

APA-1  
11/96

**TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION**

Control 420 Alabama Department of Public Health

Rule Number 420-3-18

Rule Title Shellfish Sanitation

       New XXXX Amend        Repeal        Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare or safety? Yes

Is there a reasonable relationship between the state's police power and the protection of the public health, safety or welfare? Yes

Is there another, less restrictive method of regulation available that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? No

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? n/a

Are all facts of the rulemaking process designed solely for the purpose of and so they have as their primary effect, the protection of the public? Yes

Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of §41-22-23, Code of Alabama, 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama, 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of Certifying Officer Patricia Brie Date 4/13/12

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**FORM APA2**  
**11/96**

**STATE BOARD OF HEALTH**  
**NOTICE OF INTENDED ACTION**

AGENCY NAME: Alabama Department of Public Health

RULE NUMBER AND TITLE: 420-3-18, Rules for Shellfish Sanitation

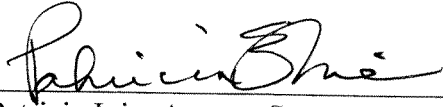
INTENDED ACTION: Revision of Rule 420-3-18.

SUBSTANCE OF PROPOSED ACTION: To amend the current Rules for Shellfish Sanitation to adopt the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, 2009 Revision, Sections I and II, and to incorporate federally required controls for oyster harvest times and temperature controls.

TIME, PLACE, AND MANNER OF PRESENTING VIEWS: A public hearing will be held at 9:00 a.m. May 22, 2012, at the Alabama Department of Public Health, RSA Tower, Suite 1540, 201 Monroe Street, Montgomery, AL 36104.

FINAL DATE FOR COMMENTS AND COMPLETION OF NOTICE: Written or oral comments will be received until the close of the record at 5:00 p.m. on June 4, 2012. All comments and requests for copies of the proposed amendments should be addressed to the contact person listed below.

CONTACT PERSON AT AGENCY: Ronald Dawsey, Division of Food, Milk, and Lodging, Bureau of Environmental Services, Department of Public Health, 201 Monroe Street, Suite 1250, Montgomery, Alabama 36104. Telephone number (334) 206-5375.

  
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Patricia Ivie, Agency Secretary

**RULES  
OF  
ALABAMA STATE BOARD OF HEALTH  
BUREAU OF ENVIRONMENTAL SERVICES  
CHAPTER 420-3-18  
FOR SHELLFISH SANITATION**

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**420-3-18-.01 Purpose.**

These rules define the harvesting, shucking, processing, handling and transportation of shellfish; prohibit the sale of adulterated and misbranded shellfish; require permits for the sale of shellfish; and establish closures regulating the harvesting areas.

AUTHORS: Lewis A. Byrd, Ph.D., Christine Collins, and Jeff McCool

STATUTORY AUTHORITY: Sections 9-12-126, 22-2-2(6) and 22-20-5, Code of Alabama, 1975.

HISTORY: Adopted November 19, 2003, filed November 20, 2003, effective date December 25, 2003; replaces Chapter 420-3-18. Repeal filed on November 20, 2003, repeal effective on December 25, 2003.

**420-3-18-.02 Applicability.**

These rules apply to all persons involved in the harvesting, from either public or private reefs as defined or designated by the Alabama Department of Conservation and Natural Resources, processing, distribution and sale of shellfish, whether in interstate or intrastate commerce. Due to special circumstances, administration and enforcement of these rules are to be conducted by the State Health Officer.

AUTHORS: Lewis A. Byrd, Ph.D., Christine Collins, and Jeff McCool

STATUTORY AUTHORITY: Sections 9-12-126, 22-2-2(6) and 22-20-5, Code of Alabama, 1975.

HISTORY: Adopted November 19, 2003, filed November 20, 2003, effective date December 25, 2003; replaces Chapter 420-3-18. Repeal filed on November 20, 2003, repeal effective on December 25, 2003.

**420-3-18-.03 Definitions.**

In addition to the terms defined by adoption in Rule 420-3-18-.08 9(1) and listed in the document entitled National Shellfish Sanitation Program Model Ordinance, ~~2004~~ 2009 Revision, the following definitions also apply in the application and enforcement of these rules:

**(1) “Adulterated”** means

(a) any shellfish harvested from ~~closed waters~~ waters that are unclassified or classified as “closed,” “prohibited,” “restricted,” or “conditionally restricted,” except as expressly permitted by the State Health Department for relaying or research projects;

(b) any shellfish shucked, packed, or otherwise processed in an establishment which has not been ~~certified and licensed~~ permitted by the State Health Department in accordance with the requirements of these rules;

(c) any shellfish contaminated as determined by microbiological or other analysis; any shellfish consisting in whole or in part of any filthy, putrid or decomposed substance, or otherwise unfit for food; any shellfish prepared, packed or held under insanitary conditions where it may have become contaminated with filth, or whereby it may have been rendered injurious to health; - or

(d) any shellfish that is not maintained under temperature control or that is not refrigerated as required by these rules.

