

**Department of State
Division of Publications**

312 Rosa L. Parks Avenue, 8th Floor Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615-741-2650
Fax: 615-741-5133
Email: register.information@tn.gov

For Department of State Use Only

Sequence Number: 05-05-11
Rule ID(s): 4949
File Date: 05/17/2011
Effective Date: 10/29/2011

Proposed Rule(s) Filing Form

Proposed rules are submitted pursuant to T.C.A. §4-5-202, 4-5-207 in lieu of a rulemaking hearing. It is the intent of the Agency to promulgate these rules without a rulemaking hearing unless a petition requesting such hearing is filed within sixty (60) days of the first day of the month subsequent to the filing of the proposed rule with the Secretary of State. To be effective, the petition must be filed with the Agency and be signed by twenty-five (25) persons who will be affected by the amendments, or submitted by a municipality which will be affected by the amendments, or an association of twenty-five (25) or more members, or any standing committee of the General Assembly. The agency shall forward such petition to the Secretary of State.

Agency/Board/Commission:	Tennessee Department of Agriculture
Division:	Regulatory Services
Contact Person:	Keith Hodges
Address:	P.O. Box 40627
Zip:	37204
Phone:	615-837-5331
Email:	keith.hodges@tn.gov

Revision Type (check all that apply):

- Amendment
 New
 Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only ONE Rule Number/Rule Title per row)

Chapter Number	Chapter Title
0080-04-10	Standards for Good Manufacturing Practices
Rule Number	Rule Title
0080-04-10-.02	Shellfish Sanitation Standards

Chapter 0080-04-10
Standards for Good Manufacturing Practices

Amendment

Paragraph (1) of Rule 0080-04-10-.02 Shellfish Sanitation Standards is amended by deleting the paragraph in its entirety and substituting the following language instead, so that, as amended, the paragraph shall read:

- (1) The Commissioner of Agriculture adopts the current version of the National Shellfish Sanitation Program Model Ordinance, as set forth in the Guide for the Control of Molluscan Shellfish, and published by the United States Department of Health and Human Services; Public Health Service; Food and Drug Administration, or the most current successor document.

Authority: T.C.A. § 4-3-203, 53-1-104 and 53-1-207.

* If a roll-call vote was necessary, the vote by the Agency on these rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)

I certify that this is an accurate and complete copy of a proposed rule(s), lawfully promulgated and adopted.

Date: April 20, 2011

Signature: _____

Name of Officer: Julius Johnson

Title of Officer: Commissioner

Subscribed and sworn to before me on: April 20, 2011

Notary Public Signature: _____

My commission expires on: 09/08/2013



All proposed rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Robert E. Cooper, Jr.

Robert E. Cooper, Jr.
Attorney General and Reporter

5-9-11

Date

Department of State Use Only

Filed with the Department of State on: _____

Effective on: _____

Tre Hargett

Tre Hargett
Secretary of State

Regulatory Flexibility Addendum

Pursuant to § T.C.A. 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

- (1) Type or types of small business subject to the proposed rule that would bear the cost of, and/or directly benefit from the proposed rule:

Producers, dealers and shippers of shellfish are subject to the proposed amendment. Small businesses will not bear any cost or realize any benefit from the proposed amendment.

- (2) Identification and estimate of the number of small businesses subject to the proposed rule:

Producers, dealers and shippers of shellfish are subject to the proposed amendment. There are ten.

- (3) Projected reporting, recordkeeping and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record:

There will be no additional reporting, recordkeeping or other administrative costs required for compliance with the proposed rules.

- (4) Statement of the probable effect on impacted small businesses and consumers:

The proposed amendment would not affect small businesses and consumers.

- (5) Description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule that may exist, and to what extent, such alternative means might be less burdensome to small business:

There are no less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rules.

