



State of Wisconsin
Governor Tony Evers

Department of Agriculture, Trade and Consumer Protection
Bradley M. Pfaff, Secretary

Report From Agency

DATE: March 12, 2019

TO: The Honorable Roger Roth
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The Honorable Robin Vos
Speaker, Wisconsin State Assembly
Room 217 West
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FROM: Brad Pfaff, Secretary
Department of Agriculture, Trade and Consumer Protection

SUBJECT: Food Processing Plants, Ch. ATCP 70; Final Draft Rule (Clearinghouse Rule #17-073)

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.

Background

This rule repeals and recreates Wis. Admin Code ch. ATCP 70 (Food Processing Plants). The rule is necessary to update Wisconsin’s food processing plant standards, to incorporate new federal requirements designed to improve the nation’s food safety system, and to clarify requirements for two specific types of food processing plants, commissaries supporting vending machines and micro-markets.

Statutes Interpreted

Statutes Interpreted:

- Wis. Stat. § 97.29, “Food processing plants.”
- Wis. Stat. § 97.30, “Retail food establishments.”

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- Wis. Stat. § 97.34, “Bottled drinking water and soda water beverage; standards; sampling and analysis.”
- Wis. Stat. § 97.42, “Compulsory inspection of livestock or poultry, and meat or poultry products.”
- Wis. Stat. § 97.605, “Lodging and vending licenses.”
- Wis. Stat. § 97.61, “Vending machine commissary outside the state.”

Explanation of Statutory Authority

The Wisconsin Department of Agriculture, Trade and Consumer Protection (“DATCP”) has broad general authority, under Wis. Stat. § 93.07 (1), to adopt rules to implement programs under its jurisdiction. DATCP also has general authority under Wis. Stat. § 97.09 (4) to adopt rules specifying standards to protect the public from the sale of adulterated or misbranded foods. DATCP has specific authority, under Wis. Stat. § 97.29 (5), to adopt rules establishing fees; setting facility construction and maintenance standards; and setting rules for the design, installation, maintenance, and cleaning of equipment and utensils; personnel sanitation; food handling and storage; sanitary production and food processing; and food sources and food labeling.

Related Statutes and Rules

21 CFR 117, Current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventive Controls for Human Food, is critically integrated with the current rule. Related Wisconsin administrative code include rules pertaining to retail food establishments (Wis. Admin. Code ch. ATCP 75 and the Appendix to that rule); dairy plants (Wis. Admin. Code ch. ATCP 65), food warehouses (Wis. Admin. Code ch. ATCP 71), and meat and poultry establishments (Wis. Admin. Code ch. ATCP 55).

Rule Content

The proposed rule updates Wis. Admin. Code ch. ATCP 70 by adopting certain federal regulations that implement the requirements of the federal Food Safety Modernization Act (“FSMA”). Specifically, the revised rule incorporates multiple subparts of the recently issued 21 CFR 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk based Preventive Controls for Human Food*, that has superseded 21 CFR 110, *Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding Human Food*. These federal regulations pertain to preventive food safety systems that have already been referenced in Wis. Admin. Code chs. ATCP 65 (Milk and Milk Products) and ATCP 71 (Food Warehouses and Milk Distributors). Since the majority of Wisconsin federally-registered food facilities are already subject to this federal rule and licensed as food processing plants, this rule features similar referencing for the sake of consistency. This revision also ensures that the requirements for Wisconsin-licensed food processing plants, which are not subject to the federal rule, are clearly articulated.

The transfer of Food Safety and Recreational License Unit (FSRL) from the Department of Health Services (DHS) to DATCP’s Division of Food Safety necessitated the merger of two food safety regulatory systems. One regulatory paradox was particularly in need of resolution: Restaurant operators were not allowed to wholesale food under the DHS regulation, while retail food establishment operators

under DATCP's authority could engage in a limited amount of wholesaling without holding a food processing plant license. By statute, restaurants are now licensed as retail food establishments and therefore also enjoy the same limited ability to wholesale food. In the current rule-making process, DATCP initially proposed to retain certain existing limits and requirements from its prior rule concerning food processing activities for wholesale conducted by a retail food establishment. The Board of Agriculture, Trade and Consumer Protection ("Board") approved a draft rule reflecting this philosophy at its January 2018 meeting. This final draft also for the first time included definitions of "wholesale" and "retail." However, after the Board meeting, it became apparent that industry participants felt that less restrictive limits and definitions would still adequately protect public health.

