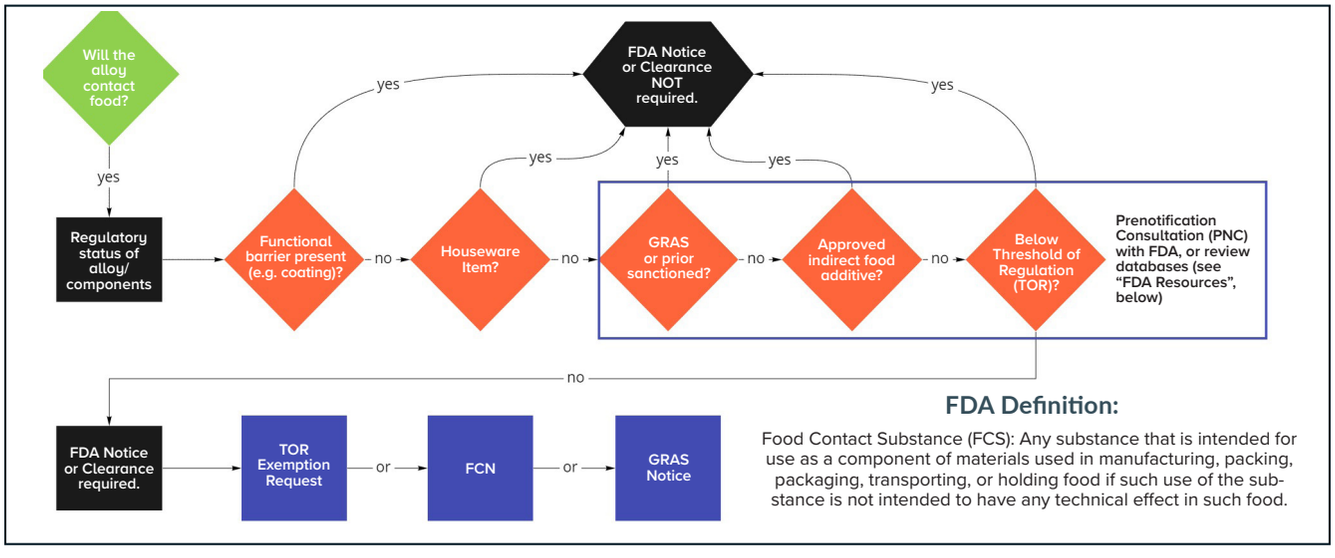
# ZINC DIE CASTING ALLOYS AND FOOD CONTACT

Requirements of the US Food and Drug Administration

## Introduction

At present, zinc die casting alloys are not specifically authorized, or prohibited, by the United States Food and Drug Administration (FDA) for contact with food.[1] Proposed uses of metals for food contact are reviewed by FDA on a case-by-case basis. Depending on the regulatory status and intended use of the alloy, there are several decision points that will dictate if FDA clearance as a food contact substance (FCS) is necessary. These decisions, along with potential options for gaining FDA clearance, are summarized in the diagram below. If clearance is needed, FDA will require information about the alloy (i.e., exact composition, corrosion and abrasion resistance, hardness based on the Rockwell scale), and assurance that there is little or no likelihood that components of the alloy would migrate to food in significant amounts.




## Is a coating applied to the die cast part?

If a die cast part is coated, compliance with food contact regulations is governed by the status of the coating. Resinous and polymeric coatings are most relevant as the FDA has approved hundreds of raw materials that can be used for this purpose. For example, some commonly used resinous and polymeric coatings include: perfluorotetraethylene (PTFE), acrylics, and epoxies. To serve as a functional barrier, coatings need to be applied as a continuous film or enamel over metal substrates.

