



Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

CERTIFIED MAIL
#7002-2410-0000-1701-6593

IN RE THE MATTER OF:

Eric D. Martin, Director of Food Safety
Texas Roadhouse Holdings, Inc.
6040 Dutchmans Lane
Louisville, KY 40205

Re: Variance Request Dated July 23, 2014 and Section 195

Order to Approve a Variance

You are hereby notified that based on the recommendation of the Indiana State Department of Health (ISDH), Food Protection Program, and as authorized by Indiana Code (IC) 16-19-3-4.3 and IC 16-42-5-5.2, the State Health Commissioner hereby orders that a variance be approved to Eric D. Martin, Director of Food Safety for Texas Roadhouse Holdings, Inc (TRH), Louisville, KY 40205, relating to 410 IAC 7-24-195, reduced oxygen packaging of a potentially hazardous (TCS) food.

Order

This **VARIANCE APPROVAL** is based on the following criteria:

- The Indiana locations listed in Appendix A:
- The Food & Drug Administration 2013 Model Food Code, section 3-502-11, Appendix B, shall be the standards and requirements forming the basis of this approval. TRH may state and use in training materials requirements which are more stringent than those stated in Appendix A.
- Some of the submitted materials were stated to be confidential and proprietary for Texas Roadhouse Holdings, Inc. TRH agrees to allow copying and transmittal of submitted HACCP materials to Indiana food regulatory authorities for regulatory purposes only. No other copying or transmittal of materials is allowed without consent of Texas Roadhouse Holdings, Inc.

Note: Indiana food regulatory authorities shall consider the information contained in the attached HACCP plan (Appendix C) as confidential and proprietary in accordance with 410 IAC 7-24-194.

- All other provisions provided in law shall be complied with at all times.
- The ISDH and/or local health department regulatory personnel may evaluate compliance with this order in the future at listed locations. A copy of this order and application information must be maintained at each location.
- Any provisions not adhered to may result in the revocation of this order.

If you wish to request an administrative review or stay of effectiveness of this decision pursuant to Ind. Code §40-21.5-3-7(a), you must petition for such review in writing. The petition must state facts demonstrating that:

- a. you are a person to whom the decision is specifically directed;
- b. you are aggrieved or adversely affected by the decision; or,
- c. you are entitled to review under any law.

Your request for review or stay of effectiveness must be filed in writing and addressed to:

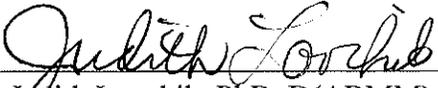
**Indiana State Department of Health
Attn: Court Administrator
Office of Legal Affairs
2 North Meridian Street, Section 3H
Indianapolis, Indiana 46204**

on or before October 14, 2014. If no request for review or stay of effectiveness is filed by October 14, 2014, this decision shall become final.

DATED AT INDIANAPOLIS, INDIANA THIS 24th DAY OF SEPTEMBER 2014.

PURSUANT TO IC 16-19-3-4.3 AND IC 16-42-5-5.2, I HEREBY APPROVE A VARIANCE OF FOOD PROTECTION RULES AS STATED ABOVE.

WILLIAM C.VAN NESS II, M.D.
STATE HEALTH COMMISSIONER

By: 
Judith Lovchik, PhD, D(ABMM)
Assistant Commissioner
Public Health Protection and Laboratory Services Commission

cc: ISDH Executive Board
ISDH Food Protection Staff
ISDH Office of Legal Affairs

Allen County Health Department
Bartholomew County Health Department
Clark County Health Department
Delaware County Health Department
Elkhart County Health Department
Hamilton County Health Department
Hendricks County Health Department
Howard County Health Department
Johnson County Health Department
Lake County Health Department
Madison County Health Department
Marion County Health Department
Monroe County Health Department
Porter County Health Department
St. Joseph County Health Department
Tippecanoe County Health Department
Vanderburgh County Health Department
Vigo County Health Department
Wayne County Health Department

