



# Memorandum of Understanding (MOU) **Combination Establishments**

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Effective Date: 6/23/2016

## MEMORANDUM OF UNDERSTANDING REGARDING COMBINATION ESTABLISHMENTS

1.1

## I. RECITALS

WHEREAS, the Oregon Health Authority (OHA) Foodborne Illness Prevention Program (FIPP) is authorized to license and inspect food service establishments and to delegate such authorities to the Local Public Health Authority (LPHA) and further is authorized to administer and enforce provisions of ORS Chapter 624 governing the sanitation of establishments where food or drink is consumed on the premises where sold and the sanitary practices used in such establishments;

WHEREAS, the Oregon Department of Agriculture (ODA) administers and enforces ORS Chapter 616 governing food safety with regard to the production, processing and distribution of all food including milk, dairy products, shellfish, consumer commodities or commodities of agricultural origin and food establishments including commercial and domestic kitchens;

WHEREAS, in some instances, the respective licensing and inspection activities of the OHA and the ODA involve the same physical establishments due to the multiple activities carried out in such establishments.

WHEREAS, in ORS 616.015, the Oregon Legislature has recognized the relationship between the production, processing and distribution of food and the public health and has directed cooperation between the OHA and the ODA to effectively utilize these agencies to protect the public health without unnecessary duplication and expense;

WHEREAS, pursuant to ORS 624.530, the Oregon Legislature has directed the Director of the OHA and the Director of the ODA to adopt rules and enter into interagency agreements necessary to ensure that only one of the agencies inspects and licenses any establishment that is subject to regulation by both agencies;

NOW THEREFORE, the OHA and ODA enter into the following Agreement with respect to Combination Food Establishments.

# II. AGREEMENT

## A. Authorities

- OHA Authorities (Food Service Establishments): Pursuant to ORS 624.010 624.121and OAR Chapter 333 divisions 150 and 157, the OHA is responsible for licensing and inspection of restaurants, temporary restaurants, and bed and breakfast establishments.
- OHA Authorities (Commissaries, Mobile Units and Vending Machines): Pursuant to ORS 624.310 – 624.430, the OHA is responsible for inspection and licensing of commissaries, mobile units and vending machines.
- ODA Authorities (Meat): Pursuant to ORS 603.010 992 and OAR Chapter 603 division 28 the ODA licenses and inspects meat sellers and slaughterers, and pursuant to ORS 619.010 – 996, the ODA licenses and inspects meat and meat food products for sanitation.
- ODA Authorities (Food Establishments): Pursuant to ORS 616.695 755 and OAR Chapter 603 division 25, the ODA licenses and inspects retail food markets, food processing, food storage and food retailing activities for sanitation.
- 5. **ODA Authorities (Bakeries):** Pursuant to ORS 625.010 990 and OAR Chapter 603 division 25 the ODA licenses and inspects bakeries for sanitation.
- 6. Intergovernmental Agreements with Local Public Health Authorities: Pursuant to ORS 624.510, the Director of the OHA must enter into intergovernmental agreement with each local public health authority established under ORS 431.375 delegating to the local public health authority the administration and enforcement within the jurisdiction of the local public health authority, the powers, duties and functions of the OHA Director under ORS 624.010 121, ORS 624.310 430, and ORS 624.650 992.

#### **B.** Definitions

- 1. "Agency" means the Oregon Department of Agriculture or the Oregon Health Authority.
- "Catering" has the meaning given in OAR 603-025-0030 Subpart 1-201.10(15) and OAR 333-150-0000 Subpart 1-201.10.
- 3. "CFRs" means the Code of Federal Regulations.
- 4. "Combination Food Service Establishment" has the meaning given in OAR 603-025-0030 Subpart 1-201.10(22) and OAR 333-150-0000 Subpart 1-201.10.
- "Commissary" has the meaning given in OAR 603-025-0030 Subpart 1-201.10(26) and OAR 333-150-0000 Subpart 1-201.10.

