Food-contact in Europe

Establishing Food-contact Compliance for Bioplastics in the EU

Having previously discussed the legal and regulatory scheme in the US that applies to bioplastics used in food-contact applications [1], we turn now to the scheme in place in the EU. Although the two schemes share some similarities, there are important differences that warrant a separate discussion of the EU system. Therefore, this article summarizes the applicable requirements in the EU to establish a suitable legal status for a bioplastic intended for use in food-contact applications [2].

The European Food Safety Authority (EFSA) is responsible for regulating food-contact materials in the EU. The so-called Framework Regulation sets forth the general requirements that apply to all food-contact materials [3]. Namely, the Framework Regulation requires that food-contact materials be produced in compliance with Good Manufacturing Practices (GMPs) such that they do not: (1) endanger human health, (2) bring about an unacceptable change in the composition of the food, and (3) bring about a deterioration in the organoleptic characteristics of the food. Importantly, Article 5 of the Framework Regulation also provides authority for the EU to enact additional measures for specific categories of food-contact materials (e.g., plastic, paper, ceramic, etc.). While legislation has not been adopted for many categories of food-contact materials, the regulation of plastic food-contact materials is harmonized at the EU level via the Plastics Regulation [4].

How are Bioplastics Regulated Under the Plastics Regulation?

The Plastics Regulation applies to materials and articles that are placed on the EU market and that are made exclusively of plastic, including plastic multilayer materials and plastic layers in multilayered materials [5]. Thus, companies that wish to market a bioplastic for use in broad food-contact applications will need to ensure their material is compliant with the Plastics Regulation. The definitions used in the Plastics Regulation are important with respect to understanding compliance requirements.

Although the US Food and Drug Administration (FDA) has not adopted any formal definition for the term "plastic," much less "bioplastic," the Plastics Regulation defines the term "plastic" to mean a "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" [6]. The term "polymer" is defined to mean a "macromolecular substance obtained by: (a) a polymerization process such as polyaddition or polycondensation, or by any other similar process of monomers and other starting substances; or (b) chemical modification of natural or synthetic macromolecules; or (c) microbial fermentation" [7].

These broad definitions bring most bioplastics into the scope of the Plastics Regulation, including bioplastics that: (1) may contain biobased content but are not biodegredable, such as polyethylene terephthalate (PET), (2) are biodegradable but may not be biobased, such as polyvinyl alcohol (PVOH), and (3) are both biobased and biodegradable, such as polyhydroxyalkanoates (PHA). That said, there are some important distinctions that arise based on these definitions. For example, a bioplastic material based on modified starch is covered by the definition of plastic under the Plastics Regulation, but a material based on a natural macromolecule that is not chemically modified, such as non-modified starch, is not covered by the definition under the Plastics Regulation [8].

Annex I (also known as the Union List) of the Plastics Regulation sets forth a positive list of permitted substances that may be used to manufacture plastic food-contact materials. Substances that are not listed in the Union List may not be used in plastic food-contact materials in the EU. This includes all monomers and additives used in plastic food-contact applications [9]. The Union List also covers polymer production aids (PPAs), though PPAs not on the Union List may also be used, provided it can be established their use complies with applicable EU member state national legislation.

While the US FDA largely regulates food-contact polymers based on their finished composition, the Union list, generally speaking, covers the monomers used to manufacture plastic. In other words, the Union List does not include listings for polymers capable of functioning as a main structural component of final materials and articles, subject to two important exceptions that are particularly relevant for bioplastics. First, polymers that are natural macromolecules which are chemically modified to make the final plastic must be on the Union List. Second, macromolecules manufactured by microbial fermentation also must be listed [10].

Specific Migration Limits (SMLs) are used in the Plastics Regulation to ensure the safety of authorized substances [11]. The SMLs, expressed as mg/kg in food, may not be exceeded. The amount that a substance migrates to food for purposes of establishing compliance with an SML may be determined through calculations, migration modeling, or through migration studies [12]. The SML is ultimately set based on the available

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toxicity data and the toxicity of the substance in question. Overall Migration Limit (OML) testing is also required [13]. Specifically, plastic materials and articles may not migrate to food simulants in quantities exceeding 10 mg/dm^2 of food contact surface [14]. The US FDA does not use SMLs or OMLs as a tool to ensure the safety of food-contact materials [15].

What Clearances Currently Exist for Bioplastics Under the Plastics Regulation?

A number of monomers that are used in the production of bioplastics are listed in the Union List, such as lactic acid (Food Contact Material (FCM) 99) and succinic acid (FCM 247). Two PHA polymers are currently included on the Union List as macromolecules manufactured by microbial fermentation: (1) poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate) as FCM 744 and (2) Poly([R)-3-hydroxybutyrate-co-(R)-3-hydroxy-hexanoate) as FCM 1069. Although Food Contact Notifications (FCNs) in US are effective only for the listed manufacturer and its downstream customers, clearances on the Union List are generic and may be relied upon by anyone. Consequently, any company can rely on the clearances on the Union List. That said, there may be practical difficulties in doing so due for macromolecules manufactured by microbial fermentation (e.g., replicating the composition of the authorized polymer, complying with the relevant specifications, etc.). In addition, companies manufacturing materials that have been used for many years in food-contact applications but are now made using biobased feedstocks can generally rely on existing clearances in the Plastics Regulation, provided the applicable SML and other requirements are met.

Companies that manufacture bioplastics using new: (1) monomers, (2) macromolecules which are chemically modified to make the final plastic, or (3) macromolecules manufactured by microbial fermentation that are not currently listed on the Union List will need to submit a petition to EFSA. This petition process is used to establish a new clearance on the Union List.