**(2) “Approved”** means acceptable to the State Health Officer based on his/her determination as to conformance with appropriate rules, regulations and good public health practices.

**(3) “Board”** means the Board of Health of the State of Alabama as constituted by Section 22-2-1, Code of Alabama, 1975, or the State Health Officer or his/her designee, when acting for the Board. For the purpose of these rules, the designee is the Division of Food, Milk and Lodging, of the State Health Department’s Bureau of Environmental Services.

**(4) “Interstate commerce”** means the movement of shellstock or shellfish across state or international borders; or the intent to continue movement within a state that originated from another state or country.

**(4) (5) “Key employee”** means the permittee, individual(s) having supervisory or management duties, or the most responsible person(s) working in a shellfish processing facility.

**(5) (6) “Permittee”** means the person(s) legally responsible for the operation of the shellfish processing facility.

**(7) “Refrigerated”** means mechanically refrigerated containers or conveyances which are equipped with automatic controls and capable of maintaining the ambient air in the storage area at temperatures of 45° Fahrenheit (7.2° Centigrade) or less.

**(8) “Repacker”** means any person, other than the original certified shucker-packer, who repackages shucked shellfish into other containers. A repacker may also repack and ship shellstock. A repacker shall not shuck shellfish.

**(6) (9) “Repeat deficiency”** means a deficiency that has been noted on the inspection report form for the same facility during the prior inspection.

**(7) (10) “Seafood processing facility”** means any place where fish or fishery products are handled, unloaded, stored, transported, frozen, prepared, changed into different market form, manufactured, preserved, packed, or labeled.

**(11) “Seed shellstock”** means shellstock that is less than 25 millimeters in diameter measured from hinge to bill.

**(8) (12) “Shellfish processing facility”** means any place where shellfish or shellfish products are handled, unloaded, stored, transported, shucked, frozen, prepared, changed into different market form, manufactured, preserved, packed, or labeled.

**(9) (13) “State Health Department”** means the Alabama Department of Public Health as defined by Section 22-1-1, Code of Alabama 1975, and any officer, agent or employee of the said department authorized to act for the department with respect to the enforcement and administration of these rules.

**(10) (14) “State Health Officer”** means the State Health Officer of the State of Alabama Department of Public Health or a County Health Officer as provided in Code of Alabama 1975, Sections 22-2-8 and 22-3-4; or his/her authorized representatives and any officer or agent or employee of the said department authorized to act for the department with respect to the enforcement and administration of these rules.

**(15) “Unclassified Area”** means waters that are presently unclassified and from which the harvest of shellfish is prohibited pending classification of the area as prohibited, restricted, conditionally approved, or approved based on a sanitary survey of the area.

AUTHORS: Lewis A. Byrd, Ph.D., Christine Collins, and Jeff McCool

STATUTORY AUTHORITY: Sections 9-12-126, 22-2-2(6) and 22-20-5, Code of Alabama, 1975.

HISTORY: Adopted November 19, 2003, filed November 20, 2003, effective date December 25, 2003; replaces Chapter 420-3-18. Repeal filed on November 20, 2003, repeal effective on December 25, 2003.

#### **420-3-18-.04 Permits.**

**(1) General** - It shall be unlawful for any person to operate any shellfish processing facility in Alabama unless such person possesses a valid permit issued by the State Health Officer for the operation of such facility. Only persons who comply with the provisions of these rules shall be entitled to receive and retain such permit. Permits shall not be

transferable with respect to person or place and shall remain the property of the State Health Department. The permit may be suspended or revoked for violation of these rules.

**(2) When applications may be denied** - Permit applications may be denied if:

(a) The applicant fails to comply with these rules.

(b) He/she has been the permittee or a key employee at a seafood processing facility that has had its permit revoked during the ninety (90) days preceding the submittal of the application.

**(3) Conditions of issuance** - Permits shall be issued in accordance with the following requirements:

(a) Any person desiring to operate a shellfish processing facility shall make written application for a permit on forms prescribed by the State Health Officer, ~~as shown in Appendix "A."~~ Permits shall automatically expire on September 30<sup>th</sup> of each year or on a date designated by the State Health Officer and are renewable each year upon written application submitted within 120 days prior to expiration.

(b) Prior to approval of an application for a permit, the State Health Officer shall inspect the proposed shellfish processing facility to determine compliance with the requirements of these rules.

(c) The State Health Officer shall issue a permit to the applicant if his/her inspection reveals the proposed shellfish processing facility complies with the requirements of these rules.