- 6. "FDA" means the Federal Food and Drug Administration.
- "Field Environmental Health Specialist" means the Environmental Health Specialist as defined in Oregon Revised Statute 700.010, which is assigned to the specific combination food establishment or to the geographic area where the combination food establishment is located.
- "Food Establishment" includes a food establishment as defined in ORS 616.695(2) and a "food service establishment" as defined OAR 603-025-0010(12), and OAR 603-025-0030(58).
- "Food Service Establishment" includes "restaurants" as defined in ORS 624.010(9) and includes "seasonal temporary restaurants" as defined in ORS 624.010(11), "single-event temporary restaurants" as defined in ORS 624.010(12) and "intermittent temporary restaurants" as defined in ORS 624.010(4).
- 10. "Local Public Health Authority (LPHA)" has the meaning given in ORS 431.260.
- 11. "ODA" means the Oregon Department of Agriculture.
- 12. "OHA" means the Oregon Health Authority.
- 13. "Predominant Activity" means the dominant or primary use of a combination food establishment to which other activities are ancillary or temporary.
- 14. "Temporary Restaurant" includes "seasonal temporary restaurants" as defined in ORS 624.010(11), "single-event temporary restaurants" as defined in ORS 624.010(12) and "intermittent temporary restaurants" as defined in ORS 624.010(4).

#### C. Responsibilities and Implementation

- Combination Food Establishments governed by this Agreement. The establishments subject to this MOU are those combination food establishments as defined in section B.1. of this Agreement.
- 2. Criteria for Determining Responsible Agency. The licensing and inspecting of combination food establishments shall be the responsibility of either the OHA or the ODA. A determination about whether OHA, ODA, or both will license and inspect a combination food establishment shall be based upon the following criteria:
  - a. The predominant activities of the combination food establishment, as determined by gross annual sales of food for immediate versus later consumption.

- b. Food processing activities where training and expertise are required in the applicable CFRs, such as Low-Acid Canned Foods (LACF), Acidified Foods, Seafood HACCP, and Juice HACCP.
- c. Food processing activities where training and expertise are required in the applicable FDA Guidance Documents such as sprouts and produce for raw consumption.
- d. Dairy and shellfish processing for wholesale.
- 3. Process for Determining Agency Authority over Combination Food Establishments. The determination of the "predominant activity" of a combination food establishment shall be made according to the following process.
  - a. The field environmental health specialists from the LPHA and the ODA in the county where a combination food establishment is located shall determine the predominant activity of the combination food establishment.
  - b. In the event the field environmental health specialists cannot reach agreement over the predominant activity of the combination establishment, field environmental health specialists will refer the decision to the program supervisors of the LPHA and the ODA for determination of the predominant activity.
  - c. If an agreement is not reached between the LPHA and the ODA program supervisors, the decision will be referred to the Director of ODA and the Director of OHA.

#### 4. Application of Criteria.

- a. Where it is determined, according to the process in paragraph C.3. that the predominant activity at a combination food establishment is related to food service and/or other activities for which the OHA has authority, the OHA shall perform the licensing and inspection authorities over the combination food establishment to the exclusion of ODA.
- b. Where it is determined, according to the process in paragraph C.3. that the predominant activity at a combination food establishment is a bakery, retail meat establishment, retail grocery, food processing and/or other activities for which the ODA has authority, the ODA shall perform the licensing and inspection authorities over the combination food establishment to the exclusion of OHA.
- c. Where it is determined, according to the process in paragraph C.3.a. that the predominant activity requires training and expertise in the applicable CFRs and processes governed by the CFRs such as LACF, Acidified Foods, Seafood HACCP, Juice HACCP, and sprouts for raw consumption and over which the

ODA has authority, the ODA shall perform the licensing and inspection authorities over the combination food establishment to the exclusion of OHA.

- d. Where it is determined, according to the process in paragraph C.3. that the predominant activity at a combination food establishment is a bakery, retail meat establishment, retail grocery, food processing and/or other activities for which the ODA has authority, but the predominant activity includes food service activities requiring a temporary restaurant license, then OHA shall perform the licensing and inspection authorities for the temporary restaurant and ODA shall perform licensing and inspection authorities for the other activities.
- e. Where it is determined, according to the process in paragraph C.3. that the predominant activity at a combination food establishment is related to food service and/or other activities for which the OHA has authority, but ancillary activities are occurring which require training and expertise in the applicable CFRs and processes governed by the CFRs such as LACF, Acidified Foods, Seafood HACCP, Juice HACCP, and sprouts for raw consumption and over which the ODA has authority, then OHA and ODA may both license and inspect the combination food establishment.
- f. Notwithstanding a determination of the predominant activity according to the process in paragraph C.3., if the Local Public Health Authority and the ODA agree that the complexity rather than the predominance of food processing activities should determine the regulating agency, licensing and inspection may be transferred to the ODA to the exclusion of the Local Public Health Authority.

