Biobased FCM: A Starter’s Guide For The Development Of New Biobased Food Contact Materials

A guide for those intending to develop new biologically based food contact materials.

Summary

Purpose

A guide for those intending to develop new biologically based food contact materials. The guide is intended to help developers and manufacturers identify and consider aspects of regulatory compliance that might influence their material choices, in order to meet customer needs for the intended use of the end product.

Legal status

Disclaimer

This guide is for information purposes only. It is intended to provide a helpful non-binding guide to developers and manufacturers of biobased food contact material, but it may not be exhaustive or applicable to all circumstances. It does not have any binding regulatory status and does not represent best practice or an interpretation of the law. It should not be relied upon by individual developers and manufacturers as to how regulatory requirements will affect them and they should seek specific advice on their own legal position.

This guide may be reviewed and amended periodically but may not always be up-to-date.

Who is this publication for?

This guide is for:

- Materials researchers, developers and manufacturers
- Local authority advisory officers and other interested parties

Which UK Countries does this guide apply to?

- England, Wales and Northern Ireland

Review date

- We will review this guidance before 2024

Key Words

- Biobased, organic, renewable, novel, alternatives
- Food Contact Materials
- Packaging, utensils, kitchenware, tableware

Introduction

The twentieth century could be described as the century of plastic. From humble beginnings as a niche material to something ubiquitous in all of our lives. Plastic is cheap, robust, flexible in properties and produced in vast quantities for many uses from a seemingly unending source of raw materials. Modern life is defined by the plastics we utilise.

The success of plastic has brought about new challenges, some of which only now society has started to recognise and is working to address. The extreme longevity of most plastics means it is a legacy that will live with us for centuries. Their interactions with eco-systems are now better understood, and the harm of indiscriminate disposal of plastic, from its immediate impact on wildlife to its disturbance of ecologies at the microscopic scale, have led to increasing emphasis on using alternatives wherever possible. The twenty first century may herald the age of plastic alternatives.

Purpose of this guide and intended audience

Biobased materials for food contact are an emerging and growing sector. This guide has been developed in response to food industry concerns over the suitability of some materials produced to assist manufacturers, researchers and developers of biologically based materials to better understand the design implications for products that come into contact with food.

What are "biobased materials"?

The UK Government is working with industry and the public on looking at new approaches - from eliminating avoidable plastic waste and creating a circular economy by supporting recycling initiatives, to encouraging replacement materials within a new supply approach.

One such solution is the use of biobased materials.

A biobased material is either:

(1) a product that mainly consists of a substance, or substances, that are derived from living matter (biomass) and which may occur naturally or be synthesised; or

(2) a product that is made by processes that utilise biomass.

Many of these are polymers, repeating chemical chains of simpler molecules, some examples of naturally occurring polymers include cellulose, chitin and starch.

Like all materials intended to come into contact with food and drink, it needs to be safe and it needs to be suitable for the use to which it is put. As with all such things there are safeguards in law to ensure public health is protected and wellbeing is not adversely impacted by the materials of intended use.

Basic principles

This guide is a generic document to help inform thinking when developing a food contact material; some content will not be relevant to the intended use for every biobased material choice. However, there are compliance aspects which apply to all food contact materials regardless of the material used:

- Materials must be demonstratively safe to use within the context of their application
- Materials must not have a detrimental effect to food or drink
- Customers must not be deceived as to the true nature or properties of the finished material or article.

The potential uses of biobased materials are highly varied, as are their sources and processing. Whilst it is not possible to cover all eventualities the following set of questions are intended to assist developers and manufactures identify issues from the outset that may impact their choices when developing a new biobased material and inform their planning process.

