

Clearinghouse Rule 12-037

DATCP Docket No. 11-R-5  
Clearinghouse No. \_\_\_\_\_

Proposed Hearing Draft  
August 1, 2012

**PROPOSED ORDER  
OF THE WISCONSIN DEPARTMENT OF AGRICULTURE,  
TRADE AND CONSUMER PROTECTION  
ADOPTING RULES**

- 1 The Wisconsin department of agriculture, trade and consumer protection proposes the following
- 2 rule *to amend* ch. ATCP 70, Subchapter IV (title); and *to create ss. ATCP 70.05 (1m) (am),*
- 3 70.07 (8) and 70.21; *relating to* regulation of Wisconsin's Shellfish Shippers and Processors.

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**Analysis Prepared by the Department  
of Agriculture, Trade and Consumer Protection**

This rule would modify ch. ATCP 70, Food Processing Plants, to adopt portions of the National Shellfish Sanitation Program (NSSP) Guide and to allow Wisconsin food processing plants to process and ship shellfish in interstate commerce.

***Statute Interpreted***

Statute Interpreted: s. 97.29 (2), Stats.

***Statutory Authority***

Statutory Authority: ss. 93.07(1), 97.09(4) and 97.29(5), Stats.

***Explanation of Statutory Authority***

DATCP has broad general authority, under s. 93.07 (1), Stats., to interpret laws under its jurisdiction. DATCP also has general authority, under s. 97.09 (4), Stats., to adopt rules specifying standards to protect the public from the sale of adulterated or misbranded foods. DATCP has specific authority, under s. 97.29 (5), Stats., to promulgate rules related to food processing, including food handling and storage, sanitary production and processing, and food sources and labeling.

### ***Related Statutes and Rules***

Related statutes include Ch. 97, Stats., “Food Regulation”, and food safety rules in Chs. ATCP 55 to 88, Wis. Adm. Code.

### ***Plain Language Analysis***

#### **Background**

This proposed rule would modify ch. ATCP 70, Food Processing Plants, to incorporate changes that apply to processing molluscan shellfish (*e.g.*, oysters, clams and scallops). Under current rules, food processing plants in Wisconsin that perform fish processing may receive and process molluscan shellfish from another state for final sale only within Wisconsin. The proposed rule would establish a program that would allow Wisconsin food processing plants, that choose to participate in the program, to process and repack molluscan shellfish for sale in other states and internationally. Thirty-seven other states are members of the Interstate Shellfish Sanitation Conference (ISSC), which is the primary voluntary national organization of state shellfish regulatory officials. Acting under a Memorandum of Understanding with the United States Food and Drug Administration (FDA), the ISSC provides guidance and counsel on matters involving the sanitary control of shellfish. Participating states codify this guidance to regulate the processing of molluscan shellfish in their jurisdictions for interstate commerce and FDA recognizes regulations based on the guidance as suitable for ensuring compliance with the Federal Food, Drug and Cosmetic Act.

#### **Rule Content**

This rule does all of the following:

- Defines terms related to activities associated with the receipt, processing, labeling, and shipping of molluscan shellfish.
- Modifies current rules to include provisions of the National Shellfish Sanitation Program (NSSP) and the guidelines of the Interstate Shellfish Sanitation Conference (ISSC) related to receiving, processing, repacking, labeling and shipping molluscan shellfish for wholesale interstate trade.
- Applies existing standards for facilities, sanitation, and personal hygiene in food processing plants to molluscan shellfish shippers and reprocessors.

- Sets standards for record-keeping consistent with NSSP guidelines.

### ***Fiscal Impact***

This rule will not have a significant fiscal impact on state government and DATCP will absorb any costs with current budget and staff since food processing plants are already regulated by DATCP, This rule will have no fiscal effect on local governments or public utility rate payers. DATCP estimates it will use the equivalent of .1 Full-Time Employee (FTE) to revise this rule, and it will utilize existing staff for that work.

