Bio-based food contact material safety challenges

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Introduction

Although the images of our polluted oceans reveal unacceptable levels of environmental pollution it must be remembered that packaging used for food is beneficial. It provides a barrier function, preventing physical contamination and contamination with spoilage or pathogenic microorganisms, or with chemicals present in the external environment during distribution or storage. The barrier function also helps regulate the internal environment, growth of microorganisms and product deterioration. Packaging also provides consumer and marketing information and also supports product safety, e.g. tamper-proof packaging.

The use of plastic packaging also helps to reduce food waste. Data reported by the FAO[1] reveals that "Roughly one third of the food produced in the world for human consumption every year — approximately 1.3 billion tonnes — gets lost or wasted" and, "Fruits and vegetables, plus roots and tubers have the highest wastage rates of any food."

Plastic packaging

Much of the food and drink packaging currently used is oil-based plastic. Plastics exhibit many of the properties required for effective food and drink packaging. In addition to food packaging, food contact articles used to prepare and serve food may also be made of plastic derived from fossil fuels; their improper disposal also has an adverse impact on the environment.

The drive to light-weight materials means that much of the innovation in the development of new plastic food contact materials has resulted in the evolution from single mono-layer materials to multi-layer materials containing two or more types of polymer (or other material type), often laminated to aluminium to provide the necessary barrier and pack integrity properties. As such opportunities for them to be recycled are reduced, further compounding the environmental impact. Polymeric coatings may also be applied to the food contact surface of metal packaging.

Packaging safety

Although food packaging is needed to protect food, it can also have a negative impact on the quality and safety of food due to chemical migration. Foods and beverages can interact strongly with materials that they touch. For example, food acids can corrode metals, fats and oils can swell and leach plastics and beverages can disintegrate unprotected paper and carton board.

In fact, no food contact material is completely inert and so it is possible for the chemical constituents of the packaging to 'migrate' into the packaged food. This release of chemicals to the food is known technically as migration and can be defined scientifically as 'the mass transfer from an external source into food by sub-microscopic processes'.

1 http://www.fao.org/save-food/resources/keyfindings/en/

Legislation

In European legislation, all materials and articles intended for contact with food must meet the requirements of the Framework Regulation (EC) No 1935/2004 (EC, 2004). This regulation is the first step to harmonizing the rules and is applicable to all material types. 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."

It defines both safety and inertness requirements that must be met by all materials and articles intended to come into contact with the food product irrespective of the material type, i.e. including bio-based food contact materials. It doesn't 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.

Despite the legislation being in place for several decades specific measures are only in place for a limited number of material types. Plastics are the main material used in food contact applications and, therefore the rules for this material type are the most advanced. Commission Regulation (EU) No 10/2011 as amended and corrected (EU, 2011) lays down the rules for plastic food contact materials. The regulation sets out rules on the composition of plastic food contact materials and establishes a Union List of substances permitted for use in the manufacture of food contact plastics.

The regulation also specifies restrictions on the use of these substances and sets out rules to determine compliance with these restrictions; it sets overall and specific migration limits (which are set following a risk assessment by EFSA using the toxicity data of each specific substance).

The legislation also defines the rules for testing to demonstrate compliance and permits the use of food simulants (simple test media intended to mimic foodstuffs). The migration testing is done under standardized exposure (time/temperature) conditions appropriate for the food contact conditions of the material or article.

For manufactured, oil-derived plastics where the monomers additives used in the manufacture are well defined, this approach can be used to support the determination of the material's safety and suitability. In addition to assessing the safety on the input chemicals consideration of what are known as NIAS (non-intentionally added substances), is also needed where NIAS are:

- **Known or unknown isomers, impurities, reaction products and breakdown products of the ingredients used to make the food contact material**
- **Possible contaminants from manufacturing process**
- **Subject to contamination from indirect sources such as printing inks, coatings, adhesives and secondary packaging**

Biobased food contact materials

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.
- Polymers produced by chemical synthesis using renewable bio-based monomers. For example, polylactic acid (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).

Some bio-based food contact materials fall within the scope of EU plastics regulation number 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 polymerization process such as polyaddition or polycondensation, or by any other similar process of monomers and other starting substances; or
- chemical modification of natural or synthetic macromolecules; or
- microbial fermentation"

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. As they fall under the definition above then they can be considered to be plastics and so their safety needs to be assessed in accordance with Regulation (EU) No 10/2011. Bio-PET is composed of purified terephthalic acid (70%) and monoethylene glycol (MEG; 30%). The MEG is derived from sugars obtained from agri-food by-products such as bagasse or crops such as sugar beet and so can be considered to be bio-based.