Sourcing the material

Let's start with the initial input, the source of a new material. It may be a crop or waste material, in its raw state or a residue from processing. Materials are chosen for their advantageous properties; however, the following factors (a non-exhaustive list) may significantly impact whether properties can be harnessed effectively:

Consistency and reliability

- Is the source of the raw materials stable, or is there the potential for fluctuations in availability and quality? Will there be a better time to acquire these materials than others with regards to quality and cost? Will that have to be specified in any commercial contracts, and controls put in place so that quality is optimised?
- Should there be variability, or desirable changes in substances used, what provisions are made to ensure this information is communicated to those within the value chain, and how is the original and new material to be differentiated? Can production be manufactured in defined batches?
- Has sufficient consideration been given in the design process to embedding the principles of "Good Manufacturing Practice" and what this may entail? Good Manufacturing Practice (GMP) in this context is the process of ensuring quality assurance and quality control throughout the whole production process.
- Are there viable alternative sources of the raw material, and if so, what are the cost implications - will the product remain economically viable if sources are changed?
- Biomass materials have to be carefully sourced to ensure they are not burdened with contaminants like heavy metals, pesticide residues or fuel oils. What constitutes a suitable provision to ensure this is not an issue?
- Is the item using materials from genetically modified organisms (GMOs) or the result of precision breeding techniques, mindful that there are restrictions on the use of GMOs and such like in some countries?

Sustainability

- Claims of sustainable sources - how is this measured and documented? Has an entire life-cycle assessment of value in undertaking this? How can this be done, is there a need for an external body to assist in this assessment, and what assurances are appropriate as to their standard of work? Has the whole production process been considered, or will one aspect negatively impact on overall sustainability? If the materials are imported, does the carbon output from the importation of the material negate the carbon savings of the sustainable sources?
- Would initial processing in one locality to prepare for export prove beneficial, and if so, is there the infrastructure in the origin site to undertake this processing? If claims are made as to tangible local benefits how are these verified? What are the potential negative impacts of this approach, and who bears the responsibility to ensure they are minimised?
- Has the starting substance a number of potential sources, such as chitin from either crustacean shells or fungi? If so, are production lines to be integrated or separate? Are

there local alternatives to cut down freight miles?

Economics

- Whilst at the moment biobased material use does not impact on the availability of food products, has this the potential to do so in the future if the scale is increased and land use changes away from food production?
- Are there potential synergies with non-food uses, or are the materials too specialised for exploitation in other economic areas?
- Are there a number of potential uses for the starting materials, and could the price of these be a limiting factor, subject to trading fluctuations due to other uses (e.g. bioethanol for plastics/as fuel)?
- If starting substances are classified as waste, there may be tax incentives for producers to divert it for commercial exploitation rather than disposal. Will investigating potential incentives identify new revenue streams and influence material choices, will this need further consideration to make a material viable?
- Conversely, if incentives for utilising raw materials are a factor in the material choice, are these incentives expected to change? If yes, do projections for the economic viability of production take future cost increases into account?
  What of the carbon dioxide (CO2) generation issue, will production be more or less favourable with respect to greenhouse gasses than alternatives, and are there tax implications as a result?
- Will disposal by composting, for example, have CO2 implications that need to be factored in?
- Are any of the chemicals used described as alcohols (particularly ethanol) which can have cultural implications for some in society, and thus any reference to alcohol use needs careful consideration to be done in an informative and sensitive way?

Processing the material

Source materials will most likely need processing before products are introduced to the market. The following issues will likely need to be considered no matter how great or small the effort required to process the materials:

- Are any harmful or detrimental waste products generated in production, and if so, how are they dealt with? Are alternatives better in this respect?
- Will the material present new hazards in working that are not recognised with traditional materials handling, will Hazard Analysis and Critical Control Point (HACCP) principles cope with potential unknowns?
- Can swarf/shavings/filings be hazardous? Could minor changes to machining processes lead to unforeseen issues (such as the tolerances of milling and sanding) and/or generate airborne particles with unexpectedly different properties, for example, which may stay airborne longer or have electrostatic properties that make them behave differently? Will any existing Health & Safety provision for workers prove adequate for such hazards?
- Will the cost of changing/upgrading personal protection equipment/fire safety/dust control and machinery safety, together with staff retraining, be a factor in the viability of a new approach? Are there insurance implications to be considered?
- Colour, does the material need to be dyed to be attractive for food presentation? Will there be natural variability in colour and will this effect on-shelf display? Will colour fastness degrade over time, with exposure to high humidity, changes in acidity, or direct sunlight?
- Is there a market for biomass produced by processing the spent biobased material? Could this be an offsetting revenue stream?