### ***Business Impact***

This rule will have a positive impact on businesses in Wisconsin. Currently, Wisconsin businesses may receive and process molluscan shellfish from out of state, but may only sell these products within Wisconsin. This rule will allow Wisconsin businesses to expand their markets for these products by allowing them to process and sell molluscan shellfish in interstate commerce. In addition, as one of only two states in the Midwest to participate in the program, this rule will provide an incentive to large wholesalers that operate in several states to locate molluscan shellfish processing operations in Wisconsin.

The implementation costs for businesses to participate in this program are expected to be minimal. The provisions of this rule are consistent with general facility and sanitation standards that food processors must already meet. Businesses that choose to participate in the program would not need to modify existing facilities or implement unusual recordkeeping. Participation in the program is voluntary and only businesses that choose to sell molluscan shellfish in interstate commerce would be required to meet the requirements. There will be no additional licensing fees beyond those already required for a food processing plant license.

This rule will primarily benefit large businesses that provide wholesale food products to retail food establishment, restaurants, and other wholesale food industries nationwide. Small businesses are unlikely to participate in this program, with current regulations allowing them to receive and sell molluscan shellfish in their local market sufficient to meet their needs. Any business regardless of size that sells molluscan shellfish products in interstate commerce must meet NSSP requirements. However, a small business that chooses to participate in the program is expected to be able to easily meet program requirements. DATCP would also provide support and guidance to any small business interested in participation to ensure they meet Hazard Analysis Critical Control Points (HACCP) and other regulatory requirements.

### ***Environmental Impact***

This rule will not have any environmental impact.

### ***Federal and Surrounding State Programs***

## **Federal Programs**

There is no federal law related to the transportation and processing of molluscan shellfish. However, FDA administers the National Shellfish Sanitation Program (NSSP), which developed a model ordinance that states may use to develop uniform shellfish regulations. Compliance with the model ordinance is deemed consistent with meeting applicable provisions in the Federal Food, Drug and Cosmetic Act.

## **Surrounding State Programs**

Illinois is the only surrounding state currently participating in this program. Illinois' rules are consistent with this proposed rule. Unlike this proposed rule, Illinois requires molluscan shellfish processors to pay additional fees to participate in the program. Iowa, Michigan, and Minnesota do not participate. These states may be potential customers for molluscan shellfish sold by Wisconsin businesses.

### ***Data and Analytical Methodologies***

DATCP staff reviewed information to determine the extent to which other states have adopted NSSP guidelines and contacted staff in Illinois involved with regulating molluscan shellfish to determine the extent to which their rules are consistent with this proposed rule. DATCP obtained additional information about the applicable requirements through communications and training with FDA officials overseeing the NSSP.

### ***Standards Incorporated by Reference***

This rule incorporates by reference Section IV Chapter III .01 of the Shellfish Industry Equipment Construction Guide, National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish, 2009. Consent will be requested from the Attorney General to incorporate these standards by reference. A copy of this document will be kept on file with DATCP and the Legislative Reference Bureau. The Shellfish Industry Equipment Construction Guide is also available in electronic format at: <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationProgram/ucm070560.htm>

### ***DATCP Contact***

Questions and comments related to this rule may be directed to:

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Rule comments will be accepted up to two weeks after the last public hearing is held on this rule. Hearing dates will be scheduled after this rule is approved by the Board of Agriculture, Trade and Consumer Protection.

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1           **SECTION 1.** ATCP 70.05 (1m) (am) is created to read:

2           ATCP 70.05 (1m) (am) If used, finger cots or gloves shall be:

3           1. Made of impermeable materials, except where the use of such material is  
4 inappropriate or incompatible with the work being done.

5           2. Sanitized at least twice daily or more often if necessary.

6           3. Properly stored until used.

7           4. Maintained in a clean, intact, and sanitary condition prior to use.

8           **SECTION 2.** ATCP 70.07 (8) is created to read:

9           ATCP 70.07 (8) ICE. Ice used to cool or maintain temperature of foods shall be made  
10 from potable water. Ice used to cool or maintain the temperature of ready-to-eat foods shall not  
11 have been previously used for any other purpose. Ice shall be received, handled, and stored in a  
12 manner to prevent contamination or adulteration.