As a result of this feedback, DATCP opted to form a work group comprised of industry personnel and local health department agent program representatives. They were tasked with further revision of the rule. During deliberations, the work group concluded that the safety of many food processing activities for wholesale, when performed by retail food establishments, could be ensured by compliance with Wis. Admin. Code ch. ATCP 75 and the appendix thereto, the Wisconsin Food Code. Thus, recourse to the requirements of Wis. Admin. Code ch. ATCP 70 was unnecessary. The work group recognized that additional training would be needed for local health department agent personnel, as well as DATCP sanitarians, who were assigned to retail food establishments performing these food processing activities for wholesale. DATCP, as part of its ongoing mission to thoroughly train food safety personnel at the state and local level, is committed to providing both the necessary initial training and ongoing technical support.

The work group's efforts culminated in this newly revised final draft of Wis. Admin. Code ch. ATCP 70 that redefines "wholesale" and "retail", clarifies the exemption for retail food establishments from the requirement to hold a food processing plant license when conducting limited (not more than 25% of gross annual food sales) food processing activities for wholesale, and redraws the boundaries delimiting the permissible types of food processing activities for wholesale. Perhaps the most salient change to the regulatory territory is that a transfer of food between two food processing plants or retail food establishments will not be regarded as wholesaling, as long the two businesses involved are operated by the same licensed entity, and the firm transferring the food does not relinquish control of the food. This change reflects current guidance by the United States Food and Drug Administration ("FDA") and the United States Department of Agriculture, Food Safety and Inspection Service.

The revised definitions of "wholesale" and "retail" reflect industry practice and the current interpretation of these terms in the marketplace, as well as FDA's recent guidance and its sanction of industry practice. The revised definitions also appear in the pending revision to Wis. Admin. Code ch. ATCP 75 (Retail Food Establishments). The revised rule continues to prohibit retail food establishments from processing canned low-acid or acidified foods for wholesale without holding a food processing plant license and complying with Wis. Admin. Code ch. ATCP 70 requirements. DATCP expects these updates to promote clarity and uniformity and to facilitate enhanced business opportunities for retail food establishments in Wisconsin.

Another theme of early discussions of the proposed rule revision was the question of whether additional regulations were necessary to ensure sanitary conditions in food processing plants sharing a building with a residence. The initial draft of the revised rule forbade the licensing of any new or remodeled food processing plant in this context. However, feedback from the working group argued against an outright

ban or other additional regulation to ensure adequate separation between residential and processing activities or access for DATCP inspections. Accordingly, the proposed revision was deleted. In addition to addressing these complex issues, the revised rule propounds several other changes. The rule adopts the Model Ordinance for molluscan shellfish, now marine shellfish, with the Ordinance replacing all of Wis. Admin. Code s. ATCP 70.21 except for the existing subsection addressing illnesses and outbreaks linked to shellfish. This modification will keep Wisconsin's regulations current with national standards for shellfish processing and marketing.

This revised rule also:

- Updates and clarifies language pertaining to the standards for and testing of operations water and ingredient water used in the various bottling and processing operations in Wisconsin, as well as finished product sampling and analysis for bottling establishments.
- Expands the scope of bottling rules to encompass more than bottled water and soda, thereby keeping pace with the expansion of this rapidly changing and innovative segment of the bottling industry.
- Removes the regulatory floor of \$25,000 in sales for food processing plants that are required to pay the canning license fee surcharge, in order to reflect the considerable time that has proved to be necessary for DATCP staff to provide information, consultation, and service to persons manufacturing small amounts of canned foods.
- Protects the consistent quality of the Wisconsin "brand" by eliminating many long-expired "grandfather clause" dates in the existing rule and replacing them with language relating to achieving compliance with structural standards in existing buildings.

