

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

DATE: June 17, 2014

SUBJECT:

Review of Supporting Material for IDREAM Model for Assessing Incidental Ingestion Exposure or Residential Antimicrobial Cleaning Products

19 NIL 2014

PC Code: NA Decision No.: NA Petition No.: NA Risk Assessment Type: NA TXR No.: NA MRID No.: 49400001. 49256701

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FROM:

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TO:

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The American Chemistry Council's Biocides Panel ("the Panel") submitted two reports to EPA's Office of Pesticide Program. One was prepared by Exponent and entitled "A Tiered Model to Assess Incidental Ingestion Exposure to Residential Antimicrobial Cleaning Products" (dated: December 16, 2013; MRID 49400001). This was submitted by the Panel in response to an earlier review done by W. Hazel (DP Barcode D3680501, dated: 5/22/13; MRID 49400101) of the Panel's original 2006 submission of IDREAM in which the Agency requested certain changes be made to the model for estimating indirect dietary exposure that may arise from the use of disinfectants on kitchen countertops in residential settings. The current submission was authored by Exponent and was intended to address the following 13 issues raised in the W. Hazel 5/22/13 review (quoting):

- 1. IDREAM has not been supported by sufficient documentation in a number of areas as summarized below.
- A more transparent discussion of the software used (e.g., User's Manual, decisions made regarding the program inputs, etc.) is necessary.
- The food consumption rates (mg/kg bw/day) in IDREAM must be updated to incorporate recent (2003-2008) food consumption data (FCID-NHANES/WWEIA).
- Both the 90th and 95th percentile values must be provided for acute assessment consumption rates for all food categories.
- Dietary exposure and risk estimates must be provided for the following subpopulations: General U.S. Population, Infants <1, Children 1 & 2, Children 3-5, Children 6-12, Youths 13-19, Adults 20-49, Adults 50+, and Females 13-49.
- Documentation describing how the food consumption rates are derived using FARE[™] for the incorporation of WWEIA data must be provided.
- Acute exposures estimated using 90th (and 95th; see Conclusion 4) percentile consumption values of the two highest contributing food categories for each population subgroup must be compared to the same percentiles of bread and meat consumption.
- 8. A more thorough and transparent discussion of the nine food categories and food ingredient assignment must be provided. The criteria identified as the basis for food assignment to a given food category needs to be explained. This model parameter must also be updated using the new WWEIA data.
- 9. The most commonly consumed food per food category (used for food surface area) based on NHANES/WWEIA data must be compared with those based on CSFII to determine if there has been a change. The agency also requests that the dimensions (USDA or other reliable source) of the five most frequently consumed foods per category be provided.
- 10. The ACC must update the serving size data using the more recent WWEIA data. A justification is required to support use of an average food weight value per food category as opposed to the serving size of each food in a food category. In addition, the weights of the five most frequently consumed food items per category must be provided.
- 11. The bases for the percent Likelihood of Contact values for the food categories must be made transparent. The data must be presented such that respondents can be isolated individually, e.g., to permit distinguishing individuals who rarely place/prepare food on treated countertops vs. those who habitually do. Additionally, a number of summary tables must be rectified from the raw data provided. The basis for the percent Likelihood of Contact values for each food category must be described and made transparent by providing the inputs, sample calculations, the equation(s) used to calculate Likelihood of Contact, etc. Until these issues have been resolved to EPA's satisfaction, the agency will use 100% Likelihood of Contact for all food categories in those cases it uses IDREAM to conduct a chronic dietary assessment.
- 12. Acute assessments must always be conducted using 100% Likelihood of Contact.
- 13. One stepwise example of both an acute and a chronic assessment using IDREAM must be conducted from start to finish and provided in model documentation. This should be clearly represented as a sequence of equations, etc. so that the user can understand the way the various inputs, parameters, and outputs are applied, are transformed, how they influence the outcome, etc.

