

## **Summary of the New Fuel and Fuel Additive Registration Regulations**

This final rule establishes new requirements for the registration of designated fuels and fuel additives (F/FAs) as authorized by sections 211 (b) (2) and 211 (e) of the Clean Air Act (CAA). The primary purpose of the new registration program is to provide information for identifying and evaluating the potential adverse effects of F/FA emissions, to help guide EPA's future regulatory decision-making activities. Manufacturers are required to analyze the combustion and evaporative emissions generated by the F/FA products, survey existing scientific information for each product and, where adequate information is not available, conduct tests to screen for the potential adverse health effects of these emissions.

A variety of provisions are included in the rule to help avoid duplication of effort and reduce costs. For example, while the requirements are strict, the rule permits adequate existing test data to be submitted in lieu of conducting new duplicative tests. In addition, manufacturers of similar F/FAs are permitted to group together and share the costs of compliance. Special provisions are also included for small businesses and for certain types of products (e.g., relabeled additives and aerosol additives).

At the present time, only gasoline and diesel F/FAs produced and commercially distributed for use in highway motor vehicles are designated for the registration and testing program. Both domestic and foreign products are included in the designation. Fuels intended for use exclusively in off-road vehicles are not currently designated. EPA is developing a separate rulemaking to designate alternative fuels and fuel additives for registration in the future.

### **I. Description of the Program**

Each manufacturer is required to submit basic registration data individually for each product being registered. As described in 40 CFR 79, the basic information already required for F/FA registration includes product and manufacturer identification, concentration and purpose-in-use, and specific compositional data. This new rule adds the following items to the basic registration data requirements: total annual production volume data, marketing distribution data, notification about group participation, and notification on the use of special provisions. If the basic registration data previously submitted for a currently registered fuel or additive is accurate and complete, then manufacturers need not resubmit this information. The new basic information requirements are to be submitted on Supplemental Notification Form 3520-16, or EPA forms in effect at the time of the submittal.

The remaining registration requirements are organized in a three-tier structure (see Figure 1). In general, standard mandatory requirements are contained in the first two tiers, while the third tier provides for additional testing on a case-by-case basis, at EPA's discretion, in response to Tier 1 or Tier 2 results or future needs. However, the tiered approach permits F/FA manufacturers to make full use of test results and other information

which may already be available about their products. Also, special provisions may reduce or eliminate requirements for some F/FAs.

As part of the requirements of Tier 1, F/FA manufacturers are to perform a literature search on the health and welfare effects of their F/FA product(s). The primary purpose of the literature search is to provide EPA with a comprehensive survey of the available data on health and welfare effects of F/FAs. A secondary purpose is to enable F/FA manufacturers to document the extent to which other required information is already available from previously performed studies. Using relevant health effects databases, F/FA producers are required for each registered product to gather all available information about the chemical composition and potential adverse effects of the whole combustion and evaporative emissions, relevant combustion emission fractions, as well as the individual emission products identified by emission speciation procedures. Information available for a "similar" product, meaning one that would be eligible for enrollment in the same group (see discussion of grouping system, below) is also considered relevant. Toxicity data on the product will most often be available from experiments conducted with laboratory animals, but other studies (e.g., exposure to humans) are also considered relevant. The data search must also include available literature on welfare effects (e.g., plant and animal response to exposure of the product's emissions). Manufacturers must search back at least 30 years for all relevant information.

Tier 1 also includes emission characterization requirements. Manufacturers are responsible for generating, collecting, and sampling the combustion emissions and, if applicable, the evaporative emissions of their F/FAs, and for conducting tests to determine the identity and concentration of individual emission products. Manufacturers are responsible for: 1) the measurement of basic emissions (i.e., total hydrocarbons, carbon monoxide, oxides of nitrogen, and particulates), 2) the speciation of volatile hydrocarbon compounds, aldehydes, ketones, alcohols, ethers, and polycyclic aromatic compounds, and 3) the speciation of "atypical" (defined later) emission products (if applicable). The characterization of emissions in Tier 1 will provide a useful inventory of potentially harmful F/FA emission products for further study and evaluation in support of the F/FA testing program, risk assessments, and future regulatory actions. This testing need not be conducted if sufficient characterization data (as defined in the rule) was identified in the literature search.

