FDA authorized?

Establishing a suitable food-contact legal status for bioplastics in the USA

Consumers and food industry stakeholders are increasingly interested in bringing products to market that are produced and packaged with sustainable and environmentally friendly materials. Due in part to these developments, bioplastics are in high demand for food packaging and other food-contact applications. This article summarizes the applicable requirements in the US to establish a suitable legal status for a bioplastic intended for use in food-contact applications.

First, however, a word about understanding use of the term "bioplastic" within the context of this article and under the law. The Food and Drug Administration (FDA), which regulates food-contact materials in the US, does not have a formal definition for the term. The US Environmental Protection Agency's (EPA) regulations define "biopolymer" to mean "a polymer directly produced by living or once-living cells or cellular components." [1]. The US Plastics Industry Association (PLASTICS) defines "bioplastic" to mean a plastic that is

1 made from a renewable resource such as corn or sugarcane (biobased),

2 breaks down completely via a natural process (biodegradable),

3 or both biobased and biodegradable [2]

Other definitions and understandings of the term, including those that are used by the public and in regulatory circles, vary in substance and scope [3].

While it may be difficult to identify a single, widely-adopted bioplastics definition, we can certainly identify examples. Current bioplastics used frequently in food-contact applications include polylactic acid (PLA), polybutylene succinate (PBS) and polyhydroxyalkanoates (PHA). Many bioplastics, such as PLA, are commercially manufactured through use of microbial fermentation. Other polymers, such as polyethylene terephthalate (PET), can now be produced using biobased feedstocks and also may be considered bioplastics.

How are food-contact materials regulated in the USA?

Section 201(s) of the US Federal Food, Drug and Cosmetic Act (FDCA) defines the term "food additive" to include any substance that, under its intended conditions of use, may reasonably be expected to result in it becoming a component of food. Substances intended for use in contact with food (including food packaging), and that are reasonably expected to become a component of food, are therefore food additives [4].

The legal definition for the term food additive is important because substances qualifying as food additives not already authorized for their intended use are subject to premarket review by FDA under Section 409 of the FDCA. Notably, a number of exemptions to the food additive definition exist, including exemptions for substances that are Generally Recognized as Safe (GRAS) and prior sanctioned under their intended conditions of use. Substances that are not reasonably expected to migrate to food also are not legally food additives [5]. Consequently, these substances are not required to undergo review by FDA before being placed on the market. The applicability of these exemptions must be considered on a case-by-case basis, with particular focus paid to the intended conditions of use for the substance in question.

Substances that are the subject of an effective Food Contact Notification (FCN) have undergone FDA premarket review. Further, substances that already are the subject of an applicable clearance in FDA's indirect food additive regulations at 21 C.F.R. § 170 et seq. may be used pursuant to that regulation. We discuss the indirect food additive regulations and FCN program in greater detail below.

What FDA authorizations exist for bioplastics used in food-contact applications?

Prior to adoption of the Food and Drug Administration Modernization Act (FDAMA) of 1997, companies that wanted to use a new polymer in a food-contact application either had to qualify for one of the food additive exemptions discussed above, comply with an existing indirect food additive regulation, or submit a petition to FDA. This petition process was time consuming and burdensome. The Agency would evaluate the petition and, assuming it agreed with the petitioner's request, would issue a new indirect food additive regulation or amend an existing regulation to authorize use of the polymer.

The FDAMA created a new pathway to market for food-contact materials by way of the Food Contact Notification (FCN) program. The FCN program allows a company to submit a notification to FDA and, unless the Agency objects to the notification within 120 days, the FCN becomes effective and the substance described in the notification may be legally used in food-contact applications. FDA maintains a list of currently effective FCNs on its website [6].

Although many bioplastics exist in nature and have been used commercially for some time in various ways, their widespread use in the food-contact arena is a more recent application of interest. Because FDA's indirect food additive regulations largely reflect materials that were already used in food-contact applications prior to 1997, many bioplastics currently used in food-contact applications are the subject of an effective FCN, rather than cleared in an indirect food additive regulation. For example, FDA's online inventory of effective FCNs lists FCNs for a number of different bioplastics, including PLA, PBS and PHA.

On the other hand, companies may not need to submit an FCN for a polymer with a long-standing history of use in

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food-contact applications just because that polymer is now manufactured using biobased feedstocks. For example, a manufacturer of PET produced using biobased feedstocks may be in a position to rely on 21 C.F.R. § 177.1630 ("Polyethylene phthalate polymers") if the polymer meets the compositional and other requirements of the regulation.