In addition, the 5/22/13 W. Hazel memo requested clarification regarding a second submission entitled "Consumer Survey of Kitchen Countertop Disinfectant Usage and Food Preparation (Project Focus") which arose during W. Hazel review of the summary tables and raw data. Specifically, Appendix A ("Likelihood of Contact Data: Raw Data Analysis") of the 5/22/13 W. Hazel memorandum requested that the following 8 points be addressed:

- Based on the presentation of the results, the agency is unable to track individual's habitually placing/preparing food on a sanitized countertop.
- 2. The raw data are not provided in tabular format to display specific counts per base group (denominator) for calculation of the percentages of individuals engaging in certain activities.
- 3. Table 5 is a replica of that in the Exponent[®] report derived from the survey and directly input into the IDREAM spreadsheet. As indicated in the detailed discussion, this table was unable to be verified or supported alongside the raw data. This confirms the agency's experience that the likelihood of contact values in IDREAM cannot be scientifically validated.
- 4. All of the raw data are presented based on the type of countertop surface found in the household. The data in some of the summary tables are presented based on individual respondents or types of cleaning products used. However, the summarized data could not be correlated with the raw data. This varying presentation results in several base subgroups (denominators) creating difficulty correlating the raw data with the summary tables.
- 5. Percent values in the summary tables appear to be calculated based on a total sample of 1,000 individuals, which was the number of respondents for the survey. When evaluating the raw data, 1,000 is identified as the total respondents (total number of respondents answering the question on the type of countertop they have in their home), but the sigma value (sum) is 1,035. There is no explanation or discussion of this difference, which could be attributable to the possibility that a person may have more than one countertop in their household.
- 6. The total number of disinfectors is reported as 842 individuals throughout several of the summary tables. However, when the raw data are used, the sum of disinfectors is 864 (625+14+2+11+7+35+51+86+5+28). While this could be due to a reason similar to that theorized in point 5 (e.g., that some people could be using a sanitizer spray on both Formica and Tile), there is no discussion provided. As a result, the values cannot be verified with the raw data provided at this time.
- 7. The total number of respondents with Formica countertops is listed as '743' in many of the summary tables. This value is consistent with the raw data for Q.1 (p. 34), Q.2 (p. 36) and Q.5 (p. 119) but is inconsistent with the raw data for Q.12 (p. 695) and Q.13 (p. 737) which report this value as '722'.
- 8. There is no indication the data provided in the summary tables have been incorporated into any other areas of IDREAM, only the values reported in Table 5.

The Panel's other submission – also reviewed here – is entitled "Reanalysis of Consumer Behavior Data and Response to Questions Raised by US-EPA" (dated 11/12/13; MRID 49256701) and was intended to address these 8 additional concern raised in the 5/22/13 Hazel review. This reanalysis was submitted by The Clorox Company, and was authored by Steptoe and Johnson, LLP.

For ease of review and interpretation, this EPA response memorandum is divided into two Parts. Part A of this EPA memorandum discusses the Panel's response to the 13 issues raised in the main text of the W. Hazel 5/22/2013 memorandum. Part B discusses The Clorox Companies response to the 8 issues raised in the Appendix B of the Hazel memorandum.

DETAILED ANALYSIS

PART A. Review of "A Tiered Model to Assess Incidental Ingestion Exposure to Residential Antimicrobial Cleaning Products" (MRID 49400001. Dated 12/16/2013)

CEB finds the Panel's response to the 13 issues raised in the W. Hazel 5/22/13 memorandum is adequate in addressing the earlier concerns raised in the W. Hazel 5/22/13 memorandum. EPA's response to each of these is addressed, in turn, below:

