



May 2006

Compliance Policy Guide

Guidance for FDA Staff

Sec. 500.500 Guidance Levels for 3-MCPD (3-chloro-1,2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces

Draft Guidance

This guidance is being distributed for comment purposes only.

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U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Center for Food Safety and Applied Nutrition
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This draft Compliance Policy Guide, when final, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance at the number listed on the title page of this guidance.

Sec. 500.500 Guidance Levels for 3-MCPD (3-chloro-1,2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces

I. INTRODUCTION:

The purpose of this Compliance Policy Guide (CPG) is to provide guidance to help FDA personnel determine whether to take enforcement action based upon the presence of 3-MCPD in acid-HP and Asian-style sauces in interstate commerce or offered for import into the United States.

FDA's guidance documents, including this CPG, do not establish legally enforceable responsibilities. Instead, guidance documents describe the agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in agency guidance documents means that something is suggested or recommended, but not required.

II. BACKGROUND:

Acid-hydrolyzed protein (acid-HP) is prepared by the hydrolysis of proteins by heat and food-grade acids.

During the production of acid-HP, the reaction of hydrochloric acid (HCl) with residual fat in the protein starting material may form 3-chloro-1,2-propanediol (3-MCPD), a member of a group of chemicals known as chloropropanols, which have been identified as carcinogens. The manufacturing process for acid-HP can be modified to reduce the levels of 3-MCPD that are formed.

Frequently, acid-HP is added to soybeans and other ingredients to produce soy sauce that does not undergo a traditional fermentation process. Acid-HP also may be added to fermented sauces to enhance the flavor of the sauce. And, in some cases, HCl may be added directly to soybeans to make soy sauce, producing acid-HP *in situ*, i.e., acid-HP is formed during production of the soy sauce. Adding HCl directly to soybeans can result in reactions with residual fat to generate chloropropanols, unless the processing conditions are well controlled. Additionally, acid-HP and soy sauce are used as ingredients in other Asian-style sauces, such as oyster sauce, black bean sauce, teriyaki sauce, stir-fry sauce and yakotori sauce.

The toxicity of chloropropanols has been discussed and reviewed worldwide. 3-MCPD has been shown to cause cancer in long-term studies with animals. Since 1996, many countries, including the European Union, Canada, and several Asian countries, have recommended or required that industry take steps to ensure that 3-MCPD is not detectable in acid-HP or Asian-style sauces at levels ranging from 0.01 parts per million (ppm) to 1 ppm.

Prior to safety findings concerning chloropropanols, FDA issued several opinion letters stating that acid-HP is generally recognized as safe (GRAS) for use in foods. These opinion letters did not identify limitations of use or specify acceptable levels of impurities and, being issued after 1958, are not the basis for any prior sanctions. Many of the opinion letters stated that the acid-HP be made from materials suitable for food use (i.e., food-grade) and produced according to good manufacturing practice.

General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food. The common knowledge element of the GRAS standard includes two facets: (1) data and information relied on to establish the technical evidence of safety must be generally available, and (2) a basis to conclude that there is consensus among qualified experts about the safety of the substance for its intended use. Neither facet is, by itself, sufficient to satisfy the common knowledge element of the GRAS standard. Actions by national and international food safety organizations and conclusions concerning the carcinogenic risk posed by 3-MCPD demonstrate that there is not a consensus on safety for the use of acid-HP when it contains 3-MCPD levels that exceed 1 ppm.

III. POLICY:

Acid-HP that contains 3-MCPD at levels greater than 1 ppm is not GRAS and is, therefore, an unapproved food additive. Additionally, a level of 1 ppm or more of 3-MCPD in food containing acid-HP indicates that the level of 3-MCPD in the acid-HP ingredient exceeds 1 ppm, because water or other food components will lower the concentration.