13           **SECTION 3.** Subchapter IV (title) is amended to read:

14           **Subchapter IV – Fish Processing Plants; Molluscan Shellfish Plants; Supplementary**  
15 **Requirements.**

16           **SECTION 4.** ATCP 70.21 is created to read:

17           **ATCP 70.21 Molluscan Shellfish Processing. (1) DEFINITIONS.** In this section:

1 (a) "Certification Number" means the number that conforms to the FDA generated-  
2 number in the ICSSL.

3 (b) "Commingle" means the act of combining different lots of food, including shell-  
4 stock or shucked shellfish.

5 (c) "Heat shock" means the process of subjecting shell-stock to any form of heat  
6 treatment to facilitate shucking, including steam, hot water or dry heat, without substantially  
7 altering the physical or organoleptic characteristics of the shellfish.

8 (d) "ICSSL" means the Interstate Certified Shellfish Shippers List, an FDA e-publication  
9 of shellfish dealers, domestic and foreign, who have been certified by a state or foreign authority.

10 (e) "Licensee" means a plant licensed in Wisconsin for the activities of shell-stock  
11 shipper, shucker-packer, repacker, or reshipper.

12 (f) "Molluscan shellfish" means any edible species of fresh or frozen oysters, clams,  
13 mussels, or scallops, or edible portions of such species, except when the product consists entirely  
14 of the shucked adductor muscle, whether shucked or in one or two shells.

15 (g) "NSSP" means the National Shellfish Sanitation Program.

16 (h) "Potable water" means water supply obtained from a source that meets the  
17 requirements of Ch. NR 809.

18 (i) "Repacker" means any plant, other than the original certified shucker-packer, that  
19 repackages shucked shellfish into other containers.

20 (j) "Repacking shell-stock" means the practice of removing shell-stock from containers  
21 and placing it into other containers.

1 (k) "Reshipper" means a plant that purchases shucked shellfish or shell-stock from shell-  
2 stock shippers, shucker-packers, and repackers and sells the product without repacking or  
3 relabeling to other dealers, wholesalers, or retailers.

4 (l) "Shell-stock" means live molluscan shellfish in the shell.

5 (m) "Shell-stock shipper" means a plant that grows, harvests, buys, repacks and sells  
6 shell-stock, or transports shucked shellfish but may not shuck shellfish or repack shucked  
7 shellfish.

8 (n) "Shucker-packer" means a plant that shucks and packs shellfish. A shucker-packer  
9 may act as a shell-stock shipper or reshipper or may repack shellfish originating from other  
10 certified dealers.

11 (o) "Shucked shellfish" means molluscan shellfish that have one or both shells removed.

12 **(2) PROHIBITED ACTS.** (a) In order to ensure that molluscan shellfish in commerce in this  
13 state is not adulterated or misbranded, as defined in ss. 97.02 and 97.03, Stats., it is unlawful to  
14 cultivate, harvest, process, store, transport, handle, or sell molluscan shellfish or molluscan  
15 shellfish products unless the molluscan shellfish is protected from contamination and unclean,  
16 unhealthy, or insanitary conditions.

17 (b) No licensee shall commingle, sort, or repack shell-stock or shucked shellfish in a way  
18 that loses the identity of the lot.

19 (c) No licensee shall handle, store, process or ship shell-stock or shucked shellfish unless  
20 it is accompanied by an existing tag or label or a tag or label that accurately reproduces all  
21 information on the original tag or label that accompanied the lot or shipment.

22 **(3) COMPLIANCE.** Molluscan shellfish processing operations shall comply with subch. II  
23 and 21 CFR 123.

1           **(4) HAACP PLAN.** (a) Prior to licensing, each applicant shall develop any necessary  
2 HACCP plans to comply with subch. II and 21 CFR 123, addressing food safety hazards in their  
3 operations. HACCP plans will be reviewed and approved by the department as part of the license  
4 application approval process.

