

TITLE 25. Health Services
Part 1. Department of State Health Services
Chapter 229. Food and Drug
Subchapter R. Issuance of Certificates of Free Sale and Sanitation and/or Certificates of Origin and Sanitation
Amendments §§229.301 - 229.306
New §229.307

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes amendments to §§229.301 - 229.306 and new §229.307, concerning the Issuance of Certificates of Free Sale and Sanitation and/or Certificates of Origin and Sanitation.

BACKGROUND AND PURPOSE

The amendments are necessary to update the department's name, clarify program policies and procedures, and update the fee schedule. The amendments also make clear the primary distinction between the two types of certificates: "Certificates of Free Sale and Sanitation" are issued for distribution of products from Texas and "Certificates of Origin and Sanitation" are issued only for products manufactured in Texas. Additional revisions are made to §§229.301 - 229.306 to include new definitions, new language, clarification on minimum requirements for certificate applicants, and other editorial corrections.

New §229.307 is added to provide for appeal procedures for certificate applicants.

Government Code, §2001.039, requires that each state agency review and consider for re-adoption each rule adopted by that agency pursuant to Government Code, Chapter 2001 (Administrative Procedure Act). Sections §§229.301 - 229.306 have been reviewed and the department has determined that the reasons for adopting the sections continue to exist and therefore the rules on this subject continue to be needed.

SECTION BY SECTION SUMMARY

The title of Subchapter R is amended to add the words: "and Sanitation" after the words "Certificates of Origin" to clarify the scope of the rule.

Amendments to §229.301 update the department's name from "Texas Department of Health" to "Department of State Health Services." Throughout the rule, the words "and sanitation" were added after the words "certificate of origin" to clarify the scope of the rules and to be consistent throughout all sections of the rule. The second sentence in §229.301 adds the word "only" after the words "Certificates are issued;" adds the words "Texas licensed" before "manufacturers;" adds the word "or" after the words "manufacturers and/" and replaces "importing" with "exporting" to clarify the intent of the rule. Additionally, §229.301 adds the following sentence

to provide specific product requirements, "Products shall be manufactured and/or distributed in Texas and/or warehoused and sold from Texas." The following new sentence is added to §229.301 to specify the requirements for issuing certificates for cosmetics: "Certificates for cosmetics can only be issued after the department has inspected the Texas manufacturing and/or warehousing facility." Also, the last sentence of §229.301 has been changed from "Certificates for meat and poultry products, which have been inspected by the United States Department of Agriculture (USDA), can only be issued to distributors of those products" to "Certificates for meat and poultry products can only be issued by the United States Department of Agriculture (USDA)." to clarify that the USDA, and not the department, issues certificates of this nature for meat and poultry products.

Throughout §229.302(1), all references to "manufacturer and/or" and "manufacturer or" are deleted to clarify that free sale certificates are issued for distribution of products from Texas. In addition, §229.302(1) replaces the words "the United States of America" with the word "Texas" to further clarify the scope of the rule.

Section §229.302(2) adds the words "and can only be issued to a Texas manufacturer" after the words "the State of Texas" to clarify that origin certificates are issued only for products manufactured in Texas.

The definitions of "Common or usual name," "Private Labeler," and "Properly labeled" are added to §229.302 to clarify minimum requirements for applicants of a certificate of free sale and sanitation and/or certificate of origin and sanitation. A definition for "Custom certificates" also is provided. Changes are reflected in new §229.302(3), (7), and (8). Subsequent paragraphs of this section are renumbered as a result of the new definitions.

Concerning new renumbered §229.302(6), the department's name is updated from "Texas Department of Health" to "Department of State Health Services."

Section §229.303(b)(1) extends the time frames for current inspections for distributors or wholesalers of foods, drugs, or medical devices, and manufacturers of foods, drugs, or medical devices from 12 months to 24 months. In addition, §229.303(b)(1) deletes "manufacturers" before "distributors" and deletes "dietary supplements, or drug products" before "within" since the specified inspection time frame does not apply to these types of establishments. "Drugs, or medical devices" is added after "foods" to include these types of establishments in the 24 month inspection time frame.