- 1. IDREAM has not been supported by sufficient documentation in a number of areas as summarized below.
 - EPA RESPONSE TO PANEL SUBMISSION: No specific response necessary. See below. EPA concludes that IDREAM is now supported by sufficient documentation in the areas previously deemed inadequate.
- 2. A more transparent discussion of the software used (e.g., User's Manual, decisions made regarding the program inputs, etc.) is necessary.
 - EPA RESPONSE TO PANEL SUBMISSION: CEB has reviewed the discussion of the Excelbased model and believes that the most recent Panel Submission, Exponent's "A Tiered Model to Assess Incidental Ingestion Exposure to Residential Antimicrobial Cleaning Products" provides adequate and transparent discussion of the model. Program inputs such as Ratio of Contact Surface Area to Food Ingredient Weight, Likelihood of Contact, Surface Residue Transfer Efficiency, Residue Translation Factor, Food Consumption Rate (both chronic and acute), Ingestion Unit Exposure, and Countertop Surface Residue are all described and discussed on pages 19-31 of the Exponent report. Additional details regarding the Contact Surface Area to Food Ingredient Weight ratio calculations are adequately described in Appendix 2 of the Exponent Report. This concern has now been adequately addressed.
- The food consumption rates (mg/kg bw/day) in IDREAM must be updated to incorporate recent (2003-2008) food consumption data (FCID-NHANES/WWEIA).
 - EPA RESPONSE TO PANEL SUBMISSION: The model has been updated to incorporate the most NHANES/WWEIA food consumption survey data. The 2009-2010 NHANES/WWEIA has now become available and the model thus uses the 2005-2006, 2007-2008, and 2009-2010 dietary survey releases as described on p.12 of the Exponent report. This concern has been addressed.

- 4. Both the 90th and 95th percentile values must be provided for acute assessment consumption rates for all food categories.
 - EPA RESPONSE TO PANEL SUBMISSION: The Exponent document now provides both the 90th and 95th percentile values for consumption rates for all food categories. This is described under the Acute Food Consumption Rates section of the Exponent report on pp. 27-30 and in Table 6 ("Per User 90th Percentile 1-day Food Consumption Rates for Select Subpopulations" and Table 7 ("Per User 95th Percentile 1-Day Food Consumption Rates for Select Subpopulations") of the report. In addition, the Exponent report illustrates the conservatism achieved by using the separate 90th or 95th Food Consumption Rates for each food category in their Tables 8 and 9 of this submission. This concern has been appropriately addressed.
- Dietary exposure and risk estimates must be provided for the following subpopulations: General U.S. Population, Infants <1, Children 1 & 2, Children 3-5, Children 6-12, Youths 13-19, Adults 20-49, Adults 50+, and Females 13-49.
 - EPA RESPONSE TO PANEL SUBMISSION: The Exponent model has been modified to provide exposure estimates for the above-listed subpopulations of interest to HED and AD (see p. 13 of the Exponent report). The Tier 2 model estimates the acute and chronic dietary exposures for each of these subpopulations in accordance with OPP dietary exposure practice. Thus, this concern has been addressed
- 6. Documentation describing how the food consumption rates are derived using FARE[™] for the incorporation of WWEIA data must be provided.
 - EPA RESPONSE TO PANEL SUBMISSION: The Exponent report adequately describes how food consumption rates are derived using the FARE software (see p.p. 24-30 in the section entitled Food Consumption Rate in the Exponent report). We note that the FARE software is a data-mining and calculation tool which uses survey response data from the CDC's NHANES/WWEIA food consumption survey along with information from various USDA databases (e.g., USDA's FNDDS, Food and Nutrient Database for Dietary Studies). FARE does not itself contain any proprietary data, and FARE output could be duplicated with any standard survey statistics-capable statistical software. FARE has been used in a number of peer-reviewed publications referenced by Exponent in the submission. This concern has been addressed.
- Acute exposures estimated using 90th (and 95th; see Conclusion 4) percentile consumption values of the two highest contributing food categories for each population subgroup must be compared to the same percentiles of bread and meat consumption.