5           (b) If a licensee will be using the heat shock process, as defined in s. 70.21(1)(c), Stats.,  
6 the licensee will include the process as a critical control point in the HAACP plan and insure that  
7 heat shock process does not do any of the following:

- 8           1. Change the physical and organoleptic properties of the species.
- 9           2. Kill the shellfish prior to shucking.
- 10          3. Increase microbial deterioration of the shucked shellfish.

11          **(4) EQUIPMENT.** (a) Prior to licensing, the department will review all equipment for  
12 conformance with the Shellfish Industry Equipment Construction Guide, Section IV Chapter III  
13 .01, of the NSSP (2009).

14          Note: A copy of the Shellfish Industry Equipment Construction Guide is on file with the  
15 Department and the Legislative Reference Bureau. You may also obtain a copy  
16 from the following website: [http://www.fda.gov/Food/FoodSafety/Product-](http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationProgram/ucm070560.htm)  
17 [SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationPro-](http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationProgram/ucm070560.htm)  
18 [gram/ucm070560.htm](http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationProgram/ucm070560.htm).

19           (b) The licensee will provide shucking blocks which may easily be removed from the  
20 shucking bench, unless the block is an integral part of the bench.

21          **(5) TRUCKS ONLY LICENSEE.** A licensee whose facilities consist of trucks only shall have  
22 either:  
23

24          (a) A licensed facility for the storage of shellfish.



1 (b) Arrangements with an appropriately licensed facility for the storage of shellfish and a  
2 permanent business address at which records are maintained and inspections of those records can  
3 be performed.

4 **(6) TRANSPORTATION.** (a) *Trucks or other vehicles used to transport shell-stock.*

5 1. The harvester, or person who transports shell-stock from the harvester to the original  
6 licensee, shall assure that all trucks used to transport shell-stock are properly constructed,  
7 operated, and maintained to prevent contamination, deterioration, and decomposition of shell-  
8 stock.

9 2. Storage bins on trucks or other vehicles used in the transport of shell-stock for direct  
10 marketing shall be kept clean with potable water; and provided with effective drainage.

11 3. Shell-stock shall be transported in refrigerated trucks when the shell-stock have been  
12 previously refrigerated or when ambient air temperature and time of travel are such that  
13 unacceptable bacterial growth or deterioration may occur.

14 4. A pre-chilling truck or other vehicle is required when ambient air temperatures are  
15 such that unacceptable bacterial growth or deterioration may occur.

16 5. When any mechanical refrigeration unit is used, the unit shall be:

17 a. Equipped with automatic controls; and

18 b. Capable of maintaining the ambient air temperature in the storage area at temperatures  
19 of 45° F (7.2°C) or less.

20 6. No animals shall be allowed in any part of any truck or other vehicle where shell-stock  
21 is stored.

22 7. Transportation agents or common carriers used by a shipper are not required to be  
23 certified.

1           (b) *Transportation storage containers.*

2           1. Containers used to transport shell-stock shall be:

3           a. Clean;

4           b. Constructed of food-contact grade material; and

5           c. Free of any substance, material or organisms that may cause the shell-stock to become  
6 contaminated or adulterated.

7           2. Any container that will be used more than one time to store and transport shell-stock  
8 shall be:

9           a. Constructed to allow for easy cleaning;

10          b. Maintained to prevent product contamination; and

11          c. Cleaned with potable water and a detergent, other cleaning chemical or sanitizer  
12 acceptable for food contact surfaces and used according to the manufacturer's specifications.

13          (c) *Shipment protection from cross contamination.*

14          1. When the entire shipment consists of molluscan shellfish products only, except for  
15 bulk shipments, shell-stock shipments shall be shipped on pallets. If the conveyance does not  
16 have a channeled floor, pallets shall be used for all shellfish.

17          2. When the conveyance has mixed shipments, the molluscan shellfish shall be shipped  
18 only when all of the following apply:

19          a. Molluscan shellfish products are protected from contamination by the other cargo;

20          b. All cargo is placed on pallets; and

21          c. No other cargo is placed on or above the molluscan shellfish unless all cargo is packed  
22 in sealed, crush resistant, waterproof containers.