Asian-style sauces for which acid-HP is not an added ingredient also may contain 3-MCPD as a result of direct addition of HCl to soybeans and other starting materials. In 21 CFR 182.1057, HCl is listed as a GRAS substance for use as a buffer and neutralizing agent in foods. In the manufacture of Asian-style sauces, HCl is used as a catalyst to stimulate a reaction between protein and water. This use is not to neutralize (it drives the pH away from neutral), and it is not part of a buffering agent (which stabilizes pH so that acid or base does not have a big effect). As such, the use of HCl in manufacturing Asian-style sauces is not covered by 21 CFR 182.1057.

FDA will consider the following concentrations of 3-MCPD to help determine whether to take enforcement action with regard to acid-HP and Asian-style sauces containing 3-MCPD:

Concentrations of 3-MCPD in Acid-HP & Asian-Style Sauces

Specimen	Concentration of 3-MCPD
Acid-HP	1 ppm (dry basis)
Asian-style sauces to which acid-HP was added (i.e., acid-HP is included in the ingredient statement)	1 ppm (liquid basis)
Asian style sauces for which acid-HP is not listed in the ingredient statement (i.e., HCl is added to produce acid-HP <i>in situ</i>).	1 ppm (liquid basis)

FDA will determine whether to take enforcement action against acid-HP and Asian-style sauces containing 3-MCPD on a case-by-case basis, considering the totality of the circumstances. In any given case, FDA may decide to initiate an enforcement action against acid-HP or Asian-style sauces with concentrations of 3-MCPD below 1 ppm or decide not to initiate an enforcement action against acid-HP or Asian-style sauces with concentrations of 3-MCPD at or above 1 ppm.

IV. REGULATORY ACTION GUIDANCE:

The following represent factors to consider in determining whether to recommend seizure or import detention to CFSAN/Office of Compliance/Division of Enforcement (HFS-605):

1. The acid-HP or Asian-style sauce contains 3-MCPD at or above the applicable concentration, and
2. A validated analytical method is used to determine the presence of 3-MCPD.

V. SPECIMEN CHARGES:

Domestic Seizure

For acid-HP and Asian-style sauces to which acid-HP was added (i.e., acid-HP is included in the ingredient statement):

The article is adulterated within the meaning of section 402(a)(2)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(2)(C)(i)) in that it is or bears or contains the food additive acid-HP, which is unsafe within the meaning of section 409 of the FD&C Act (21 U.S.C. 348).

For Asian-style sauces for which acid-HP is not listed in the ingredient statement (i.e., HCl is added to produce acid-HP *in situ*):

The article is adulterated within the meaning of section 402(a)(2)(C)(i) of the FD&C Act (21 U.S.C. 342(a)(2)(C)(i)) in that it bears or contains the food additive hydrochloric acid, which is unsafe within the meaning of section 409 of the FD&C Act (21 U.S.C. 348).

Import Detention

For acid-HP and Asian-style sauces to which acid-HP was added (i.e., acid-HP is included in the ingredient statement):

The article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act (21 U.S.C. 381(a)(3)) in that it appears to be adulterated within the meaning of section 402(a)(2)(C)(i) of the FD&C Act (21 U.S.C. 342(a)(2)(C)(i)) because it is or bears or contains a food additive,

acid-HP, which is unsafe within the meaning of section 409 of the FD&C Act (21 U.S.C. 348).

For Asian-style sauces for which acid-HP is not listed in the ingredient statement (i.e., HCl is added to produce acid-HP *in situ*):

The article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act (21 U.S.C. 381(a)(3)) in that it appears to be adulterated within the meaning of section 402(a)(2)(C)(i) of the FD&C Act (21 U.S.C. 342(a)(2)(C)(i)) because it bears or contains a food additive, hydrochloric acid, which is unsafe within the meaning of section 409 of the FD&C Act (21 U.S.C. 348).

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Chemical Name: 3-MCPD = 3-chloro-1,2-propanediol = 3-monochloropropane-1,2-diol
IUPAC International Chemical Identifier: InChI=1/C3H7ClO2/c4-1-3(6)2-5/h3,5-6H,1-2H2/t3-/m1/s1

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