



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: October 4, 2016

SUBJECT: **Review of Estimating Dietary Exposure from the Use of Food Contact Sanitizing Solutions in Commercial Settings Model.**

PC Code: NA
Decision No.: 514442
Petition No.: NA
Risk Assessment Type: NA
TXR No.: NA
MRID Nos.: 49964100, 49964101

DP Barcode: D434853
Registration No.: NA
Regulatory Action: NA
Case No.: NA
CAS No.: NA
40 CFR: NA

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The American Chemistry Council's Biocides Panel ("the Panel") submitted two documents to EPA's Office of Pesticide Program in July 2016 entitled "American Chemistry Council Biocides Panel (2016) submission of Exposure and Risk Data in Support of the Risk Assessment" (MRID 49964100) and "Estimating Indirect Dietary Exposure from the Use of Food Contact Sanitizing Solutions in Commercial Settings" (MRID 49964101). These were submitted by the Panel in response to an earlier EPA review (DP Barcode D431928, dated: 4/19/2016) of the Panel's

January 2016 submission of the revised version of Food Contact Sanitizing Solution (FCSS) model in which the Agency requested clarification as to why certain whipped toppings and cream substitutes were categorized as fruit juice instead of milk. The Agency also requested the Panel to provide a User Guide for the model. The current submission by the Panel was intended to address those aforementioned issues which were originally raised in the EPA April 2016 review, referenced above. The current memorandum (DP Barcode D434853) reviews the revised FCSS model and the Panel responses and concludes that the issues have been satisfactorily addressed. The most recent submission of the Panel adequately addressed all of the data component and modeling issues that were identified. EPA's response to each of these is addressed, in turn, below.

EPA September 2016 Comment to the July 2016 Panel Submission about Categorization of Cream Substitute and Whipped Toppings:

In EPA's April 2016 memo, the Panel was asked to provide additional clarification regarding the classification used by the Panel in its January 2016 submission for 'cream substitutes and whipped toppings.' For some of the cream substitutes and whipped topping with first three digits '122', the Panel used the 'milk' category. For others with same first three digits, the Panel used the 'fruit juice, not fresh' category. USDA FNDDS¹ classified all food items with first three digits equal to '122' as 'cream substitutes' subcategory which belongs to broader 'milk and milk products' category. The Panel, in their response, concurred with EPA that these food items were inappropriately categorized and has reclassified them in the milk category which is consistent with FNDDS classification. The Panel has also reanalyzed the data to account for the reclassifications in the current July 2016 submission. The changes are identified within attachment 4b to the model, and the other attachments are updated to account for the reclassification. The most recent submission of the Panel adequately addressed all of the data component and modeling issues that were identified. No further action is required.

EPA September 2016 Comment to the July 2016 Panel Submission about a User Guide:

In EPA's April 2016 memo, the Panel was asked to provide a User Guide to assist dietary exposure assessors in using the model to estimate dietary exposure and risk. The Panel provided a draft User Guide that provides background information on the model and instructions for how to use the model to calculate dietary exposure and risk for a specific set of exposure scenarios. The HED-AD Dietary Support Team has reviewed the User Guide and found it to be useful in dietary exposure evaluation. The draft was finalized by HED with some minor edits.

Conclusion: EPA has reviewed two submission from the Panel including: 1) the Panel responses to address the previous EPA comments; and 2) the revised FCSS model. These were provided to the Agency in July 2016 in response to the earlier April EPA memorandum (DP Barcode D431928, dated: 4/19/2016) that requested that additional clarification be provided with respect to the rationale regarding some cream substitutes and whipped toppings foods being categorized as fruit juice. The Panel in their response concurred with EPA that these food items were

¹ *USDA Food and Nutrient Database for Dietary Studies 2011-2012 Documentation and User Guide* at http://www.ars.usda.gov/SP2UserFiles/Place/80400530/pdf/fndds/fndds_2011_2012_doc.pdf

inappropriately categorized and has reclassified them in milk category which is consistent with FNDDS classification and reanalyzed the data to account for the reclassifications in July 2016 submission. Additionally, the Panel has submitted an adequate User Guide for the model, as requested which HED had modified and finalized. **The current submission from the Panel adequately addressed all of the data component and modeling issues that were previously identified.**

References:

American Chemistry Council Biocides Panel (2016) submission of Exposure and Risk Data in Support of the Risk Assessment. Transmittal of 1 study. MRID 49964100

Brown, E. (2016) Estimating Indirect Dietary Exposure from the Use of Food Contact Sanitizing Solutions in Commercial Settings. Unpublished study prepared by Steptoe & Johnson, LLP. 14p. MRID 49964101

Sarkar, B. and Van Alstine, J. 4/19/2016. D431928. Review of Proposal for Estimating Dietary Intake from the Use of Food Contact Sanitizing Solutions in Commercial Settings [review of Brown, E. (2016) submission].