Appendix A

StoreID	Name	Address	City	State	Zip	Phone	Fax	Email	Managing Partner	County
1	CLARKSVILLE,IN	757 Lewis and Clark Parkway	Clarksville	IN	47129	812-280-1103	812-280-1913	store_clkville@texasroadhouse.com	David Palazzo	Clark
11	TERRE HAUTE,IN	2941 S. 3rd Street	Terre Haute	IN	47802	812-234-3378	812-235-9332	store_terrehaute@texasroadhouse.com	Cindy Perkins	Vigo
14	MUNCIE,IN	200 W. McGalliard Road	Muncie	IN	47303	765-282-7113	765-282-8505	store_muncie@texasroadhouse.com	Mark Horton	Delaware
15	COLUMBUS,IN	2508 25th Street	Columbus	IN	47201	812-378-4632	812-378-4665	store_columbus@texasroadhouse.com	Jerrold Hove	Bartholomew
24	KOKOMO,IN	5107 Clinton Drive	Kokomo	IN	46902	765-455-1500	765-455-2500	store_kokomo@texasroadhouse.com	Don Saunders	Howard
27	ANDERSON,IN	2115 Scatterfield Road	Anderson	IN	46013	765-649-2637	765-649-1761	store_anderson@texasroadhouse.com	Bob Kirk	Madison
29	SHARPELAND,IN	1405 N. Shadland Avenue	Indianapolis	IN	46219	317-356-8081	317-356-8420	store_shadland@texasroadhouse.com	Steve Sarjent	Tipton
31	BLOOMINGTON,IN	110 Franklin Road	Bloomington	IN	47404	812-323-1000	812-323-1077	store_bloomington@texasroadhouse.com	Nick Workman	Monroe
39	LAFAYETTE,IN	3615 State Road 38 East	Lafayette	IN	47905	765-446-0404	765-446-0606	store_lafayette@texasroadhouse.com	Scott Baker	Tipton
42	RICHMOND,IN	3799 National Road East	Richmond	IN	47374	765-939-9100	765-939-9550	store_richmond@texasroadhouse.com	David Owens	Wayne
52	AVON,IN	10340 US 36 East	Avon	IN	46123	317-209-9152	317-209-9354	store_avon@texasroadhouse.com	Mike Cradick	Hendricks
56	FT. WAYNE,IN	710 W. Washington Center Road	Fort Wayne	IN	46825	260-416-6919	260-416-0519	store_ftwayne@texasroadhouse.com	Matt Cobb	Allen
59	SOUTHPORT,IN	4335 Southport Crossings Drive	Indianapolis	IN	46237	317-859-7000	317-859-8111	store_southport@texasroadhouse.com	Ken Sullivan	Marion
72	EVANSVILLE,IN	7900 Eagle Crest Boulevard	Evansville	IN	47716	812-477-7427	812-477-3224	store_evansville@texasroadhouse.com	Lynda Sneecker	Vanderburgh
106	FISHERS,IN	12950 Publisher Drive	Fishers	IN	46038	317-585-5020	317-585-5022	store_fishers@texasroadhouse.com	Dan Kellman	Hamilton
109	ELKHART,IN	3015 Britanny Court	Elkhart	IN	46514	574-266-1927	574-266-1937	store_elkhart@texasroadhouse.com	Tommy Herrell	Elkhart
128	MICHIGAN ROAD,IN	9111 N. Michigan Road	Indianapolis	IN	46268	317-876-5480	317-876-5484	store_michiganroad@texasroadhouse.com	Matthew Mathias	Marion
191	GREENWOOD,IN	270 S. Masfin Drive	Greenwood	IN	46142	317-859-8800	317-859-0977	store_greenwood@texasroadhouse.com	George Hill	Johnson
308	SOUTH BEND,IN	4655 South Michigan Street	South Bend	IN	46614	574-291-7427	574-291-7428	store_southbend@texasroadhouse.com	Rick Logston	St. Joseph
343	PORTAGE,IN	6130 E. US Highway 6	Portage	IN	46368	219-762-5500	219-762-5888	store_portage@texasroadhouse.com	Douglas Giltrap	Porter
344	DYER,IN	2070 Callumet Avenue	Dyer	IN	46911	219-322-9420	219-322-7069	store_dyer@texasroadhouse.com	Kelly Black	Lake

Appendix B

***Clostridium
botulinum and
Listeria
monocytogenes
Controls***

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria.

(A) Except for a FOOD ESTABLISHMENT that obtains a VARIANCE as specified under § 3-502.11, a FOOD ESTABLISHMENT that PACKAGES TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a REDUCED OXYGEN PACKAGING method shall control the growth and toxin formation of *Clostridium botulinum* and the growth of *Listeria monocytogenes*.^P

(B) Except as specified under ¶ (F) of this section, a FOOD ESTABLISHMENT that PACKAGES TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a REDUCED OXYGEN PACKAGING method shall implement a HACCP PLAN that contains the information specified under ¶¶ 8-201.14 (B) and (D) and that:^{Pf}

(1) Identifies the FOOD to be PACKAGED;^{Pf}

(2) Except as specified under ¶¶ (C) - (E) of this section, requires that the PACKAGED FOOD shall be maintained at 5°C (41°F) or less and meet at least one of the following criteria: ^{Pf}

(a) Has an A_w of 0.91 or less, ^{Pf}

(b) Has a PH of 4.6 or less, ^{Pf}

(c) Is a MEAT or POULTRY product cured at a FOOD PROCESSING PLANT regulated by the USDA using substances specified in 9 CFR 424.21, Use of food ingredients and sources of radiation, and is received in an intact PACKAGE, ^{Pf} or

(d) Is a FOOD with a high level of competing organisms such as raw MEAT, raw POULTRY, or raw vegetables; ^{Pf}

(3) Describes how the PACKAGE shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to: ^{Pf}

