DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

PROCESSING IN STEAM-AIR RETORTS

(Retort Survey)

INSTRUCTIONS

Complete the question blocks below. Narrative responses to each item can be entered in the item's "comments" area or where otherwise prompted. Draw a diagram of the retort or obtain one from the firm. Attach the diagram as an exhibit to the EIR. Report all pipe sizes as inside diameter (ID). Cross-sectional area = $3.14r^2$ (r = $\frac{1}{2}$ diameter).

If problems are found with the firm's retort equipment or processing system, refer the reader to the narrative Turbo EIR under "Objectionable Conditions and Management's Response," and include a narrative explanation of specific problems and evidence under the subheading "Supporting Evidence and Relevance." Submit the completed form as an EIR attachment.

Steam-air retorts are covered by 113.40(j) – "Other Systems" and must meet the requirements found in applicable sections of 113.40. The retorts and operating procedures must be carefully evaluated to insure that they comply with Part 113.

Some of the questions in this form are designed to capture information useful in evaluation of the retort system and may not indicate a deviation from LACF Regulations, Part 113. The FDA "Guide to Inspections of Low Acid Canned Foods, Part 2" should be used as a guide when conducting inspections of steam-air retort systems.

Steam-air retorts are made by a variety of different manufacturers. They are normally horizontal batch type still or rotary end-over-end retorts. Steam-air has been used in some installations as the heating medium in continuous rotary, hydrostatic and hydrolock retorts. Photographs are an excellent means of enhancing the description of a retort system.

		RETORT DES	SCRIPTION			
RETORT NO.	TYPE OF RETORT	- Horizontal 🗌 Other 🗌	LENGTH O	R HEIGHT	DIAMETER	
RETORT MANUFACTURER:						
RETORT MODEL:						
TEMPERATURE RANGE OF	THERMAL PROCES	S (E.G., 245/250/2	260 DEGREES F):		
NUMBER OF BASKETS OR	CRATES PER RETO	RT:				
PROCESSING MODE:		Static Still	Agitating	End-over-End	Axial 🗌 Rockii	ng 🗌
ARE THERE ANY PROTRUSIONS INSIDE THE RETORT OR THE RETORT DOOR CASING WHICH COULD DAMAGE CONTAINERS DURING LOADING/UNLOADING OF CRATES?				No 🗌		
		COMPUTER	CONTROLS			
DOES A COMPUTER CONT EXPLAIN:	ROL ANY OF THE R	ETORT FUNCTION	JS?		Yes 🗌 🛛 🕅	No 🗌
DOES THE FIRM HAVE DOC	CUMENTATION ON H	IAND THAT INDICA	ATES THAT THE	COMPUTER SYST	EM HAS BEEN VALID. Yes 🗌 🕴	ATED?

IS RECORD KEEPING PART OF THE COMPUTER FUNCTION?Yes □ No □ IF YES DOES THE RECORD KEEPING COMPLY WITH 21 CFR PART 11?Yes □ No □ EXPLAIN:
AGITATION
IS THE AGITATING RETORT OPERATED IN THE STILL MODE?
HAVE PROCESS ESTABLISHMENT TESTS DETERMINED THAT RETORT CRATE POSITION IS CRITICAL TO THE PROCESS OR COME UP PROCEDURE?
HOW DOES THE FIRM DETERMINE CRATE POSITION?
WAS THE RECOMMENDED CRATE POSITION BEING USED DURING THE INSPECTION?
EXPLAIN HOW THE RETORT ROTATION SPEED IS DETERMINED:
EXPLAIN HOW THE RETORT ROTATION SPEED IS RECORDED:
STEAM-AIR MIXTURE

WHAT IS THE PROCESSING PRESSURE USED DURING THERMAL PROCESSING? (NOTE IF SEVERAL DIFFERENT PROCESSING TEMPERATURES ARE USED; PLEASE NOTE THE PRESSURE AT EACH TEMPERATURE. IF THE FIRM PROCESSES DIFFERENT CONTAINER TYPES, PLEASE NOTE THE PRESSURE FOR EACH CONTAINER TYPE.) COMMENTS:

WHAT IS THE PERCENT STEAM/AIR MIXTURE USED DURING PROCESSING:

(NOTE: % STEAM CAN BE DETERMINED BY DIVIDING THE STEAM PRESSURE POUNDS PER SQUARE INCH ACTUAL BY THE TOTAL SYSTEM PRESSURE.)