Public Hearings

The Department held five public hearings around the state. Following the public hearings, the hearing record remained open until December 15, 2017. The following is a summary of the hearing attendees, including those who submitted written comments.

Public Hearing Summary

Date and Time	Location
Thursday, November 16, 2017 9:30 a.m. to 3:30 p.m.	Mead Public Library, Rocca Room 710 N. 8 th Street, Sheboygan, WI
Wednesday, November 22, 2017 9:30 a.m. to 3:30 p.m.	Division of Public Health Regional Office 2187 N. Stevens Street, Rhineland, WI
Friday, November 24, 2017 9:00 a.m. to 3:30 p.m.	Prairie Oak State Office Building, Room 106 2811 Agriculture Drive, Madison, WI
Friday, December 1, 2017 9:30 a.m. to 3:30 p.m.	Wisconsin State Office Building, Room 129 718 W. Clairemont Ave., Eau Claire, WI
Friday, December 8, 2017 9:30 a.m. to 3:30 p.m.	Shawano Public Library 128 South Sawyer Street, Shawano, WI

List of Comments and Department Response

The following is a complete list of the persons who attended the public hearings or submitted written comments on the proposed rule during the public comment period, the position taken and/or comments submitted by the commenter, and the Department’s response.

Commenter #	Name and Address	Position Taken (Support or Opposed)	Method of Commenting and Department Actions Taken
1. 11/27/17	Shawn K. Stevens Representing the Food Industry Council, LLC. 11414 West Park Place, Suite 202 Milwaukee, WI 53224 (920) 698-2561 stevens@foodindustry council.com	Suggested revisions based on the 4 th Edition <i>Fish and Fishery Product Hazards and Controls Guidance</i> to the rules involving reduced-oxygen packaged fish products as follow: 1) Request that Wisconsin remove the requirement to hold fish that is reduced-oxygen packaged at or below 38 degrees F., and allow it to be held at 40 degrees F. or below.	Provided Written Comments – The Department agrees and has amended the sections on Fish in ATCP 70 (Sections 70.44 and 70.46) to reflect the science in the 4 th Edition of the <i>Fish and Fishery Products Hazards and Controls Guidance</i> . The language was amended to account for the lack of hazard in hot-smoked fish and allows industry to use the Guidance document to address reduced-oxygen packing issues. However, language was maintained the 38 degree F. holding temperature as proposed on p. 258 of the Guidance document for raw fish or cold-smoked fish that is reduced-oxygen packaged and held at refrigeration temperatures.
2. 12/1/17	Kristina Burning 57805 North Rd. Eau Claire, WI 54701	None – Present at December 1, 2017 Hearing	Did not wish to testify. Looking for information.
3. 12/1/17	Chelsea A. Peabody 100 Colenan St. W Rice Lake, WI 54868 McCain Foods USA, Inc.	None – Present at December 1, 2017 Hearing	Did not wish to testify. Looking for information.
4. 12/1/17	Stephen Bant 2699 23 rd Street, Rice Lake, WI 54868 McCain Foods USA, Inc.	Did not wish to speak – Registered as taking no position at December 1 st Hearing.	Did not wish to testify. Looking for information.
5. 12/1/17	Corey P. Sukalich 723 Creekwood Lane West Bend, WI 53095 Herbal Symphony (a business) and himself listed as the owner/operator	Spoke – Opposed the proposal Mr. Sukalich stated he has run his business from his home for 8 years and strongly objects to provisions in the proposed ATCP 70 that would require businesses currently located in homes to : 1.) Upgrade the facilities to require separation. 2.) Not allow currently home-based facilities to expand in the homes.	The Department initially disagreed with this comment and planned to prohibit issuance of a new food processing plant license to a business sharing a building with a residence. However, a work group convened by the Department and comprised of industry and local health department agent partners concluded that the existing rule language requirements for separation between food processing and residence areas in a building were adequate to protect public health. Therefore the planned prohibition was removed from the final rule draft.

