**Conference for Food Protection**

**2016 Issue Form**

**Issue: 2016 III-038**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Council Recommendation:** | Accepted asSubmitted |  | Accepted as Amended |  | No Action |  |
| **Delegate Action:** | Accepted |  | Rejected |  |  |  |

*All information above the line is for conference use only.*

**Issue History:**

This is a brand new Issue.

**Title:**

Use of pre-formulated sanitizing solutions

**Issue you would like the Conference to consider:**

Add a new paragraph to the 2013 FDA Food Code Section 4-302.14 that states the availability of a test kit or other device, currently specified in this section, does not apply to pre-formulated hard food-contact surface sanitizing solutions.

**Public Health Significance:**

Section 7-204.11 Sanitizers, Criteria of the 2013 FDA Food Code states that chemical sanitizers and other chemical antimicrobials applied to food-contact surfaces shall meet the requirements specified in 40 CFR (Code of Federal Regulations) 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions) or 40 CFR 180.2020 Non-food Determinations. Section 4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration and Hardness indicates that a chemical sanitizer used in a sanitizing solution shall be used in accordance with the U.S. Environmental Protection Agency (EPA) labeling requirements, among other things.

For most sanitizing solutions, a minimum and maximum concentration of the active ingredient has been established. It is specified to ensure sanitizer efficacy and to prevent excessive exposure at a concentration level that exceeds an established maximum concentration and minimize any environmental impact. Food establishment operators use test kits to routinely measure the concentration of sanitizing solutions to ensure they are prepared at the proper use concentration and that the minimum labeled concentration is maintained throughout the sanitizing solution's use as specified in the manufacturer's directions for use.

Currently, Section 4-302.14 Sanitizing Solutions, Testing Devices states that a testing kit or other device that accurately measures the concentration of a sanitizing solution shall be provided. However, FDA recognizes that when EPA-registered pre-formulated hard food-contact surface sanitizing solutions are used in accordance to their label instructions, the need to ensure the concentration of the active ingredient through a testing kit or other device is not necessary.

**Recommended Solution: The Conference recommends...:**

that a letter be sent to FDA requesting the 2013 Food Code be amended by adding a new paragraph to Section 4-302.14 as follows (language to be added is underlined; language to be deleted is in strikethrough format):

**4-302.14 Sanitizing Solutions, Testing Devices.**

(A) Except as specified under ¶(B) of this section, a test kit or other device ~~that~~ shall be provided to accurately measure~~s~~ the concentration in mg/l of sanitizing solutions ~~shall be provided~~. Pf

(B) The availability of a test kit or other device specified under ¶(A) of this section, does not apply to pre-formulated sanitizing solutions that are ready-to-use, not diluted or mixed in the food establishment, and are sprayed directly onto food contact surfaces.

Note: italic font is consistent with Food Code formatting; it offers an exception or another possibility and is pursuant to a preceding provision that states a requirement (exception to the rule).

**Submitter Information:**

|  |  |
| --- | --- |
| Name: | Mary Cartagena |
| Organization:  | Food and Drug Administration |
| Address: | 5100 Paint Branch ParkwayHFS-320 Rm 3B038 |
| City/State/Zip: | College Park, MD 20740 |
| Telephone: | 240-402-2937 |  |  |
| E-mail: | mary.cartagena@fda.hhs.gov |  |  |

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.