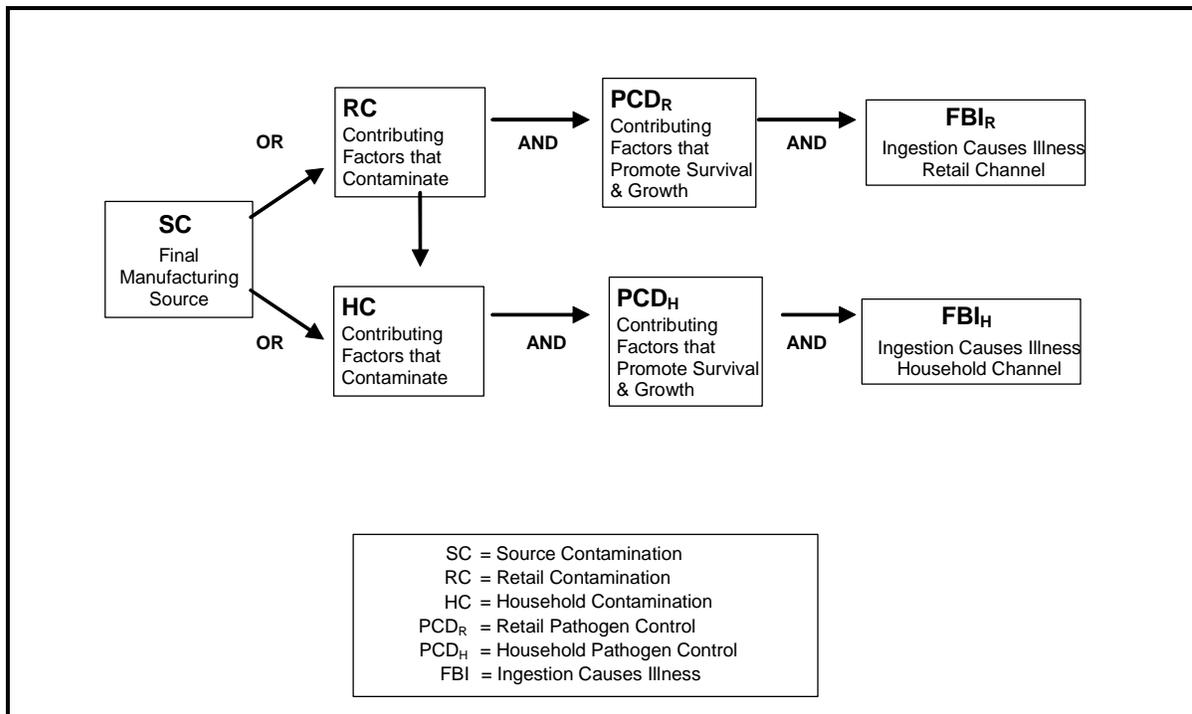


## FDA Backgrounder The Food Handling Practices Model (FHPM) Version 1.1

Each year millions of cases of foodborne illness occur in the United States. Preceding most cases of foodborne illness is contamination by pathogens and failure to destroy or sufficiently control pathogens in retail and foodservice establishments or households. FDA under contract with RTI International developed a quantitative simulation model of the effects of contributing factors on the incidence of foodborne illness.

The food handling practices model is a computer simulation model that allows users to estimate how one or more changes in food handling practices at the retail, foodservice, or household level may affect the annual number of food-related illnesses in the US. The model operates by simulating, tracking, and counting servings of food that become contaminated with one or more pathogens, followed by survival and growth of pathogens and subsequent ingestion that results in foodborne illness. The model does not track or count servings of food that are not contaminated with pathogens.

### Simplified Schematic of the Food Handling Practices Model



#### Source Contamination

Source contamination is represented in the model by the probability that dairy, eggs, meat, poultry, produce, seafood, and water leave the final manufacturing source contaminated. These types of foods are estimated to be contaminated upon leaving the final manufacturing source based on contamination with bacillus cereus, Campylobacter jejuni, Clostridium perfringens, Cryptosporidium parvum, Cyclospora cayetanensis, E. coli O157:H7, other E. coli spp., Hepatitis A, Listeria Monocytogenes, Norovirus, Salmonella enteritidis, all other non-typhoidal Salmonella spp., Shigella spp.,

Staphylococcus aureus, Streptococcus spp., Vibrio spp., and Yersinia enterocolitica. The specificity of food or pathogen type in the model does not go past the source contamination stage due to data limitations. Model results are estimated as changes in contaminated food servings and foodborne illnesses, but cannot be attributed to a specific type of food or pathogen.

