

## Printing Inks for Food Packaging – FAQ

The following FAQ's have been prepared to clarify the Food and Drug Administration (FDA) regulatory requirements related to printing inks used on food packaging materials. The FDA regulations are listed in Title 21 of the Code of Federal Regulations (CFR).

### DEFINITIONS

1. **Q: What is a direct or indirect food additive?**

A: Direct food additives are not naturally a part of the food but are approved by the FDA for direct addition to food in order to perform a specific function. There must be an intent to affect some characteristic of the food by the addition of the food additive. Typical direct food additives are stabilizers, preservatives, flavoring agents and the many chemicals generally found on food ingredient labels. Many food additives approved for direct addition to food have purity requirements and/or limitations relative to quantity and/or specific foods to which they may be added. These restrictions, if any, are specifically stated in the FDA guidelines.

Indirect food additives are not approved for direct addition to food. There is no intent that they have a functional effect on the food, however, they may reasonably be expected to migrate into, that is, become a component of the food. Components of printing inks or coatings that are used on food packaging materials may be potential indirect food additives. Some indirect food additives have limitations to allowable quantity, conversion on specific substrates (paper, film, etc.), specific foods and food processing conditions. These limitations, if any, are specifically stated in the guidelines.

2. **Q: What is a (direct) food contact ink?**

A: Direct food contact ink refers to a printing ink or coating that is intended by design to be the printed surface that is in intimate contact with a food product. By virtue of this intimate contact, components of the printing ink or coating have the potential to migrate into the food and, therefore, must be in compliance with the indirect food additive guidelines at 21CFR Parts 170-189.

3. **Q: What is an indirect food contact ink?**

A: Indirect food contact is a term inappropriately used in the printing industry to describe a printing ink or coating whose components are not intended by design to be the surface in intimate contact with a food product,

but which *might* come in contact with a food product. This type of contact does not in and of itself require compliance with the indirect food additive guidelines.

4. **Q: What are GRAS substances?**

A: Generally Recognized As Safe (GRAS) are food additives that have a long history of safety. FDA designates GRAS substances that are considered safe for their intended use. There are three distinct GRAS listings incorporated in 21CFR.

5. **Q: What is incidental contact?**

A: According to the FDA regulations Incidental contact refers to chemicals used on equipment or machinery used for producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food. By virtue of these processes, the chemicals may contact food although any food contact is unintended. There are a few parts at 21CFR 178 which list chemicals approved by the FDA for incidental contact.

6. **Q: What is a GMP?**

A: Good Manufacturing Practices (GMP) or current Good Manufacturing Practices (cGMP) are FDA regulations, which have the force of law, that require that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood to take proactive steps to ensure that their products are safe, pure, and effective.

**GENERAL**

7. **Q: Do printing inks used on food packaging need to comply with the FDA requirements?**

A: Components of inks used for food packaging that may become an indirect food additive because the packaging construction is such that the printed surfaces are in direct contact with food must comply with certain FDA requirements. Additionally, ink components that migrate (usually unintentionally) into the food product from the printed surface would be regulated as an indirect food additive and must also comply with certain FDA requirements.

8. **Q: How do I know if the components from the printed surface are “migrating” into the food product?**

A: The degree to which a component of the printed surface may be reasonably expected to migrate into food is its potential to migrate. Migration can occur with either wet or dry food products. If the printed surface is in direct contact with the food product analytical testing must be used to support a claim of no migration.

9. **Q: How do I prevent the print components from migrating into the food product?**

A: Components on a printed surface can migrate from a printed substrate into both wet and dry food products. Typically, a “functional barrier” is used between the printed surface and the food product.

10. **Q: What is a “functional barrier”?**

A: The purpose of the functional barrier is to prevent transfer from the printed surface to the food product. FDA has defined a functional barrier as a resinous coating, protective film, transparent covering or the substrate separating the printed matter from the food. FDA has also indicated that the effectiveness of a material to act as a barrier will depend not only on the physical and chemical properties of the barrier material and the potential of the migrant but also on the conditions of use.

11. **Q: How can the printer insure that an effective functional barrier exists?**

A: Extraction testing using FDA protocols, conducted by an independent third party on the finished product under the conditions of use is the only certain means for insuring that an effective functional barrier exists.

12. **Q: Can you give me an example of how a non-FDA compliant ink can be used in a direct food contact application?**

A: A coupon printed with non-FDA compliant ink components can be inserted directly into a dry cereal box if:

- The coupon is enclosed in a polymeric bag; or
- An FDA-compliant overprint varnish/coating is properly applied to the printed surface that forms a functional barrier.

In either case, a functional barrier must be employed to prevent the transfer of the ink components from the printed surface.

13. **Q: How can I print a functional barrier?**

A: In a printing application the functional barrier could be a properly applied overprint varnish or coating made from FDA compliant materials.. However the printer must also employ good manufacturing practices to ensure that the coating has formed a uniform, continuous coating over the ink and the substrate so that no “pinholing” is present and/or the coating is of sufficient thickness to prevent migration of the ink components through it and is resistant to the components of the contacted food product.