



**INTERNATIONAL FOOD ADDITIVES COUNCIL
QUALITY SYSTEMS, FOOD SAFETY AND GOOD
MANUFACTURING PRACTICES AUDIT GUIDE FOR
FOOD ADDITIVES AND GRAS SUBSTANCES**

ACKNOWLEDGEMENTS

This Guide was prepared by the International Food Additives Council (IFAC) through its Food Safety Committee. IFAC is a global association representing manufacturers and users of food ingredients, including food additives and GRAS substances. IFAC strives to promote science-based regulations, standards and specifications for food ingredients worldwide.

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INTRODUCTION

In the food industry, it is the responsibility of the manufacturer of a finished food product to ensure the safety and quality of all components of that food. Through the auditing of food additive and GRAS substance producers, a finished food manufacturer is able to determine whether adequate controls are in place to ensure its producers are capable of providing product components of suitable safety and quality. The IFAC Quality Systems, Food Safety, Good Manufacturing Practices Audit Guide for Food Additives and GRAS Substances (IFAC Audit Guide) is a tool to assist in evaluating the manufacturing practices and quality systems of food additive and GRAS substance manufacturers. It is also a helpful reference to assist food additive and GRAS substance manufacturers in meeting appropriate cGMP requirements to assure consistent product safety and quality.

The IFAC Audit Guide is applicable whenever a food additive or GRAS substance manufacturer is audited, and may be used in conjunction with the IFAC Quality Systems, Food Safety and Good Manufacturing Practices Guide for Food Additives and GRAS Substances (IFAC GMP Guide). Although the IFAC GMP Guide does not guarantee legal compliance, it is intended to have international application and address relevant national regulations, including the U.S. Food Safety Modernization Act, and specifications provided by the Food Chemicals Codex, Codex Alimentarius (JECFA), the European Commission and others. While the audit may include other areas such as delivery logistics and order processing, the IFAC Audit Guide is intended to address Title 21, Part 117 of the U.S. Code of Federal Regulations and Current Good Manufacturing Practice (CGMP) requirements relating to food additive and GRAS substance manufacture.

CONTENT AND USAGE

The IFAC GMP Guide was used as the basis to construct the questions contained in the IFAC Audit Guide, and should serve as the primary source for evaluating responses provided by the auditee. The auditors should be familiar with the introduction, definitions, and general guidance that are contained within the IFAC GMP Guide, and should refer to the Guide if further details are needed.

The IFAC Audit Guide is intended to address the foundation of the requirements, and not all of the details, necessary to manufacture food additives and GRAS substances in compliance with 21 CFR Part 117 and applicable cGMPs. It may not include all of the appropriate questions for a specific audit, nor may all of the points be appropriate to every audit. As an international document, it also cannot specify all national legal requirements, nor cover in detail the particular characteristics of every food additive and GRAS substance. However, its use is intended for individuals experienced and competent in the area of auditing who should be diligent in selecting which areas of Good Manufacturing Practice are relevant to a specific particular audit and in determining the appropriateness of questions (and the answers provided) based on the characteristics of the food additive or GRAS substance manufactured, the processes employed, and specific requirements of the food additive or GRAS substance user.

FORMAT

The IFAC Audit Guide is formatted to provide detailed questions arranged in the same sequence as in the IFAC GMP Guide. This format is frequently useful as a training tool for personnel of both the auditing company and one being audited.

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AUDIT GUIDE FOR FOOD ADDITIVES AND GRAS SUBSTANCES

Table I: Detailed Questions in Sequence of the IFAC Quality Systems, Food Safety and Good Manufacturing Practices Guide for Food Additives and GRAS Substances

	NOTES
4. FOOD SAFETY & QUALITY MANAGEMENT SYSTEM-FOOD ADDITIVE GRAS SUBSTANCE QUALITY SYSTEMS	
4.1 General Requirements	
4.2 Documentation Requirements	
4.2.1 General	
4.2.2 Written Plan and Documentation of Preventive Controls -Does the plan address requirements for FSMA compliance?	
4.2.3 Quality Manual -Is there a Quality Manual? -If there is a Quality Manual, is it current? -If the Quality Manual is not current, is there a suitable alternative? -Does the Quality Manual include a quality policy, a description of the Quality Management System and a commitment of intent to meet food safety and GMP requirements for food additives and/or GRAS substances?	

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