- ⇒ EPA RESPONSE TO PANEL SUBMISSION: Exponent provide the rationale and basis for its selection of meat and fruit as the two highest contributing food categories which was determined to be true for all population subgroups of interest. Specifically, Exponent indicated (and EPA agrees) that the sum of the 90th (or 95th) percentile food consumption values for each of the 9 food categories would produce an estimate that was far in excess of the 90th (or 95th) value of the total. Thus, the Exponent IDREAM spreadsheet model uses the two food categories which, at the 90th percentile, would produce the highest exposures, and sets the remaining (7) categories at their mean per capita value. This calculation - and the selection of meat and fruit as the two "high end" categories - is adequately described in Appendix 4 of the Exponent report. More specifically, Appendix 4 describes the calculations behind the identification of meat and fruit as the two categories which taken at the 90th percentile – would lead to the highest acute exposure and are thus "worst case" categories for evaluating exposure. Tables 4-1 and 4-2 in this Appendix provide the background calculations and illustrate that these two categories provide the highest 90th percentile unit ingestion exposures (expressed as [(mg ai/kg bw – day/(mg product/cm²)]). Inspection of these two tables shows that for all age categories, meat and fruit are the largest categories in magnitude. This is true for both the 90th (Table 4-1) and 95th (Table 4-2) percentile per use exposures. It is apparent from these tables that bread is not one of the two highest. EPA concludes that this concern has been adequately addressed.
- 8. A more thorough and transparent discussion of the nine food categories and food ingredient assignment must be provided. The criteria identified as the basis for food assignment to a given food category needs to be explained. This model parameter must also be updated using the new WWEIA data.
 - ➡ EPA RESPONSE TO PANEL SUBMISSION: The food ingredient classifications are important because they are used to estimate the transfer of surface residues. The Exponent report provided an adequate and transparent discussion of the nine food categories and how food ingredients were assigned on p.p. 13-18 of the report under the section entitled Food Ingredient Classification. Specifically, Exponent used the first 5 digits of the hierarchical NHANES food code and assigned each ingredient to one of nine food categories based on consideration of food ingredient type, food preparation method, food physical properties, and the potential for contact with countertop surfaces in residences. Initially, Exponent had divided foods into five groups (solids, semi-solids, pieces, powders, and liquids), but – due to the wide variety of foods in the "solid" category – this was subsequently subdivided into five subcategories to better represent the important above-named considerations with the transfer of residues to food added to this list. This resulted in the solid category being subdivided into 5 subcomponents: bread, cheese, fruit, meat, and vegetables. Exponent provides in its report a description of and diagnostic/inclusion criteria for each of these nine categories and subcategories. Additionally, more detailed discussion and rationale is provided for what may be less intuitive food category

assignments. Further, Exponent discusses the rationale for assigning certain foods to different categories based on age group (children less than or equal to 2 y.o. vs. the rest of the population of 3+ y.o.). As an example, foods that may be categorized as "pieces" for the remainder of the population and have an expected greater likelihood of contact and residue transfer with countertop surfaces (e.g, popcorn, ready-to-eat cereals, pretzels, etc.) were classified as "bread" for children less than 2 y.o. since young children may eat these foods from treated countertops.

Appendix 1 of the Exponent report provides the categories used for all NHANES/WWEIA ingredient codes used to generate food consumption rates.

EPA considers this concern adequately addressed.

9. The most commonly consumed food per food category (used for food surface area) based on NHANES/WWEIA data must be compared with those based on CSFII to determine if there has been a change. The agency also requests that the dimensions (USDA or other reliable source) of the five most frequently consumed foods per category be provided.

and

- 10. The ACC must update the serving size data using the more recent WWEIA data. A justification is required to support use of an average food weight value per food category as opposed to the serving size of each food in a food category. In addition, the weights of the five most frequently consumed food items per category must be provided.
 - EPA RESPONSE TO PANEL SUBMISSION: The section of the Exponent report entitled Ratio of Contact Surface Area to Food Ingredient Weight provides the range of CSA/FW ratios for the five most commonly consumed foods in Table 2 ("Range and Worst Case Ratios of the Contact Surface Area to Weight for Each Food Category"). Supporting information is detailed in Appendix 2 of the Exponent report and adequately addresses this issue. Specifically, Appendix 2 provides information about how contact surface areas and weights were obtained for each of the five most consumed foods in each IDREAM food category. These dimensions and gram weights were obtained from the NHANES "What's in the Foods You Eat" search tool. Table 2-1 in this Appendix list the top 5 foods in each category, the daily consumption by children 2-5 y.o., the dimensions of the food, and the associated weight. Exponent notes that when dimensions were not available, a representative sample was selected from a supermarket or home-prepared sample and measured by hand.

