

POSITION STATEMENT

STRATEGIC PLAN ON FOOD GAS MONOGRAPHS

Background

Gases used in foods and in the production of foods are themselves defined as food by the Federal *Food, Drug, and Cosmetic Act*, and their production is monitored by the U.S. Food and Drug Administration (FDA) [1].

The FDA regards the specifications in the *Food Chemicals Codex* (FCC) as defining an appropriate food grade within the meaning of Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) [2, 3].¹ The FCC is a compendium of internationally recognized standards for the purity and identity of food ingredients. Monographs have been included in the FCC for many gases used as ingredients and for other applications in the food industry; however, not all gases used in food applications have been included. Commonly used food gases that have an FCC monograph include but are not limited to carbon dioxide, nitrogen, nitrous oxide, helium, nitrogen enriched air and oxygen.

As a result of the *Food Safety Modernization Act* (FSMA) and its implementing regulations, food manufacturers are more closely analyzing all inputs to their processes to understand and further mitigate food safety risks [4]. Therefore, customers are increasingly requesting an industry specification that is appropriate for food use. CGA member companies have historically provided commercial specifications to food manufacturers. Those specifications have a history of safe use.

CGA is proposing monographs for some food gases that do not currently have monographs. In the absence of a current monograph, this position statement recommends the information that should be provided to food manufacturers seeking to understand suitability of these gases used for food applications.

Question 1

How is CGA providing assistance to the food industry with regard to FCC monographs?

Answer 1

CGA is working with FCC to develop new monographs for the following gases currently not listed in the compendium:

- argon;
- hydrogen; and
- carbon monoxide.

CGA proposed an oxygen food monograph that was published in the FCC, 11th edition (3rd supplement) [2].

Gases used in food applications that are not listed in this position statement may be evaluated and addressed by CGA at a later date.

¹ The first edition of the FCC, which was published in 1966 by the Institutes of Medicine, was given quasi-legal recognition in July 1966 by means of a letter of endorsement from FDA Commissioner James L. Goddard, which was reprinted in the book. The letter stated that "the FDA will regard the specifications in the FCC as defining an 'appropriate food grade'."

Question 2

How should CGA member companies respond to customer requests for statements of food gas compliance where an FCC monograph does not exist?

Answer 2

Until such time as the new monographs are approved, CGA member companies should utilize the commodity specifications published by CGA and meet the current commercially available quality verification levels (QVL) in those specifications to meet agreed customer requirements, along with assuring the gases are produced in accordance with current FDA food regulations. CGA member companies should also inform customers that CGA is continuing to work with FCC to review current FCC monographs for potential revisions.

Some gases that do not currently have FCC monographs are generally recognized as safe (GRAS) for specific applications under the FDA GRAS notification program.

References

Unless otherwise specified, the latest edition shall apply.

[1] *Food, Drug, and Cosmetic Act*, U.S. Food and Drug Administration. www.fda.gov

[2] *Food Chemicals Codex*, United States Pharmacopeia. www.usp.org

[3] *Code of Federal Regulations*, Title 21 (Food and Drugs), U.S. Government Printing Office. www.gpo.gov

[4] *Food Safety Modernization Act*, U.S. Food and Drug Administration. www.fda.gov

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Food Gases Committee

NOTE—Technical changes from the previous edition are underlined.

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