(d) Permits are issued only to applicants who meet the following inspection requirements:

1. A Hazard Analysis Critical Control Point (HACCP) Plan for the facility is approved by the State Health Officer.

2. There are no critical deficiencies found during the inspection for permit.

3. There are no more than two (2) key deficiencies found during the inspection for permit.

4. There are no more than three (3) other deficiencies found during the inspection for permit.

**~~(4) Permit suspension~~**

~~(a) Permits may be suspended temporarily by the State Health Officer for failure of the permittee to comply with the requirements of these rules.~~

~~(b) When a permittee fails to comply with any notice issued under the provision of 420-3-18-.04(7), the permittee or key employee shall be notified in writing that the permit is,~~

~~upon service of the notice, immediately suspended and that an opportunity for an informal administrative review and/or formal hearing is provided in accordance with the provisions of 420-3-18-.08.~~

~~(c) Notwithstanding the other provisions of these rules, whenever the State Health Officer finds other insanitary conditions in the operation of a shellfish processing facility, which, in his/her judgment, constitutes an imminent public health hazard, such as, but not limited to, an uncorrected critical deficiency, he/she may without warning or notice, issue a written notice to the permittee or key employee citing such conditions, specifying the corrective action to be taken, and specifying the time period within which such action shall be taken; and, if deemed necessary, such order shall state that the permit is immediately suspended, and all shellfish processing operations are to be immediately discontinued.~~

#### ~~(5) Reinstatement of Suspended Permits -~~

~~(a) Any person whose permit has been suspended under the provisions of 420-3-18-.04(4) may make application for a reinspection for the purpose of reinstatement of the permit. A reinspection shall be conducted by the State Health Officer within seven (7) days following receipt of a written request, including a statement signed by the applicant that, in his/her opinion, conditions causing suspension of the permit have been corrected, and, when the permit has been suspended for continuing violations, an approved plan has been established to prevent reoccurrence of said conditions.~~

~~(b) If the applicant has corrected the deficiencies and complies with the rules of the State Health Department, the permit shall be reinstated.~~

#### ~~(6) Revocation of Permits -~~

~~(a) The State Health Officer may, after providing opportunity for an informal administrative review and/or formal hearing as provided in Chapter 420-3-18-.08, revoke a permit for failure to comply with conditions of permit suspension, or repeat deficiencies, or failure to comply with these rules, or for interference with the State Health Officer in the performance of his/her duties.~~

~~(b) Prior to revocation, the State Health Officer shall notify, in writing, the permittee or key employee of the specific reason(s) for which the permit is to be revoked and that the permit shall be revoked at the end of fifteen (15) days following service of such notice.~~

~~(c) Whenever a revocation has become final, the period of revocation shall be not less than ninety (90) days from the date of revocation.~~

~~(7) Service of notice - A notice provided for in these rules is properly served when it is delivered to the permittee or key employee, or when it is sent by registered or certified mail, return receipt requested, to the last known address of the permittee. A copy of the notice shall be filed in the records of the State Health Officer.~~

(4) Permit denials, suspensions, and revocations - The State Health Officer's denial, suspension and/or revocation of a permit shall be governed by the Alabama Administrative Procedure Act, § 41-22-1, et seq., Code of Alabama 1975.

**(5) Hearings** – Contested case hearings shall be provided in accordance with the Alabama Administrative Procedure Act, § 41-22-1, et seq., Code of Alabama 1975, and the State Board of Health's Contested Case Hearing Rules, Chapter 420-1-3. Informal settlement conferences may be conducted as provided in the State Board of Health's Contested Case Hearing Rules, Chapter 420-1-3.

**(6) Suspension of permits** - Permits may be suspended temporarily by the State Health Officer for failure of the permittee to comply with the requirements of these rules.

(a) Notwithstanding the other provisions of these rules, whenever the State Health Officer finds conditions which, in his judgment, constitute an imminent hazard to the public health, he may without warning or notice, issue a written notice to the permittee citing such conditions and specifying the corrective action to be taken, the time period within which such action shall be taken; and, if deemed necessary, such order shall state that the permit is immediately suspended, and all shellfish processing operations are to be immediately discontinued.

**(7) Revocation of permits** - The State Health Officer may, after providing opportunity for hearing, revoke a permit for serious or repeated violations of any of the requirements of these rules or for interference with the Health Officer in the performance of his or her duty or for failure to comply with the provisions of a notice of permit suspension issued under Rule 420-3-18-.04(4).

**(8) Application after revocation** - Whenever a revocation of a permit has become final, the holder of the revoked permit may make written application for a new permit after 90 days from the date of revocation.

AUTHORS: Lewis A. Byrd, Ph.D., Christine Collins, and Jeff McCool

STATUTORY AUTHORITY: Sections 9-12-126, 22-2-2(6) and 22-20-5, Code of Alabama, 1975.

HISTORY: Adopted November 19, 2003, filed November 20, 2003, effective date December 25, 2003; replaces Chapter 420-3-18. Repeal filed on November 20, 2003, repeal effective on December 25, 2003.