**D.** Licensing and Inspecting of Combination Establishment Activities Where the Predominant Activity is Governed by ODA. This section provides direction and clarification of the licensing requirements relating to food service operations at combination food establishments where the predominant activity is regulated by ODA. Food service (for immediate consumption) that is ancillary to the predominant ODA-regulated activity may only be conducted as follows.

- 1. **Mobile Food Units.** Mobile food units that operate at an ODA-licensed food establishment shall be licensed as follows.
  - a. If the mobile food unit is operated by the ODA-licensed food establishment and the mobile food unit is either inside or outside of the ODA-licensed establishment and on establishment property, it shall be licensed and inspected by ODA consistent with ODA's statutes and rules.
  - b. If an entity other than the ODA-licensed food establishment operates the mobile unit whether the mobile unit is inside or outside the food establishment, the mobile food unit shall be licensed by the LPHA consistent with OHA's statutes and rules.

- c. If the mobile food unit is owned by the ODA-licensed food establishment and operates off the food establishment property, the mobile food unit shall be licensed by the LPHA consistent with OHA's statutes and rules.
- d. A mobile food processing or mobile grocery unit that predominantly prepares or sells foods not for immediate consumption shall be licensed and inspected by ODA consistent with ODA's statutes and rules.
- Outdoor Cooking. Outdoor cooking or barbequing on the premises by store employee(s) may be allowed as part of an ODA-licensed food establishment pursuant to OAR 603-025-0010 – 0020 (General Standards of Food Establishment Construction and Maintenance) and under the ODA retail food code (OAR 603-025-0030).
- 3. Temporary Restaurant (Food Booth) Events. Food service operations beyond what is allowed as part of an approved outdoor cooking operation may be conducted only in conjunction with an event under a temporary restaurant license issued by the LPHA and consistent with laws governing temporary restaurants. For the purposes of this paragraph an "event" includes, but is not limited to, activities such as fairs, festivals, holidays, fundraising and other community activities.
  - a. Temporary restaurants shall be licensed and inspected by the LPHA. ODA shall not license or inspect temporary restaurants.
  - b. A temporary restaurant license may not be issued simply because it is an outdoor food service activity, provided the outdoor food service activity is conducted consistent with paragraph D.2.
  - c. If not in conjunction with an event, retail markets licensed by ODA may not sell food for immediate consumption such as hot dogs, potato salad and drinks outside the retail market unless associated with an approved mobile food unit operated by the ODA-licensed food establishment.
  - d. ODA-licensed food processing establishments, such as wineries and breweries, may conduct food service activities upon approval from ODA on the condition that ODA determines that adequate food service facilities are present and approved in accordance with ORS Chapter 616 and OAR 603-025-0010 to 603-025-0930.
  - e. ODA-licensed establishments that host public events and do not have ODA approval as described in paragraph D.3.d. must obtain a temporary restaurant license from the LPHA to serve food. Licensed caterers may also be used to provide food for public events if a temporary restaurant license is obtained.

- f. Food service activities at wineries, breweries, farmers' markets and seasonal farm-based product promotions such as pumpkin patches, corn mazes, and apple orchards may be considered temporary restaurant events licensed and inspected by the LPHA.
- 4. Catering and Commissaries. Excluding domestic kitchen food processors and bakeries, ODA-licensed food establishments are allowed to conduct catering activities as part of their ODA license. If an ODA-licensed food establishment provides catering services, ODA's oversight shall include the catering activities at the production site. An ODA-licensed food establishment catering an offsite public event must obtain a temporary restaurant license from the LPHA.