E.g., 10 PSI (generated by temp of 240 degrees F) + 14.7 PSI Atmospheric pressure = 24.7 = 83% steam 15 PSI gauge reading on retort + 14.7 PSI Atmospheric pressure = 29.7 (24.7/29.7 x 100 = 83%)

HOW IS STEAM ADDED TO THE RETORT? Steam Spreader Other Other IF OTHER, EXPLAIN:
IS THE STEAM SPREADER OR OTHER SYSTEM IN A GOOD STATE OF REPAIR?
DESCRIBE THE LOCATION WHERE COMPRESSED AIR IS ADDED TO THE RETORT:
IS THE COMPRESSED AIR HEATED PRIOR TO BEING ADDED TO THE RETORT?
IS A DIFFUSER USED ON THE AIR ENTRY TO INSURE MIXING OF THE AIR AND STEAM?
HAS THE AREA WHERE AIR ENTERS THE RETORT BEEN IDENTIFIED AS A COLD SPOT IN THE RETORT? Yes \Box No \Box COMMENTS:
HOW IS PRESSURE CONTROLLED IN THE RETORT? Set Pressure Relief Valve Card Reader Computer Program Analog Controls Other Computer Program Analog Controls Other
DOES THE FIRM HAVE DOCUMENTATION WHICH INDICATES THE PERCENT AIR OR AIR PRESSURE PARAMETERS CRITICAL TO THE THERMAL PROCESS?
DOES THE FIRM MONITOR AND RECORD RETORT PRESSURE DURING PROCESSING?
IF A PRESSURE GAGE IS PRESENT, IS IT GRADUATED IN DIVISIONS OF 2 LBS. OR LESS?

DO THE PRESSURES NOTED MEET THOSE ESTABLISHED BY THE TEMPERATURE DISTRIBUTION STUDIES?
EXPLAIN:
DOES THE FIRM HANDLE DEVIATIONS FROM PROCESSING PRESSURES AS PROCESS DEVIATIONS?
WHAT METHOD IS USED TO MIX THE STEAM AND AIR? Fan 🗌 Bleeders 🗌 Other 🗌 DESCRIBE:
IS WATER OR CONDENSATE ADDED TO THE STEAM AIR MIXTURE? Yes D No C EXPLAIN:
HOW DOES THE FIRM INSURE THAT THE FAN IS OPERATING? Indicator Light Computer Monitoring Visual Inspection DESCRIBE INSPECTION FREQUENCY:
MERCURY IN GLASS THERMOMETERS/TEMPERATURE INDICATING DEVICES
IS THE RETORT EQUIPPED WITH A MIG THERMOMETER? Yes No COMMENTS:
IS THE RETORT EQUIPPED WITH ANOTHER TYPE OF TEMPERATURE INDICATOR DEVICE? IF SO, DESCRIBE THE INDICATOR
ARE SCALE DIVISIONS EASILY READABLE TO 1°F (.5°C)?
NO. OF DEGREES F OR C/IN. OF GRADUATED SCALE: (TEMP. RANGE MUST NOT EXCEED 17°F(8°C) PER INCH (4°/CM) OF GRADUATED SCALE – 113.40(a)(1). ALSO, SEE LACF GUIDE, P. 14.) COMMENTS:

DATE TEMPERATURE INDICATING DEVICE LAST TESTED FOR ACCURACY: _

(THERMOMETERS SHALL BE TESTED FOR ACCURACY AGAINST A KNOWN ACCURATE STANDARD THERMOMETER UPON INSTALLATION AND AT LEAST ONCE A YEAR THEREAFTER; RECORDS OF ACCURACY CHECKS THAT SPECIFY DATE, STANDARD USED, METHOD USED, AND PERSON PERFORMING THE TEST SHOULD BE MAINTAINED. EACH THERMOMETER SHOULD HAVE A TAG, SEAL, OR OTHER MEANS OF IDENTITY THAT INCLUDES THE DATE IT WAS LAST TESTED FOR ACCURACY – 113.40(a)(1).)