#### **420-3-18-.05 Inspections.**

**(1) General** - After a shellfish processing facility is permitted, inspections shall be conducted during periods of operation and at such frequency as necessary to assure that adequate operational and sanitary conditions are maintained. Inspection report forms shall be prescribed by the State Health Officer, ~~similar to the inspection report shown in Appendix "B."~~ A copy of the completed inspection report form listing any deficiencies found and a compliance schedule shall be provided to the key employee(s) of the facility.

**(2) Right of entry** - The State Health Officer, after proper identification, shall be permitted to enter any shellfish processing facility at any time during periods of operation or at any other reasonable time for the purpose of making inspections to determine compliance with the provisions of these rules. The State Health Officer shall be permitted to examine the records of the facility to obtain information pertaining to shellfish processing.



**(3) Report of findings -**

(a) Whenever an inspection of a shellfish processing facility is made, the findings shall be recorded on the prescribed inspection report form. Remarks shall be written to reference the requirements of these rules, and to state the corrections needed and time frame in which they are to be made.

(b) A copy of the completed inspection report listing deficiencies found and a compliance schedule shall be provided to the permittee or key employee(s) of the facility. A copy of the inspection report shall be filed and maintained with the records of the facility for at least one year.

(c) The completed inspection report form shall state that failure to comply with any time limits for corrections may result in cessation of operations. Critical, key and other deficiencies are to be corrected as specified under Rule 420-3-18-.06, Enforcement.

(d) The completed inspection report form is a public document that shall be available for public disclosure to any person who requests it according to law.

**(4) Inspections -**

(a) Inspections will be conducted at reasonable time intervals to assure compliance.

(b) The minimum inspection frequency shall be:

1. Within ~~(30)~~ thirty (30) days after the issuance of a permit on the basis of a pre-operational inspection;
2. Quarterly for shucker-packers and repackers; and
3. Semi-annually for shellstock shippers and reshippers.

AUTHORS: Lewis A. Byrd, Ph.D., Christine Collins, and Jeff McCool

STATUTORY AUTHORITY: Sections 9-12-126, 22-2-2(6) and 22-20-5, Code of Alabama, 1975.

HISTORY: Adopted November 19, 2003, filed November 20, 2003, effective date December 25, 2003; replaces Chapter 420-3-18. Repeal filed on November 20, 2003, repeal effective on December 25, 2003.

**420-3-18-.06 Enforcement.**

**(1) Correction of violations -** The completed inspection report form shall specify a reasonable period of time for the correction of the deficiencies found. Correction of the deficiencies shall be accomplished within the period specified, in accordance with the following provisions:

(a) All critical deficiencies shall be corrected immediately, during the course of the inspection, or the shellfish processing facility permit shall be immediately suspended in accordance with ~~420-3-18-.04(4)(e)~~ Rule 420-3-18-.04(6) and all shellfish processing operations shall cease until the permit is reinstated. Whenever a critical deficiency is corrected during the course of the inspection, legal notice to maintain compliance without repeat critical deficiencies shall be issued to the permittee or key employee.

(b) All key deficiencies shall be corrected as soon as possible, but in any event within at most thirty (30) days from the date of the inspection and in accordance with the following provisions:

1. A compliance schedule, including dates for corrections to be completed, shall be noted on the inspection report form.

2. Legal notice to correct key deficiency(ies) shall be issued to the permittee or key employee whenever key deficiency(ies) are not corrected according to the compliance schedule. Refusal of the permittee or key employee to sign the inspection report form, compliance schedule, or any legal notice shall not negate the compliance schedule.

(c) All other deficiencies shall be corrected as soon as possible, but in any event by the time of the next routine inspection and in accordance with the following provisions:

1. A compliance schedule, including dates for corrections to be completed, shall be noted on the inspection report form.

2. Legal notice to correct other deficiencies shall be issued to the permittee or key employee whenever other deficiency(ies) are not corrected according to the compliance schedule. Refusal of the permittee or key employee to sign the inspection report form, compliance schedule, or any legal notice shall not negate the compliance schedule.

**(2) Reinspection to determine compliance** - Reinspection shall be conducted as necessary to determine compliance with schedules or notices.

(a) If on reinspection the deficiencies noted on the inspection report have been corrected according to the compliance schedule, the facility is returned to routine inspection status.

(b) If on reinspection, repeat deficiency(ies) are found, the permittee shall be subject to punishment as provided by law.

(c) A "Notice of Intent to Suspend/Revoke Permit" ~~such as shown in Appendix "C"~~ shall be issued when ~~the reinspection finds~~ repeat deficiency(ies) are found on reinspection.