23          (d) *Shipping times.*

1           1. When the expected shipping time for any molluscan shellfish or shell-stock is four  
2 hours or less, the shipper shall be responsible for the following:

3           a. Using ice or mechanical refrigeration to maintain the required temperature of the  
4 molluscan shellfish or shell-stock;

5           b. If the shipper uses mechanical refrigeration units, the units shall be:

6                 i. Equipped with automatic controls; and

7                 ii. Capable of maintaining the ambient air in the storage area at temperatures of  
8 45°F (7.2°C) or less;

9           c. The shipper is not required to provide thermal recorders during shipment; and

10           d. Lack of ice or other acceptable types of refrigeration shall be considered an  
11 unsatisfactory shipping condition.

12           2. When the expected shipping time is greater than four hours, the shipper shall ship all  
13 shellfish in accordance with the following conditions:

14           a. The product shall be shipped in mechanically refrigerated conveyances which are  
15 equipped with automatic controls and capable of maintaining the ambient air in the storage area  
16 at temperatures of 45° F (7.2°C) or less or containers with an internal ambient air temperature  
17 maintained at or below temperatures of 45°F (7.2°C) or less;

18           b. Unless the shipper has an approved HACCP plan with an alternate means of  
19 monitoring time-temperature, the shipper shall assure that a suitable time-temperature recording  
20 device accompanies each shipment of shellfish;

21           c. The shipper shall note the date and time shown on the temperature-indicating device;

1 d. Each shipment receiver shall record the date and time shown on the temperature-  
2 indicating device when the shipment is received and the doors of the conveyance or the  
3 containers are opened;

4 e. The final shipment receiver shall keep the time-temperature recording chart or other  
5 record of time and temperature in a file and shall make it available to the department upon  
6 request; and

7 f. An inoperative temperature-indicating device shall be considered a failure to provide  
8 the required recording device.

9 **(7) SHIPPING DOCUMENTS AND TRANSACTION RECORDS. (a) *Shipping documents.***

10 1. Each shellfish shipment shall be accompanied by a shipping document.

11 2. The shipping document shall contain:

12 a. The name, address, and license number of the shipping plant;

13 b. The name and address of the receiving licensee; and

14 c. The kind and quantity of the shellfish product.

15 3. The licensee shall do all of the following:

16 a. Maintain in a file a copy of the completed shipping document; and

17 b. Make the shipping document available to the department upon request.

18 4. If the shipment is subdivided to different licensees, each receiving licensee shall  
19 maintain records sufficient to trace the portion received back to the original shipment.

20 5. Shell-stock that is shipped bearing a restricted use tag shall only be shipped to a  
21 licensed shucker-packer and shall include specific language detailing the intended use of the  
22 shell-stock.

23 **(b) *Transaction records.***

- 1           1. Each licensee shall have a business address at which transaction records are  
2 maintained.
- 3           2. Each licensee shall maintain complete, accurate, and legible records of the required  
4 information in a form specified by the department.
- 5           3. Transaction records shall be sufficient to:
- 6           a. Document that the shellfish are from a source authorized under this section;
- 7           b. Permit a container of shellfish to be traced back to the specific incoming lot of shucked  
8 shellfish from which it was taken; and
- 9           c. Permit a lot of shucked shellfish or a lot of shell-stock to be traced back to the growing  
10 area(s), date(s) of harvest, and if possible, the harvester or group of harvesters.
- 11          4. Purchases and sales shall be recorded:
- 12          a. In a permanently bound ledger book; or
- 13          b. Using other recording methods acceptable to and authorized by the department.
- 14          5. The transaction records shall be retained:
- 15          a. In the case of fresh shellfish, for a minimum of one year; and
- 16          b. In the case of frozen shellfish, for at least two years or the shelf-life of the product,  
17 whichever is longer.
- 18          6. If computer records are maintained, the department shall approve the format and  
19 availability for inspection by the department.
- 20          **(8) SHELL-STOCK IDENTIFICATION.** (a) The licensee shall buy shellfish only from sources  
21 listed in the current ICSSL.
- 22          (b) The licensee shall keep the harvester's tag affixed to each container of shell-stock  
23 until the container is either shipped or emptied to wash, grade or pack the shell-stock.