(a) Maintain the FOOD at 5°C (41°F) or below, ^{Pf} and

(b) Discard the FOOD if within 30 calendar days of its PACKAGING if it is not served for on-PREMISES consumption, or consumed if served or sold for off-PREMISES consumption; ^{Pf}

(4) Limits the refrigerated shelf life to no more than 30 calendar days from PACKAGING to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first; ^P

(5) Includes operational procedures that:

(a) Prohibit contacting READY-TO-EAT FOOD with bare hands as specified under ¶ 3-301.11(B), ^{Pf}

(b) Identify a designated work area and the method by which: ^{Pf}

(i) Physical barriers or methods of separation of raw FOODS and READY-TO-EAT FOODS minimize cross contamination, ^{Pf} and

(li) Access to the processing EQUIPMENT is limited to responsible trained personnel familiar with the potential HAZARDS of the operation, ^{Pf} and

(c) Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES; ^{Pf} and

(6) Describes the training program that ensures that the individual responsible for the REDUCED OXYGEN PACKAGING operation understands the: ^{Pf}

(a) Concepts required for a safe operation, ^{Pf}

(b) EQUIPMENT and facilities, ^{Pf} and

(c) Procedures specified under Subparagraph (B)(5) of this section and §§ 8-201.14 (B) and (D). ^{Pf}

(7) Is provided to the REGULATORY AUTHORITY prior to implementation as specified under § 8-201.13(B).

Fish

(C) Except for FISH that is frozen before, during, and after PACKAGING, a FOOD ESTABLISHMENT may not PACKAGE FISH using a REDUCED OXYGEN PACKAGING method. ^P

*Cook-Chill or
Sous Vide*

(D) Except as specified under § (C) and § (F) of this section, a FOOD ESTABLISHMENT that PACKAGES TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a cook-chill or sous vide process shall:

(1) Provide to the REGULATORY AUTHORITY prior to implementation, a HACCP PLAN that contains the information as specified under §§ 8-201.14 (B) and (D); ^{Pf}

(2) Ensure the FOOD is:

(a) Prepared and consumed on the PREMISES, or prepared and consumed off the PREMISES but within the same business entity with no distribution or sale of the PACKAGED product to another business entity or the CONSUMER; ^{Pf}

(b) Cooked to heat all parts of the FOOD to a temperature and for a time as specified under §§ 3-401.11 (A), (B), and (C); ^P

(c) Protected from contamination before and after cooking as specified under Parts 3-3 and 3-4; ^P

(d) Placed in a PACKAGE with an oxygen barrier and sealed before cooking, or placed in a PACKAGE and sealed immediately after cooking and before reaching a temperature below 57°C (135°F),^P

(e) Cooled to 5°C (41°F) in the sealed PACKAGE or bag as specified under § 3-501.14 and:^P

(i) Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F) and held at that temperature until consumed or discarded within 30 days after the date of PACKAGING;^P

(ii) Held at 5°C (41°F) or less for no more than 7 days, at which time the FOOD must be consumed or discarded;^P or

(iii) Held frozen with no shelf life restriction while frozen until consumed or used.^P

(f) Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily,^{Pf}

(g) If transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation,^{Pf} and

(h) Labeled with the product name and the date PACKAGED;^{Pf} and

(3) Maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP PLAN and:

(a) Make such records available to the REGULATORY AUTHORITY upon request,^{Pf} and

(b) Hold such records for at least 6 months;^{Pf} and

(4) Implement written operational procedures as specified under Subparagraph (B)(5) of this section and a training program as specified under Subparagraph (B)(6) of this section.^{Pf}

Cheese

(E) Except as specified under ¶ (F) of this section, a FOOD ESTABLISHMENT that PACKAGES cheese using a REDUCED OXYGEN PACKAGING method shall:

(1) Limit the cheeses PACKAGED to those that are commercially manufactured in a FOOD PROCESSING PLANT with no ingredients added in the FOOD ESTABLISHMENT and that meet the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese or 21 CFR 133.187 Semisoft cheeses;^P

(2) Have a HACCP PLAN that contains the information specified under ¶¶ 8-201.14 (B) and (D) and as specified under ¶¶ (B)(1), (B)(3)(a), (B)(5) and (B)(6) of this section;^{Pf}

(3) Labels the PACKAGE on the principal display panel with a "use by" date that does not exceed 30 days from its packaging or the original manufacturer's "sell by" or "use by" date, whichever occurs first;^{Pf} and

(4) Discards the REDUCED OYGEN PACKAGED cheese if it is not sold for off-PREMISES consumption or consumed within 30 calendar days of its PACKAGING.^{Pf}

(F) A HACCP Plan is not required when a FOOD ESTABLISHMENT uses a REDUCED OXYGEN PACKAGING method to PACKAGE TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is always:

(1) Labeled with the production time and date,

(2) Held at 5°C (41°F) or less during refrigerated storage, and

(3) Removed from its PACKAGE in the FOOD ESTABLISHMENT within 48 hours after PACKAGING.

Appendix C

See HACCP Plan Submitted 9-12-14.