

thermal shock that may occur from water, sleet, snow, soldering, or welding.

### III. Comparison Methodology

In the 2008 analysis, DOE reviewed each of the five sets of shipment data that were collected in consultation with NEMA and applied two curve fits to generate unit sales estimates for the five lamp types after calendar year 2006. One curve fit applied a linear regression to the historical data and extended that line into the future. The other curve fit applied an exponential growth function to the shipment data and projected unit sales into the future. For this calculation, linear regression treats the year as a dependent variable and shipments as the independent variable. The linear regression curve fit is modeled by minimizing the differences among the data points and the best curve-fit linear line using the least squares function.<sup>5</sup> The exponential curve fit is also a regression function and uses the same least squares function to find the best fit. For some data sets, an exponential curve provides a better characterization of the historical data, and, therefore, a better projection of the future data.

For 3-way incandescent lamps, 2,601–3,300 lumen general service incandescent lamps, and shatter-resistant lamps, DOE found that the linear regression and exponential growth curve fits produced nearly the same estimates of unit sales (*i.e.*, the difference between the two forecasted values was less than 1 or 2 percent). However, for rough service and vibration service lamps, the linear regression curve fit projected lamp unit sales would decline to zero for both lamp types by 2018. In contrast, the exponential growth curve fit projected a more gradual decline in unit sales, such that lamps would still be sold beyond 2018, and it was, therefore, considered the more realistic forecast. While DOE was satisfied that either the linear regression or exponential growth spreadsheet model generated a reasonable benchmark unit sales estimate for 3-way incandescent lamps, 2,601–3,300 lumen general service incandescent lamps, and shatter-resistant lamps, DOE selected the exponential growth curve fit for these lamp types for consistency with the selection made for rough service and

vibration service lamps.<sup>6</sup> DOE examines the benchmark unit sales estimates and actual sales for each of the five lamp types in the following section and also makes the comparisons available in a spreadsheet online: [http://www1.eere.energy.gov/buildings/appliance\\_standards/product.aspx/productid/63](http://www1.eere.energy.gov/buildings/appliance_standards/product.aspx/productid/63).

### IV. Comparison Results

#### A. Rough Service Lamps

For rough service lamps, the exponential growth forecast projected the benchmark unit sales estimate for 2012 to be 5,780,000 units. The NEMA-provided shipment data reported shipments of 6,045,000 rough service lamps in 2012. As this finding exceeds the estimate by only 4.6 percent, DOE will continue to track rough service lamp sales data and will not initiate regulatory action for this lamp type at this time.

#### B. Vibration Service Lamps

For vibration service lamps, the exponential growth forecast projected the benchmark unit sales estimate for 2012 to be 3,019,000 units. The NEMA-provided shipment data reported shipments of 1,077,000 vibration service lamps in 2012. As this finding is only 35.7 percent of the estimate, DOE will continue to track vibration service lamp sales data and will not initiate regulatory action for this lamp type at this time.

#### C. Three-Way Incandescent Lamps

For 3-way incandescent lamps, the exponential growth forecast projected the benchmark unit sales estimate for 2012 to be 50,131,000 units. The NEMA-provided shipment data reported shipments of 28,854,000 3-way incandescent lamps in 2012. As this finding is only 57.6 percent of the estimate, DOE will continue to track 3-way incandescent lamp sales data and will not initiate regulatory action for this lamp type at this time.

#### D. 2,601–3,300 Lumen General Service Incandescent Lamps

For 2,601–3,300 lumen general service incandescent lamps, the exponential growth forecast projected the benchmark unit sales estimate for 2012 to be 33,979,000 units. The NEMA-provided shipment data reported shipments of 12,373,000 2,601–3,300 lumen general service incandescent lamps in 2012. As this finding is 36.4

percent of the estimate, DOE will continue to track 2,601–3,300 lumen general service incandescent lamp sales data and will not initiate regulatory action for this lamp type at this time.

#### E. Shatter-Resistant Lamps

For shatter-resistant lamps, the exponential growth forecast projected the benchmark unit sales estimate for 2012 to be 1,663,000 units. The NEMA-provided shipment data reported shipments of 1,455,000 shatter-resistant lamps in 2012. As this finding is only 87.5 percent of the estimate, DOE will continue to track shatter-resistant lamp sales data and will not initiate regulatory action for this lamp type at this time.

### V. Conclusion

None of the shipments for rough service lamps, vibration service lamps, 3-way incandescent lamps, 2,601–3,300 lumen general service incandescent lamps, or shatter-resistant lamps crossed the statutory threshold for a standard. DOE will monitor the situation for these five currently exempted lamp types and will reassess 2013 sales by March 31, 2014, in order to determine whether an energy conservation standards rulemaking is required, consistent with 42 U.S.C. 6295(l)(4)(D)–(H).

