

developed from it are among the tools available to FDA to aid in the evaluation of risk mitigation strategies and in the formulation of effective guidance for the industry. The risk assessment focused on raw oysters because that is the food in the United States predominately linked to illness from *V. parahaemolyticus* outbreaks since 1997. This risk assessment is a quantitative analysis in which the levels of pathogen in oysters were estimated beginning with harvest of the oysters through post-harvest handling, processing, and storage to predict exposure from consumption of raw oysters. The likelihood of illness following exposure to pathogenic *V. parahaemolyticus* from consumption of raw oysters was determined for different geographical areas and for various times of the year. The baseline model was used to develop "what-if" scenarios to evaluate the likely impact of potential intervention scenarios on the exposure to pathogenic *V. parahaemolyticus*. Elsewhere in this issue of the **Federal Register**, FDA is announcing a public meeting to provide clarification about the results of the risk assessment and information about how the risk assessment may be utilized.

The risk assessment follows the framework recommended both by the National Academy of Sciences and the Codex Alimentarius Commission. This structured framework involves the following steps:

- **Hazard Identification.** The review of data and information on health effects (e.g., gastroenteritis and septicemia) associated with consumption of raw oysters containing pathogenic *V. parahaemolyticus*.
- **Hazard Characterization/Dose-Response.** Characterization of the relationship between *V. parahaemolyticus* exposure level (dose) and probability and severity of illness (response) using data from clinical trials and epidemiological surveys. Anyone exposed to *V. parahaemolyticus* can become infected and develop gastroenteritis; however, individuals with concurrent underlying chronic medical conditions have a greater probability of developing septicemia.
- **Exposure Assessment.** The determination of the likelihood and level of exposure to *V. parahaemolyticus* from consumption of raw oysters using data on prevalence, water and air temperature, growth and survival of *V. parahaemolyticus*, oyster landings, and consumption.
- **Risk Characterization.** The integration of the exposure and dose-response data to estimate both the risk to the public health and the uncertainty associated with this estimate. The risk

assessment provides estimates of the following: (1) The predicted illness burden as the risk of an individual becoming ill when they consume a single serving of oysters, (2) the predicted number of illnesses (gastroenteritis) in the United States each year, and (3) the predicted number of cases of gastroenteritis that progress to septicemia.

The results of the risk assessment identified the following several significant factors that contribute to the probability of illness: (1) Levels of total *V. parahaemolyticus* in oysters at time of harvest, (2) harvesting and handling practices that allow growth of *V. parahaemolyticus* in oysters after harvest, and (3) mitigations that reduce levels of *V. parahaemolyticus* in oysters post-harvest.

III. Electronic Access

The risk assessment document is available electronically at www.cfsan.fda.gov.

Dated: July 11, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: June 2005

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of June 2005, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusions is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive

Branch procurement and non-procurement programs and activities.

Subject, city, state	Effective date
PROGRAM-RELATED CONVICTIONS	
ALONSO, TERESA HIALEAH, FL	7/20/05
BOGGS, CHRISTINA NEWPORT, WA	7/20/05
BRACKETT, AMOUEL UNION, SC	7/20/05
BRIAR CREST NURSING HOME, INC GREENWICH, CT	7/20/05
CARDELLE, CLARA MIAMI, FL	7/20/05
CARNET, GUILLERMO MIAMI, FL	7/20/05
COMMUNITY INTEGRATION ASSOCIATES, INC CAMPBELL, NY	7/20/05
COOKE, JEFFERY ROCHESTER HILLS, MI	7/20/05
COX, KATHLEEN KINGSTON, WA	7/20/05
CRAVEN, ALBERTA COLUMBUS, OH	7/20/05
CROOKS, LYNN GOSHEN, OH	7/20/05
DAVIS, MARK FAIRTON, NJ	7/20/05
DONETS, NISON BAYSIDE, WI	3/28/05
EISENBERG, LESTER SOUTHOLD, NY	7/20/05
EKONG, AFFIONG RICHARDSON, TX	7/20/05
EKONG, PATRICK SEAGOVILLE, TX	7/20/05
FERRER, SONIA MIAMI, FL	7/20/05
FLOYD, LINDA KIMBOLTON, OH	7/20/05
FOJON, LILLIAN MIAMI, FL	7/20/05
GEZALYAN, SARKIS GLENDALE, CA	7/20/05
GOMEZ, MARIO MIAMI, FL	7/20/05
GOWIN, AMY NORFOLK, VA	7/20/05
GREENBAUM, MARK NEW ROCHELLE, NY	7/20/05
GRIGORYAN, KONSTANTIN .. ALTADENA, CA	7/20/05
GRIMES, LUMESHIA COLUMBIA, SC	7/20/05
HARTER, ANA MIAMI, FL	7/20/05
HERRERA, GILBERTO MIAMI, FL	7/20/05
HOWARD, KYLE LEBANON, OH	7/20/05
JACKSON, BETHEARL SAN DIEGO, CA	7/20/05
JAGO, ROBERT JACKSONVILLE, OH	7/20/05
JAGO, SHARON JACKSONVILLE, OH	7/20/05
JENKINS, JOHN CAMPBELL, NY	7/20/05
JILES, E TEXARKANA, TX	7/20/05
JONES, NICOLE	7/20/05