Interactions of the material

However good a material is in theory, once exposed to the environment in its intended normal use the unexpected can arise. Consideration of the following issues will provide assurance that the material choices and manufacturing process are appropriate for the intended use:

- Mouth contact, is there the potential for an interaction with saliva? Is there a defined mouth contact area, or will all the item be potentially in contact in expected normal use?
- How will the material interact with food? Are fatty or acidic foods a particular concern? Are there potential enzymic actions to be considered?
- Could the food/biobased material interaction lead to organoleptic changes (taste, aroma) that may be detrimental, for example by the absorption of particular flavouring compounds?
- Is there a time limit to the structural integrity of the material, will it degrade during its expected shelf life? What is the best way of conveying this information to the end user?
- Will the biobased material form a hospitable environment for microbial growth that may impact on shelf life? Is biofilm formation likely?
- How will the material react to different temperatures, for example, will it become brittle and break if subject to refrigeration? Will it shatter or soften if rapidly heated such as in a microwave oven?
  For biobased packaging, are there gas containment issues? i.e., some preservative gasses may leak or permeate the material – this is a potential problem with, for example, sulphur dioxide (SO2). Will the material concentrate such gasses by selective permeability? If the material is for potentially pressurised systems, such as carbonated drinks, will the material maintain its strength throughout its expected life span in all reasonable conditions of storage?

Compliance of the material

All this hard work is for nothing if the material fails to comply with applicable safety legislation. The following points are likely to be relevant for consideration, and to demonstrate the safety of the end product as a food contact material:

Hazards and problems

- What are the safety requirements for the intended use of materials? Will further investigation be required before committing to production?
- Has sufficient scientific evidence been collated to show the material would and does comply in normal and expected use?
- What measures are in place to ensure purity? Could they prove insufficient to remove potential allergens? Whilst there are recognised food allergens, could there be other allergens present in this material not traditionally associated with foods? If so, is there a viable route of exposure that could conceivably be a problem? Could, for example, heat treatment denature potential allergenic substances to assure compliance?
- Do the recognised main food allergens need to be taken into account? Are there sensitisers such as nickel or latex to consider? Is the biobased material more permeable and will thus allow potential allergens to reach food easier? Could the processing of the material improve this?
- Could the material be confused with something edible? If it can be eaten the material may be deemed food, so will it fully meet the requirements on food in its proposed use?
- If colouring agents have been used, do they meet the general food contact safety requirements? To determine safety can reference be made to food additives legislation?
- Has the material a physical property that could be detrimental if accidentally swallowed, for example by infants? Could it be friable under certain circumstances and potentially expand in the presence of saliva to form a choking hazard?

- Could the breakage or breakdown of the material cause a physical danger - sharp edges, splinters, will it explode if suddenly heated, or is it unusually flammable?

Remedies

- Testing materials to ensure compliance is often the preferred way, however this presents issues as to what is considered appropriate. Is there sufficient rationale to reference, for example, food contact plastics legislation? How will the rationale be presented in a meaningful way to enforcement authorities?
- Any testing needs to be representative of the materials in use, and thus “worst-case” scenarios are necessary to cover all eventualities. What are the worst-case scenarios for the product once on the market? How will this be determined and how will the validity of that approach be demonstrated? Who is best placed to advise on that, are there trade bodies or authorities that might have experience of similar materials? Will a literature search be sufficiently diligent to identify potential issues? What criteria will be used to select what is relevant and will a formally recognised appraisal process be available to use?
- The unexpected is to be expected, as mentioned substances can find their way into materials, or be generated during processing or through interactions with the environment. These are commonly termed ‘ Non-Intentionally Added Substances’ or ‘NIAS’ for short. Some provision has to be made to ensure these do not present a hidden danger during use. There are four general categories which cover NIAS: Detected and covered by an authorisation for food contact; Detected but not covered by an authorisation; Detected but unidentified; Not detected. Has sufficient consideration been given to this aspect to adequately address this potential issue?
- NIAS can be hidden behind a functional barrier but usually only if they are not known carcinogens, mutagens or toxic to reproduction (“CMR substances”). How are these to be identified, are they safe behind the barrier and what is the rationale for that conclusion?
- What constitutes a functional barrier in this context, and is there some independent justification that can be cited for an assurance it is appropriate?
- Are there material-specific legal requirements for food contact materials which may have relevance that are not immediately apparent (i.e. regenerated cellulose film -RCF)?
- For exports, will the item meet all local laws of the chosen market?
- Have you considered that any claims made are justified? Unless the material is meant to be eaten it cannot claim to be vegan or vegetarian. It can, however, proclaim it is animal product free for contact with vegan/vegetarian foods. There are a number of definitions as to “animal free”, so care is required to ensure any claims are generally supported, some chemicals can have fossil, animal or plant sources but be indistinguishable once processed. In this context such phrases such as “cruelty free” are meaningless. Is this aspect something to consider at the marketing stage? Once embedded at the outset, how is it to be ensured that continuity is maintained during development to the market?
- If claims are made as to the material adventitiously acting on packaged food, then a scientific assessment needs to be made and the material authorised as an “Active and Intelligent Material (AIM).” Are there claims pertaining to the material that may need this aspect to be addressed? Could it be construed that the material falls under this category and thus is there a need to clarify its status?
- What testing for mechanical security is suitable for the product, e.g. are handles secure enough for the weight of a full container? Can this be accredited in some way?
- If it is to be used in other, non-food items, will the compliance requirements conflict with each other? Or are they complimentary, such as for toys?
- Is there the potential for misrepresentation and fraud in the materials use? If it is more expensive, could it be substituted for similar cheaper materials? What identifying features preclude this?
- If the material is intended to breakdown over a given period, are there factors that could enhance that during its active life? Could undesirable chemicals or structures (like

