermoplastic starch