## Is the die cast part a houseware item?

Houseware items (e.g., flatware, cooking utensils, cutlery, and electrical appliances) used by a consumer to hold, prepare, and serve food, are exempt from premarket clearance requirements from FDA. The "housewares exemption" recognizes that such products do not generally give rise to public health concern. However, it is the responsibility of the producers of housewares to ensure that their products are suitable for use with food and will not create a health hazard when used as intended. The FDA provides guidance to industry related to the "housewares exemption", and additional legal discussion on the topic is available here.

[1] Includes consideration of Title 21 Code of Federal Regulations Parts 173-178; recognition by US FDA or United States Department of Agriculture prior to September 6, 1958; generally recognized as safe (GRAS) status; Threshold of Regulation exemption (TOR, 21 CFR 170.39), or an effective Food Contact Substance Notification (FCN).

## Obtaining pre-market approval from the FDA

If the alloy is not coated with an FDA compliant material or if it is not considered a houseware item, it must comply with FDA regulations for a particular use. Regulatory status of a potential FCS can be checked by FDA through a pre-notification consultation (PNC), or by reviewing FDA databases (see "FDA Resources", below). A PNC will determine if an FCS is compliant with existing regulations, exemptions, and notifications. The consultation will however require information related to the intended use and composition of the material, physical properties (resistance to corrosion/abrasion), and potential migration to food. If the potential FCS is not covered by an existing regulation or exemption, then there are three options to consider. None of these approaches involve a submission fee, but there are supporting information requirements whose costs will be dependent upon the potential FCS, the intended use, and the amount of information available in the scientific literature.

**Table: Available options if potential FCS is not covered by an existing regulation or exemption**

| Approval Approach | Supporting Costs | Review Period | Additional Info |
|---|---|---|---|
| TOR Exemption | $ | 60-90 days | Cannot be suspected carcinogen |
| FCN | $$ | 120 days | Applies only to manufacturer identified in notice |
| GRAS Notification | $$$ | 180 days | Manufacturer makes conclusion; FDA reviews |

## Option A: Threshold of regulation (TOR) exemption

The FDA has developed guidance for industry regarding TOR exemptions. A TOR exemption offers the potential for recognizing an intended use for an alloy, regardless of manufacturer or supplier (i.e., not proprietary). Therefore, any manufacturer/supplier can market an exempted substance, as long as the identity and intended use are the same as those for which the exemption was issued. IZA has a wealth of information on the migration of zinc and possible alloy impurities.

## Option B: Food contact notification (FCN)

The FCN process is the primary means by which FDA reviews new FCSs or new uses of FCSs. An FCN is specific to a manufacturer/supplier (proprietary) and can be applied when consumer exposure exceeds the upper limit for TOR exemption (i.e., 0.5 ppb). The notifier has the burden to demonstrate a reasonable certainty of no harm from the intended use of the substance. Accordingly, specific information is needed related to the chemistry, data on migration to food items, manufacturing process, stability, impurities, intended use, estimated daily intake, toxicological information, and environmental information.

## Option C: Generally recognized as safe (GRAS)

The GRAS notification program is voluntary but encouraged if there is intention to market a food substance on the basis of the GRAS provision. Safety is determined by the characteristics of the substance and route of exposure. Any manufacturer may conclude that a substance is GRAS for an intended use and submit supporting information to FDA for review. If a "no questions" letter is issued, the use is considered GRAS, and therefore is not subject to FDA's premarket review and approval as a food additive.

### FDA Resources

Food Additive Status List

GRAS Overview, Guidance, and Regulations

Select Committee on GRAS Substances Database

GRAS Notice Inventory Database

Inventory of Effective Food Contact Substance Notifications Database

Threshold of Regulation (TOR) Exemptions Database

## + HOW CAN IZA HELP?

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ZINC | international zinc association

**Data Collection**

IZA is currently assembling relevant exposure and effects information for zinc die casting alloys that can be used for consultations and submissions with FDA.

**Cooperation**

Since intended use of an FCS is central to FDA's regulations, IZA would benefit from member feedback on the potential uses of zinc die casting alloys that could or would result in contact with food.