

Proposal Subject:	Thermazyme™ ACP Test
Specific NSSP Guide Reference:	NSSP Section IV Guidance Documents Chapter II. Growing Areas .11 Approved Laboratory Tests
Text of Proposal/ Requested Action	Advanced Instruments, Inc. request ISSC adoption of this method for use in the National Shellfish Sanitation Program
Public Health Significance:	Thermazyme™ ACP Test will provide the basis for determining if shellfish have been thermally processed. This test will allow decisions to be based on a rapid, quantitative method rather than sensory related methods.
Cost Information (if available):	Not available
Action by 2005 LMRC	Recommended the Conference direct the ISSC Executive Office to continue to investigate the issue of standards and pursue the development of standards and report back to the Laboratory Methods Committee with progress on the issue in six (6) months.
Action by 2005 Task Force I	Recommended adoption of the Laboratory Methods Review Committee recommendation for Proposal 05-115.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force I.
Action by USFDA	Concurred with Conference action.
Action by 2007 LMRC	Recommended referral of Proposal 05-115 to the Executive Board for consideration for interim approval. Insufficient data at this time to approve this method under Procedure XVI. Need AP curves at 145 for 15 seconds for each type of shellfish.
Action by 2007 Task Force I	Recommended adoption of the Laboratory Methods Review Committee recommendation on Proposal 05-115.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force I.
Action by USFDA	December 20, 2007 Concurred with Conference action.
Action by 2009 LMRC	Recommended referral of Proposal 05-115 to an appropriate Committee as determined by the Conference Chairman, to review new data as it becomes available.
Action by 2009 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 05-115.
Action by 2009 General Assembly	Adopted recommendation of 2009 Task Force I on Proposal 05-115.
Action by USFDA 02/16/2010	Concurred with Conference action on Proposal 05-115.
Action by 2011 LMRC	Recommends referral of Proposal 05-115 to the appropriate committee as determined by the Conference Chairman to continue the validation of the Thermazyme ACP Test for possible use in the NSSP. LMRC further recommends the information requested by the testing lab and Advanced Instruments for validation be submitted within 6 months to be considered as an emerging method.

Action by 2011 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 05-115.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force I on Proposal 05-115.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 05-115.
Action by 2013 Laboratory Methods Review and Quality Assurance Committee	Recommended no action on Proposal 05-115. Rationale: There is insufficient data to determine if the method is fit for purpose within the NSSP
Action by 2013 Task Force I	Recommended adoption of Laboratory Methods Review and Quality Assurance Committee recommendation on Proposal 05-115.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 05-115.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 05-115.