Issued in Washington, DC, on March 5, 2013.

**Kathleen B. Hogan,**

*Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 117

[Docket No. FDA–2012–N–1258]

#### **Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm; Availability; Reopening of the Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification; reopening of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA or “we”) is reopening the comment period for a document entitled “Draft Qualitative Risk Assessment of Risk of Activity/

<sup>5</sup> The least squares function is an analytical tool that DOE uses to minimize the sum of the squared residual differences between the actual historical data points and the modeled value (*i.e.*, the linear curve fit). In minimizing this value, the resulting curve fit will represent the best fit possible to the data provided.

<sup>6</sup> This selection is consistent with the 2010 and 2011 comparisons. See DOE’s 2008 forecast spreadsheet models of the lamp types for greater detail of the estimates.

Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm” (the draft RA) that we made available for public comment in the **Federal Register** of January 16, 2013. We are reopening the comment period to update comments and to receive any new information.

**DATES:** Submit either electronic or written comments by May 16, 2013.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2166.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of January 16, 2013 (78 FR 3824), we published a notification with a 30-day comment period announcing the availability of, and requesting comment on, a document entitled “Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm.” The purpose of the draft RA is to provide a science-based risk analysis of those activity/food combinations that would be considered low risk. We conducted this draft RA to satisfy requirements of the FDA Food Safety Modernization Act (FSMA) to conduct a science-based risk analysis and to consider the results of that analysis in rulemaking that is required by FSMA. In the **Federal Register** of January 16, 2013 (78 FR 3646), we announced that we had used the results of the draft RA to propose to exempt certain food facilities (i.e., those that are small or very small businesses that are engaged only in specific types of onfarm manufacturing, processing, packing, or holding activities identified in the draft RA as low-risk activity/food combinations) from the proposed requirements of the Federal Food, Drug, and Cosmetic Act for hazard analysis and risk-based preventive controls (the proposed preventive controls rule). Interested persons were originally given until February 15, 2013, to comment on the draft RA.

**II. Request for Comments**

Following publication of the notification announcing the availability of, and requesting comment on, the draft RA, we received three requests to allow interested persons additional time to comment. The requesters asserted that the time period of 30 days was insufficient to respond fully to FDA’s specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues. Two requesters considered that the comment period for the draft RA should conform to the comment period of the proposed preventive controls rule. (One of these requesters further requested that the comment period conform to that of another proposed rule published in the **Federal Register** of January 16, 2013 (78 FR 3504; the proposed produce safety rule) and other major rulemakings that FDA would be conducting under FSMA but were not yet published.) For similar reasons, another requestor considered that the comment period should be extended by another 120 days, to June 14, 2013.

We have considered the requests and are reopening the comment period for the draft RA until May 16, 2013, which conforms to the comment periods of the proposed preventive controls rule and the proposed produce safety rule. We believe that this extension allows adequate time for interested persons to submit comments without significantly delaying the associated rulemaking in the proposed preventive controls rule.

**III. How To Submit Comments**

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: March 7, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[EPA-R04-OAR-2009-0140; FRL-9789-6]

**Approval and Promulgation of Air Quality Implementation Plans: North Carolina; Control Techniques Guidelines and Reasonably Available Control Technology**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to approve several State Implementation Plan (SIP) revisions submitted to EPA by the State of North Carolina, through the North Carolina Department of Environment and Natural Resources (NC DENR), to address the nitrogen oxides (NOx) reasonably available control technology (RACT) requirements for the North Carolina portion of the Charlotte-Gastonia-Rock Hill, North Carolina-South Carolina 1997 8-hour ozone nonattainment area (hereafter referred to as the “bi-state Charlotte Area”). The bi-state Charlotte Area for the 1997 8-hour ozone national ambient air quality standards (NAAQS) includes six full counties and one partial county in North Carolina; and one partial county in South Carolina. Additionally, EPA is proposing to approve in part, and conditionally approve in part, several SIP revisions to address the volatile organic compounds (VOC) RACT requirements which include related control technology guidelines (CTG) requirements. Together, these SIP revisions establish the RACT requirements for sources located in the North Carolina portion of the bi-state Charlotte Area. In a separate rulemaking, EPA has already taken action on RACT and CTG requirements for the South Carolina portion of the bi-state Charlotte Area. EPA has evaluated the proposed revisions to North Carolina’s SIP, and has made the preliminary determination that they are consistent, with the exception of applicability for some CTG VOC sources, with statutory and regulatory requirements and EPA guidance.

**DATES:** Comments must be received on or before April 12, 2013.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R04-OAR-2009-0140 by one of the following methods:

1. [www.regulations.gov](http://www.regulations.gov): Follow the on-line instructions for submitting comments.
2. *Email:* R4-RDS@epa.gov.