

# **ENVIRO TECH**

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### **FCN's (Food Contact Notification) vs. AMENDMENT:**

The first use of a product in or on food or beverages requires that one *petition* the FDA to establish an official use citation in the Code of Federal Regulations, usually in Chapter 21 (known as the *Amendment* route). The FDA will evaluate the effectiveness and the dietary and environmental safety of the additive and subsequently will approve or deny the petitioned use. The first use of peroxyacetic acid (PAA) and Hydrogen Peroxide (HP) chemistry was approved by the FDA some years ago, and the subsequent regulations 21 CFR 173.315 and 21 CFR 173.370, were established for the use of this Food Contact Substance (FCS) on fruits, vegetables, meat and poultry. In the case of 21 CFR 173.370 (meat and poultry) other components are listed in the regulation, such as octanoic acid and acetic acid, but they are GRAS ingredients by prior sanction, and are not given a ceiling tolerance nor do they have bearing on the regulation or the subsequent tolerance levels, which was established for approval of the 3 primary components that heretofore had no regulatory approval for this intended use ...namely peroxyacetic acid, hydrogen peroxide, and HEDP. There are no specific exclusions or conditions of use listed for the FCS, so it may be safely used in most if not all methods and conditions of use, notwithstanding the tolerance ceiling listed in the regulations for either use.

If a company has a 'similar' product to those listed in the regulations, that they wish to market or introduce into the marketplace, their product must comply (at the maximum or recommended feed rate) with the ceiling tolerances established in 21 CFR 173.370 or 173.315. If the FCS does not comply, they have a choice of (a) petitioning the FDA to *amend* the CFR's, or (b) submitting a Food Contact Notification (FCN). The FCN is a very precise and complicated regulatory avenue that allows a manufacturer or distributor to obtain specific FCS approval by the FDA when their specific product's chemistry is not in compliance with the existing regulations. Often the FCN is the *preferred* route, because the FCN is specific to *that* manufacturer, and competitors cannot cite "same-as" claims and (instantly) market their version of the formulation. It is an anticompetitive route, to be sure. The FDA "Opinion" letter policy (about a substance's safe or acceptable use) was discontinued in the 1990's and replaced with the more formalized Notification procedure.

On the other hand, if a company has a formulation that already complies in all respects to the appropriate CFR citation they *cannot* use any FDA approval routes, because the FDA will *not* evaluate a FCS if the formulation chemistry is already *in compliance* with the appropriate regulation. Reminder: the FDA approves *chemistry only*, not products, companies or brand names.

Using an example:

FMC Corporation submitted a FCN application to the FDA, which was approved on May 27, 2003, and assigned FCN #323, which eventually became the name of their meat and poultry product “323”. The reasoning FMC may have used the Food Contact Notification route is simple: (1) for marketing reasons they chose to use the Notification route of approval vs. the Amendment route because it is manufacturer (and distributor) specific as discussed earlier, and (2) the FCS components PAA, HP, and HEDP *all* exceeded the FDA limits established in 21 CFR 173.370. For example: Peroxyacetic acid 220 ppm max. CFR vs. 230 (FMC); Hydrogen Peroxide 75-110 ppm max. CFR vs. 165 (FMC); and HEDP 13 ppm max. CFR vs. 14 (FMC).

Therefore:

- (1) An FDA Notification letter is only valid for a manufacturer and their approved distributor for a given specific use, if their product is not otherwise in compliance with a FDA CFR regulation.
- (2) If your specific use requires a certification of compliance of an FDA regulation, then you should obtain either a Letter of Certification from your supplier/distributor for that use, or require a Letter of Notification issued by the FDA. Samples of FDA Notifications can be visited at:  
[www.cfsan.fda.gov/~dms/opa-fcn.html](http://www.cfsan.fda.gov/~dms/opa-fcn.html)