Food Packaging and health

Food Packaging Regulation in US

In the U.S. the Food and Drug Administration (FDA) charged with the control of food safety, and supervises the implementation and the enforcement of the various existing regulations.

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It is important to note, that contrary to the EU, where risk assessment and risk management are clearly separated between EFSA and European Commission, in the U.S. the Food and Drug Administration (FDA) charged with the control of food safety, carries out both risk assessment and risk management. Further the regulation of food contact materials is based on exposure rather than on migration, as in the EU.

The FDA enforces the Food, Drug and Cosmetic Act from 1958, which is the basic regulation on food contact materials, as well as other relevant acts. Mostly, food contact materials (FCM) are regulated in the Code of Federal Regulations (C.F.R.) under Title 21 on food and drugs, Part 176-186 (21 C.F.R. Parts 174-186) and further fall under specific regulations depending on their use. Clearance for food contact materials is required for those that are considered additives, also referred to as indirect additives, which are those that can reasonably be expected to migrate into the food stuff. Companies determine whether migration of a substance can reasonably be expected. Food additives are regulated under the Food Additive Directive. A substance may be authorized as a food additive because it is in accordance with an applicable food additive regulation (21 CFR Part 170.3)[1]. If this is not the case it may be expressly approved by the FDA through an indirect food additive petition (21 CFR 174-178). Both of these processes require the FDA to notify the public in the Federal Registry and allow for comments. However, this process has practically ceased to be used, as it is very time consuming [2]. The most prominent process today is the Food Contact Notification (FCN) program, which was implemented in 2002. In the FCN program a submission from a notifier (f.e. a company) is reviewed by an FDA committee. The FDA is obliged to object to the supposed safety of a substance within 120 days or else issues a no objection letter, after which the company may market the substance. In the case that the FDA does not respond timely, the notifying company may market the product after the passing of the 120 days [1]. Particular to this program is that the manufacturer may withdraw the notification, in the case that the FDA is likely to have objections. Further no public review takes place before the notice promulgated as a rule in the C.F.R. Finally, other manufacturers cannot rely on the “no objection” letter, it is only valid for the notifying company [2].

Alternatively, a substance used in FCM may be cleared from authorization for various reasons.

One such exemption occurs if the substance was used before 1958. Such substances where grandfathered into the regulation and their status cannot be revoked by the FDA.

Another option is if a substance is “generally recognized as safe” (GRAS). GRAS substances may be approved by the FDA. Originally, the FDA listed GRAS substances in the C.F.R. which where expressly allowed in food (21 CFR 182). After 1973 the FDA affirmed GRAS substances in response to an affirmation petition similar to the direct and indirect food additive petition (21 CFR §184). Neither of these processes is employed today. Now the GRAS notifications program is used, which allows manufacturers to submit a notification that is approved by a “no objections” letter. Competitors may rely on such an approval, but the FDA has no deadlines and further, its decision is based on a summary rather than the original chemical or biological data.

Alternatively, a GRAS substance may be exempted not only from authorization but also from notification. This is the case if a substance was a common food ingredient used before 1958. Further, under the Threshold of Regulation rule (TOR), non-carcinogenic substances having a dietary concentration below 0.5 ppb are also exempted from the authorization process. Under this rule, a substance previously regulated as a direct food additive, and for which the use in food contact materials will not result in an exposure above 1% of the average daily intake (ADI) can also be exempted. Finally, a substance can become a GRAS substance if a published study demonstrates that it is not harmful to health under the intended conditions of use. This approach is termed manufacturer self-determined GRAS. Irrespective of whether the study was published independently or commissioned by the company, the company will not have to notify the FDA of its use. The same is true for those substances used before 1958 and those falling under the Threshold of Regulation rule.

The GRAS approach has recently come under critique, as the FDA consequently has neither information on applications of the substance nor its effective quantities of use. Further, manufacturers are not obliged to reassess their risk estimates over time [2, 3].

Regarding printing inks, colorants that are permitted for use in food are also permitted for use in the printing of packaging materials. Further, some printing inks, such as high purity furnace black for use in polymers (21 CFR §178.3297), may also be cleared in separate specific regulations[1]. Also waxes used in food contact materials are regulated in the Code of Federal Regulations, Title 21 on food and drugs, part 174 to 180. As such, paraffins (synthetic) are authorized as adhesives and coatings in §175.250 (21 CFR §175.250) with certain specifications. Petroleum waxes, synthetic petroleum wax and reinforced wax are permissible in food contact materials as adjuvants, production aids and sanitizers if they meet certain specifications (21 CFR §175.3710/3720/3850)[1].

Table 1. US Legislative Overview

General Regulations on FCM	
Food, Drug and Cosmetic Act (1958)	
Title 21, Code of Federal Regulation	
Authorization/Notification required*	**Exempted from authorization**
Direct Additive (21 C.F.R. Part 170.3)	Threshold of Regulation rule
Indirect Additive (21 C.F.R. Part 174-179)	GRAS • Common food ingredient before 1958 • Manufacturer self-determined GRAS • FDA listed GRAS • FDA approved GRAS • FDA GRAS notification
Food Contact Notification (FCN) program *(only notification required)*	Sanctioned before 1958

*Substances requiring authorization rely upon the explicit authorization by the FDA. They are evaluated by the FDA based on the original toxicological data and the evaluation is published in the Federal Registry to allow for public comments. Substances only requiring notification, may also be used if the FDA does not respond timely within a 120 days, and as such requires the explicit objection by the FDA. Further it allows for withdrawal by the notifier, if the FDA is likely to object.

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