Retail establishments evaluated in the FHPM:

- Grocery stores            -Full-service restaurants            -Child care centers
- Convenience stores    --Hospitals                    -Seafood stores            -Fast-food restaurants
- Schools                    -Temporary establishments            -Nursing homes

Types of households evaluated in the FHPM:

- Single female            -single male                    -single parent without children
- Single parent with children            -Couple without children            -Couple with Children
- Senior male                -Senior female

Contributing factors that may contaminate food (included in the model)

- food handling by asymptomatic (infected) food handler
- Food handling by ill food handler
- Inappropriate bare-hand contact with ready-to-cook foods
- Inappropriate bare-hand contact with ready-to-eat foods
- Inappropriate gloved-hand contact with ready-to-cook foods
- Inappropriate gloved-hand contact with ready-to-eat foods
- Inappropriate hand washing
- Inappropriate sanitation of equipment or utensils
- Inappropriate sanitation or cleaning of cutting boards

Contributing factors that may allow survival and growth of pathogens in food (included in the model)

- Food kept at room temperature too long
- Food served raw or lightly cooked
- Inappropriate advance preparation
- Inappropriate thawing of frozen foods
- Inappropriate time or temperature for cold holding
- Inappropriate time or temperature for cooking

- Inappropriate time or temperature for cooling
- Inappropriate time or temperature for hot holding
- Inappropriate time or temperature for reheating

### Using the Model

To use the model, the user must first select a baseline with which to compare the changes in food handling practices that the user wishes to estimate. The baseline represents the current number of food servings in the retail and household sectors, the probabilities associated with contamination of food at the final manufacturing source, retail, foodservice, and household levels, and the probabilities associated with ingestion of contaminated food causing illness. The baseline in Version 1.0 of the food handling practices model is set to result in 76,000,000 total cases of foodborne illness, as predicted in Mead's 1999 paper.

Running baseline simulations of the model shows the user the number of contaminated servings, and the foodborne illnesses that result, by retail, foodservice, and household type. With the current data in Version 1.0, assuming that Mead's estimate of 76,000,000 cases of foodborne illness annually is correct, the baseline simulation results show how many contaminated servings of food are served at retail, or foodservice or in households.

To estimate how a change in a current food handling practice affects the number of contaminated food servings and resulting foodborne illnesses, the user must estimate the change in a baseline probability for a particular food handling practice in the model. For example, assume the baseline probability (in the model) associated with inappropriate time or temperature for cooking food in the household was 0.25 (25 percent of the time the time or temperature used for cooking food in the household was inappropriate). Then assume FDA plans to conduct a consumer education campaign to reduce the chances that consumers cook food unsafely. By assuming that the education campaign lowers the probability of inappropriate household cooking by 10 percent (from 0.25 to 0.15) we can re-run the model and get estimates of how many fewer food servings get contaminated in the household and how many fewer foodborne illnesses result because of the impact of the consumer education campaign.

### Primary and Secondary Data

Both primary and secondary data sources were used to estimate parameters for a national baseline calibration of the model. Before any change in food handling practice, and therefore foodborne illness incidence, can be assessed, we must develop a baseline of the current number of foodborne illnesses based on current handling practices and food consumption patterns.

Government sources provide a majority of the secondary data we collected for the food handling practices model. Various publications from the U.S. Department of Agriculture's Economic Research Service (ERS) and Food Safety and Inspection Service (FSIS) and the U.S. Department of Human Health Services' Food and Drug Administration (FDA) (including the Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors, 2000) and Centers for Disease Control and Prevention (CDC). In addition to research reports published by these agencies, the U.S. government

sponsors several ongoing surveys of consumers that were helpful (e.g., FDA's Food Safety Survey, USDA's Continuing Survey of Food Intakes by Individuals [CSFII]).

Data from peer-reviewed scientific literature (including the seminal 1999 Mead et al article) was also used to calibrate the model to generate the national baseline. For example, to estimate source contamination probabilities, we used data from several studies that estimate the prevalence of pathogen contamination in food. In cases where we found independent estimates from multiple studies, we calculated a weighted average estimate using study sample size as the basis for weighting.

Secondary data published on the web sites of the International Bottled Water Association, the Food Marketing Institute, and the National Association of Convenience Stores also helped us to estimate some parameters in the national baseline.

### Expert Elicitation

To estimate probabilities of improper food handling practices, we conducted an expert elicitation. We used an expert elicitation because for some probability parameters needed in the model, our only sources were the experts. For other probabilities used in the model, we created probability estimates from the scientific literature. For still other probability parameters, we combined estimates from the scientific literature and the expert elicitation to create averages.

The following people were members of the expert elicitation panel:

- Janet B. Anderson, R.D, M.S., Clinical Associate Professor, Dietetics Program, Nutrition and Food Sciences Department, Utah State University, Logan, UT
- Dr. Christine M. Bruhn, Center for Consumer Research, University of California, Davis
- Roy Costa, R.S., M.S., Hospitality and Tourism Institute, Valencia Community College, Orlando, FL
- John F. Schulz, Director of Quality Assurance, Marriott International, Washington, DC
- Dr. O. Peter Snyder, Jr., Hospitality Institute of Technology and Management, St. Paul, MN

### Additional Data Challenges

As anticipated, data needed to calibrate the food handling practices model for a national baseline were not readily available in the proper form. For example, the basic metric of the model is annual servings of food, but secondary sources typically report annual consumption measured in pounds or grams. Thus, to calculate annual servings of each food type, we divided annual consumption figures by an estimate of average serving size.

