



State of Wisconsin
Governor Scott Walker

Department of Agriculture, Trade and Consumer Protection
Ben Brancel, Secretary

DATE: January 28, 2013

TO: The Honorable Mike Ellis
President, Wisconsin State Senate
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The Honorable Robin Vos
Speaker, Wisconsin State Assembly
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FROM: Ben Brancel, Secretary
Department of Agriculture, Trade and Consumer Protection

**SUBJECT: Food Processing Plants, ch. ATCP 70; Final Draft Rule
(Clearinghouse Rule #12-037)**

Introduction

The Department of Agriculture, Trade and Consumer Protection (“DATCP”) is transmitting this rule for legislative committee review, as provided in s. 227.19 (2) and (3), Stats. DATCP will publish notice of this referral in the Wisconsin Administrative Register, as provided in s. 227.19 (2), Stats. This rule adopts portions of the National Shellfish Sanitation Program (NSSP) Guide that will allow Wisconsin food processing plants to process and ship molluscan shellfish in interstate commerce.

Background

This proposed rule modifies ch. ATCP 70, Food Processing Plants, to incorporate changes that apply to processing molluscan shellfish (e.g., oysters, clams, mussels and certain forms of scallops). Under current rules, food processing plants in Wisconsin that perform fish processing may receive molluscan shellfish from another state and process the shellfish 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 shellfish program, to process and repack molluscan shellfish for sale in other states and internationally. Thirty-eight other states participate in 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),

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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, storage, and shipping of molluscan shellfish.
- Modifies current rules to include provisions of the National Shellfish Sanitation Program (NSSP) and the guidelines of the ISSC related to receiving, processing, repacking, labeling, storage, and shipping molluscan shellfish for wholesale interstate and intrastate trade.
- Applies existing standards for facilities, sanitation, and personal hygiene in food processing plants to molluscan shellfish shippers, reshippers and reprocessors.
- Clarifies that NSSP guidelines for ice and hand-coverings are applicable to food processing plants.
- Sets standards for critical control points, critical limits, record-keeping and traceability, consistent with NSSP guidelines.

Analysis and Supporting Documents Used to Determine Effect on Small Business or in Preparation of the Economic Impact Analysis

This rule will not have a significant fiscal impact on state government and DATCP will absorb any costs with current budget and staff because food processing plants are already regulated by DATCP. This rule will have no fiscal effect on local governments or public utility rate payers. To determine the potential economic impact of the rule, the department posted the rule on the website and contacted appropriate organizations to solicit information and advice from businesses, business sectors, associations, local governmental units, and individuals that may be affected by the proposed rule.

Effect on Small Business

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 shellfish by allowing them to process and sell molluscan shellfish in interstate commerce. In addition, this rule may provide an incentive to large Wisconsin wholesalers that also operate in Iowa, Minnesota, and the Dakotas 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 extensively modify existing facilities or implement unusually burdensome 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 establishments, restaurants, and other wholesale food industries nationwide. It is unlikely that a large number of small businesses will participate in this program, because current regulations allow them to receive and sell molluscan shellfish in their local market areas. Any business, regardless of size, that sells molluscan shellfish products in interstate commerce must meet NSSP requirements. A small business that chooses to participate in the program is expected to be able to easily meet program requirements. In addition, 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.

Small Business Regulatory Review Report

The Small Business Regulatory Review Board did not issue a report on this rule.

Public Hearings

DATCP held three public hearings on the following dates and locations:

October 9, 2012	Madison
October 11, 2012	Waupaca
October 12, 2012	Green Bay

Following the public hearings, the hearing record remained open until October 25, 2012 for additional written comments. No one attended the public hearings. The department received

written and oral comments from FDA, represented by two Regional Shellfish Specialists (See Appendix A). FDA recommended the addition of provisions related to equipment, sanitation, and processing requirements beyond what is already required in ATCP 70. FDA also recommended including details associated with inspection frequencies, the certification process for shellstock shippers, shucker-packers, repackers, reshippers and depuration processors; detailed HACCP plan requirements for shellfish processors; lot identification to be used when shellstock undergoes intermediate processing or is sold from dealer to dealer; lot identification of in-shell products; and shellfish processors' and DATCP's responsibilities when an illness outbreak is linked to shellfish. These comments led to revision of the hearing draft.

Changes from the Hearing Draft

The rule was revised to make technical changes in response to comments received from the FDA. DATCP also made changes suggested by the Legislative Council Rules Clearinghouse.

Summary of Factual 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 has been received 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>