

fails to recall molluscan shellfish determined to be unsafe for human consumption;

xiii. ensuring that each container in a lot of molluscan shellfish certified for export to the United States of America is properly labeled in accordance with the NSSP;

xiv. maintaining a central file of all MSSP records, including an English version of all sanitary survey reports, patrol reports, and laboratory evaluation reports and make them available to FDA upon request;

xv. providing FDA evaluation reports, interpretations, laboratory quality assurance program information, and other molluscan shellfish program information from FDA to federal and state government agencies having responsibility for the MSSP;

xvi. reviewing, at least annually, the level of conformity with the NSSP and summarizing the findings in a written report and providing an English translation of the report to FDA annually;

xvii. providing FDA with information concerning current or potential public health problems affecting molluscan shellfish intended for export to the United States of America; and

xviii. making travel arrangements in the United Mexican States for, and conducting joint inspections with, FDA evaluation officers at FDA's request. Providing transportation for FDA officials while in the United Mexican States.

- c. Permit the harvesting of molluscan shellfish for processing by MSSP certified processors and shipment to the United States of America only from growing areas approved by COFEPRIS with concurrence from the FDA.
 - d. Within 30 days of written notification from FDA of NSSP deficiencies, develop a written Corrective Action Plan, and submit it to FDA for review and concurrence. If a Plan is not developed within 30 days, FDA will remove Mexican processors from the ICSSL and/or take other appropriate action to stop molluscan shellfish from the United Mexican States from entering the United States of America. Such action should remain in effect until all MSSP deficiencies have been corrected and FDA has determined that the MSSP is in compliance with the NSSP.
3. COFEPRIS may designate a MSSP laboratory evaluation officer to:
- a. certify laboratories participating in the MSSP;