New §229.303(b)(2) establishes the time frame of 12 months for current inspections of manufacturers of foods, drugs, or medical devices. The subsequent paragraph is renumbered as a result of the new paragraph.

New renumbered §229.303(b)(3) replaces the 12-month time frame with the new 24-month time frame for current inspections of manufacturers, distributors, or wholesalers of cosmetic products.

Current §229.303(b)(3) and (b)(4), concerning manufacturers and distributors of medical devices, are deleted because these paragraphs are no longer necessary due to the new proposed clarified language in §229.303(b)(1). Subsequent paragraphs are renumbered as a result of the deleted paragraphs.

New §229.303(c) is added to provide requirements for applicants for certificates of free sale and sanitation who meet the definition of private labelers and to clarify that certificates of origin and sanitation can not be issued to private labelers.

New §229.303(d) is added to clarify the minimum requirements for the products eligible for issuance of certificates of free sale and sanitation and/or certificates of origin and sanitation. The products must originate or be physically present in Texas. The subsequent subsection is renumbered as a result of adding new subsections (c) and (d) to this section.

New renumbered §229.303(e) provides that those whose applications for certificates are denied may appeal the adverse decision under the procedures set out in new §229.307.

Amendments to §229.304(a) update the agency name and contact information by deleting the words "Bureau of Food and Drug Safety, Texas Department of Health," and replacing them with "Department of State Health Services" and updating the Licensing Group's website by deleting "www.tdh.state.tx.us/bfds/bfds-hom.htm" and replacing it with "www.dshs.state.tx.us/fdlicense." In addition, §229.304(a) deletes the address "1100 West 49th Street, Austin, Texas 78756-3182" since this address is not applicable to this section.

Section 229.304(b) and its paragraphs 1, 4, and 5 add verbiage to clarify the minimum information required to properly complete applications for these certificates. Subsection b adds "and verified" after "signed" and replaces "furnished" with "authorized" to clarify the intent of the rule. Section §229.304(b)(1) adds "and/or licensed" after "conducted" for clarification. Concerning §229.304(b)(4), "required" is replaced with "requested" to clarify the intent of the rule. Section §229.304(b)(5) adds "full, common or usual" before "name of the product" and adds: "Each product size shall be submitted as a separate product. Products on the certificate will be listed exactly as submitted."

Amendments to §229.304(c) clarify the terms under which an application for a certificate is deemed complete by adding: "An application is not considered complete unless all information including the correct fee and any supplemental information is submitted and meets all regulatory requirements." In addition, the word "must" is deleted after the word "Applications" and before the words "be completely filled out and shall be accompanied by the appropriate fee." and replaced with the word "shall" for consistency in language throughout the rule.

Section §229.304(d) adds "distribution records" after "clearance letters" to clarify the term "supplemental information." The following new language is added to §229.304(d) to clarify requirements for product labeling in a foreign language: "If labeling is in a foreign language, applicant shall provide English translation. Labeling information shall be in final format. Label prototypes and drafts will not be accepted."

Concerning §229.304(e), the sentence, "If the applicant requests additional information be included on the certificate, an additional fee will be charge" is deleted to limit and standardize the information that will be listed on all certificates of free sale and sanitation and/or all certificates of origin and sanitation.

Concerning §229.305, new subsection (a) undesignated title head is being added to comply with *Texas Register* format. New renumbered §229.305(a)(1) replaces "Within 10" with "No later than 15" before "business days" to extend the department's time frame to issue a certificate, deny a certificate, request supplemental information and/or schedule an inspection after receiving a completed application. Section §229.305(a) also adds new language to clarify conditions for suspending the new 15 business day time frame by adding, "Time frames are suspended any time the applicant is requested to submit additional information, the applicant submits additional information, or the applicant requests a custom certificate."

New renumbered §229.305(a)(2) replaces "Within 30" with "No later than 45" before "business days" to extend the department's time frame to inspect an establishment that requires a current compliant inspection. Section §229.305(a)(2) also adds new language to clarify conditions for suspending time frames if substantive violations exist. The new language is as follows: "If substantive violations exist the department shall notify the applicant. Time frames are suspended any time substantive violations exist."