However, bio-PET as described is only partially derived 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 bioplastics PLA, PHA, PHB and polybutylene succinate (PBS) are fully bio-based materials.

Where a bio-based food contact material meets the definition of a plastic (as above) then the starting substances will need to be assessed for their migration and toxicity and the NIAS will need to be investigated. The rules for plastic materials and articles are well described and the authorization process for these materials is published on the website of the European Commission.

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 as a filler to a polymer (plastic) backbone and so it may be considered that the addition of the bamboo to the polymer means it is an additive that should be assessed and approved for use in a food contact plastic.

In August 2020, the European Commission published an updated summary "of discussions of the Expert Working Group on Food Contact Materials ('FCM') on the use and placing on the market of plastic food contact materials and articles containing ground bamboo or other similar constituents."[2]

> The working group stated "For such materials and articles consisting of a polymer but also containing ground bamboo or other similar constituents as an additive, the Working Group considers that Regulation (EU) No. 10/2011 applies." Bamboo has not been approved as an additive for use in the manufacture of food contact plastics."

Wood flour and fibres, untreated, are authorized and included in the Union List of approved starting substances for food contact plastics. However recent evaluation by the European Food Safety Authority (EFSA) concluded that the safety of wood should be evaluated species by species and the EFSA opinion stated that "no legal basis exists for the use of bamboo flour as an additive in plastics."

Potential health issues were highlighted, "although additives from a natural origin such as bamboo in a plastic matrix may themselves constitute a low health risk. Health risks may arise however if the quality of those natural additives is poor, if they contain impurities or contaminants, if they contain or contribute to the formation of reaction or decomposition products which constitute a health risk, or if the material swells and thus results in adverse surface alterations."

2 https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_meeting-ind_20200623.pdf

Potential safety risks associated with bio-based food contact materials

Fera Science conducted a review of the data and evidence relating to potential risks and other unintended consequences of replacing fossil based plastic food contact materials with bio-based food contact materials. Data from a range of sources including scientific and grey literature (for example, government, not-for-profit organizations, academic and industry reports) were reviewed.

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. Bio-based food contact materials manufactured from diverse biomass resources including agri-food by-products, may lead to additional sources of risk that are not observed with fossil-based plastics. The exploitation of biomass for the production of bio-based food contact materials, 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), allergens, mycotoxins and plant toxins. The latter examples may arise due to horticultural or agricultural practices or misuse of agrochemicals. The processing of these materials will also provide a source of NIAS, with potential to migrate upon contact with food.

Only limited information was available from the literature review; however, this is not a reflection of the relative risk of the contaminants but indicates the state of the knowledge about them and whether or not they constitute a risk. The conversion of biomass into packaging, especially if subject to thermal processing, may also generate processing contaminants more frequently associated with food.

All of this is speculative as only limited research has been carried out. The main driver in the manufacture of new materials is to reduce the amount of plastic littering and as such the most recent research reports focus on achieving performance characteristics that are at least comparable to those obtained from the use of fossil-based food contact materials.

In general, this has been reported to be achieved through the inclusion of bioactive materials, often derived from agri-food by-products and/or the use of nanosized or nanostructured materials included as a means of obtaining enhanced barrier properties, anti-microbial or antioxidant capabilities or other active packaging applications.

> Drinking straws in the UK is a good example of how good intentions may solve one problem only to lead to another. Following a consultation, effective April 2020, the UK government banned the supply of plastic straws (except for medical requirements). This has led to the production and marketing of straws made from agri-food products such as wheat.

Perception is that if something is natural then it is better for you. However, some of the most toxic substance are natural contaminants of foods, for example mycotoxins. Mycotoxins are toxic compounds that are naturally produced by certain types of moulds (fungi) that may grow on foodstuffs such as cereals, dried fruits, nuts and spices. Mould growth and toxin production can occur either before or after harvest, during storage, on/in the food itself often under warm, damp and humid conditions.

So, if the wheat used to manufacture the straws has been subject to such conditions and mould has developed, there is the potential for these contaminants to remain in the food contact material once manufactured with potential exposure by dermal or oral contact prior to ingestion.

Therefore, this risk should be evaluated and specifications on the source material should be set. Numerous mycotoxins have been identified. Those most linked to wheat are the toxins produced by Fusarium funghi, the ergot alkaloids and ochratoxin A which can occur when the grain is subjected to poor storage conditions. According to the World Health Organization, the adverse health effects of mycotoxins range from acute poisoning to long-term effects such as immune deficiency and cancer.

Similarly, pesticide residues should be considered in case of mis-use of agrochemicals prior to harvest. Another risk specifically linked to wheat straws is allergenicity, do the allergenic epitopes that remain in the straw that comes into contact with the lips.

None of these potential safety risks would be apparent in fossil-based plastics.