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		<p>3.) Not allow future businesses to be licensed in homes so that if he moved, he could not be licensed in a home at a new location.</p> <p>Mr. Sukalich desires an exemption for an unspecified disability or perhaps a dollar/volume - based exemption based on perceived risk of product. He cites possible economic and physical hardship.</p>	
6. 12/1/17	<p>Joy Durbin 723 Crestwood Drive West Bend, WI 53095 Herbal Symphony (a business) and herself listed as the owner/operator</p>	<p>Spoke – Opposed the proposal</p> <p>Ms. Durbin spoke in favor of allowing small businesses to operate from the home. She made the following points:</p> <ol style="list-style-type: none"> 1) Small businesses operating from the home are a necessary starting point for entrepreneurs in the State of Wisconsin. 2) Small businesses are vital to the State’s economic growth. 3) “Many” of her colleagues started as small businesses from homes. 4) Products produced by small, home-based businesses are important to local retailers, co-ops, and local communities in general. 5) She fears that eliminating the option of operating from the home will eliminate “mom and pop” stores. 6) She cited enthusiastic support from the City of West Bend. 7) Suggest she may move out of state if she can no longer expand or license a new business at home. 	<p>The Department initially disagreed with this comment and planned to prohibit issuance of a new food processing plant license to a business sharing a building with a residence. However, a work group convened by the Department and comprised of industry and local health department agent partners concluded that the existing rule language requirements for separation between food processing and residence areas in a building were adequate to protect public health. Therefore the planned prohibition was removed from the final rule draft.</p>
7. 12/15/17	<p>Nickolas George, Jr. Midwest Food Products Association, Inc. 4600 American Parkway, #210 Madison, WI 53718</p>	<p>Written Comments</p> <p>Mr. George made several Points:</p> <ol style="list-style-type: none"> 1) ATCP 70.08 – The requirement for a requisite number of “foot candles” in the lighting section is outdated. He suggests that 	<p>Provided Written Comments –</p> <ol style="list-style-type: none"> 1) The Department believes that using an indefinite word like “adequate” in a rule does not provide sufficient guidance. Lighting parameters were instituted to ensure that processors can see mechanical problems, packaging issues, and other situations that could lead to food

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		<p>the words “adequate lighting” be substituted.</p> <p>2) ATCP 70.14 - Cleaning frequencies should not be dictated by regulation. He suggests that because of Good Manufacturing Practices, Sanitation Standard Operating Procedures, and both internal and third-party audits, the wording in this section should be changed to “as needed to keep the equipment and utensils clean and in a suitable sanitary condition.”</p> <p>3) Under ATCP 70.08, Faucets – He suggests that the 15 second standard for water in an automatic faucet to run does not represent a reasonable time and suggests inserting the wording “until warm water is present”.</p> <p>4) ATCP 70.36, 38, and 40, Canning – He objects to the requirement for a sanitizing step in the case of equipment used in a low-acid canned food operation in addition to the rigorous cleaning steps. The following suggestions are made:</p> <ul style="list-style-type: none"> • Strike the references to “alternative cleaning and sanitizing.” Sanitization should be determined by the processor with input from the 3rd party sanitation provider. • The Department’s attention is called to New York State which mandates the use of sanitizers “as necessary”, and to California and Washington where the use of sanitizers is “based on risk by product, targeting 	<p>adulteration. The “foot candle” unit is still a recognized, measurable standard, and alternative “lux” units are also provided. No change.</p> <p>2) ATCP 70.14 – Cleaning Frequencies: The Department’s position is that the regulations define a commonly-accepted baseline interval for cleaning which industry may lengthen if it can support the extended interval with scientifically valid data. The term “suitable sanitary condition” is not clearly defined and is possibly open to subjective interpretation. No change.</p> <p>3) ATCP 70.08, Faucets. ATCP 70.08 (8) (c) 2. does not mean that the water must be warm but must only run for 15 seconds. The Department agrees with the suggestion that the warm water must be available and already mandates “tempered” water in 70.08 (8) (c) 1. The intent of subdiv. 2. is that the tempered water be available for at least 15 seconds. No change.</p> <p>4) ATCP 70.40 – It is the intent in ATCP 70.40 that cleaning steps as well as any alternative method of cleaning be formulated by competent authority. Sanitizing is not required unless deemed appropriate in the plan written by the authority. The Department has edited the proposed ATCP 70.40 accordingly. The term, “alternative”, in relation to cleaning and sanitizing is not necessarily applicable to a low-acid canned foods plant, which could follow specific requirements in ATCP 70.40. ATCP 70.16 has been edited accordingly.</p> <p>5) The language allowing the “grandfathering” of certain conditions in plants has been removed from the proposed rule. Much of it was 30 years old. Many of these situations have already been corrected in conjunction with transfers of ownership and/or remodeling. The Department’s position is that it is in the best interest of sanitary and</p>