The final requirement under Tier 1 is a qualitative discussion of potential population exposures to the F/FA emissions based on the production and use of the particular fuel or additive (or group of F/FAs) in question. This qualitative analysis must consider the actual and/or projected total annual production volumes and the market distribution patterns (e.g., percent of sales by state or region) of the particular product or group of products.

Tier 2 consists of testing requirements designed to detect potential adverse health effects related to the inhalation of F/FA emissions. These requirements generally involve the generation of emissions from a vehicle or engine in a laboratory setting, exposure of laboratory test animals to these whole emissions, and evaluation of the effects of this exposure. The test requirements of Tier 2 include a 90-day subchronic inhalation study with additional tests to screen for possible carcinogenicity, mutagenicity, teratogenicity, reproductive toxicity, and neurotoxicity effects. These tests are to be conducted to the extent that the results of the data

search activities in Tier 1 do not include comparable existing information (as defined in the rule) from previously performed studies.

When Tier 1 and Tier 2 are complete, manufacturers are to submit the results to EPA for evaluation. On the basis of the submitted data or any other available information, EPA will determine whether further testing and/or analysis for the subject F/FA is needed under the provisions of Tier 3. Any confirmatory studies to be conducted in Tier 3 will be determined individually for each case, generally focusing on areas of concern which are identified in the earlier tiers.

## **II. Provisions to Ease the Burdens of the Program**

The final rule provides a number of special provisions to avoid duplication of effort, to alleviate the financial impact on small businesses, and to ease the burden on the regulated industry in general. Some of these provisions are described briefly below.

### **A. Grouping and Cost-Sharing Provisions**

The new registration program includes a voluntary grouping scheme, which permits manufacturers of similar F/Fas to pool their resources- and efforts in satisfying the new registration requirements. Manufacturers taking advantage of the grouping provisions will be able to share their planning efforts, research capabilities, and financial resources in satisfying the information-gathering and testing requirements of the F/FA registration program. Required testing is to be done on one selected representative for each group (test subject) and results submitted jointly for all members of the group. Applicable costs are to be shared by the respective manufacturers. The grouping system is expected to substantially reduce the burden of complying with this rule.

Under the grouping system, each fuel or additive is first sorted into one of six broad "fuel families" (see Figure 2). Each fuel family consists of F/FA products which share basic characteristics in regard to their chemical/physical properties and engine/vehicle applicability. The fuel families are then subdivided into the following three F/FA categories: "baseline," "non-baseline," and "atypical." In the case of the gasoline and diesel fuel families, the baseline categories consist of fuels and associated fuel additives which contain no chemical elements other than carbon, hydrogen, oxygen, nitrogen, and sulfur and conform to certain quantitative limits on oxygen content (i.e., less than 1.5 weight percent oxygen in gasoline, less than 1.0 weight percent oxygen in diesel). Non-baseline F/Fas contain no chemical elements other than those allowed in the baseline category, but they exceed the applicable oxygen limitations. The atypical categories consist of F/FAs that contain elements other than those allowed in the baseline category. For fuel additives, the category determination, is based on the characteristics of the mixture which results when the additive is mixed in the appropriate base fuel at the maximum concentration recommended by the additive manufacturer. If the fuel or fuel/additive mixture is both non-baseline (e.g., exceeds allowable oxygen content) and contains atypical elements (e.g., a metal), the formulation is

characterized as atypical. Thus, atypical characteristics take precedence over non-baseline characteristics.

Finally, within these categories, products are further subdivided into one or more "fuel/additive groups" which represent the final level of product classification within the grouping system. The groups consist of F/FAs sorted together on the basis of the assumption that their emission products will be similar on a qualitative basis. All baseline gasoline F/FAs comprise a single F/FA group, as do all baseline diesel F/FAs. Non-baseline F/FAs are divided into groups depending on the oxygenate compound(s) they contain. Similarly, atypical F/FAs are classified into groups based on the particular "atypical" element(s) they contain. The final rule contains detailed specifications for grouping F/FAs. It also specifies criteria for selecting a test representative from each group. The results and associated costs are to be shared by the participating manufacturers. EPA expects that F/FA industry trade organizations, such as the American Petroleum Institute (API) and the Chemical Manufacturers Association (CMA), will take an active role in organizing the group efforts for their members.

## **B. Other Provisions to Minimize Duplication of Effort**

Additives registered as relabeled products are exempt from the evaluation and testing requirements of this program. A relabeled product is a repackaged version of a product, which is also registered by the original manufacturer. Testing of relabeled products would clearly duplicate the efforts of the original manufacturer. Consequently, only the basic registration information is required for relabeled products.