Amendments to §229.305(a)(3) replace "Within" with "No later than" before "30 business days" to clarify the time frames for the department to issue certificates of free sale and sanitation and/or certificates of origin and sanitation. In addition, §229.305(a)(3) adds "or acceptable documentation of correction of substantive violations after "requested supplemental information" and replaces "the supplemental" with "all" after "the department shall review" to specify the information required by the department. In the second sentence of §229.305(a)(3), "supplemental" is deleted before "information;" "if" is removed before "the establishment;" and "all fees" replaces "if the fees for review of the supplemental information" before "have been received" to clarify the conditions for the department to review and approve the issuance of the certificate. Section 229.305(a)(3) also adds the following new language to clarify conditions for suspending time frames if an applicant is requested to submit supplemental information, "Time frames are suspended any time the applicant is requested to submit supplemental information."

New §229.305(a)(4) clarifies conditions that must be met for the department to consider an application withdrawn by adding "If any time frame is suspended for 60 business days or more with no response from the applicant, the application is considered withdrawn."

New §229.305(b) is added to clarify the dates by which these certificates expire and are rendered invalid.

Section 229.306(a) increases the fees that will be charged for these certificates. The phrase "of \$50 for the certificate and \$.10 per product to be listed on the certificate" which appears after "nonrefundable fee" is deleted and replaced with the following new fee schedule, one that

enables the programs to recover the costs of these regulatory activities as required by the legislature:

"\$50 for 1-50 products; \$5 for each additional identical certificate."

"\$60 for 51-200 products; \$6 for each additional identical certificate."

"\$75 for 201-500 products; \$8 for each additional identical certificate."

"\$100 for 501-1000 products; \$10 for each additional identical certificate."

"\$150 for 1001+ products; \$15 for each additional identical certificate."

Section §229.306(b) deletes reference to "Cosmetic products" and adds "Non-licensed Establishments," and deletes the word "cosmetic" and replaces it with "any" establishments to clarify that this requirement is applicable to any establishment not required to be licensed with the state. In addition, §229.306(b) deletes the current fee of "\$50 for the certificate, \$.10 per product to be listed on the certificate, and \$328" for an inspection conducted by the department staff and replaces it with the new inspection fee of "\$400" for any establishments not required to be licensed by the department but which must have a current compliant inspection for a certificate to be issued. The following language is added to §229.306(b), after "required," to specify that these establishments are also subject to the costs outlined in §229.306(a), "in addition to costs outlined in subsection (a) of this section."

New §229.306(c) is added to specify that a fee is required for single service container establishments regulated by the department. Subsequent subsections are renumbered as a result of this new subsection.

New renumbered §229.306(d) adds language to clarify that applicants who request a supplemental information review are responsible not only for the fees outlined in new §229.306(a), but also for the nonrefundable review time fees, by adding the words, "in addition to fees as outlined in subsection (a) of this section," before "Nonrefundable fees." Additionally, §229.306(d) increases the fees for supplemental information reviews from \$33 to \$72 per hour and establishes a minimum one-half hour charge for applicants of certificates of free sale and sanitation and/or certificates of origin and sanitation. In addition, a grammatical correction for clarity and language consistency was made to §229.306(d) by deleting the words "This fee must" and adding the words "These fees shall" before the words "be paid prior to the certificate being issued."

Current §229.306(d) that specifies a \$1 fee per page for each additional identical original certificate is deleted because this subsection is no longer necessary due to the new clarified fee schedule in §229.306(a).

New §229.306(e) adds language to clarify minimum requirements and applicable fees for applicants for issuance of custom certificates. The new §229.306(e) also specifies that fees shall be paid before a certificate can be issued.

New § 229.306(f) prohibits the forging or tampering with these certificates.

New § 229.306(g) provides that the certificates will be delivered by first class U.S. mail and that applicants are responsible for the cost of delivery by any other means.

New §229.307 is added to specify the appeal procedures for applicants for certificates of free sale and sanitation and/or certificates of origin and sanitation whose applications were denied.

