Spoke

Solving Solubility with Science

Food Additive Petitions (FAP)

In this Brief we share general background information on food additives and Food Additive Petitions (FAP)

Technical Brief

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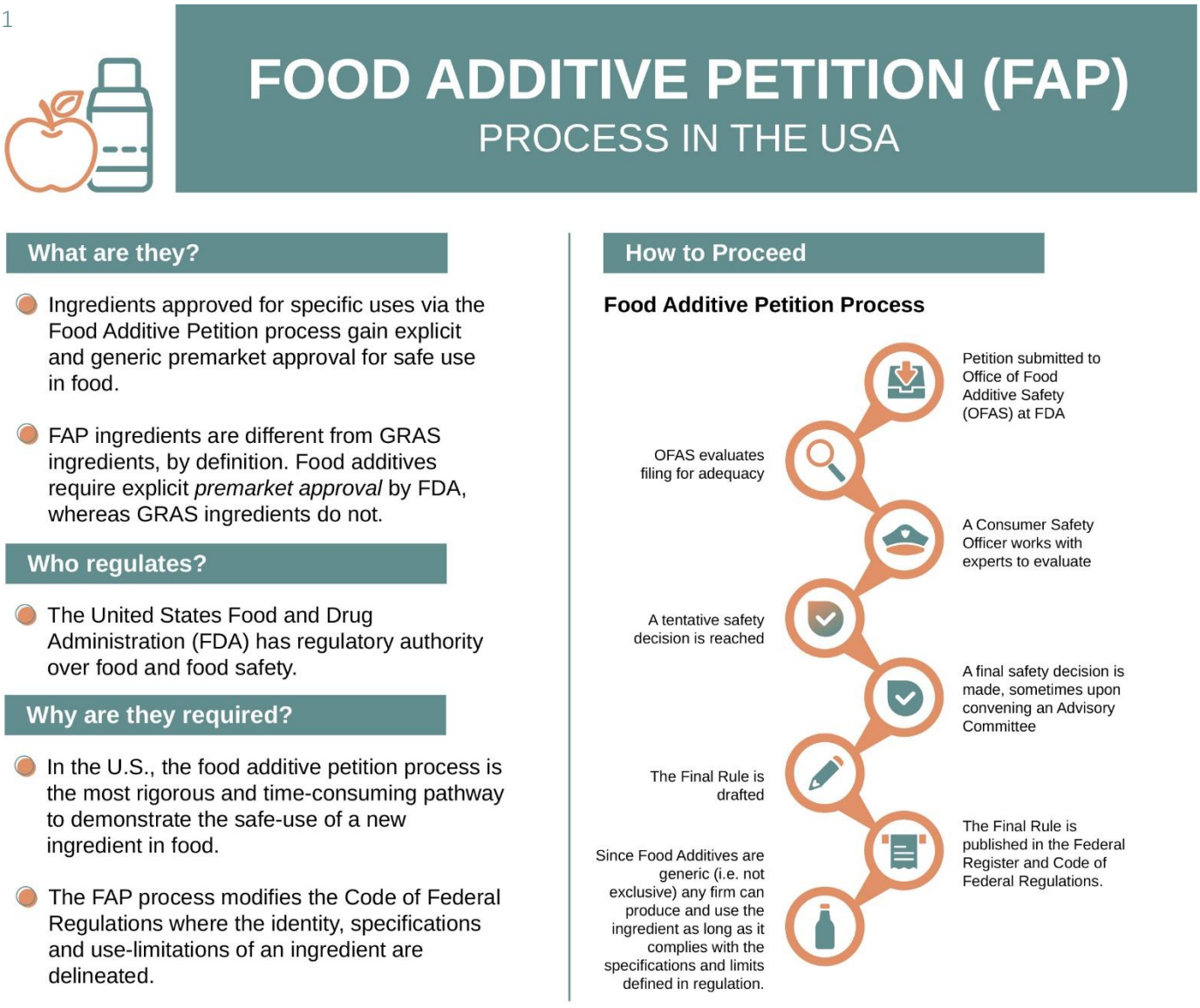
Introduction to Food Additives

Although the phrase "food additive" may appear to be self-explanatory, the legal definition in the United States is purposefully broad to exert a mechanism of premarket approval over anything that *could* become a part of food. This definition includes any substance that may be incorporated into food due to processing, packaging, storage or transportation methods. The overarching purpose is to help protect the health of consumers before a substance is sold for consumption. This pre-approval process involves a Food Additive Petition (FAP) to the U.S. Food and Drug Administration (FDA) as depicted in Figure 1.

Fig. 1



This Technical Brief describes what a Food Additive Petition is and briefly touches upon how FAPs are related to two other pathways that can be used to bring an ingredient to market, Generally Recognized As Safe (GRAS) designations and New Dietary Ingredient Notifications (NDIN). The GRAS and NDI pathways are similar to FAPs in that their primary purpose is to evaluate and validate the safe use of an ingredient.