EPA has also provided a special provision for manufacturers of non-baseline and atypical products to avoid duplicative efforts. Since there is a substantial overlap in emission species for different F/FAs in the same fuel family, requiring all manufacturers to submit literature data on all emission products is unnecessary. Thus, manufacturers of non-baseline and atypical F/FAs are required to submit Tier 1 literature data only for the emission species, which are different from the emission products of the respective base fuel. The base fuel is a generic "industry average" fuel which serves as the representative of the baseline group. It also serves as the fuel to which additives are mixed prior to testing.

## **C. Small Business Provisions**

The final rule defines a small business for this program as any motor vehicle fuel or fuel additive manufacturer with total annual sales of less than \$50 million.<sup>1</sup> In cases where subsidiary, divisional, or other complex business arrangements exist, the business entity to which this sales level pertains is the parent company with ultimate ownership. The "ultimate" parent is defined as the uppermost headquarters or topmost company encompassing all related parents, subsidiaries, divisions, branches, or other operating units. This definition follows that used by the Small Business Administration. It also helps to ensure that companies will not subdivide merely to become eligible for the small business provisions of this program. These provisions are defined below.

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<sup>1</sup> "Total annual sales" means the average of the manufacturer's sales revenue in each of the previous three years (i.e., the three years prior to submittal of the supplemental notification form).

In regard to registration of products in the baseline and non-baseline categories, the final rule permits companies with annual sales less than \$50 million to submit only the basic registration data. Such companies are not required to meet the Tier 1 and Tier 2 requirements in order to register their baseline and non-baseline F/FAs. Since nearly every registered F/FA manufacturer produces at least one baseline or non-baseline product, the larger companies will still be submitting the data for products in these groups. Thus, this provision should not cause EPA to be without the data needed to evaluate these kinds of products.

However, the number of companies producing atypical products is much less. If the same small business provisions available for baseline/non-baseline F/FAs were also applied to atypical F/FAs, then no data at all would be submitted for many atypical F/FA groups. For this reason, special small business provisions applicable to atypical F/FAs are available only to a subset of small F/FA manufacturers: those with less than \$10 million in annual sales. For their atypical F/FAs, these very small manufacturers are exempt from Tier 2 responsibility, although they must still meet the basic registration and Tier 1 requirements. These requirements fall between those applicable to small manufacturers of baseline/nonbaseline products (basic registration data only) and the general requirements of the program for larger manufacturers (basic registration, Tier 1, and Tier 2).

Since small business exemptions are based on both the manufacturer's annual sales and the product category, it is possible for a particular manufacturer to have some products excused from program requirements but not others. For example, an additive manufacturer having both baseline and atypical products and annual sales of \$30 million will be excused from Tier 1 and Tier 2 requirements for the baseline additives, but will not be excused from program requirements for the atypical products. On the other hand, a manufacturer with sales under \$10 million will be excused from both Tier 1 and Tier 2 requirements for his baseline products, and will be excused from Tier 2 for his atypical products. At EPA's discretion, any product exempt from Tier 1 and/or Tier 2 testing may nevertheless be required to be tested under the provisions of Tier 3.

#### **D. Special Provision for Aerosol Additives**

For aftermarket additives that are sold to be applied in aerosol form (e.g., starter fluids, carburetor cleaners), manufacturers are required to provide only a summary of existing scientific literature on their products and their components, a discussion of the potential population exposures to these products, and the basic registration data. Thus, aerosol products are exempt from Tier 1 emission characterization requirements and Tier 2. Testing of aerosols may be required under Tier 3 at EPA's discretion.