This concern has thus been addressed.

- 11. The bases for the percent Likelihood of Contact values for the food categories must be made transparent. The data must be presented such that respondents can be isolated individually, e.g., to permit distinguishing individuals who rarely place/prepare food on treated countertops vs. those who habitually do. Additionally, a number of summary tables must be rectified from the raw data provided. The basis for the percent Likelihood of Contact values for each food category must be described and made transparent by providing the inputs, sample calculations, the equation(s) used to calculate Likelihood of Contact, etc. Until these issues have been resolved to EPA's satisfaction, the agency will use 100% Likelihood of Contact for all food categories in those cases it uses IDREAM to conduct a chronic dietary assessment.
 - EPA RESPONSE TO PANEL SUBMISSION: The Likelihood of Contact values are discussed on p. 20-21 of the Exponent submission and are derived from a study conducted by Synovate Research from a panel survey done during April 2004. The study was designed to understand consumer behavior with respect to countertop disinfection and food preparation practices, and was a cross sectional survey among a nationally representative sample of US households. A total of 1,035 respondents who described themselves as primarily responsible for cleaning and food preparation in the household were recruited. Exponent extracted the survey results that relate to likelihood of contact with countertops, which are presented in Table 3 ("Likelihood of Food Contacting Residential Countertops") and in Appendix 3 of the Exponent report. In order to produce conservative estimates, the model uses these Likelihood of Contact probabilities for only the chronic assessment; for acute assessments, the likelihood of contact is assumed to be 100%. EPA concludes that the description of the survey and the rationale of the selection of the Likelihood of Contact values are adequate.

With respect to issues related to the presenting data "such that respondents can be isolated individually, e.g., to permit distinguishing individuals who rarely place/prepare food on treated countertops vs. those who habitually do" the original survey data is indicated to be not available. This issue is covered in more detail in Part B of this EPA memorandum, but we believe that Exponent's use of the survey results is sufficiently conservative to provide us confidence that the values used are protective. This includes the fact that the Exponent model assumes for acute assessments that all foods (except liquids) contact treated countertops and only uses survey results for likelihood of contact from chronic dietary exposure assessments. Given the age of the survey (it is now more than 10 years old), we may recommend that an updated survey be done at some point in the future, perhaps to coincide with the release of the NHANES 2013-2014 cycle release in the late summer of 2016.

EPA concludes that this these concerns have been adequately addressed.

12. Acute assessments must always be conducted using 100% Likelihood of Contact.

- ➡ EPA RESPONSE TO PANEL SUBMISSION: The Exponent models assumes 100% likelihood of contact for all acute assessments (and 100% use of disinfectant countertop cleaners). This, this concern has been addressed.
- 13. One stepwise example of both an acute and a chronic assessment using IDREAM must be conducted from start to finish and provided in model documentation. This should be clearly represented as a sequence of equations, etc. so that the user can understand the way the various inputs, parameters, and outputs are applied, are transformed, how they influence the outcome, etc.
 - EPA RESPONSE TO PANEL SUBMISSION: The Exponent report provides an adequate example of both acute and chronic assessment using IDREAM in the section entitled Dietary Exposure Calculations on p. 31-46 of the submission. This description include the various formulae/equation sequences, as well as spreadsheet-like tables for chronic (Table 10) and acute (Table 11) assessments. The way the various inputs, parameters, and outputs are applied, are transformed, and how they influence the outcome is clear from both the report and the included Excel spreadsheet.