- 1 (c) The licensee's tags shall:
- 2 1. Be durable, waterproof, and sanctioned by the administrator prior to use;
- 3 2. Be at least 13.8 square inches;
- 4 3. Contain the following indelible, legible information in the order specified below:
- 5 a. The licensee's name, address and license number;
- 6 b. The original shell-stock shipper's license or certification number;
- 7 c. The date of harvest;
- 8 d. The most precise identification of the harvest location as is practicable including the
- 9 initials of the state of harvest, and the designation of the growing area by indexing,
- 10 administrative or geographic designation. If growing areas have not been indexed then an
- 11 appropriate geographical or administrative designation must be used:
- 12 e. When the shell-stock has been transported across state lines and placed in wet storage
- 13 in a licensee's operation, the statement: "This product is a product of (name of state) and was
- 14 wet stored at (facility certification number) from (date) to (date)";
- 15 f. The type and quantity of shell-stock;
- 16 g. The following statement in bold capitalized type on each tag **"THIS TAG IS**
- 17 **REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED**
- 18 **AND THEREAFTER KEPT ON FILE FOR NINETY DAYS"**; and
- 19 h. All shell-stock intended for raw consumption shall include a consumer advisory. The
- 20 following statement, or an equivalent statement, shall be included on all shell-stock; *"Retailers,*
- 21 *inform your customers of the following:" "Consuming raw or undercooked meats, poultry,*
- 22 *seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have*
- 23 *certain medical conditions"*.

1 (d) When both the licensee and harvester tags appear on the container, the dealer's tag is  
2 not required to duplicate the information on the harvester's tag.

3 (e) If the shell-stock is removed from the original container, the tag on the new container  
4 shall meet the requirements in par. (c).

5 **(9) BULK TAGGING SHELL-STOCK LOTS FOR SALES BETWEEN LICENSEES.** (a) When a single  
6 lot of shell-stock is sold, multiple containers may be used on a wrapped pallet, in a tote, in a net  
7 bailer, or other container and the unit tagged with a single tag in accordance with sub. (8) (c).

8 (b) This bulk tagging provision shall not apply to sales to re-shippers;

9 (c) The shipment must be accompanied by a transaction record stating the name of the  
10 consignee who must be a certified dealer;

11 (d) In addition to the information required in sub. (8) (c), the unit tag shall also include:

12 1. A statement that "All shell-stock containers in this lot have the same harvest date and  
13 area of harvest"; and

14 2. Number of individual containers in the unit.

15 **(10) TAGGING OF SHELL-STOCK LOTS DURING INTERMEDIATE PROCESSING.** (a) When the  
16 shell-stock is removed from the original container, the licensee shall:

17 1. Keep the harvester tag for 90 days;

18 2. Keep track of the growing area and date of harvest for shell-stock; and

19 3. Maintain the lot identity of all shell-stock during any intermediate stage of processing.

20 (b) A licensee receiving bulk tagged lots of shell-stock must have an intermediate  
21 processing plan approved by the department to ensure that each lot of shell-stock is kept separate  
22 and identified in a way which prevents commingling or misidentification.

1 (c) In order for a licensee to tag a lot container of shell-stock, in lieu of meeting the  
2 requirement in sub. (8) (c) for a harvester or licensee tag on each individual container, the  
3 licensee shall have an intermediate processing plan approved by the department which  
4 establishes the procedures the dealer shall use to tag the lot during the washing, packing or  
5 staging of molluscan shellfish.

6 (d) If shell-stock is sold in bulk, the licensee shall provide a transaction record prior to  
7 shipment. This transaction record shall contain all the information required in paragraph (7) (b)  
8 3., with the addition of the name of the consignee.