Subject, city, state	Effective date	Subject, city, state	Effective date	Subject, city, state	Effective date
UNCASVILLE, CT		MONTICELLO, KY		DURHAM, NC	
HOHL, DONNA	7/20/05	BAROFF, DAVID	7/20/05	HALE, KIMBERLY	7/20/05
VANDALIA, MO		GIRARD, OH		MOREHEAD, KY	
HOPPER, CRYSTAL	7/20/05	BEAUCHAMP, MAVIS	7/20/05	HALL, SHARON	7/20/05
FOREST GROVE, OR		HEBRON, ND		TWAIN HARTE, CA	
JACKSON, RAYSHON	7/20/05	BEISWANGER, JILL	7/20/05	HALL, YVONNE	7/20/05
MILWAUKEE, WI		NEW ORLEANS, LA		MERCED, CA	
LAOH, BENNY	7/20/05	BLAIR, DAVID	7/20/05	HAMILTON, DIANE	7/20/05
SHELTON, WA		AVONDALE, AZ		MOUNT JULIET, TN	
LAURIE, JASON	7/20/05	BLANKENSHIP, LINDA	7/20/05	HARRISON, SANDY	7/20/05
CARSON CITY, NV		DECATUR, AL		LAGRANGE, GA	
LAURIER, DIANNE	7/20/05	BOSWELL, DONNA	7/20/05	HARTER, SUSAN	7/20/05
SHELTON, WA		DE LEON, TX		TUCSON, AZ	
LEDESMA, VICTORIA	7/20/05	BOUDREAU, DOROTHY	7/20/05	HARTWELL, VICTORIA	7/20/05
ROSEVILLE, CA		HUMBLE, TX		LEWSTON, ID	
LEE, TERRI	7/20/05	BOWERS, AMY	7/20/05	HERNANDEZ, VARINIA	4/20/05
BALTIMORE, MD		DALHART, TX		PITTSBURG, CA	
LOPEZ, BRANDICE	7/20/05	BREDEMEIER, HENRY	7/20/05	HILL, ROGER	7/20/05
CARMICHAEL, CA		LOMBARD, IL		KNOXVILLE, TN	
LUNESMAN, SANDRA	7/20/05	BRUGGEMAN, JAMES	7/20/05	HOCHSPRUNG, CAROLYN	7/20/05
MONTICELLO, IA		CLEAR LAKE, IA		WEST FARGO, ND	
MATTHEWS, THOMASINA	7/20/05	BRYANT, ANGELA	7/20/05	HOLBROOK, JANE	7/20/05
PIKESVILLE, MD		LOVES PARK, IL		BOISE, ID	
MCMASTERS, LAURA	7/20/05	BUCK, NADENA	7/20/05	HOLMAN, THELON	7/20/05
TECUMSEH, OK		MURRAY, UT		CHAPEL HILL, NC	
MILLER, GERRENE	7/20/05	BUGOS, ROSEMARY	7/20/05	HURLEY, CHARLES	7/20/05
MILL HALL, PA		BUENA PARK, CA		CHICOPEE, MA	
MORTON, JOANN	7/20/05	BUSH, LISA	7/20/05	INNES, GEORGE	7/20/05
ANADARKO, OK		ETHELVILLE, AL		FAYETTEVILLE, NY	
NOOR, FARID	7/20/05	CARNEY, NANETTE	7/20/05	IRVING, JENNIFER	7/20/05
MEDFORD, NJ		VIDALIA, LA		COUNCIL BLUFFS, IA	
OROZCO, CONSUELO	7/20/05	CASEY, NOLA	7/20/05	JAMES, GLORIA	7/20/05
OAK VIEW, CA		CADDO MILLS, TX		JERSEY CITY, NJ	
PETERSON, MELISSA	7/20/05	COBBS, FREDERICK	7/20/05	JENSEN, MEGAN	7/20/05
CHEROKEE, IA		WAKE FOREST, NC		ORLAND, CA	
SAJJAD, AYSHA	7/20/05	COLEMAN, MARCIA	7/20/05	JOHNSON, SHERRY	7/20/05
