

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: HACCP REGULATION FOR FISH AND FISHERY PRODUCTS
Date: Thursday, July 24, 2014 1:30:32 PM

Good afternoon –

I am sorry I cannot specifically answer your question. You will need to contact someone in the Center for Food Safety (CFSAN). See their web page and contact information below on the lower right hand side of the page.

[Foods](#)

Kind regards,

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Senior Health Policy Analyst
Office of Good Clinical Practice
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From: [Redacted]
Sent: Thursday, July 24, 2014 10:54 AM
To: OC GCP Questions
Cc: [Redacted]
Subject: HACCP REGULATION FOR FISH AND FISHERY PRODUCTS

To whom it may concern:

I have been reviewing the FDA's Questions and Answers section regarding the HACCP Regulation for Fish and Fishery Products. However, I have not found on you website the section which states if these questions and answers are legally enforceable, or if on the contrary, they're simply recommendations.

On the Frequently Asked Questions - Statement of Investigator (Form FDA 1572) document, I found that it includes the following statement:

"FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances 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 guidances means that something is suggested or recommended, but not required."

I would like to know if these statement is applicable to the HACCP Regulation. If your answer is on the affirmative, I would like to know where I could find this statement linked to the HACCP Regulation. Moreover, if there's an FDA bylaw or regulation that states that the questions and answers that you provide will only be

recommendations, I would like to locate it.

I thank you in advance for your help.

Cordially,

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[redacted]