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		<p>certain pathogens in certain segments.”</p> <p>5) 70.08 (3) MWFPFA understands the rule to require that adding a new piece of equipment would be a sufficient change to trigger the upgrading of a “grandfathered” facility. They recommend no change to the current rule which allows certain no-longer-acceptable-conditions to exist if the plant was licensed prior to a certain date.</p>	<p>efficient operation to work with industry to bring outdated facilities into compliance. No change.</p>
8. 11/24/17	Stephanie Mackey DATCP 2811 Agriculture Dr. Madison, WI 53718	<p>Spoke – Suggested a Name Change for Formatting</p> <p>Suggested we change the chapter title to “Wholesale Food Manufacturing”</p>	<p>Provided Written Comments</p> <p>The Department made the change for consistency.</p>
9. 10/26.17	Andrea Charney acpc@wi.rr.com	<p>E-mail to department</p> <p>Ms. Charney cites the expense of starting a business and the high cost of renting commercial kitchen space.</p> <p>Cites the opportunities available for small producers at a Farmer’s market.</p>	<p>The Department initially disagreed with this comment and planned to prohibit issuance of a new food processing plant license to a business sharing a building with a residence. However, a work group convened by the Department and comprised of industry and local health department agent partners concluded that the existing rule language requirements for separation between food processing and residence areas in a building were adequate to protect public health. Therefore the planned prohibition was removed from the final rule draft.</p>
10. 10/27/17	Demetria Lueneburg FDA Minneapolis District Office 250 Marquette Ave., Suite 600 Minneapolis, MN 55401 Demetria.lueneburg@fda.hhs.gov	<p>Provided e-mail giving clarification to a point on alcohol amenability for regulatory purposes.</p>	<p>E-Mail on Alcohol as a food Ingredient</p> <p>The Department made the change as suggested by FDA: Create “ATCP 70.26 (7), Alcohol in Food” that states: (a) “Alcohol is allowed as an ingredient in a food product and is regulated by this chapter if it is between 1% and 7% by volume, or under 2% in ice cream. It shall be listed in the ingredient statement as “alcohol.”</p> <p>(b) If alcohol is part of an ingredient in another product such as the solvent in a flavoring and is less than 0.5% by volume, then it may be treated as an incidental ingredient.</p> <p>(c) More than 7% alcohol, by volume, falls, in the federal system, under the Alcohol and Tobacco Tax and Trade</p>

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11. 12/15/17	Comments during hearing period from multiple department staff.	Discussions on the definition of “wholesaling” in the proposed ATCP 70.02 (47)	Bureau (TTB). The Department initially agreed with these comments and adjusted the definition of “wholesale” accordingly. However, industry groups later raised important issues about whether transfer of food from a retail food establishment at which it was processed to another retail food establishment operated by the same license-holder actually constituted wholesaling. The workgroup convened by the Department and comprised of industry and local health department agent partners agreed that this activity was not wholesaling and the definition of “wholesale” was revised further. This change eliminated the issue raised by the commenter.

DATCP’s Rule Changes in Response to Public Hearings and Rules Clearinghouse Comments

The Department incorporated all Rules Clearinghouse comments and suggestions into the final draft of the rule.