BARTON, VT		LAKESWOOD, OH		BOISE, ID	
SANNI, ELIZABETH	7/20/05	COLSHAN, STACY	7/20/05	JONES, ILONA	7/20/05
NORTH PROVIDENCE, RI		MAPLETON, IA		TUCSON, AZ	
SHACKLEFORD, GWEN- DOLYN	7/20/05	CORDELL, CRYSTAL	7/20/05	JONES, ROBBIE	7/20/05
DAYTON, OH		ELIZABETHTOWN, TN		BYHALIA, MS	
SIMPSON, LESLIE	7/20/05	CORNISH, CHRISTY	7/20/05	KELLY, DENNIS	7/20/05
BRONX, NY		BENTON, AR		MARKHAM, IL	
THOMAS, TRESHA	7/20/05	CROSBY, CHARLES	7/20/05	KELLY, PATRICK	7/20/05
VILLE PLATTE, LA		ORLANDO, FL		BASTROP, TX	
TINSLEY, ANGELA	7/20/05	DALLOLIO, DENISE	7/20/05	KINDELSPIRE, KATHLEEN	7/20/05
SUSANVILLE, CA		RUPERT, ID		MESA, AZ	
UGWU, CHARLES	7/20/05	DAVENPORT, KIMBERLY	7/20/05	KLEIN, CARL	7/20/05
OKLAHOMA CITY, OK		WARWICK, RI		KNOXVILLE, TN	
VIELMA, LEANDRO	7/20/05	DAWSON, NANCY	7/20/05	KNIGHT, ROBIN	7/20/05
KISSIMMEE, FL		UNIONTOWN, OH		BLOUNTSVILLE, AL	
WHEELER, AUDREY	7/20/05	DICKERSON, DANA	7/20/05	LAVALLO, JULIA	7/20/05
WATERFORD, ME		NEW HEBRON, MS		NEW PARIS, OH	
WHITWORTH, BEVERLY	7/20/05	DOHERTY, ERIN	7/20/05	LEE, DIANA	7/20/05
CARNEGIE, OK		CHARLOTTE, NC		TWIN FALLS, ID	
		DOVE, RICHARD	7/20/05	LEWIS, WANDA	7/20/05
		NEWTON, KS		DENVER, CO	
		ECHOLS, EVERETT	7/20/05	LINDSEY, DEBBIE	7/20/05
		SOUTHERN PINES, NC		TECUMSEH, OK	
		EDWARDS, LESA	7/20/05	LOVIER, PATRICIA	7/20/05
		MEAD, OK		GRANDVIEW, MO	
		FIDALGO, CATHERINE	7/20/05	LUCK, DIANNE	7/20/05
		NEW BEDFORD, MA		GREAT POND, ME	
		FREEMAN, JANET	7/20/05	MADERE, ANNA	7/20/05
		KNOXVILLE, TN		LULING, LA	
		FRISCH, JULIE	7/20/05	MARTIN, ROSALIND	7/20/05
		LAKE FOREST, CA		CHICAGO, IL	
		GALE, LORETA	7/20/05	MARTIN, SHELLY	7/20/05
		NATIONAL CITY, CA		HENDERSON, KY	
		GARNETT, HAZEL	7/20/05	MARTINEAU, WADE	7/20/05
		BEACON, NY		SALT LAKE CITY, UT	
		GRIEGO, MAHRI	7/20/05	MASNEY, RICHARD	7/20/05
		BISHOP, CA		ROCKY MOUNT, NC	
		HABERMAN, JENNIFER	7/20/05	MATUTE, PATRICIA	7/20/05
CONVICTION-OBSTRUCTION OF AN INVESTIGATION					
JOHNSON, LENA	7/20/05				
HOUMA, LA					
LICENSE REVOCATION/SUSPENSION/SURRENDERED					
ABEL, PHIL	7/20/05				
ROY, UT					
AMEN, CHRISTINE	7/20/05				
MANTECA, CA					
ANDERSON, JENNIE	7/20/05				
BROCKTON, MA					
ANDREWS, RALEIGH	7/20/05				