(d) ~~If, on reinspection,~~ a "Notice of Intent to Suspend/Revoke Permit" was issued on reinspection, a second reinspection shall be conducted within fifteen (15) days. The permit shall be suspended if any repeat critical, key, or other deficiencies are found. The facility is will be returned to routine inspection status if:

1. no new critical or repeat critical deficiencies are found;
2. no repeat key deficiencies are found; and
3. no repeat other deficiencies are found.

**(3) Penalty provided by law** - Any person who knowingly violates or fails or refuses to obey or comply with any rule or regulation adopted and promulgated by the State Board of Health of this state shall be guilty of a misdemeanor and, upon conviction, shall be fined not less than \$25.00 nor more than \$500.00 and, if the violation or failure or refusal to obey or comply with such rule or regulation is a continuing one, each day's violation, or failure or refusal shall constitute a separate offense and shall be punished accordingly.

AUTHORS: Lewis A. Byrd, Ph.D., Christine Collins, and Jeff McCool

STATUTORY AUTHORITY: Sections 9-12-126, 22-2-2(6), 22-2-14, and 22-20-5, Code of Alabama, 1975.

HISTORY: Adopted November 19, 2003, filed November 20, 2003, effective date December 25, 2003; replaces Chapter 420-3-18. Repeal filed on November 20, 2003, repeal effective on December 25, 2003.

**420-3-18-.07 Nuisances per se.**

The State Board of Health hereby declares the following to be a nuisance per se and a menace to public health: any adulterated shellfish found in the possession of any person for commercial purposes; or any improperly identified, improperly tagged, unidentified or untagged sack or container of shellfish found in possession of any person for commercial purposes, including transport by the harvester to the dealer, other than on board the fisherman or harvester's vessel within the harvest area. Agents of the State or County Health Department or Department of Conservation and Natural Resources, Marine Resources Division are authorized to seize and hold such, or to order such to be seized and held, or to summarily destroy such in accordance with law.

AUTHORS: Lewis A. Byrd, Ph.D., Christine Collins, and Jeff McCool

STATUTORY AUTHORITY: Sections 9-12-126, 22-2-2(6), 22-10-1 *et seq.*, and 22-20-5, Code of Alabama, 1975.

HISTORY: Adopted November 19, 2003, filed November 20, 2003, effective date December 25, 2003; replaces Chapter 420-3-18. Repeal filed on November 20, 2003, repeal effective on December 25, 2003.

**420-3-18-.08 Appeals**

~~(1) Any person who, (a) after proper application, is denied a permit, license, or authorization; or (b) is in possession of a valid permit, license, or authorization, and is notified in writing of the intent to suspend, revoke, or deny renewal of said permit, license or authorization, shall be provided the reasons therefore and may, within fifteen (15) days following receipt of said notice, apply in writing for an informal hearing to the Office of General Counsel or designee, in accordance with the rules of the State Board of Health governing Hearing of Contested Cases.~~

~~(2) If, after the informal hearing, the matter is not resolved to the satisfaction of the aforesaid person, written appeal in accordance with the rules of the State Board of Health governing Hearing of Contested Cases may be made within fifteen (15) days following said hearing to the State Health Officer. This appeal shall be sent directly to the Office of General Counsel, State Department of Health, 201 Monroe Street, Suite 1540, Montgomery, Alabama 36130-1701 with a copy furnished to the Director, Seafood Branch, 4168 Commander's Drive, Mobile, Alabama 36615.~~

~~AUTHORS: Lewis A. Byrd, Ph.D., Christine Collins, and Jeff McCool~~

~~STATUTORY AUTHORITY: Sections 9-12-126, 22-2-2(6) and 22-20-5, Code of Alabama, 1975.~~

~~HISTORY: Adopted November 19, 2003, filed November 20, 2003, effective date December 25, 2003; replaces Chapter 420-3-18. Repeal filed on November 20, 2003, repeal effective on December 25, 2003.~~

#### **420-3-18-.08 9 Requirements for Harvesting, Processing and Distribution of Shellfish.**

**(1) Adoption by reference** - The document entitled National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, 2004 2009 Revision, Sections I and II, promulgated by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, is hereby incorporated by reference and made a part of this rule as if set out in full and all provisions thereof are adopted as a rule of the State Board of Health.

**(2) Availability** - Said document is available at the office of Director, Division of Food, Milk, and Lodging, RSA Tower Suite 1250, 201 Monroe Street, Montgomery, Alabama 36104.

**(3) Control** - Where there is inconsistency between Chapter 420-3-18 and the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, 2004 2009 Revision, Section I and Section II, these rules control. Where these rules are silent, the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, 2004 2009 Revision, Sections I and II, controls.

#### **(4) Water supply for permitted establishments –**

(a) The State Health Officer may sample a shellfish processing establishment's water supply as often as necessary to ensure compliance with these rules.