This concern has been adequately addressed

PART B. Review of "Reanalysis of Consumer Behavior Data and Response to Questions Raised by US-EPA" (MRID 49256701, provided as supplemental information for MRID 47802501)

As indicated earlier, this second submission was intended to address an additional 8 issues described in Appendix A of the 5/22/13 W. Hazel memorandum. These additional issues relate primarily to questions that arose relating to summary tables and raw data that were used as several inputs into the IDREAM model. These 8 issues are addressed below:

- 1 Based on the presentation of the results, the agency is unable to track individuals habitually placing/preparing food on a sanitized countertop.
 - ➡ EPA RESPONSE TO PANEL SUBMISSION: The Clorox Company's response is that EPA is correct. Clorox indicated that the original survey research firm, Synovate, provided

the results to them in 2004, but Synovate was purchased in 2011 by IPSOS. The Clorox Company reported that standard practice for market research survey data is to purge the data files after 5 years. Thus, The Clorox Company states that the individual response data is no longer available.

While this raw data would ideally have been available for review and analysis by the Agency, EPA believes based on its review of this submission and the details provided therein that the raw data is not critical to a determination that the inputs used in the IDREAM model are generally supported by the data. Specifically, the relevant component of the survey relates the likelihood of food contacting residential countertops and this information is used only in the <u>chronic</u> (and not acute, which assumes 100% likelihood of contact) assessment. While Synovate's original (2004) numbers in the earlier submission that relate to this probability were unable to be precisely replicated by the current submission, the numbers were closely – and EPA believes adequately -- replicated as indicated below in a table provided on p. 14 of the current submission and excerpted here:

Food Group	Synovate 2004 ^a		Re-analysis of MRID 47802501 ^b	
	Number	Percent People	Number	Percent Response
Bread, sandwich, toast	227	60	264	57
Dough	224	59	249	53
Fruit	152	40	170	36
Cheese	121	32	138	30
Vegetable/Salad	98	26	111	24
Meat, poultry, seafood	68	18	77	16
Other**	42	11	97	21
TOTAL	379		467	Second Pro-

^a Based on people using disinfectant products who report preparing certain foods directly on kitchen countertops

^b Based on people who report preparing certain food directly on kitchen countertop, regardless of whether disinfectant products are used

* Numbers based on calculation using the 379 persons reported by Synovate (45% of 842)

** Synovate 2004 identified this as "other includes mentions of pasta, spices, and herbs among other various food mentions". However, the components of that category cannot be clearly identified in MRID 47802501 and has been more broadly defined.

This concern has been adequately addressed.

- 2 The raw data are not provided in tabular format to display specific counts per base group (denominator) for calculation of the percentages of individuals engaging in certain activities.
 - EPA RESPONSE TO PANEL SUBMISSION: The Clorox Company indicated that they retabulated the most critical data and provided this in its submission. EPA has reviewed this new material and finds it to be acceptable and to adequately address its concern.
- 3. Table 5 is a replica of that in the Exponent® report derived from the survey and directly input into the IDREAM spreadsheet. As indicated in the detailed discussion, this table was unable to be verified or supported alongside the raw data. This confirms the agency's experience that the likelihood of contact values in IDREAM cannot be scientifically validated.
 - EPA RESPONSE TO PANEL SUBMISSION: The Clorox Company indicates that the data here in EPA's Table 5 ("What do Disinfectors Prepare on the Countertops") are a result of an analysis that cannot be duplicated because the data are no longer available. As describe in EPA's response to Item (1) above, this has been adequately addressed and the new IDREAM submission (dated December 16, 2013) appropriately uses the data resulting from the Re-analysis of MRID 47802501.

This concern has been addressed.

- 4. All of the raw data are presented based on the type of countertop surface found in the household. The data in some of the summary tables are presented based on individual respondents or types of cleaning products used. However, the summarized data could not be correlated with the raw data. This varying presentation results in several base subgroups (denominators) creating difficulty correlating the raw data with the summary tables.
 - ➡ EPA RESPONSE TO PANEL SUBMISSION: The Clorox Company has re-tabulated the most critical data to address this issue. EPA finds this to be acceptable and adequately

addressed, and notes the type of countertop surface is not a data input used by the IDREAM model.