Subject, city, state	Effective date	Subject, city, state	Effective date	Subject, city, state	Effective date
RESEDA, CA		BUCKEYE, AZ		ROARING RIVER, NC	
MCCLURE, VICKIE	7/20/05	SCHROYER, GREGORY	7/20/05	WILBANKS, NANCY	7/20/05
OVERTON, TX		FAIRVIEW HEIGHTS, IL		ASHLAND, MS	
MCKINNEY, MARTHA	7/20/05	SEEFELDT, REBECCA	7/20/05	WILLIAMS, ELIZABETH	7/20/05
GARLAND, TX		PHOENIX, AZ		GILBERT, AZ	
MCPEAK, CATHERINE	7/20/05	SHELburne, KRISTI	7/20/05	WILLSON, JENNIFER	7/20/05
AVERY, TX		LEBANON, IN		LYNDON CENTER, VT	
MENDOZA, CHARLES	7/20/05	SHOEMAKER, MICHELLE	7/20/05	WISE, THOMAS	7/20/05
VALLEJO, CA		HAMILTON, OH		ASHWAY, RI	
MENDOZA, DAVID	7/20/05	SIMMONS, LISA	7/20/05	WYLEY, MARQUITA	7/20/05
TUCSON, AZ		ROCKFORD, IL		TOLEDO, OH	
MERCHANT-KEOSATHIT, LEE		SMITH, DEBORAH	7/20/05	YANKURA, JOSEPH	7/20/05
ANN	7/20/05	SAN ANTONIO, TX		FREEPORt, NY	
ST PETERSBURG, FL		SMITH, JAMIE	7/20/05	ZUCCO, MICHAEL	7/20/05
MOODY, JOLENE	7/20/05	BETHANY, OK		PITTSBURGH, PA	
SOUTH JORDAN, UT		SMITH, MICHAEL	7/20/05	ZUZELSKI, KAREN	7/20/05
MORRIS, KENYA	7/20/05	GREENVILLE, NC		LOVELAND, CO	
EL CAJON, CA		SMITH, NANCY	7/20/05		
O'DONOHUE, BARBARA	7/20/05	SUPPLY, NC			
CEDAR RAPIDS, IA		SMITH, RICHARD	7/20/05	OWNED/CONTROLLED BY CONVICTED ENTITIES	
OAKMAN, RANDALL	7/20/05	RIVERHEAD, NY			
MOUNT ZION, IL		SOOKHU, LLOYD	7/20/05	ALROD MEDICAL EQUIP-	
OLF, VICKIE	7/20/05	DIX HILLS, NY		MENT CORP	7/20/05
INDEPENDENCE, MO		SPARLING, KAREN	7/20/05	MIAMI, FL	
OUTLAW, TERESA	7/20/05	AMARILLO, TX		BRIAN H JENKINS, D S, P A ..	7/20/05
MT OLIVE, NC		SPOONER, COLLEEN	7/20/05	KANSAS CITY, MO	
PABLO, JENNIFER	7/20/05	COLORADO SPRINGS, CO		CARES R US, LTD	3/8/05
PHOENIX, AZ		STANLEY, JENNIFER	7/20/05	BAYSIDE, WI	
PARRA, ANNA	7/20/05	CLEVELAND, TX		CHARLES J CROSBY, D O,	
TUCSON, AZ		TARLTON, NORA	7/20/05	P A	7/20/05
PARSLEY, JAMES	7/20/05	DECATUR, AL		WINTER PARK, FL	
WHEELERSBURG, OH		TAYLOR, JOHN	7/20/05	CROSBY ADVANCED MED-	
PARSONS, BETH	7/20/05	VASS, NC		ICAL SYSTEMS, INC	7/20/05