(b) When a water sample of a non-public water system used by a shellfish processing establishment shows coliform present as reported by the Alabama Department of Public Health Bureau of Clinical Laboratories, a resample shall be taken within seven days. Whenever two consecutive samples taken on separate days show coliform present, the permit to operate shall be suspended by the State Health Officer in accordance with appropriate administrative procedures. A sample result of coliform absent with no confluent growth is required prior to reinstatement of the permit.

#### **(5) Harvest restriction times for control of Vibrio bacteria –**

(a) In order to control growth of the bacteria *Vibrio parahaemolyticus* and *Vibrio vulnificus*, all shellfish harvested for sale as shellstock (that is, for sale to the final consumer as shellstock or half-shell service) shall be conducted within the time limits specified in Appendix "A" for any month.

(b) For harvesting from private reefs, as defined or designated by the Alabama Department of Conservation and Natural Resources, the licensed shellfish harvester shall keep documentation noting the time going onto, and coming off, the private reef. Each harvest container shall be tagged when full with a completed, approved private lease tag purchased from the Alabama Department of Conservation and Natural Resources. Total time from first harvest until harvested shellfish are placed under approved mechanical refrigeration shall not exceed the time limits specified in Appendix "A" for any month, except as allowed in Rule 420-3-18-.08(5)(d).

(c) Any shellfish harvested outside the designated harvest times, or without an approved time documentation to confirm, or verify, the time limits of the shellfish harvest, shall be deemed adulterated, except as allowed in Rule 420-3-18-.08(5)(d).

(d) Shellfish harvested for approved post-harvest processing to control *Vibrio* bacteria, or for sale to a permitted shellfish processing facility for the purpose of shucking, and with tags attached to the harvest container (bag, sack, or box) stating such restricted use, shall be exempted from the time controls stated in Appendix A, column 3, of this rule. Nothing in this rule shall be deemed to exempt any licensed shellfish harvester from a more restrictive harvest time that may be set by the Alabama Department of Conservation and Natural Resources.

(e) If shellfish are received by a permitted shellfish processing facility with "Restricted Use" information on any tag or label attached to the shellfish container (bag, sack, or box), then the shellfish in that container shall be processed and sold in accordance with the attached "Restricted Use" information. The permitted shellfish processing facility receiving the shellfish shall document in the facility's Hazard Analysis Critical Control Point (HACCP) Plan that all further processing in the facility was done in accordance with the "Restricted Use" instructions.

#### **(6) Transportation –**

(a) Shellstock for commercial use and with a dealer tag attached stating "Keep refrigerated," or similar language on the dealer tag indicating temperature maintenance is required, shall be transported in refrigerated equipment as defined in these rules, and the internal temperature of the shellstock meat shall be maintained at 45°F or below.

(b) A shellfish processing establishment may transport shellstock from one permitted shellfish processing establishment to another permitted shellfish processing establishment within short distances, and use alternate temperature maintenance such as ice and adequate protection from contamination, if such transport is made a part of the shellfish processing establishment's HACCP Plan and is approved by the Health Officer prior to any shellstock transport.

AUTHORS: Lewis A. Byrd, Ph.D., Christine Collins, and Jeff McCool

STATUTORY AUTHORITY: Sections 9-12-126, 22-2-2(6) and 22-20-5, Code of Alabama, 1975.  
HISTORY: Adopted November 19, 2003, filed November 20, 2003, effective date December 25, 2003; replaces Chapter 420-3-18. Repeal filed on November 20, 2003, repeal effective on December 25, 2003.

**420-3-18-.09 40 Criteria for Opening and Closing of Shellfish Growing Areas.**

**(1) Criteria for closing shellfish growing areas to harvesting -**

- (a) All Areas classified as Prohibited shall be closed to the harvesting of shellfish.
  - (b) All Areas classified as Restricted shall be closed to the harvesting of shellfish.
  - (c) All Areas classified as Temporarily Closed shall be closed to the harvesting of shellfish.
  - (d) All Areas that are unclassified shall be closed to the harvesting of shellfish.
  - (e) Areas classified as Conditionally Approved shall be open to the harvesting of shellfish except during the following conditions:
    1. The discharge or spillage of any substance that is considered hazardous to public health.
    2. The presence of biotoxins in concentrations of public health significance.
    3. When the fecal coliform geometric mean "most probable number" (MPN) of the growing area water exceeds 14 per 100 milliliters, as reported by the Alabama Department of Public Health Bureau of Clinical Laboratories.
    4. When the stage of the Mobile River reaches eight (8) feet at Barry Steam Plant, Bucks, Alabama, as measured and reported by the U.S. Army Corps of Engineers.
    5. If the river stage reading at Barry Steam Plant is not available, the river stage reading at the most appropriate river gauge as determined by the State Health Officer, that is correlated to the eight (8) feet river level at Barry Steam Plant,
- ~~5.~~ 6. Any event that, in the judgment of the State Health Officer, poses a significant public health problem.