microparticles) emerge during that breakdown that could be detrimental? Will labelling be required to avoid that? If so, does that need to be for initial reading only or indelibly added to the item?
- What are the storage conditions that will optimise shelf-life for the material over the period of intended use? Are they relevant for the intended market, or could climatic factors like temperature or humidity need to be factored in?

Presentation and packaging

Presentation and packaging are essential elements to compliance, not just marketing. The following may be relevant to the biobased material under consideration:

- User instructions, if there are detrimental conditions of potential use clear guidance is essential to avoid failure of the product. If user instructions are required, will language and other accessibility factors need to be considered for the intended market? Care should also be taken, will warnings avoid confusing iconography (for example a skull and crossed bones does not denote “Danger” in all cultures)?
- If binding agents are used, care should be taken to ensure any labelling is not misleading as to the nature of the product; “100% biodegradable” means for the whole discarded item, not just the biobased component.
- If claims are made as to the material being edible then it will have to meet all requirements with regards to food, regardless of any other considerations. If this is the case, producers are required to register as a Food Business with the local authority, what is required to do that and where is that information to be found?
- Will the product be capable of holding a sticky label, or will essential information need to go on added external packaging?
- Any adhesive labelling for promotional purposes will need to comply with the requirements and have easily removable adhesive properties to aid in disassembly for disposal, will this include provision for price labelling if not part of any external packaging?
- Any maintenance, care and repair instructions must be realistic, using techniques available to the average purchaser. Directions should be “sense checked” and refined accordingly, has suitable individuals to do this been identified and what criteria was the deciding factor in choosing them?
- Washing and care instructions, are they robust and effective? Given the nature of the material is the interaction with cleaning regimes as expected? If the material absorbs detergents and cleaning agents then consideration of alternatives needs to be made, or the structural properties of the material changed. Can it be safely washed in a dishwasher? If not, has that warning been adequately labelled?
- Would use in a microwave oven be detrimental? If so, has that warning been adequately labelled?
- If transparency is a favourable characteristic, will this deteriorate in time? If so, how can that be avoided? Specific care instructions may be required to maintain transparency, are they easy to follow and avoid expensive or hard to get cleaning agents?
- Closure integrity - if the materials are used for a lidded container, will the seal be sufficient, or will it leak fluids in normal use? Does a gasket need to be used and if so, what is its composition? Will that infringe any claims as to the materials used?

