

Environmental Safety of Fuel and Fuel Additives

The United States Clean Air Act (CAA) provides an excellent basis on which to judge the environmental safety of fuels and fuel additives (F/FA) brought to market.

This paper presents the Authentix position on the subject.

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Executive Summary

The United States Clean Air Act (CAA) provides an excellent basis on which to judge the environmental safety of fuels and fuel additives (F/FA) brought to market. The United States Environmental Protection Agency (EPA) administers the law and has provided the guidelines by which new fuels and additives can comply with the CAA. The guidelines are quite clear that only additives and fuels that “Contain no elements other than carbon, hydrogen, oxygen, nitrogen, and/or sulfur (CHONS)” are to be considered safe for registration without further testing in accordance with existing fuel data. Any other elements are considered “atypical.” Additives containing atypical elements should undergo rigorous testing to ensure they have no detrimental environmental impact, and the law lays out the type of testing and a process to get such other additives approved.

While there is no public database listing F/FA groups, we have confirmed with the EPA that there is no existing F/FA group for gasoline or diesel for the following atypical elements: chlorine, bromine, fluorine, silicon, aluminum, and zinc. Therefore, fuel additives that contain such elements have not been subjected to the type of testing required to gain registration with the CAA. Countries looking to define requirements for acceptable compositions for fuel additives, including tagging products, would be benefitting from the EPA’s long history of testing and approvals by banning atypical elements and adopting a CHONS strategy.

The Fuel / Fuel Additive Grouping System

The United States Clean Air Act (CAA) Section 211(a)¹ requires that EPA designate particular fuel/fuel additive (F/FA) that must be registered, and prohibits any sale or distribution in commerce of designated fuels and additives unless they are registered. CAA Section 211(b)(2)² states, *inter alia*, that EPA must require registrants of fuels and additives to “conduct tests to determine potential health and environmental effects of the fuel or additive,” and to determine “the emissions resulting from the use of the fuel or additive” and “the extent to which such emissions affect the public health or welfare.” CAA Section 211(e)³ required EPA to promulgate regulations by August 7, 1978, to implement the testing requirements in CAA Section 211(b)(2).

The EPA issued regulations establishing testing requirements for registered F/FAs in 1994.⁴ In the 1994 final rule, EPA adopted 40 C.F.R. § 79.56, which created a grouping system for registered F/FAs. Although this grouping system does not always operate this way in practice, it was designed and intended by EPA to make the required testing of emissions and their effects less burdensome.

The basic premise underlying this new grouping system was stated by EPA as follows:

EPA expects F/FAs within each group to have similar emission characteristics and thus essentially the same general effects on the public health and welfare. Therefore, chemical or toxicologic information associated with individual members of a given group can reasonably be generalized to all F/FAs in the group.⁵

EPA wanted to make the groups inclusive enough to prevent unnecessary testing, but not so broad that meaningful differences in emissions and their effects between different groups of F/FAs would be missed. EPA stated:

In establishing the F/FA categories (and the groups within them), EPA has sought to avoid overly narrow definitions which would result in unnecessary and duplicative testing by manufacturers, as well as overly

¹ 42 U.S.C. § 7545(a).

² 42 U.S.C. § 7545(b)(2).

³ 42 U.S.C. § 7545(e).

⁴ EPA, Final Rule, Fuels and Fuel Additive Registration Regulations, 59 Fed. Reg. 33042 (June 27, 1994).

⁵ 59 Fed. Reg. at 33054.

broad definitions which would cause potentially important toxicologic differences between F/FAs to be obscured.⁶

The grouping system for motor vehicle fuels (gasoline and diesel) consists of three general categories: baseline, non-baseline, and atypical. Baseline and non-baseline gasolines, diesels, and the associated additives must “Contain no elements other than carbon, hydrogen, oxygen, nitrogen, and/or sulfur.”^{7,8}

Non-baseline gasolines and the associated additives must meet all of the requirements for baseline gasoline “except that they contain 1.5 percent or more oxygen by weight and/or may be derived from sources other than those listed in [baseline criterion 5].”⁹ Non-baseline diesel fuels and the associated additives must meet all of the requirements for baseline diesel fuels “except that they contain 1.0 percent or more oxygen by weight and/or may be derived from sources other than those listed in [baseline criterion 5].”¹⁰

Atypical gasolines are “gasoline fuels and associated additives which contain one or more elements other than carbon, hydrogen, oxygen, nitrogen, and sulfur.”¹¹ Atypical diesel fuels are “diesel fuels and associated additives which contain one or more elements other than carbon, hydrogen, oxygen, nitrogen, and sulfur.”¹²

Within these gasoline and diesel categories, EPA has established discrete F/FA groups. F/FA registrants may meet testing requirements either on an individual or group basis if the product in question meets the criteria for enrollment in a group.¹³ All baseline gasolines and the associated additives are in one group.¹⁴ All baseline diesel fuels and the associated additives are also in a single group.¹⁵ Non-baseline gasolines and non-baseline diesel fuels are registered in separate groups, depending on the oxygenate(s) used and the source materials from which the fuel is made.¹⁶

A separate atypical gasoline group or atypical diesel group is required for “each atypical element (or other atypical characteristic) occurring separately, *i.e.*, in the absence of any other atypical element or characteristic.”¹⁷ EPA’s rationale for requiring separate F/FA groups for each atypical element was that the presence of such elements might cause changes in vehicle emissions. EPA stated:

[A]llowing additional elements in the baseline definition would introduce substances not characteristic of most F/FA products in the fuel family... [I]f the group representative did contain the additional element, then the results of the testing would be influenced by the presence and activity of this

⁶ 59 Fed. Reg. at 33057.