What is a Food Additive?

The definition of "food additive" was established by the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act (FD&C Act).

> *Food additive* - "any substance the intended use of which results or may reasonably be expected to result—directly or indirectly—in it becoming a component or otherwise affecting the characteristics of any food."

The Food Additives Amendment also established certain exemptions from the definition and the regulation process, including the GRAS provision. The GRAS provision states that a substance is not considered a food additive, for purposes of premarket approval by FDA, if "the use of the substance is generally recognized as safe." In practice, this resulted in two classes of exempted ingredients for food. This does not include New Dietary Ingredients and NDINs, which only pertain to dietary supplements—a subcategory of food.

Group 1 – Prior Sanctioned Substances

These are substances that FDA or USDA had determined were safe for use in food prior to the 1958 Amendment. An example is sodium nitrite used to preserve deli meats.

Group 2 – GRAS Ingredients

These are substances generally recognized by experts as safe, based on their extensive history of use in food before 1958 or based on published scientific evidence, such as is the basis for GRAS notifications. Examples include spices, vitamins and some probiotic organisms.

What is a Food Additive Petition (FAP)?

A Food Additive Petition is meant to include the necessary information and data for FDA to make a determination of ***reasonable certainty of no harm***. In evaluating the safety of a substance and whether it should be approved, FDA considers the following four areas:

1) Composition and properties of the substance

2) Amount that would typically be consumed

3) Immediate and long-term health effects

4) Various safety factors

To enable FDA's evaluation of these four areas, FAPs are required to include the following sections as described in the Food Additive Petitions section of the Code of Federal Regulations.[1] FDA has produced guidance documents for many of the individual sections outlined below for further detail.

Name and Identifying Info

This includes the chemical identity and composition of the food additive, including physical, chemical, and biological properties of the proposed additive. FDA also needs to understand how the additive is manufactured to assess whether manufacturing byproducts, leftover reagents or processing aids could be cause for concern.

Amount to be Used

In addition to the expected quantity and exposure to a consumer, FDA requires a description of all of the proposed technical functions of the substance together with all directions, recommendations, and suggestions regarding the proposed use.

Data Supporting Technical Effects

This section should justify all of the proposed functions stated in the previous section and if the petition pertains to an indirect additive, the rationale for concluding how and to what extent the substance or substances will migrate into food.

Analytical Method Data

Practicable methods to determine the amount of the food additive in the raw, processed, and/or finished food and of any substance formed in or on such food because of its use.

[1] 21 CFR 171.1

Safety Data

Full reports of all safety and toxicological evaluations conducted including detailed data on ALL animal and *in vitro* experiments are expected to be included. A petitioner should not omit experiments that skew the data in an undesired direction.

Tolerances (not always needed)

If tolerances (on acceptable levels) are required to ensure the safe use of the additive, they should be included.

Environmental Assessment

Submit an Environmental Assessment (EA) as described in 21 CFR 25.40 or submit a claim for categorical exclusion as described in 21 CFR 25.30 and 25.32.

Why are FAP important?

The FAP pathway allows for the introduction of articles into the food supply that have neither been used traditionally in food nor are known to be safe to qualified experts based upon published data. In striking this balance of allowing new ingredients into the food supply, a rather high bar of *premarket approval* has been established to make best efforts at achieving a *reasonable certainty of no harm*.

Since all ingredients permitted for use in food can also be used in dietary supplements, if for an accepted technical function, the FAP pathway is one route for sanctioning ingredients for use in dietary supplements that do not fall under the definition of a dietary ingredient. GRAS notifications can also be utilized to achieve a similar objective.

How is a FAP Accomplished?

In practice, the content of FAPs are not unlike the data and information included in NDINs and GRAS notifications. The purpose of all three pathways is the safe use of an ingredient in food and/or dietary supplements such that significant overlap in the data required is expected. However, since food additives are often substances that do not have a history of use in the food-supply, the safety bar is effectively set to a higher level.

The mechanics of FAPs differ significantly from GRAS notifications and NDINs. Unlike GRAS notifications and NDINs that do not require Agency approval, *per se*, a FAP does. In practice, this often involves more meetings with the FDA and a longer time-horizon before an ingredient can reach the market; twenty-four (24) months is common from beginning to end for successful food additive petitions and the resulting regulatory updates. All of this often comes with a much larger price tag. In fact, the significantly greater time and cost is one reason why firms often pursue GRAS or NDIN pathways instead of FAPs.

Conclusion

In the United States, any manufacturer of finished food and dietary supplement products is ultimately responsible for producing safe and legal products. One critical step in doing so is working with suppliers that thoroughly understand and comply with Federal requirements such as FAPs and GMPs.

Spoke Sciences builds regulatory strategy and compliance into our solutions. We do not simply solve the solubility problem for your favorite ingredients, we also incorporate regulatory intelligence to up-level your compliance. Please contact us if you would like to learn more.