- 5. Percent values in the summary tables appear to be calculated based on a total sample of 1,000 individuals, which was the number of respondents for the survey. When evaluating the raw data, 1,000 is identified as the total respondents (total number of respondents answering the question on the type of countertop they have in their home), but the sigma value (sum) is 1,035. There is no explanation or discussion of this difference, which could be attributable to the possibility that a person may have more than one countertop in their household.
 - EPA RESPONSE TO PANEL SUBMISSION: The Clorox Company responded that the Agency is correct. There were 1000 participants in the survey, but some participants had multiple surfaces in their kitchen and separate responses were prepared for each surface type. As a result, there are 1035 responses for the 1000 respondents. EPA believes this response to be satisfactory.
- 6. The total number of disinfectors is reported as 842 individuals throughout several of the summary tables. However, when the raw data are used, the sum of disinfectors is 864 (625+14+2+11+7+35+51+86+5+28). While this could be due to a reason similar to that theorized in point 5 (e.g., that some people could be using a sanitizer spray on both Formica and Tile), there is no discussion provided. As a result, the values cannot be verified with the raw data provided at this time.
 - EPA RESPONSE TO PANEL SUBMISSION: The Clorox Company indicated that this number arose from a specialized analysis of the original individual respondent data that cannot be duplicated because that data is no longer available. While ideally this data would be available and could be checked, EPA believes that the generally minor discrepancy is not substantive with respect to the inputs and intended use of the model. This concern has been adequately addressed.
- The total number of respondents with Formica countertops is listed as '743' in many of the summary tables. This value is consistent with the raw data for Q.1 (p. 34), Q.2 (p. 36) and Q.5 (p. 119) but is inconsistent with the raw data for Q.12 (p. 695) and Q.13 (p. 737) which report this value as '722'.

- EPA RESPONSE TO PANEL SUBMISSION: The Clorox Company indicates in its response that the basis for this difference cannot be confirmed but is likely due to nonresponses. They state, however, that this issue is not related to inputs to the IDREAM model and has not been re-evaluated. EPA concurs with this response, and no longer has concerns with this issue.
- 8. There is no indication the data provided in the summary tables have been incorporated into any other areas of IDREAM, only the values reported in Table 5.
 - EPA RESPONSE TO PANEL SUBMISSION: The Clorox Company indicates that the Table 5 values resulted from a specialized analysis of the original respondent data cannot be duplicated because the data are no longer available. The Clorox Company agrees that the majority of the data presented in the summary tables is not relevant to IDREAM and thus was not incorporated into IDREAM. EPA concurs with The Clorox Company response and determines that this issue has been resolved.

CONCLUSION

EPA has reviewed two submission from the ACC Biocides Panel relating to 1) the IDREAM model; and 2) survey responses used to address the likelihood of contact input into the IDREAM model. These were provided to the Agency in December, 2013 and November, 2013 respectively in response to an EPA memorandum (W. Hazel, 5/22/2013) that requested that additional information be provided to support IDREAM and its inputs. The current memorandum reviews these responses and concludes that they have been satisfactorily addressed. The W. Hazel 5/22/2013 memorandum concluded with a list of issues that needed to be resolved for EPA to use IDREAM for regulatory decisions. These issues have – with these two most recent submissions – been adequately addressed for present purposes and EPA thus concludes that it is able to use IDREAM for regulatory decisions.

We note that that the use practice survey was originally conducted in 2004 and is now about 10 years old. We also note that NHANES dietary consumption data is released on a biannual basis approximately two years after data is collected. Thus, the Panel may wish to consider refreshing these surveys in about 5 years when the 2011-2012, 2013-2014, and 2015-2016 NHANES dietary consumption data is released. We recognized that the raw NHANES survey data is fully publically available and retained by CDC indefinitely, but would caution the Panel that any future raw use/usage survey data that is collected to support IDREAM should be retained for submission to the Agency for verification purposes.

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