Small Business Regulatory Review Board Report

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

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

Before drafting the rule, DATCP attended a listening session/discussion with the Midwest Food Products Association and made some changes suggested by this group to the provisions governing extended runs. However, no economic impact comments were received during the August 8 - September 7, 2017 comment period. DATCP convened an industry-regulator work group to develop policy recommendations on several issues.

Effect on Small Business

If the revised rule is adopted, some small food processing plants may incur immediate costs to meet requirements that will be in effect after the elimination of various “grandfather clauses” dating from over thirty years ago. For example, small plants may now need to upgrade warewashing and handwashing sinks. Another cost that may be incurred by a few very small businesses is the \$320 canning surcharge, which currently is not assessed for food processing plants manufacturing and selling less than \$25,000 of food per year. DATCP’s Manufactured Food Specialists spend a considerable amount of time working with very small canning businesses, and this surcharge recoups a portion of these costs. The service provided by DATCP is comparable to that provided by consultants, but at a significantly lower cost for operations in the sub-\$25,000/year category.

Much of the focus of the proposed rule revision is on the clarification and updating of existing regulations, such as the various exemptions from a food processing plant license and the clarification of various record-keeping requirements. Many of these changes are not anticipated to have a financial or other impact.

A positive impact of this rule revision on all classes of business is the expanded ability of food processing plants to apply for processing or procedural waivers. This change may allow the use of new and innovative techniques and processes so long as the processor can demonstrate that food safety is not compromised.

No economic impact comments were received during the August 8, 2017-September 7, 2017 comment period.

This rule will not have a significant adverse effect on “small business” and is not subject to the delayed “small business” effective date provided in s. 227.22(2)(e), Stats.

Summary of, and Comparison with, Existing or Proposed Federal Statutes and Regulations.

The proposed rule updates Wis. Admin. Code ch. ATCP 70 by adopting certain federal regulations that implement the requirements of the federal Food Safety Modernization Act (“FSMA”). Specifically, the revised rule incorporates multiple subparts of the recently issued 21 CFR 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk based Preventive Controls for Human Food*, that has superseded 21 CFR 110, *Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding Human Food*. These federal regulations pertain to preventive food safety systems that have already been referenced in Wis. Admin. Code chs. ATCP 65 (Milk and Milk Products) and ATCP 71 (Food Warehouses and Milk Distributors). Since the majority of Wisconsin federally-registered food facilities are already subject to this federal rule and licensed as food processing plants, this rule features similar referencing for the sake of consistency. This revision also ensures that the requirements for Wisconsin-licensed food processing plants, which are not subject to the federal rule, are clearly articulated.

21 CFR 117 is the cornerstone of the regulations implementing FSMA. Current language on the molluscan shellfish program was deleted in order to adopt the Federal Model Ordinance, in order to provide that segment of the Wisconsin food industry with regulatory consistency within interstate commerce.

Comparison with Rules in Adjacent States

Michigan, Iowa, and Minnesota license and regulate food processing facilities within their borders as does Wisconsin. Illinois food processors are regulated only by the FDA. Wisconsin, Illinois, and Michigan also have state programs for the National Shellfish Sanitation Program which allows them to receive, process, and ship shellfish interstate.

Summary of Factual Data and Analytical Methodologies

In order to identify potential changes to the rule, DATCP reviewed recent changes in FDA regulations such as those implementing FSMA; FDA guidance on the applicability of Hazard Analysis and Critical Control Point (“HACCP”) requirements for juice and seafood processors; Wisconsin statutes and rules for food processing plants, retail food establishments, meat establishments, and dairy plants; and current industrial practices. Upon learning of industry concerns about proposed licensing and regulatory requirements for retail food establishments conducting food processing for wholesale activities, DATCP delayed further consideration of the rule and convened a collaborative work group comprised of industry and local health department agent personnel to review and revise the requirements. The work group approved requirements in the present revised rule.

Standards Incorporated by Reference

There were no standards incorporated by reference as defined under s. 227.21.

DATCP Contact

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

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