FORT WAYNE, IN		THOMAS, SUSAN	7/20/05	ORLANDO, FL	
PATTEN, JANICE	7/20/05	OCALA, FL		K E S MEDICAL SUPPLIES	
CENTENNIAL, CO		TONUBBEE, KIMBERLY	7/20/05	CORP	7/20/05
PAWLOWSKI, JOAN	7/20/05	CARROLLTON, TX		HIALEAH, FL	
BURNHAM, IL		TOWLES, TRACY	7/20/05	STANBRIDGE CHIRO-	
PAYNE, MELODY	7/20/05	NICHOLASVILLE, KY		PRACTIC	7/20/05
SECTION, AL		TRUE, ROBERT	7/20/05	WHITTIER, CA	
PIATT, SANDRA	7/20/05	CLARKSDALE, MS		STAR B REST PERSONAL	
MURRAY, UT		TURAN, ROXANNE	7/20/05	CARE HOME	7/20/05
POLAND, WAYNE	7/20/05	SAUCIER, MS		COLUMBUS, MS	
N CONWAY, NH		TURNER, BETTY	7/20/05		
PONWITH, PAULA	7/20/05	TUCSON, AZ		DEFAULT ON HEAL LOAN	
ARVADA, CO		TURNER-GAINES,			
QUICHOCHO, RICHARD	7/20/05	WINNIFRED	7/20/05	CASTALINE, PERREN	7/20/05
OLYMPIA, WA		MONROE, LA		CANYON COUNTRY, CA	
RANDALL, BETHANY	7/20/05	VALENTINO, NANCY	7/20/05	JOHNSON, TIMOTHY	7/20/05
SKOWHEGAN, ME		HEMET, CA		CHISAGO CITY, MN	
REID, YOLANDA	7/20/05	VENECHANOS, JACQUELINE	7/20/05	LENT, ROSELLA	7/20/05
TUCSON, AZ		CHARLESTOWN, RI		NAHANT, MA	
REPKO, LINDA	7/20/05	VIVEROS, CHRISTOPHER	7/20/05		
JESSUP, PA		TEHACHAPI, CA		OWNERS OF EXCLUDED ENTITIES	
REYNOLDS, PATRICIA	7/20/05	WAITLEY, TIMOTHY	7/20/05		
CHARLOTTE, NC		GLENDALe, AZ		JENKINS, ELIZABETH	7/20/05
RIZZO, MICHELLE	7/20/05	WATSON, KELLY	7/20/05	CAMPBELL, NY	
SCOTTSDALE, AZ		OKLAHOMA CITY, OK		SHARMA, RENU	4/5/04
ROGERS, ANNETTE	7/20/05	WEBB, BONNIE	7/20/05	KALAMAZOO, MI	
LOMPOC, CA		SWEET WATER, AL			
ROMERO, EMMA	7/20/05	WEISE, ELAINE	7/20/05		
MARENO VALLEY, CA		GLENDALe, AZ			
RUDY, ANDREW	7/20/05	WHITAKER, REGINA	7/20/05		
MERRITT ISLAND, FL		PEORIA, IL			
RUMBOLZ, SARA	7/20/05	WHITE, KELLY	7/20/05		
GILBERT, AZ		CULLMAN, AL			
RYGIEL, KATARZYNA	7/20/05	WHITE, VICKIE	7/20/05		
SAN DIEGO, CA		RANCHO CUCAMONGA, CA			
SCHALL, TRACY	7/20/05	WHITLEY, ANGELIA	7/20/05		

Dated: July 12, 2005.
Maureen Byer,
*Acting Director, Exclusions Staff, Office of
Inspector General.*
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BILLING CODE 4152-01-P