9 **(11) LABELING SHUCKED SHELLFISH.** (a) The licensee shall maintain lot integrity when  
10 shucked shellfish are stored using in-plant reusable containers

11 (b) If the licensee uses returnable containers to transport shucked shellfish between plants  
12 for the purpose of further processing or packing, the returnable containers are exempt from the  
13 labeling requirements in this rule. When returnable containers are used, the shipment shall be  
14 accompanied by a transaction record containing:

- 15 1. The original shucker-packer's name and license or certification number;
- 16 2. The shucking date; and
- 17 3. The quantity of shellfish per container and the total number of containers.

18 (c) If the licensee uses master shipping cartons, the master cartons are exempt from these  
19 labeling requirements when the individual containers within the carton are properly labeled.

20 (d) The licensee shall label each individual package containing fresh or frozen shucked  
21 shellfish meat in a legible and indelible form in accordance with 21 CFR 161.30 and 161.136.

22 (e) Each package containing less than 64 fluid ounces of fresh or frozen shellfish shall  
23 have:



- 1           1. The plant license number on the label; and
- 2           2. A “Sell by date” which provides a reasonable subsequent shelf-life or the words “Best
- 3 if used by” followed by a date when the product would be expected to reach the end of its shelf-
- 4 life. The date shall consist of the abbreviation for the month and number of the day of the month.
- 5 For frozen shellfish, the year will be added to the date.

6           (f) Each package containing more than 64 fluid ounces of fresh or frozen shellfish shall

7 have:

- 8           1. The plant license number on the label; and
- 9           2. A “Date shucked” which shall:
- 10           a. For fresh shellfish, consist of the number of the day of the year or the month and the
- 11 number of the day of the month;
- 12           b. For frozen shellfish, include the year; and
- 13           c. Appear on the lid and sidewall or bottom of disposable containers.

14           (g) If the licensee thaws and repacks frozen shellfish, the licensee shall label the shellfish

15 container as previously frozen.

16           (h) The licensee shall provide all label information in a legible and indelible form.

17           (i) If the licensee elects to repack molluscan shellfish, the licensee shall pack and label all

18 shellfish in accordance with this subsection except that the original date of shucking shall be

19 used in establishing the sell by date.

20           (12) RECEIVING. (a) *Shipment acceptability*. Fresh molluscan shellfish shipments shall be

21 considered acceptable when all of the following apply:

- 22           1. Each shipment is properly identified with tags and shipping documents;

1           2. All shell-stock in the shipment is alive and cooled to an internal shell-stock body  
2 temperature of 50° F (10°C) or less;

3           3. All shucked shellfish in the shipment is cooled to a temperature of 45° F (7.2°C) or  
4 less;

5           4. The time-temperature indicating device shows that the ambient air temperature has  
6 exceeded 45°F (7.2°C) but the shell-stock internal body temperature is 50° F (10°C) or less; and

7           5. All other conditions of shipment in this chapter are met.

8           (b) *Shipment rejection.*

9           1. Any shipment of molluscan shellfish shall be rejected when any of the following  
10 apply:

11           a. Any molluscan shellfish are not properly identified with tags or shipping documents.

12           b. Any internal shell-stock body temperature exceeds 60°F (15.6°C).

13           c. Any shucked shellfish temperature exceeds 50°F (10°C).

14           d. Any frozen shellfish is thawed.

15           e. The department determines for any other reason that the product is adulterated or  
16 unsafe for human consumption.

17           2. The department shall notify the shipper, the licensee, and the state where the shipment  
18 originated, of the shipment's rejection.