- (6) Comparison of the proposed rule with any federal or state counterparts:

There is no federal counterpart, per se. The NSSP, which publishes the publication referred to by the proposed amendment, is the federal/state cooperative program recognized by the U.S. Food and Drug Administration (FDA) for the sanitary control of shellfish produced and sold for human consumption. Many states participate in the program and have adopted the guidelines contained in the NSSP Model Ordinance by reference.

- (7) Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.

If small businesses were exempted from the proposed rules, it would undermine the rules' objectives and put the public's health and safety at risk.

Impact on Local Governments

Pursuant to T.C.A. 4-5-220 and 4-5-228 "any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments." (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

If adopted, these rules will not have any impact on the expenditures or revenue of local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to TCA 4-5-226(i)(1).

- (A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

The proposed amendment would change the name of the federal shellfish standards adopted by the rule to reflect the new name of those standards.

- (B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

There is no federal or state law or regulation that mandates promulgation of such rule. The "guidelines" for the state's shellfish program are set forth under the Model Ordinance, or Section II, of the National Shellfish Sanitation Program's Guide for the Control of Molluscan Shellfish, as published by the United States Department of Health and Human Services; Public Health Services; Food and Drug Administration.

- (C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Producers, dealers and shippers of shellfish would be most directly affected if the proposed amendment were adopted. Such groups would probably not oppose adoption of the proposed amendment, as it would not substantively change existing Tennessee law on the subject.

- (D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

There are no attorney general and reporter opinions or judicial rulings directly relating to these rules.

- (E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

There will be no increase or decrease in state and local government revenues and expenditures resulting from the promulgation of this rule.

- (F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Buddy Woodson, Tennessee Department of Agriculture, Division of Regulatory Services, Food and Dairy Administrator

- (G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Buddy Woodson, Tennessee Department of Agriculture, Division of Regulatory Services, Food and Dairy Administrator

- (H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Tennessee Department of Agriculture, Ellington Agricultural Center, P.O. Box 40627, Nashville, TN 37204. Office number: 615-837-5177, buddy.woodson@tn.gov

- (I) Any additional information relevant to the rule proposed for continuation that the committee requests.

**RULES
OF
THE TENNESSEE DEPARTMENT OF AGRICULTURE
DIVISION OF QUALITY AND STANDARDS**

**CHAPTER 0080-4-10
STANDARDS FOR GOOD MANUFACTURING PRACTICES**

TABLE OF CONTENTS

0080-4-10-01 Current Good Manufacturing Practices 0080-1-10-02 Shellfish Sanitation Standards

0080-4-10-.01 CURRENT GOOD MANUFACTURING PRACTICES.

- (1) The Commissioner of Agriculture adopts the federal standards titled "Current good manufacturing practice in manufacturing, packing, or holding human food" codified as 21 C.F.R. 110 and Published in the Federal Register at 51 FR 24475 and the following subsections codified and published as indicated:
 - (a) 29 C.F.R. 110 (A) at 51 FR 24475 as amended at 54 FR 24892.
 - (b) 29 C.F.R. 110 (B) at 51 FR 24475 as amended at 54 FR 24892.
 - (c) 29 C.F.R. 110 (C) at 51 FR 24475.
 - (d) 29 C.F.R. 110 (E) at 51 FR 24475.

Authority: T.C.A. § 53-1-207. **Administrative History:** Original rule filed May 27, 1994; effective September 28, 1994.

0080-4-10-.02 SHELLFISH SANITATION STANDARDS.

- (1) The Commissioner of Agriculture adopts the ~~standards titled "Sanitation of the harvesting, processing, and distribution of shellfish" as published in the most recent version of the National Shellfish Sanitation Program Manual of Operations as issued by the U. S. Department of Health and Human Services~~ current version of the National Shellfish Sanitation Program Model Ordinance, as set forth in the Guide for the Control of Molluscan Shellfish, and published by the United States Department of Health and Human Services, Public Health Services, Food and Drug Administration, or the most current successor document.

Authority: T.C.A. §§ 4-3-203, 53-1-104 and 53-1-207. **Administrative History:** Original rule filed May 27, 1994; effective September 28, 1994.