

FDA & USDA CONFORMITY

How many times have you heard people talk about FDA or USDA approval of coatings, varnishes, or adhesives? Quite a few times I imagine, but the fact is neither gives approvals.

In the U.S.A., we have the Code of Federal Regulations (CFR). Within these there is Title 21 which refers to Food and Drug Administration (FDA) regulations. Under these regulations the FDA allows or permits the safe use of substances as per defined listings of specifications.

The listings under various parts of the CFR, Title 21 provide information which allows suppliers to assess and make a conformity statement.

The regulations are concerned with substances that will be in direct contact with food or those that may have indirect contact with food such that they need to be considered as indirect food additives.

The concern is for the potential of any substance to become a harmful food additive. Food additive in this definition becomes any substance in its intended use that may reasonably be expected to result in becoming a part of food or affect the characteristics of food, either directly or indirectly. Any material used in the production of food packaging must be considered for its potential to become an indirect food additive.

A substance, such as a cured packaging coating, which becomes an inside package surface that has direct food contact must be considered as an indirect food additive. Contrasted to this would be a direct food additive such as an edible substance added to food like a colorant or a preservative.

Regulations concerning coatings are:

- 21 CFR 175.105
- 21 CFR 175.300
- 21 CFR 175.320
- 21 CFR 176.170
- 21 CFR 176.180

Part 175 of CFR, Title 21 deals with indirect food additives related to adhesives and components of coatings. Section 105 deals with adhesives. Section 300 refers to resinous and polymeric coatings while section 320 refers to these types of coatings for use on polyolefin films.

Part 176 discusses indirect food additives related to paper and paperboard components. Section 170 refers to components of paper and paperboard making direct contact with aqueous and fatty foods. Section 180 refers to components of paper and paperboard making direct contact with dry foods.

Each listing provides detailed information that defines suitability or conformity. This material is divided into five groupings which are:

1. a definition of allowed applications for a cured coating.
2. a listing of the raw materials that can be used in a formulation.
3. a definition of food type.
4. the extraction test permitted.
5. the maximum extractables and the analytical methods allowed.

The list of raw materials that can be used to formulate a coating to provide conformance is known as the GRAS list, which is short for, Generally Recognized As Safe. The GRAS list for the CFR sections that we're concerned with related to packaging coatings lists raw materials considered safe for use with foods. This is a historical list of materials that were in common use with foods before Jan 1, 1958, all of which were thought to be safe. The law allows for additions to the GRAS list with the support of data submissions required to prove safety.

When a coating is formulated using raw materials that appear on the appropriate GRAS list or the ingredients that form the dry coating film are listed, then the coating may be cited by the supplier as conforming to a specific CFR. For example, CORK-KOTE 4130A offers FDA compliance with 175.105 allowing it's use on the outside of a package where there is not direct food contact, or CORK-KOTE 71-93-12 which offers FDA compliance with 176.170 and 176.180 allowing it's use both in direct contact with aqueous and fatty as well as dry foods.

The USDA also follows these guidelines for the packaging of fish, meat, poultry and dairy products. When substances like coatings, varnishes, inks and adhesives are formulated using raw materials that are not on the appropriate GRAS list, then use on food packaging may be considered related to the so called "functional barrier" concept.

OVER

This means that if the substance in question is protectively separated from food by a substrate, overwrap, or in some cases by a barrier overprint varnish or coating whose raw materials are on the GRAS list, then the substance may be used. Coatings and varnishes as acceptable functional barriers are dependent upon being pin-hole free, continuous and sufficiently thick to prevent migration through, all very difficult to guarantee.

In spite of the “functional barrier” concept the end user of packaging still has the responsibility for conducting extraction testing to ascertain that nothing objectional will migrate into or onto any packaged food.

Concluding, remember the FDA and the USDA do not give approvals. It is the formulator of coatings, varnishes, adhesives and inks that can cite conformance with the proper sections of the U.S.A. Code of Regulations and Title 21, Food and Drug Administration regulations.

However, both packaging suppliers and food companies must thoroughly understand each food contact packaging application in order to correctly state FDA compliance since FDA regulations are application specific.

LOOK TO CORK!..... for your coating and varnish needs, for both **aqueous** & **UV/EB** coatings/ and varnishes.