STANDARD USF	D FOR T	HE TEST

NAME AND TITLE OF PERSON WHO PERFORMED TEST:

DESCRIBE THE FIRM'S ACTIONS REGARDING MIG THERMOMETERS/TEMPERATURE INDICATORS THAT WERE OUT OF CALIBRATION:

IS THE TEMPERATURE INDICATING THERMOMETER LOCATED WHERE IT IS EASY TO READ ACCURATE	ELY?	
COMMENTS:	Yes	No 🗌
THE SENSOR BULB IS LOCATED IN THE Retort Shell	External V	Vell
DIAMETER OF OPENING TO EXTERNAL WELL:		
HOW DOES THE FIRM INSURE THAT THE TEMPERATURE MEASURED IN THE WELL IS REPRESENTATIVE (TEMPERATURE IN THE RETORT SHELL?	OF THE	

TEMPER	
TYPE OF TEMPERATURE RECORDER: COMMENTS:	Round Circular Chart 🗌 Strip Chart 🗌 Other 🗌
IS THE TEMPERATURE CHART ADJUSTED TO AGREE AS ACCURATE MERCURY-IN-GLASS THERMOMETER DURIN (<i>SHALL REQUIREMENT OF 113.40(b)(2))</i> NOTE ANY DIFFERENCE BETWEEN THE RECORDING TH WHICH READING IS HIGHER:	NEARLY AS POSSIBLE WITH BUT NOT HIGHER THAN THE KNOWN G THE PROCESSING PERIOD? Yes No C
IS THERE A MEANS FOR PREVENTING UNAUTHORIZED (A MEANS OF PREVENTING UNAUTHORIZED CHANGES MANAGEMENT STATING "ONLY AUTHORIZED PERSONS A THE RECORDING DEVICE IS A SATISFACTORY MEANS F COMMENTS:	ADJUSTMENTS?Yes No IN ADJUSTMENTS SHALL BE PROVIDED. A LOCK OR NOTICE FROM ARE PERMITTED TO MAKE ADJUSTMENTS" & POSTED AT OR NEAR OR PREVENTING UNAUTHORIZED CHANGES – 113.40(b)(2).)
IS THE CHART DRIVE TIMING MECHANISM ACCURATE? . IF NO, EXPLAIN:	
IS THE RECORDER COMBINED WITH A STEAM CONTROL COMMENTS:	LLER? Yes 🗌 No 🗌
THE TEMPERATURE SENSING BULB IS INSTALLED IN TH IF THE TEMPERATURE SENSING BULB IS INSTALLED IN A TEMPERATURE SENSED IS REPRESENTATIVE OF THE TI	ERetort Shell External Well AN EXTERNAL WELL, HOW DOES THE FIRM INSURE THAT THE EMPERATURE IN THE RETORT SHELL?
AUTOMATIC	STEAM CONTROLLER
IS THE STEAM CONTROLLER AUTOMATIC? (EACH RETORT <u>SHALL</u> BE EQUIPPED WITH AN AUTOMA TEMPERATURE – 113.40(a)(4).) COMMENTS:	TIC STEAM CONTROLLER TO MAINTAIN THE RETORT
IS THE STEAM CONTROLLER TEMPERATURE ACTUATED	