FISCAL NOTE

Susan E. Tennyson, Section Director, Environmental and Consumer Safety Section, has determined that for each of the five years the revisions are in effect, there will be fiscal implications to state government in the form of an estimated increase in revenue of \$26,094 from fees as a result of enforcing and administering §229.306 as proposed. These fees will be used to cover the cost for requested certificates, duplicates, and professional time to review labels and supplemental information. Due to the complexity of the inspections and label reviews, additional inspection and review times are required for certificates of free sale and sanitation and/or certificates of origin and sanitation. The department has been conducting the label reviews and inspections at a cost to the state; the average cost per hour for label review is estimated at \$72 per hour while the cost per hour currently charged for label review is \$33 per hour. House Bill 2292, 78th Legislature, 2003 requires the department to recover costs of performing activities of the program. Further Ms. Tennyson has determined that there will be no fiscal implications to local governments as a result of administering and enforcing §229.306 as proposed. Ms. Tennyson also has determined that there will be no fiscal implications to state and local governments as a result of administering and enforcing §§229.301 - 229.305 and new §229.307 as proposed.

The new nonrefundable fees for original certificates prescribed in §229.306(a) will be:

"\$50 for 1-50 products; \$5 for each additional identical certificate."

"\$60 for 51-200 products; \$6 for each additional identical certificate."

"\$75 for 201-500 products; \$8 for each additional identical certificate."

"\$100 for 501-1000 products; \$10 for each additional identical certificate."

"\$150 for 1001+ products; \$15 for each additional identical certificate."

It is estimated, based on a review for all fees for certificates of free sale and sanitation and/or certificates of origin and sanitation for the 2008 fiscal year, there will be an increase in revenue of \$26,094 or 48%. The review of fiscal year 2008 fees included fees for the inspection conducted by the department of establishments not required to be licensed by the department and that do not have a current compliant inspection, fees for supplemental information reviews, and costs for issuing a custom certificate. The comparison of the fiscal year 2008 fees with the fees contemplated in these amended rules also included an estimate of new fees for single service containers and the higher review fees of \$72 an hour. Due to the complexity of the inspections and label reviews required, inspection times and review costs will increase. Therefore, any increase in revenue will be offset by normal costs.

SMALL AND MICRO-BUSINESS ECONOMIC IMPACT ANALYSIS

In reviewing applicants for certificates of free sale and sanitation and/or certificates of origin and sanitation, 16 firms that fall into the category of small or micro-businesses would be affected. Depending on the varying fees for certificates, the amount of supplemental review and customization, small and micro-business applicants may experience anywhere between a 24% decrease to a 17.5% increase in fees.

Alternatives were not considered because of House Bill 2292, 78th Legislative Session, 2003 which requires the department to recover costs of performing activities of the program.

There are no anticipated significant economic costs to persons who are required to comply with the section as proposed. There is no anticipated impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Tennyson has also determined that for each year of the first five years these rules are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing or administering the sections is to ensure that Texas manufacturers and distributors of foods, drugs, medical device products, cosmetics, dietary supplements, milk and dairy products, and molluscan shellfish products are able to export safe products.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule, the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed rule amendments and new rule do not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Claire Perkins, Environmental and Consumer Safety Section, Division of Regulatory Services, Department of State Health Services, MC 1987, P.O. Box 149347, Austin, Texas 78714-9347, (512) 834-6670. ext. 2173, or

Claire.Perkins@dshs.state.tx.us. Comments will be accepted for 30 days following publication of this proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The amendments and new rule are authorized by House Bill 2292, 78th Legislative Session, 2003; Health and Safety Code, §§431.202, 431.204, 431.222, 431.224, 431.241, 431.272, 431.276, 435.006, 435.009, 436.103, 436.112, 436.113, 440.006, 440.012, and 440.013 which require the department to charge fees to recover the costs of performing activities and for issuing or renewing licenses or permits; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of the Health and Safety Code, Chapter 1001. The review of the rules implements Government Code, §2001.039.

The amendments and new rule affect the Health and Safety Code, Chapters 431, 435, 436, and 440.