

MEMORANDUM

DATE: February 19, 1993

TO: Division of Shellfish Sanitation Staff

THROUGH: Eric H. Bartsch, P.E., Director
Office of Water Programs

FROM: Robert E. Croonenberghs, Ph.D., Director
Division of Shellfish Sanitation

SUBJECT: Shellfish and Crustacea Plants - Policy - FDA Inspections and Warning Letters

FOLLOW UP TO ROUTINE FDA INSPECTION REPORTS

When the field office receives a copy of an FDA plant inspection report, the shellfish specialist who inspects that facility will address the deficiencies identified in the report during their next routine inspection. They shall write a very brief description of the deficiency, identify the current plant condition, the response of the plant, and record this on the respective shellfish or crab plant inspection form (HPD-1B or HPD-2B).

FOLLOW UP TO FDA WARNING LETTERS

If the field office receives a copy of a warning letter issued by the FDA to a plant, the Processing Chief, the Field Director and the Shellfish Specialist assigned to the plant will coordinate follow up actions with the following responsibilities:

- * The Processing Chief will be the lead person in the Central Office.
- * The Processing Chief, the Field Director, and the Shellfish Specialist will jointly inspect the facility in question and point out to the owner all deficiencies. They will also provide suggestions as to how the deficiencies may be corrected along with any other necessary technical advice to help them solve these and any other deficiencies.
- * Offer to the owner advice as to the proper manner in which to prepare a written response to the FDA and offer to review their response after it is written.
- * The Deputy Director may become involved to provide advice and direction if it is felt to be necessary.
- * After corrective actions have been instituted by the plant owner, the Field Director and Shellfish Specialist will monitor the plant during their routine inspection duties to assure that these measures remain in place. They will record their observations on the inspection form (HPD-1B or HPD-2B).