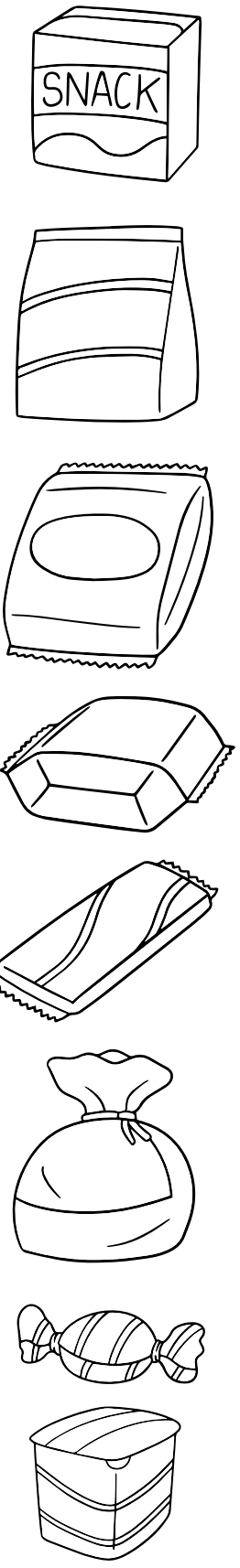
What Information Does One Need to Provide EFSA to Obtain a Clearance on the Union List?

The information submission requirements for a petition to EFSA are explained in detail in relevant guidance [16]. Aside from general administrative information such as the name and address of the petitioner, a petition must 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 migrating to food; and
- safety information for the bioplastic and its impurities.

Many of these requirements are similar or the same compared to the information that must be submitted to FDA, though there are important differences. For example, an environmental assessment is not required in a petition to EFSA, though such assessments are often needed in an FCN submission to FDA. In addition, the methods used to determine the amount of the bioplastic and its constituents in food are different in the EU compared to the US [17]. Like FDA, EFSA assesses the safety of food-contact materials using a sliding scale of data requirements. However, in the EU, the toxicity data submission requirements increase as the level of migration of the substance to food (as opposed to the concentration in the diet) increases. EFSA also applies different toxicity data tiers and has adopted slightly different toxicity data requirements. These differences result in additional toxicity tests being needed for EU purposes in many instances.

Importantly, EFSA also requires that petitioners specifically address the safety of any non-intentionally added substances (NIAS) that may be present in food-contact materials (e.g., impurities, decomposition products, residual reaction intermediates, etc.). In the case of



bioplastics, and particularly bioplastics that may be random polymers and/or polymers that are manufactured via microbial fermentation, this may result in the need for some additional screening work to identify potential NIAS and assess their safety.

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. ■

www.steptoe.com/en/lawyers/joseph-dages.html

References:

[1] Dages, J.: FDA Authorized? Establishing a Suitable Food-contact Legal Status for Bioplastics in the US, bioplastics MAGAZINE, Vo. 15, Issue 05/20.

[2] For a discussion of regulatory interpretations of the term "bioplastic," please see the aforementioned article in Edition 05/20 of bioplastics MAGAZINE.

[3] See Commission Regulation (EC) No. 1935/2004.

[4] See Regulation (EU) No 10/2011.

[5] See Regulation (EU) No 10/2011, Article 2. The Plastics Regulation also applies to other discrete categories of products that are comprised of plastic, as articulated in Article 2.

[6] See Regulation (EU) No 10/2011, Article 3(2).

[7] Id. at 3(3).

[8] See Union Guidelines on Regulation (EU) No 10/2011 on Plastic Materials and Articles Intended to Come into Contact with Food, available at https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_plastic-guidance_201110_en.pdf.

[9] Certain substances used in plastic food-contact materials are not required to be the subject of a listing on the Plastics Regulation, such as aids to polymerization, as the term is defined in Article 3(10). Substances that are not Carcinogens/Mutagens/toxic to Reproduction (CMRs) or nanomaterials, and that are used behind a "functional barrier" in a multilayer article such that they do not migrate to food at levels exceeding 10 parts per billion (ppb) also can be used in the EU in plastic food-contact applications absent an explicit clearance on the Plastics Regulation.

[10] See Union Guidelines on Regulation (EU) No 10/2011 on Plastic Materials and Articles Intended to Come into Contact with Food.

[11] See Regulation (EU) No 10/2011, Article 11.

[12] If migration studies are needed, the study must be designed by considering the time and temperature conditions of use for the substance in question, as well as the types of food that may be used in contact with the substance.

[13] See Regulation (EU) No 10/2011, Article 12.

[14] Plastic materials and articles intended to be brought into contact with food intended for infants and young children may not migrate to food in quantities exceeding 60 mg/kg. Id.

[15] Rather, the safe use of food-contact materials in the US is typically ensured by placing other kinds of limitations on the clearance for a material. For example, the clearance language for an effective Food Contact Notification (FCN) might provide the authorized substance may only be used in contact with certain food types or at certain use levels. These limitations are designed to ensure the amount of the substance that migrates to food and, in turn, enters the diet, does not exceed a level that might give rise to a safety concern.

[16] See Note for Guidance for the Preparation of an Application for the Safety Assessment of a Substance to be Used in Plastic Food Contact Materials, available at https://www.efsa.europa.eu/en/efsajournal/pub/rn-21.

[17] In this regard, we note that some of the food simulating solvents recommended in the Plastics Regulation for use in migration testing are different when compared to those recommended by FDA. The recommended time and temperature test conditions in the Plastics Regulation also differ when compared to those recommended by FDA.