⁷ 40 C.F.R. § 79.56(e)(3)(i)(A).

⁸ 40 C.F.R. § 79.56(e)(3)(ii)(A).

⁹ 40 C.F.R. § 79.56(e)(3)(i)(B).

¹⁰ 40 C.F.R. § 79.56(e)(3)(ii)(B).

¹¹ 40 C.F.R. § 79.56(e)(3)(i)(C).

¹² 40 C.F.R. § 79.56(e)(3)(ii)(C).

¹³ 40 C.F.R. § 79.56(a).

¹⁴ 40 C.F.R. § 79.56(e)(4)(i)(A).

¹⁵ 40 C.F.R. § 79.56(e)(4)(i)(B).

¹⁶ 40 C.F.R. §§ 79.56(e)(4)(ii)(A) and (B).

¹⁷ 40 C.F.R. § 79.56(e)(4)(iii)(C)(1).

element, and would therefore not be valid for the large majority of the baseline F/FAs.¹⁸

Applying all of these grouping rules and policies, a taggant additive product may be enrolled in a baseline gasoline group and/or a baseline diesel group when it contains no elements other than CHONS. If a taggant additive contains a deliberately added element other than CHONS, it may only be enrolled in an atypical gasoline group or an atypical diesel group with other fuels and additives containing the same element. If a taggant additive contains more than one deliberately added element other than CHONS, it may only be enrolled in an atypical gasoline or an atypical diesel group with other fuels and additives containing the same combination of atypical elements.

We have investigated some atypical elements that may be included in molecules that have potential utility as gasoline or diesel fuel taggants. While there is no public database listing F/FA groups, we have confirmed with our contacts at EPA that there is no existing F/FA group for gasoline or diesel for the following atypical elements: chlorine, bromine, fluorine, silicon, aluminum, and zinc. Given this situation, a new taggant additive product that includes one of these atypical elements could not be registered in the U.S. for use in domestic gasoline or diesel fuels without establishing a new F/FA group in which the product in question could be enrolled.

¹⁸ 59 Fed. Reg at 33058.

Establishing a New Atypical F/FA Group

If a company wishes to register a new taggant additive product that includes an atypical element for which there is no existing F/FA group, a new F/FA group in which the product can be enrolled would have to be established. EPA defines a new additive as follows:

A fuel additive product shall be considered new with respect to a specific type of fuel if it is not expressly registered for that type of fuel pursuant to subpart C of this part as of May 27, 1994 and if, under the criteria established by § 79.56, the fuel/additive mixture resulting from use of the additive product in the specific type of fuel cannot be enrolled in the same fuel/additive group with one or more currently registered fuels or bulk fuel additives.¹⁹

For any additive that cannot be enrolled in an existing F/FA group, the applicant must submit Tier 1 and Tier 2 data, and any Tier 3 data EPA may elect to require, before the product can be registered.²⁰

Under the general regime for testing emissions that EPA established in 1994, the first step is Tier 1 testing, in which emissions utilizing the test fuel and new additive are characterized by generating emissions in test vehicles and then analyzing the components of those emissions.²¹ There are several contractors who have expertise performing Tier 1 testing.

Tier 2 requires extensive testing of health effects associated with vehicle emissions generated with the test fuel and the new additive.²² Required Tier 2 tests include a subchronic toxicity study, a fertility assessment/teratology study, an *in vivo* micronucleus assay, an *in vivo* sister chromatid exchange assay, a neuropathology assessment, and a glial fibrillary acidic protein assay.²³

¹⁹ 40 C.F.R. § 79.51(c)(3).

²⁰ *Id.*

²¹ See 40 C.F.R. §79.52. Detailed specifications for generating emissions are set forth in 40 C.F.R. § 79.57.

²² See 40 C.F.R. § 79.53.

²³ Detailed guidance for these studies is provided in 40 C.F.R. §§ 79.62-79.67.

EPA can also require Tier 3 testing after receiving Tier 1 and Tier 2 data and before granting registration,²⁴ but EPA is not likely to utilize this provision unless it has a significant unresolved concern regarding the health effects of emissions. Once all applicable test requirements have been met, a new F/FA product must be registered.²⁵

²⁴ See 40 C.F.R. § 79.54.

²⁵ 40 C.F.R. § 79.51(d)(2)(iii).

Conclusion

The United States Clean Air Act (CAA) provides an excellent basis on which to judge the environmental safety of fuels and fuel additives (F/FA) brought to market. The United States Environmental Protection Agency (EPA) administers the law and has provided the guidelines by which new fuels and additives can comply with the CAA. The guidelines are quite clear that only additives and fuels that “**Contain no elements other than carbon, hydrogen, oxygen, nitrogen, and/or sulfur (CHONS)**” are to be considered safe for registration without further testing in accordance with existing fuel data. Any other elements are considered “atypical.” Additives containing atypical elements should undergo rigorous testing to ensure they have no detrimental environmental impact, and the law lays out the type of testing and a process to get such other additives approved.

If such testing is performed and the additive containing atypical elements is deemed safe, then obtaining registration with the EPA as an approved additive is straightforward. Therefore, other countries which adopt the EPA guidelines (and require registration of additives with the EPA) would be benefitting from the EPA’s long history of testing and approvals by banning atypical elements and adopting a CHONS strategy. While there is no public database listing F/FA groups, we have confirmed with the EPA that there is no existing F/FA group for gasoline or diesel for the following atypical elements: chlorine, bromine, fluorine, silicon, aluminum, and zinc. Therefore, fuel additives that contain such elements have not been subjected to the type of testing required to gain registration with the CAA.

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