

Legislation – Food Packaging – United States of America - FDA

In contrast to Europe, the United States regulates the foodstuff, rather than the food contact material. Substances in printing inks or coatings used for food packaging may become indirect food additives if they are reasonably expected to migrate into the foodstuff. If a substance does not, and is not reasonably anticipated to migrate into food, then it is out of scope and not required to be regulated. Indirect food additives may become a component of the food, but are not intended to have any functional effect, and are not approved for direct addition to food. Printing ink applied to food packaging is required to be compliant with Good Manufacturing Practices. Printing inks on the exterior of food packaging are considered to have a low potential for migration into food. However, inks applied to the food contact side of food packaging, where the print will (foreseeably) be in physical contact with the food have a much greater potential for migration. A component in a printed or coated surface in direct contact with food is always considered to be an indirect food additive, unless it can be proven that there is no migration to the food. **Compliance** can be demonstrated by:

- Listing in the appropriate part of Chapter 21 of the Code of Federal Regulations (21CFR 170-186) – this covers direct and indirect food additives, prior sanctioned food ingredients and substances generally recognized as safe (GRAS) – subject to any restrictions or limitations therein
- Approval via the Food Contact Notification (FCN) process
- Being under the Threshold of Regulation (21CFR 170.39)

Historically the U.S. Food and Drug Administration (FDA) has not required pre-market authorisation for components of inks on the exterior of packaging. However, more recent data indicates that some intended uses of ink and ink components on the exterior of food packaging may result in their migration into food. Consequently, potential development of a US regulatory framework for ink and ink components on the exterior of food packaging is currently being evaluated by the FDA.

The U.S. Food and Drug Administration (FDA) has published a final rule detailing the criteria for concluding that the use of a substance in human or animal food is **generally recognized as safe** (GRAS). This GRAS rule may also be applied to certain substances present in food contact materials that may become indirect additives in food. The final rule specifies the types of scientific evidence that can be used to demonstrate safety and details the voluntary GRAS notification procedure. Although GRAS substances do not require pre-market approval, the FDA encourages companies to follow the notification procedure and inform the agency of GRAS conclusions to aid the FDA's food safety monitoring efforts.

The FDA has issued a **final rule** which includes food contact substances in foreign supplier verification programmes (FSVP) for importers of food for humans and animals. The FSVP regulation requires importers to verify the safety of the food that they import into the USA, under the same requirements as domestic producers, based on hazard analysis and risk-based preventative controls and standards of the Federal Food, Drug and Cosmetic Act. In the final rule the FDA did not exclude food contact substances, which would include indirect food additives from the components of materials in the food packaging. Therefore, any chemical in the food packaging which migrated to the food, would be regulated as a food contact substance, including those chemicals from non-direct food contact packaging inks and coatings.

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This information contained herein is based on data believed to be up-to-date and correct at the time writing. It is provided to our customers in order that they are able to comply with all applicable health and safety laws, regulations, and orders. In particular, customers are under an obligation to carry out a risk assessment under relevant Good Manufacturing Practices (GMP) in line with legislation and as a result take adequate measures to protect consumers.