## 5. Packaged Untreated Juice Sales.

- a. ODA has adopted the 2015 version of Title 21, Chapter 1, Parts 1, 7, 70, 73, 74, 81, 82 and 100 through 199 of the Code of Federal Regulations by reference in OAR 603-025-0190. 21 CFR 120 includes Hazard Analysis and Critical Control Points (HACCP) requirements for juice processing. The following delineation of responsibilities, requirements and exemptions in this section between ODA and OHA is based on FDA guidance for industry on the types of juice processing activities that are subject to and exempt from 21 CFR 120:
  - i. A food establishment that sells untreated juice at the primary location where the juice is processed and packaged, may also sell untreated juice at their own secondary location under a retail exemption granted under the FDA's Guidance for Industry: Juice HACCP Hazards and Controls Guidance (first edition, final guidance) and the FDA's Guidance for Industry: The Juice HACCP Regulation-Questions & Answers (August, 2001 and September, 2003).
  - ii. Only food establishments that sell juice at the processing location may sell untreated packaged juice retail at another location without complying with the FDA Juice HACCP regulations (21 CFR part 120: *Hazard Analysis and Critical Control Point [HACCP] Systems*).
- b. With the exception of vending machines, packaged juice sales at secondary locations other than the processing facility, such as from a retail cooler (merchandiser) or similar display case situated in another licensed establishment or location (e.g. grocery store or sales kiosk) shall be licensed by ODA.
  - i. If such locations are not owned and staffed by employees of the juice processor, then the juice must be produced under Juice HACCP since it is considered sold/distributed wholesale to the sales location, rather than retail to the ultimate consumer.

c. Vending machines that dispense packaged juice shall be licensed by the LPHA. If a juice processing operator packages untreated juice for vending machines they own, maintain, and service, the retail exemption applies and the processor will be licensed by LPHA. Juice HACCP is not required.

# E. Applicability of Statutes and Rules

- 1. Any food establishment licensed and inspected by the OHA pursuant to this Agreement shall be subject to ORS 624 (Food Service Facilities) and the applicable rules under OAR Chapter 333 (Food Sanitation Rules).
- 2. Any food establishment licensed and inspected by the ODA, pursuant to this Agreement, shall be subject to ORS Chapter 561, ORS Chapter 603 (Meat Dealers and Slaughterers), ORS Chapter 616 (General and Miscellaneous Provisions), ORS Chapter 619 (Labeling and Inspection of Meat and Meat Food Products), ORS Chapter 621 (Milk, Dairy Products, Substitutes), ORS Chapter 622 (Shellfish), ORS Chapter 625 (Bakeries and Bakery Products), ORS Chapter 628 (Refrigerated Locker Plants), ORS Chapter 632 (Production, Grading and Labeling Standards for Agricultural and Horticultural Products), ORS Chapter 635 (Non-Alcoholic Beverages) and all rules adopted thereunder.

**F.** Licenses and Permits. Licenses and permits issued pursuant to this Agreement shall be subject to the statutes and administrative rules of the licensing agency, including but not limited to regulatory actions, penalties, fees and legal remedies. Licenses and permits issued pursuant to this Agreement that are in compliance with the statutes and administrative rules of the licensing agency shall be deemed to satisfy the statutes and administrative rules of the other agency.

G. Intergovernmental Agreements with Local Public Health Authorities. The authority, responsibilities and functions of the OHA under this Agreement may be delegated through an intergovernmental agreement to any LPHA pursuant to ORS 624.510 and ORS 190.

I. Periodic Review. Re-evaluations of predominance of food establishment activities shall be made by the regulating agencies and changes in jurisdiction shall be made where indicated and as needed.

J. Effective Date of Agreement. This Memorandum of Understanding shall become effective upon signature by the Oregon Health Authority, Public Health Division Director and the Director of the Oregon Department of Agriculture and shall remain in effect without renewal unless terminated by either agency by written notice. As of the effective date of this Agreement, all previous agreements are terminated. Amendments to this Agreement shall only be made by written addendum executed by both agencies.

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Lillian Shirley, Administrator Public Health Division Oregon Health Authority

5/24/2016 DATE

And. Director ann Katy Coba, Director

Oregon Department of Agriculture

6/23/2016

DATE