Importantly, a clearance in FDA's indirect food additive regulations may be relied upon by anyone, but FCNs are proprietary and only are effective for the listed manufacturer of the Food Contact Substance (FCS) and its downstream customers. The proprietary nature of an FCN renders it a particularly valuable asset for the manufacturer. FCNs also impart value because some companies in the food and food-contact industry expect or insist that their upstream suppliers have an effective FCN for a new bioplastic, even in cases where an FCN might not technically be required. And, for companies that may want to market their bioplastics in other jurisdictions, a preexisting FCN may be helpful to reference when a foreign regulatory authority conducts its own evaluation.

What information does one need to provide FDA in an FCN?

Unless the proposed use of a new bioplastic qualifies for one of the exemptions to the food additive definition, or an existing indirect food additive regulation applies, a company will likely need to submit an FCN to FDA. In addition to general administrative information such as the name and address of the Notifier and its Agent, an FCN must typically include:

- information to identify and characterize the bioplastic;
- information on the manufacturing process;
- the concentrations of all major impurities;
- the molecular weight profile of the bioplastic;
- physical/chemical specifications;
- technical effect information;
- a complete description of the intended use of the bioplastic, including the use level, target applications, and times and temperatures of contact with food;
- the amount of the bioplastic and its constituents in food and entering the diet; [7]
- safety information for the bioplastic and its impurities; and
- an environmental assessment.

A number of critical questions often need to be answered in the course of an FCN submission for a bioplastic. For example, one must identify any relevant limitations of condition of use. Some bioplastics may not be capable of withstanding use in contact with certain types of food or at higher temperatures. If migration testing is conducted, food simulant selection can be a challenging and important decision, as some widely used solvents may not be appropriate for use with bioplastics given their unique characteristics.

Care also must be taken to establish the safety of the proposed food-contact use of the bioplastic. FDA assesses the safety of food-contact materials using a sliding scale of data requirements; as the concentration in the diet to a substance increases, so do the toxicity data submission requirements. In some cases, a Notifier may rely on toxicity data in the public domain, or even data previously submitted to FDA, but it also may be necessary to produce new data if the bioplastic or its impurities present novel safety questions or if the intended use results in high potential levels of exposure. That said, some bioplastics are largely comprised of substances that are present in nature and that may already be present in the diet, so some submissions do not give rise to any safety questions from FDA.

Steptoe and Johnson LLP is well positioned to assist companies in bringing new bioplastics and other related food-contact materials to market. Please contact the author with any questions.

Comments and References:

[1] 40 C.F.R. § 723.250(b).

[2] Bioplastics, Plastics Industry Association, available at https://www.plasticsindustry.org/supply-chain/recycling-sustainability/bioplastics.

[3] Affiliated terms, such as the term "natural polymer," also may be used coextensively with the term "bioplastic," even though these terms have different meanings and regulatory definitions. For example, the European Chemical Agency considers natural polymers to be "polymers which are the result of a polymerization process that has taken place in nature, independently of the extraction process with which they have been extracted." See Guidance for Monomers and Polymers, Guidance for the Implementation of REACH, European Chemicals Agency (Version 2.0), April 2012, available at https://echa.europa.eu/documents/10162/23036412/polymers_en.pdf/9a74545f-05be-4e10-8555-4d7cf051bbed.

[4] Section 409(h) of the FDCA uses the term "food-contact substance" to refer to substances that are "intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food." Thus, the term food-contact substance includes food packaging materials that do not have an ongoing technical effect in food, and also includes other materials, such as those that might be used in food processing facilities.

[5] FDA also exempts, on a case-by-case basis, non-carcinogenic substances from regulation as food additives under its Threshold of Regulation (ToR) review program, provided the exposure is very small (1% or less) relative to an established Acceptable Daily Intake (ADI) for the substance in question, or where its concentration in the diet is below 0.5 parts per billion (ppb).

[6] Inventory of Effective Food Contact Notifications, US FDA, https://www.accessdata.fda.gov/scripts/fdcc/?set=fcn.

[7] The amount of the food-contact substance that migrates to food and, in turn, becomes part of the diet, is something that may be assessed through calculations using established FDA model parameters, migration modeling, or through migration studies using food-simulating solvents.

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