The categories of households and retail establishments typically reported in the secondary literature did not match those defined in the model. For instance, households headed by senior citizens are often grouped into one category, while the model splits senior

households by sex. To address these issues, we aggregated data, left parameters blank for specific categories, or reanalyzed primary datasets. We also used not-otherwise-listed categories for groups of households or institutions not defined in the model.

Similarly, contributing factors reported in the scientific literature do not always match those defined in the model. For example, we found no studies that reported the prevalence of food handling by colonized, asymptomatic food handlers, nor did we find studies that reported prevalence of inappropriate handling of food with gloved hands.

Ideally for the model, food shares would be based on volume data. But secondary data needed to estimate shares are often reported in terms of annual sales. Lacking volume data, we were forced to use sales data in some instances.

As mentioned previously, we used the USDA CSFII survey dataset to calculate several parameters. However, CSFII data may not be an ideal source of information for calibrating the model. The primary objective of the CSFII is to monitor dietary status of the national population, particularly the low-income population (USDA, 2000b). Because the food handling practices model requires estimates of food consumption in terms of annual servings for various categories of food prepared by retail establishments or household, estimating parameter values using CFSII data requires considerable manipulation and calculation.

### Important Model Limitations

Version 1.0 of the food handling practices model is constructed on an aggregate level due to data limitations. This aggregation means that version 1.0 does not distinguish between different pathogens or types of contaminated food past the source (final manufacturing) stage of the model. Thus, in version 1.0, servings of “food” are counted as simply contaminated or not contaminated at different stages of model, regardless of pathogen or virus type. Version 1.0 solely looks at foodborne, not waterborne or airborne, related illnesses.

Version 1.0 of the food handling practices model baseline has been constructed so that total foodborne illnesses caused in the retail and household sectors sum to 76,000,000 illnesses. The model was constructed in this manner because foodborne illness estimates from the Mead, et. al. paper (1999) are the best estimates available of both observed and unobserved foodborne illnesses. It is from this baseline that the incidence of foodborne illness may increase or decrease, depending on how inappropriate food handling practices (e.g., inappropriate time or temperature for cold holding of foods) are estimated to change. If a different baseline number of foodborne illnesses is used with the model, different reductions (or increases) in foodborne illnesses would result if the probability of an inappropriate food handling practice was changed.

### Model Software

The operational model is a software model that allows users to estimate changes in annual cases of food-related illness, given one or more changes in food handling practices in retail food establishments or in households. The model operates using Microsoft Excel combined with Microsoft Access and the add-in application software @Risk Version 4.5. Using visual basic programming, RTI designed the model to operate

through an interface that allows users who may be unfamiliar with Excel, Access, or @Risk 4.5 to operate the model effectively and efficiently. The model also allows users who are familiar with Excel, Access, and @Risk 4.5 to access the model's spreadsheets and database and to make full use of the graphical and analytical features of the @Risk 4.5 software without using the user interface.

#### Summary and Future Direction

Version 1.0 of the food handling practices model provides FDA with a valuable tool that can estimate potential changes in contaminated servings of food, and therefore changes in foodborne illness, when probabilities of inappropriate food handling practices change. This tool allows FDA to estimate the value, or benefit, of changes to the Food Code, the potential benefits from regulatory changes involving manufacturing or retail food handling practices, and the potential benefits of consumer education on food safety in the household.

Currently, FDA, under contract with RTI International is working on Version 2.0 of the food handling practices model. This version will improve upon the aggregated nature of version 1.0 by allowing the user to follow specific pathogens and types of food through the model from start to finish—provided that the user has specific data to input into the model set-up. Version 2.0 of the model will also assign pathogen loads to contaminated servings of food, an improvement over Version 1.0 which just estimates that a serving of food is contaminated or not contaminated. Version 2.0 also adds a new agricultural stage to the model. This allows the user to estimate handling practices on the farm and in the manufacturing plant; an improvement over the final manufacturing source contamination probability that is the starting point in Version 1.0 of the model.

Finally, perhaps the most useful improvement to the model is that Version 2.0 is being constructed in a different software operating package than Version 1.0. This new operating base, Analytica, will be even easier to use than the current software base of @RISK 4.5. Using Analytica as the operating platform of the model allows anyone to run Version 2.0 of the model regardless of whether or not they have actually purchased the Analytica software package.

#### Location and Contact Information for Version 1.0 of the FHPM

The Food Handling Practices Model Version 1.0, Model User's Guide, and Final Contract Report will be forthcoming on May 1, 2004 on the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) Food Safety Risk Analysis Clearinghouse website at: <http://www.foodriskclearinghouse.umd.edu>

For further information on the Food Handling Practices Model Version 1.0, please contact:  
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