End of life considerations

The disposal or recycling of the article may lead to issues that have to be factored in during the development phase of the products development, whilst ensuring food safety is maintained. Consideration of the following factors may therefore be helpful in this regard:

- Labelling - any reference to disposal needs to be accurate, any reference to a standard will need to be verifiable, is there the right documentation for that?
- Is the packaging of the items a source of waste/pollution the item itself is stated as avoiding?
- Could waste storage encourage vermin such as rats, cockroaches or flies?
- For fabrication, are any potential adhesives/colourants/inks used equally biodegradable as the substrate, or do they have the potential to contaminate a composting system? Some current biobased materials specify compostable inks. Printing inks and print solutions are available which allow the production of packaging certified in accordance with appropriate standards. Is research necessary to identify appropriate standards for any particular materials?
- Has the breakdown of the material a propensity to produce microparticles? If so, do these have different properties to the macroscale materials? Have the risks associated with such microparticles been considered, or is that something that needs to be addressed?
- Are the biobased materials capable of being recycled, thereby preserving a measure of the energy input used in manufacture, or are they only capable of being broken down to their initial chemicals? Is there the potential for down-cycling even if recycling like-for-like is impractical?
- If recycling is an option, is it truly available in the expected areas of sale, or is that only in certain localities? Are their viable alternative options for areas lacking adequate recycling? Will the availability of the material stimulate recycling efforts for it and similar materials, and will collaboration with prospective recyclers be beneficial to meet these objectives?
- Disassembly for recycling, is it easy to remove component layers/parts for aiding recycling waste stream sorting? Can everyone do it, or will some users have particular difficulties?
- Will the material contaminate existing recycling streams?
- Is the material visible to current and potential future detection systems in municipal refuse sorting facilities (e.g. will it be visible to Near Infra-Red scanning)? Will there be the need for manual picking lines at materials recycling facilities (MRFs) to deal with the items? Is there a technical solution to this issue?
- Is energy recovery viable at end of life? Are their contamination/emission concerns with this?
- Can the item be reasonably repurposed at end of life? Will guidance be appropriate for that and how will that be communicated? Under such repurposing will all safety considerations of the existing use hold true, or will additional dangers need to be addressed? For example, packaging used as plant pots, will sharp edges result from a reworking of the structure? Are there disposal/recycling implications for such defined repurposing, could exposure to some environments lead to contamination of the waste stream?

Advice and guidance available to developers of biobased food contact materials

This guide is intended to help developers and manufacturers identify and consider aspects of regulatory compliance that might influence their material choices, in order to meet customer needs for the intended use of the end product.

For further advice and guidance on the development of such products, including specific issues on regulatory compliance, risk assessment and environmental or other manufacturing considerations, developers should consider the exploring following sources:

- Individual UK Government Departments and regulators that have lead responsibility for the issue under consideration: Gov.uk is the best place to find government services and information. Independent government regulators may also maintain independent websites providing relevant information.

- Local authorities: These have the responsibility of ensuring compliance and may have dedicated resources to assist local businesses in achieving and maintaining that compliance.
- Trade Bodies: These may represent either materials, uses or interested parties, both broad based, such as food in general, or very specific aspects such as regional associations. Even if these are unable to assist directly, they may provide a rationale why not that could lead to more appropriate bodies, such as a pertinent Government Department.
- International Bodies: As with Trade Bodies these may be able to guide developers towards other sources of relevance.
- Open Literature: A diligent search of what is known is an expectation under the legislation. Peer reviewed work is a common preference to ensure quality of the information used.
- Internal Resources: Material researchers and developers are likely to be best placed to understand their products and intended uses and are therefore best positioned to assess or commission research on material properties and manufacturing processes. Proprietary data may also be of value to others, therefore research undertaken on materials may present a wider investment opportunity.
- Feedback: The testing of prototypes and samples “in action” can uncover unthought of issues. Though care is needed to ensure subjects are not exposed to harm, practical use of the proposed item can show where development needs to focus. Guidance may be available from an appropriate body on how to undertake user testing safely.
- Ongoing Considerations: Producers should anticipate the need to be reactive to any issues that arise once the product is on the market. Legislation and public attitudes may change over time, or new concerns may arise. Embedding procedures to monitor and address issues that arise into systems before a material is brought to market, is therefore sensible.

This Guide is intended as a first step and is not exhaustive in scope. We have provided information on the considerations developers and manufacturers will need to take into account when developing biobased materials.

Further information on food contact materials from the Food Standards Agency can be found on our food contact materials regulation page.

Some materials (plastics, RCF, AIMs) have requirements on the substances that can be used when food contact is an expectation. These are regulated products; the substances have to be authorised for use.

Further information on making a regulated products application can be found on our food contact materials authorisation guidance page.

Contacting us

Further FSA contact details can be found on our Contact Us page.