19           (c) *Receiving molluscan shellfish.* The licensee receiving molluscan shellfish shall do all  
20 of the following:

21           1. Reject or discard any molluscan shellfish shipments which:

22           a. Do not originate from a licensed harvester or dealer listed in the current ICSSL; and

1           b. Are unwholesome or adulterated, inadequately protected, or whose source cannot be  
2 identified;

3           2. Place molluscan shellfish under temperature control within 2 hours after receipt from  
4 the harvester, or when the shipper is also the harvester, when shell-stock reaches the shipper's  
5 facility;

6           3. Ensure that once shell-stock is placed in storage under temperature control and until  
7 sale to the processor or final consumer, it shall be:

8           a. Iced or placed and stored in a storage area or conveyance maintained at 45° F (7.2° C)  
9 or less;

10          b. Not permitted to remain without ice, mechanical refrigeration or other approved  
11 methods of refrigeration for more than two hours at points of transfer such as loading docks; and

12          c. Not permitted to be placed in wet storage; and

13          4. Ensure that frozen shellfish remains frozen.

14          **(13) PROCESSING.** (a) *Shell-stock processing.*

15          1. For shell-stock refrigerated prior to shucking, chill shucked meats to an internal  
16 temperature of 45° F (7.2°C) or less within four hours of removal from refrigeration.

17          2. Where an employee works in both the shucking and packing activities, the employee  
18 shall wash their hands thoroughly after entering and before each shucking or packing activity.

19          3. Ensure that shell-stock is reasonably free of sediment without placing shell-stock in  
20 containers with standing water for the purposes of washing shell-stock or loosening sediment.

21          4. Cull to remove any dead or damaged shell-stock.

22          5. Shell-stock lots may not be commingled during shucking.

23          6. Shell-stock packing activities must conform to applicable food additive regulations.

- 1           7. Not allow the use of dip buckets for hand or knife rinsing or sanitizing.
- 2           8. Not have on the premises any usable containers or container covers bearing a number  
3 different from the one issued for those premises.
- 4           9. A plant that uses heat shock to prepare shell-stock for shucking shall:
- 5           a. Post the schedule for the heat shock process in a conspicuous location;
- 6           b. Make sure all responsible persons are familiar with the requirements;
- 7           c. Cool all hot dipped shell-stock immediately after the heat shock process by either  
8 dipping in an ice bath or using flowing potable water; and
- 9           d. If a heat shock water tank is used, and the water is maintained at or above 140°F  
10 (60°C), the plant shall completely drain and flush the tank at three hour intervals or more often if  
11 necessary so that all mud and debris in the dip tank are eliminated. If the temperatures are  
12 maintained below 140°F (60°C), the plant shall completely drain and flush the tank at not less  
13 than three hour intervals.
- 14           ***(b) Shucked shellfish processing.***
- 15           1. If heat shock is used, once heat shocked shell-stock is shucked, cool the shucked  
16 shellfish meats to 45° F (7.2°C) or less within two hours after the heat shock process.
- 17           2. Wash, blow, and rinse all specified shucked shellfish meats in accordance with 21 CFR  
18 161.130.
- 19           3. Shucked shellfish meats must be thoroughly drained, cleaned as necessary, and packed  
20 promptly after delivery to the packing room.
- 21           4. Completely empty shucking buckets at the packing room so that no overage is returned  
22 to the shucker.

1           5. Store shucked and packed shellfish in covered containers at an ambient air temperature  
2 in the storage area of 45° F (7.2°C) or less.

3           6. Store packaged shellfish, if they are to be frozen, at an ambient temperature of 0°F (-  
4 18°C) or less; and frozen solid within twelve hours following the initiation of freezing.

5           (c) *Re-packing shucked shellfish.*

6           1. Maintain repacked fresh or thawed shucked shellfish, including any portion of frozen  
7 shellfish for repacking, at 45° F (7.2°C) or less.

8           2. Store repacked, shucked shellfish in covered containers at an ambient air temperature  
9 of 45° F. (7.2° C.) or less.

10       **SECTION 5. EFFECTIVE DATE AND INITIAL APPLICABILITY.** This rule take effect on the first  
11 day of the month following publication in the Wisconsin administrative register, as provided in s.  
12 227.22 (2) (intro), Stats.

Dated this \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_.

WISCONSIN DEPARTMENT OF AGRICULTURE,  
TRADE AND CONSUMER PROTECTION

By: \_\_\_\_\_

Ben Brancel  
Secretary