**(2) Criteria for reopening a closed shellfish growing area -**

Reopening any area will occur only when the following conditions are met:

- (a) When, based upon analyses of samples of water from the growing area and/or shellfish from the growing area, the threat of a public health hazard no longer exists.

(b) When, based upon analyses of samples of water from the growing area and/or shellfish from the growing area, a threat to public health due to marine biotoxins no longer exists.

(c) When, based upon analyses of samples of water from the growing area, the geometric mean of samples from each sampling station does not exceed a fecal coliform MPN of 14 per 100 milliliters of water, as reported by the Alabama Department of Public Health Bureau of Clinical Laboratories.

(d) When a time interval sufficient to permit natural biological cleaning of the shellfish has elapsed.

(e) When the stage of the Mobile River falls below eight (8) feet at Barry Steam Plant, Bucks, Alabama, as measured and reported by the U.S. Army Corps of Engineers— or, if the river stage reading at Barry Steam Plant is not available, the river stage reading at the most appropriate river gauge as determined by the State Health Officer, that is correlated to the eight (8) feet river level at Barry Steam Plant.

### **(3) Classification of growing waters -**

Classification of growing waters as approved, conditionally approved, restricted, conditionally restricted, prohibited, or temporarily closed shall be made as specified in the document entitled National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, 2004 ~~2009~~ Revision, Sections I and II, promulgated by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, and adopted by reference in Rule 420-3-18-.08 ~~9~~(1).

AUTHORS: Lewis A. Byrd, Ph.D., Christine Collins, and Jeff McCool

STATUTORY AUTHORITY: Sections 9-12-126, 22-2-2(6) and 22-20-5, Code of Alabama, 1975.

HISTORY: Adopted November 19, 2003, filed November 20, 2003, effective date December 25, 2003; replaces Chapter 420-3-18. Repeal filed on November 20, 2003, repeal effective on December 25, 2003.

### **420-3-18-.10 ~~11~~ Repealer.**

Except for those rules promulgated under the authority of Code of Alabama, 1975, Sections 22-21-20, *et seq.*, all rules promulgated by the Board which are in conflict with these rules or any portion thereof are hereby expressly repealed.

AUTHORS: Lewis A. Byrd, Ph.D., Christine Collins, and Jeff McCool

STATUTORY AUTHORITY: Sections 9-12-126, 22-2-2(6) and 22-20-5, Code of Alabama, 1975.

HISTORY: Adopted November 19, 2003, filed November 20, 2003, effective date December 25, 2003; replaces Chapter 420-3-18. Repeal filed on November 20, 2003, repeal effective on December 25, 2003.

**420-3-18-.1112-Severability.**

The parts, section, paragraphs and provisions of this Chapter are severable. Should any portion thereof be ruled unconstitutional or unenforceable by any court, the said ruling shall not offset any other provision of this Chapter not ruled upon.

AUTHORS: Lewis A. Byrd, Ph.D., Christine Collins, and Jeff McCool

STATUTORY AUTHORITY: Sections 9-12-126, 22-2-2(6) and 22-20-5, Code of Alabama, 1975.

HISTORY: Adopted November 19, 2003, filed November 20, 2003, effective date December 25, 2003; replaces Chapter 420-3-18. Repeal filed on November 20, 2003, repeal effective on December 25, 2003.



APPENDIX "A"

Time limits for harvest and refrigeration of shellfish to be sold to the final consumer as shellstock or for half-shell service.

Shellfish harvested for approved post-harvest processing to control *Vibrio* bacteria, or for sale to a permitted shellfish processing facility for the purpose of shucking, **and with tags attached to the harvest container (bag, sack, or box) stating such restricted use**, shall be exempted from the time controls stated in Column 3.

Column 1 MONTH	Column 2 DAILY MAXIMUM WATER TEMPERATURE	Column 3 MAXIMUM TIME ALLOWED ON HARVEST REEF FOR ONE TRIP	Column 4 MAXIMUM TIME ALLOWED FROM LANDING TO DELIVERY TO PERMITTED PROCESSOR	Column 5 *MAXIMUM TIME TO COOL OYSTERS TO °F, from time of receiving
JANUARY	56°F	Set by ADCNR – MRD**	1.5 hours	6 hours to 55°
FEBRUARY	57°F	Set by ADCNR – MRD**	1.5 hours	6 hours to 55°
MARCH	63°F	Set by ADCNR – MRD**	1.5 hours	6 hours to 55°
APRIL	70°F	Set by ADCNR – MRD**	1.5 hours	6 hours to 55°
MAY	78°F	5 hours	1.5 hours	6 hours to 55°
JUNE	85°F	4 hours	1.5 hours	6 hours to 55°
JULY	86°F	4 hours	1.5 hours	6 hours to 55°
AUGUST	86°F	4 hours	1.5 hours	6 hours to 55°
SEPTEMBER	83°F	4 hours	1.5 hours	6 hours to 55°
OCTOBER	74°F	5 hours	1.5 hours	6 hours to 55°
NOVEMBER	66°F	Set by ADCNR – MRD**	1.5 hours	6 hours to 55°
DECEMBER	56°F	Set by ADCNR – MRD**	1.5 hours	6 hours to 55°

"Maximum time allowed on harvest reef for one trip" based on National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, 2009 Revision, Section II, Chapter II, Parts .04 and .05, and allows one hour 30 minutes for transport time from harvest area landing to approved refrigeration. This delivery time is noted in "Maximum time allowed from landing to delivery to permitted processor".

