INK, HEART & SOUL

SIEGWERK

Customer Information

Siegwerk Printing Inks for Food Packaging

Regulations in USA and Canada

Siegwerk regularly receives inquiries about the suitability of its printing inks for food applications. The purpose of this statement letter is to clarify many of the issues that arise, including those concerning the regulatory authorities in both Canada and the United States.

INKS FOR DIRECT FOOD CONTACT

There are two agencies in the USA and in Canada that manage the regulations affecting the use of printing inks for food packaging applications.

United States:
The Food and Drug Administration (FDA) is the authority in the United States that regulates food additives. Direct food additives are approved by the FDA for a direct addition to food in order to perform a specific function whereas indirect food additives are not approved for this. The FDA does not approve specific products, such as printing inks, for direct or indirect food contact. Their sole concern is with materials that may become, either by default or design, food additives. Printing inks or coatings which are used for direct food contact applications are potential indirect food additives and must therefore comply with the requirements of the indirect food additive guidelines. These are regulated in the Code of Federal Regulations (CFR) under Title 21, Part 170-190. As only a few colorants are listed in these guidelines, only very few printing inks are acceptable as indirect food additives and are suitable for direct food contact applications.

The United States Department of Agriculture (USDA) regulates the packaging materials used primarily for meat and poultry products. It is important to note that the USDA stresses that the responsibility for providing guarantees to food packers rests with the converters who provide the finished packaging material. If direct contact between the foodstuff and the printing ink is intended, then the USDA follows the same food additive regulations as the FDA.

Canada:
Canada's Health Protection Branch sets standards and evaluates food packaging with respect to the standards. Although it is not mandatory, the Health Protection Branch recommends that for any packaging material, including the printed layer that may have direct contact with food, a letter of non-objection should be obtained from Health Canada. This letter can only be given after properly designed extraction tests have been made

using materials that represent the foodstuff which is to be packed. If the extraction tests are not done, Health Canada will commonly use a worst-case scenario in which the majority of the ink components are assumed to migrate into the food in significant quantities. Toxicological data will then be requested.

The Canadian Food Inspection Agency (CFIA) handles food-packaging issues. The CFIA is responsible for the inspection of food facilities and enforcement of the Canadian Food and Drug Regulations.

INKS FOR NON-DIRECT FOOD CONTACT

United States:

The Food and Drug Administration (FDA) does not have specific guidelines for applications that have printing inks or coatings on the non-food contact surface of food packaging. The FDA is solely concerned that a barrier of migration is sufficiently in place and that the ink or coating materials will not become food additives. The functional barrier as defined by the FDA could be a protective film, a resinous coating or a transparent covering which separates the printed matter from the food. The converter is responsible to ensure that the barrier is sufficient to prohibit migration. In this case there is no legal requirement to comply with the demands of the corresponding indirect food additive sections of 21 CFR.

However, if a substance becomes an indirect food additive by migration or set-off, then the indirect food additive guidelines (21 CFR 170-190) must be complied with and migration calculation or testing might be needed to support a claim of no migration. The FDA has determined that up to 50 ppb limits in migration could be seen as *"negligible"*, but this is dependent on the dietary exposure of the material along with known risks of the migrating material/substance (*"Ramsey Proposal").*

Canada:

In Canada, when no direct food contact with the ink is intended, there is no requirement for a food packager to obtain a letter of non-objection from Health Canada provided that the following conditions are met:

1. The package design should incorporate a functional barrier between the foodstuff and the ink film; and
2. The inks must be properly and completely dried or cured after printing, such that the print does not set-off or mark during the stacking or nesting of the packages prior to their being filled with food.

There are instances; however, when a food packager may wish to obtain a non-objection status from Health Canada, to be assured of the suitability of the package design. For these instances, a full disclosure of the printing ink's ingredients is required. It may take months to years from the initial application before a letter of non-objection issued, if at all. It is also important to understand, that a letter of non-objection does not absolve the packager from the liability should there be a failure in the package design leading to the contamination of the food product.

SUMMARY

Understanding the information provided above, Siegwerk's ink and coating systems are designed and considered safe for indirect food contact applications, provided that an effective functional barrier to migration exists.

If a Siegwerk ink system will be utilized in such a manner that migration can occur, Siegwerk inks would then be regulated under FDA 21 CFR parts 170-190 and would require compliance with the proper jurisdictional regulations. In these cases, please contact your Siegwerk Sales or Technical Account Manager and discuss the requirements for your application.

Additional information is available from the National Association of Printing Ink Manufactures (NAPIM) and the Canadian Printing Ink Manufactures Association (CPIMA).