> It's not known if mycotoxins, pesticide residues or allergenic epitopes present in wheat remain once the product has been processed and manufactured into food contact material. 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 and may breakdown any chemical residues or contaminants.

What they break down into and any reactions the products produced would need to form part of the safety assessment of the material using approaches commonly applied to assess NIAS in other material types, e.g. 'Bradley *et al.* (2009)'.

At present there is no evidence to indicate that biobased food contact materials pose a risk to consumers from these contaminants and allergens. However, it might be considered prudent for manufacturers to review the use of potentially allergenic materials as components of biobased food contact materials and/or to set specifications as to the quality of the input material and define tests to demonstrate that the input materials are suitable and safe for incorporation into a food contact material.

Following on from their review, Fera Science is currently developing methods to assess the risks highlighted. 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 bio-based food contact materials. However, the complex nature of bio-based food contact materials, suggests that *in vitro* screening methods based on cellular toxicity may be useful adjuncts to the accepted chemical analytical methods used to establish safety, ('Severin *et al.,* 2017').

Biodegradability and compostability and risks to the environment

For a bio-based food contact material to exhibit biodegradability it generally will contain a hydrolysable linkage in its structure and as such most are polyester based. 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 which leads to mis-interpretation by the consumer as to the appropriate disposal of such packaging materials.

Compostable materials are biodegradable under specific conditions as described in standards such as BS EN 13432:2000 Packaging. Requirements for packaging recoverable through composting and biodegradation. 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 exhibit the same environmental behavior and fate.

In September 2019 the UK House of Commons Environment, Food and Rural Affairs Committee published the 'Plastic food and drink packaging Sixteenth Report of Session 2017–19'. The summary states: "…. In the backlash against plastic, other materials are being increasingly used as substitutes in food and drink packaging. We are concerned that such actions are being taken without proper consideration of wider environmental consequences, such as higher carbon emissions. Compostable plastics have been introduced without the right infrastructure or consumer understanding to manage compostable waste."

In addition to these chemicals transferring into food it is also possible that they leach into the environment once disposed. Therefore, whether compostable and/or biodegradable, any innovation and development of new materials that are more "environmentally friendly" must consider the migration of any chemicals used into foodstuffs as well as the environment when the packaging is no longer needed.

Safety-related packaging standards

BRCGS Packaging – framework for all types of packaging manufacturer to assist them in the production of safe packaging materials and to manage product quality to meet customers' requirements, while maintaining legal compliance.

IFS PAC – secure assesses the quality and safety of packaging materials and the compliance with customer requirements, and supports businesses in meeting new requirements on quality, transparency and efficiency resulting from globalization.

ISO/TS 22002-4:2013 Prerequisite programmes on food safety — Part 4: Food packaging manufacturing specifies requirements for establishing, implementing and maintaining prerequisite programmes (PRPs) to assist in controlling food safety hazards in the manufacture of food packaging.

ISO/TS 21975:2020 Nanotechnologies — Polymeric nanocomposite films for food packaging with barrier properties — Specification of characteristics and measurement methods specifies characteristics including barrier properties to be measured of polymeric nanocomposite films used for improving food packaging.

Fraud

Other potential barriers to the adoption of bio-based food contact materials, 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 may also need to be considered to ensure supply chain integrity.

With market research suggesting consumers may be willing to pay more for products contained in bio-based packaging, there is potential for food fraud practices to expand into packaging for economic gain.

Conclusions and recommendations

It's expected that there will be an increase in new bio-based food contact materials developed, this suggests that a risk assessment and approval processes for new material types should be standardized and guidelines documented. In general, it's considered that risk assessment procedures applied to conventional fossil derived plastic food contact materials will be applicable to those that are bio-based and so existing protocols can form the basis of such a guideline.

However, for agri-food derived materials, additional supply chain controls and specifications should be developed along with methods developed to ensure that they are adhered to. In this way the safety of the input materials can be controlled alongside impacts on the health of the consumer and the environment while also mitigating potential fraudulent claims.

Design-related packaging standards

BS 8001:2017 Framework for implementing the principles of the circular economy in organizations provides guidance and recommendations that will help an organization rethink how their resources are managed to create financial, environmental and social benefits.

ISO 11156:2011 Packaging — Accessible design — General requirements provides a framework for design and evaluation of packages so that more people, including persons from different cultural and linguistic backgrounds, older persons and persons whose sensory, physical, and cognitive functions have been weakened or have allergies, can appropriately identify handle and use the contents.

ISO/TS 26030:2019 Social responsibility and sustainable development — Guidance on using ISO 26000:2010 addresses several aspects of social responsibility including considerations for improving an organization's level of social responsibility by lowering the environmental impact of its packaging.

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