FDA compliance for food contact material

Export to the US: an opportunity, more than a challenge. In recent years European exports to the United States have increased significantly and become strategically important to companies. However, the introduction of products into the US market must comply with strict regulations. Materials intended for food contact are regulated by the Food and Drug Administration (FDA) which defines them as Indirect Food Additives.

How to get FDA approval?

Legislative framework
Food contact material is regulated by the US Code of Federal Regulations (CFR), which lists the indirect additives, including adhesives, coatings, paper and paperboard, polymers and adjuvants to the production process (Title 21, Part 170). Moreover, the Code defines permitted additives and limits, and provides a list of recommended tests.

Request for approval
The request for approval of food contact material goes through a compliance process – i.e. Food Contact Notification (FCN) or Food Additive Petition (FAP). The process starts with the quantification of the substances migrating from packaging into food. In this respect, Mérieux NutriSciences is a competent, reliable partner.

How will Mérieux NutriSciences assist your company?

We carry out compliance analyses on single materials and/or polymers, according to the CFR and the “Guidance for Industry - Preparation of premarket submissions for food contact substances: chemistry recommendations”.

- Assessment of packaging documentation
- Preparation of analytical protocols to check compliance with the US market
- Extractable analysis
- Innovative screening tests according to customized analytical protocols (volatile, semi-volatile, non-volatile substances and quantification of the residue content)
- Check of requirements for adhesives in multilayer materials (art. 175.105 Adhesives – Title 21, CFR)
- SEM analysis to examine any defects in packaging edges