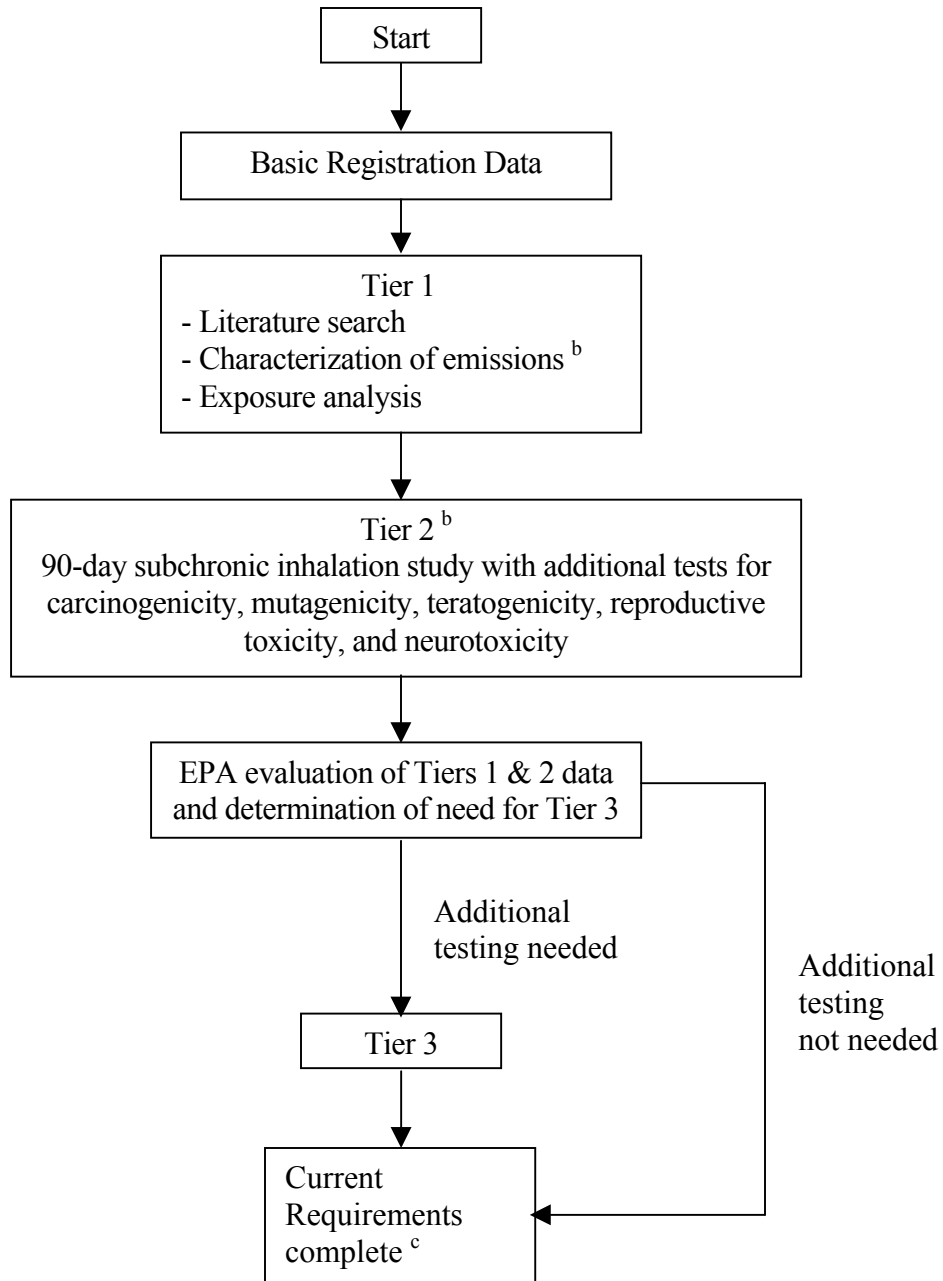
### **III. Timing and Compliance Requirements**

The timing and compliance requirements for the F/FA registration program are dependent on the type of product and the registration status of the product. Both Tier 1 and Tier 2 are mandatory requirements for all F/FAs (or groups), except as may be modified by the special

provisions described above. For F/FAs that were registered as of the effective date of this rule (May 27, 1994), the additional basic registration data items must be submitted to EPA by November 28, 1994. Tier 1 data and evidence of a suitable contractual arrangement for satisfactory completion of Tier 2 requirements must be submitted to EPA by May 27, 1997. The results of Tier 2 must be submitted to EPA no later than May 26, 2000. The schedule for completion of any Tier 3 requirements, which EPA may prescribe will be based on the nature of the particular requirements. The manufacturers may continue to market the registered F/FA while these test requirements are met.