"Daily maximum water temperature" source is Middle Bay Light weather station, maintained by Dauphin Island Sea Lab and is the monthly average (mean) for the years 2007 – 2010.

\*Time limits apply to permitted shellfish processing facilities (dealers) receiving shellstock and shall be included in the permitted shellfish processing facilities' HACCP plan.

\*\*ADCNR – MRD is the Alabama Department of Conservation and Natural Resources, Marine Resources Division. As noted in 420-3-18-.08(5)(d), ADCNR-MRD may set time limits in any month that are less than the maximum allowed by the Alabama Department of Public Health.

APPENDIX A

ALABAMA DEPARTMENT OF PUBLIC HEALTH

APPLICATION FOR A PERMIT

Date \_\_\_\_\_, 20 \_\_\_\_\_

Name of Establishment \_\_\_\_\_

Street Address \_\_\_\_\_ Zip Code \_\_\_\_\_

Name of Owner/Proprietor \_\_\_\_\_

Mailing Address (if different) \_\_\_\_\_

Manager's Name \_\_\_\_\_ Telephone Number \_\_\_\_\_

Type of Permit - Check one:

Crab Plant

Repacker Oyster Plant

Seafood Processor

Shucker/Plant Oyster Plant

Shellstock Dealer

Other: \_\_\_\_\_

I hereby certify that the above statements are true and correct, and I (we) agree to comply with all of the provisions of the State Board of Health Rules, and hereby authorize the State Health Officer, or his representatives to enter upon the premises of the above named establishment for inspection purposes.

Signed \_\_\_\_\_

Title \_\_\_\_\_

<b>FOR OFFICIAL USE ONLY</b>	
Application Approved By: _____	Permit Number Issued: _____
State Health Officer or Representative _____	ISSUE DATE: _____
Date _____	Expiration Date: _____

**APPENDIX B  
ALABAMA DEPARTMENT OF PUBLIC HEALTH  
NSSP STANDARDIZED SHELLFISH PROCESSING PLANT INSPECTION FORM**

<b>Agency Name:</b>		<b>Date:</b>	
<b>Type of Inspection:</b> Pre-Operational ( ) Routine ( ) Follow-up ( ) Standardization ( )		<b>Time Begin:</b>	<b>Time End:</b>
<b>Firm Name:</b>		<b>Certification Number:</b>	
<b>Mailing Address:</b>		<b>Location: (Street Address)</b>	
<b>City / State / Zip Code:</b>		<b>Telephone:</b>	
<b>Plant Representative Name:</b>		<b>Title:</b>	
<b>Inspector Name:</b>		<b>Expiration Date of Standardization:</b>	

Failure to comply with time limits for corrections of deficiencies specified in this report or through subsequent notification may result in cessation of your operation and withdrawal of certification.

Item Number	Remarks	Correction Date

Inspector's Signature:

APPENDIX C

STATE OF ALABAMA )

Establishment Operator \_\_\_\_\_

COUNTY OF )

Establishment Name \_\_\_\_\_

Establishment Address/Location \_\_\_\_\_

Establishment Permit Number \_\_\_\_\_

NOTICE OF INTENT TO SUSPEND/REVOKE PERMIT

WHEREAS, an inspection of your food establishment, \_\_\_\_\_, on \_\_\_\_\_ (Date) disclosed violations of Rules of Alabama State Board of Health Chapter (420- - ), and

WHEREAS, Official Notice of Violation was issued to you on \_\_\_\_\_ (Date) notifying you of corrective action to be taken on/or before \_\_\_\_\_ (Date)

WHEREAS, a reinspection dated \_\_\_\_\_ disclosed that you have not complied with the Official Notice dated \_\_\_\_\_,

THEREFORE, under the provisions of Section 22-20-5, Code of Alabama, 1975 and Chapter (420- - ), I, as Health Officer of \_\_\_\_\_ County, intend to suspend your permit on \_\_\_\_\_ (Date).

You have a period of fifteen (15) days, after receipt of this notice, in which you may make a written request for a hearing with the Health Officer.

ISSUED on this the \_\_\_\_\_ day of \_\_\_\_\_, 20 \_\_\_\_\_.

\_\_\_\_\_  
Health Officer