F/FAs not registered as of May 27, 1994 are considered either "registrable" or "new" (see Figure 3). "Registrable" F/FAs are compositionally similar to currently registered products in general use, as evidenced by their ability to meet the criteria for grouping with a currently registered fuel or bulk additive. For these products, the content and timing of requirements is essentially the same\_ as for the currently registered F/FAs. Thus, manufacturers of these products will be granted registration and be permitted to market registerable F/FAs upon EPA's receipt of basic registration data for such products. In contrast, for products which are new and dissimilar to current F/FAs, all testing requirements must be completed prior to registration and introduction into commerce, including Tier 3 when prescribed by EPA. Manufacturers of "registrable" and "new" products are strongly encouraged to submit the basic registration data prior to starting the evaluation tiers.

Figure 1. Overview of Evaluation Tiers <sup>a</sup>



<sup>a</sup> This chart shows the general requirements for most F/FAs, and do not take into account any special provisions which may apply.

<sup>b</sup> Required unless adequate data exist.

<sup>c</sup> EPA retains the authority to require additional testing if new concerns arise.

Figure 2. Fuel/Additive Classification Hierarchy

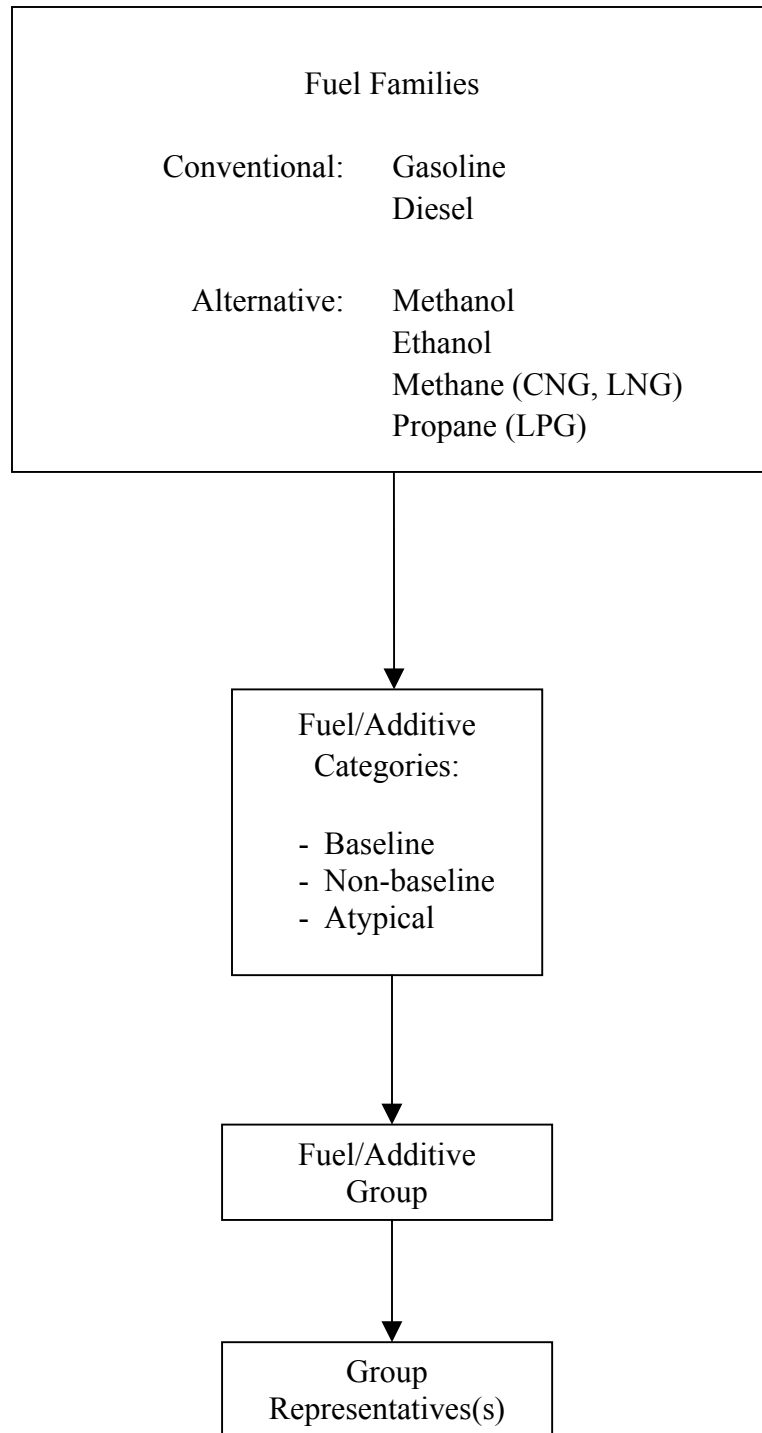
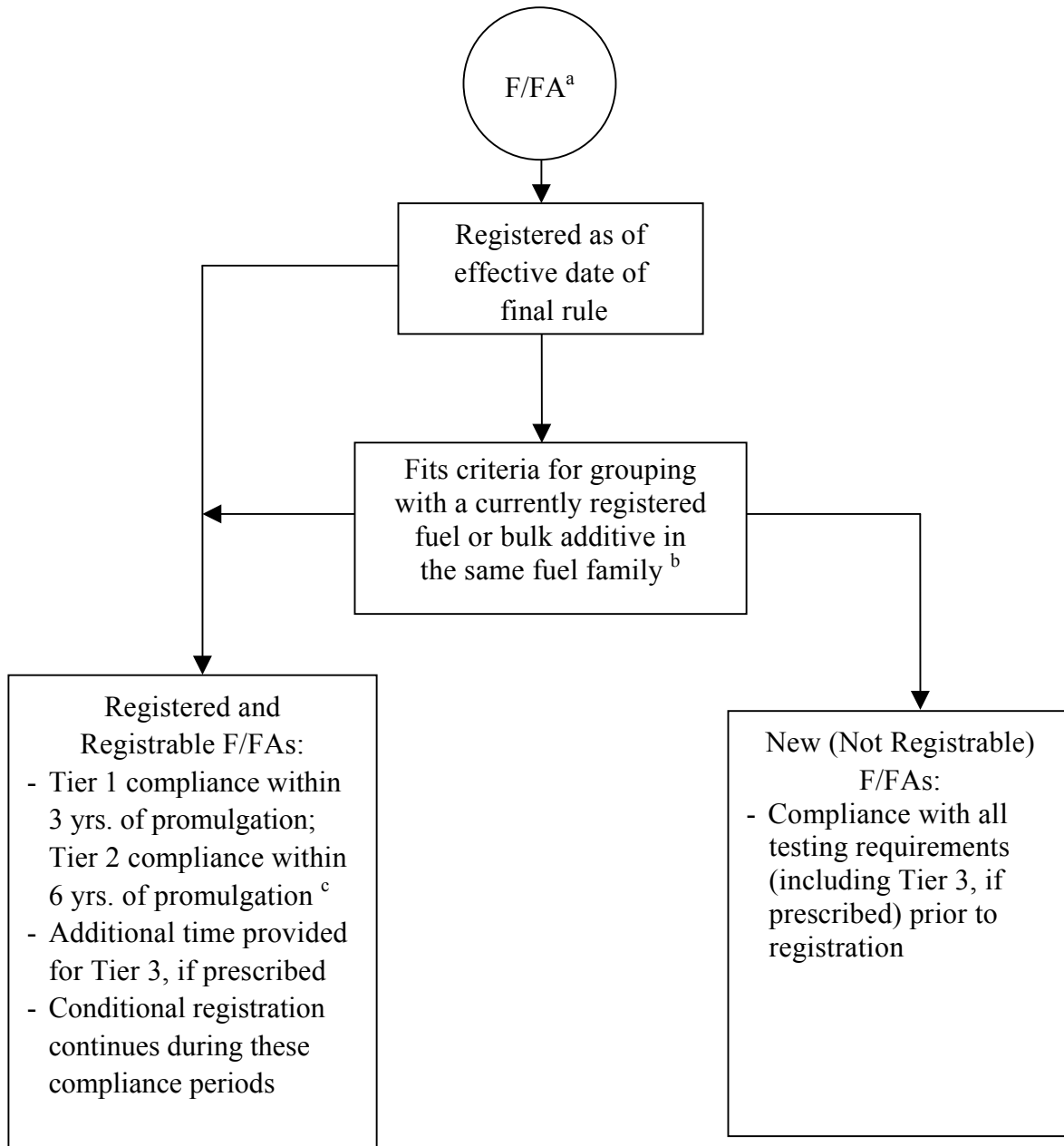




Figure 3. Determination of F/FA Registrability and Compliance Time Requirements



<sup>a</sup> Any fuel or additive (bulk or aftermarket).

<sup>b</sup> The term "currently" refers to the date on which EPA receives the registration application for the fuel or fuel additive in question.

<sup>c</sup> After this time period, a manufacturer of a registrable fuel or additive can usually rely on data previously submitted for a similar registered product in the same group.