COME UP PROCEDURE
DOES THE FIRM USE A STEAM BYPASS DURING COME UP?
DOES THE FIRM (VENT) PURGE AIR FROM THE RETORT PRIOR TO THE THERMAL PROCESS?
DESCRIBE THE FIRMS PURGE PROCEDURE:
DESCRIBE THE PROCEDURES USED BY THE FIRM TO BRING THE RETORT UP TO OPERATING TEMPERATURE:
CAN THE FIRM DOCUMENT ALL STEPS OF THE COME UP PROCEDURE?
DOES THE FIRM IDENTIFY PROCESS COME UP STEPS AS CRITICAL ON THE PROCESS FILING FORMS? Yes No (NOTE: PROCESSING STEPS ARE REQUIRED ON THE PROCESS FILING FORM WHEN THEY HAVE BEEN IDENTIFIED AS CRITICAL TO THE THERMAL PROCESS.) COMMENTS:
HEAT/TEMPERATURE DISTRIBUTION
DOES THE FIRM HAVE ON HAND TEMPERATURE DISTRIBUTION DATA OR OTHER SUITABLE INFORMATION THAT DEMONSTRATES THAT HEAT DISTRIBUTION IN THE RETORT IS ADEQUATE?
EXPLAIN AND PROVIDE COPIES OF SUPPORTING DOCUMENTS:
DATE OF LAST TEMPERATURE DISTRIBUTION STUDY:

RETORT.

MIXING OF STEAM-AIR IN THE RETORT, CAN POTENTIALLY HAVE AN EFFECT ON TEMPERATURE DISTRIBUTION IN THE

HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH INDIVIDUAL RETORT?
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH CONTAINER SIZE? Yes No COMMENTS:
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH CONTAINER TYPE <i>(E.G., GLASS, METAL, PLASTIC)</i>
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH CONTAINER HOLDING ARRANGEMENT/ RACKING SYSTEM USED BY THE FIRM?
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH INDIVIDUAL PRODUCT OR PRODUCT TYPE? (E.G., SEAFOOD SOUP VERSUS CANNED TUNA)
DID EACH TEMPERATURE DISTRIBUTION STUDY IDENTIFY A COLD SPOT IN THE RETORT?
HAVE TEMPERATURE DISTRIBUTION STUDIES BEEN PERFORMED TO DETERMINE THE EFFECTS OF TEMPERATURE DROPS DURING COME UP AND PROCESSING?Yes □ No □ REPORT RESULTS:
HAVE TEMPERATURE DISTRIBUTION STUDIES BEEN PERFORMED TO DETERMINE THE EFFECTS OF PRESSURE DROPS OR EXCESS PRESSURE IN THE RETORT?
ARE PARTIAL LOADS PROCESSED IN THE FIRMS RETORTS? Yes No COMMENTS:
ARE BAFFLE PLATES OR DUMMY LOADS USED DURING THE PROCESSING OF PARTIAL LOADS?
HAVE TEMPERATURE DISTRIBUTION STUDIES BEEN PERFORMED WITH PARTIAL LOADS?

RETORT CRATES, RACKS
DESCRIBE THE RETORT CRATES.
DIMENSIONS:
NUMBER OF HOLES:
SIZE OF HOLES:
LOCATION OF HOLES:
ARE CONTAINERS POSITIONED IN THE RETORT AS SPECIFIED IN THE SCHEDULED PROCESS?
ARE DIVIDERS, TRAYS, RACKS OR OTHER MEANS OF POSITIONING FLEXIBLE CONTAINERS DESIGNED AND EMPLOYED TO INSURE EVEN CIRCULATION OF HEATING MEDIUM AROUND ALL CONTAINERS?
ARE DIVIDER PLATES USED?
IS THE SAME TYPE OF DIVIDER PLATE USED FOR ALL CONTAINERS?
ARE CONTAINERS PROCESSED WITHOUT DIVIDER PLATES?
IS CONTAINER NESTING POSSIBLE?
DOES THE FIRM PROCESS? Metal Cans Yes Glass Jars No Pouches Yes No Rigid Plastic COMMENTS: Kanage

LIST ALL CONTAINER SIZES:
METAL CANS –
GLASS JARS –
POUCHES –
RIGID PLASTIC -
IF MORE THAN ONE CONTAINER SIZE OR TYPE IS PROCESSED AT ONE TIME DESCRIBE PROCEDURE USED:
FOR POUCHES, ARE TRAYS ADEQUATELY DESIGNED WITH POCKETS TO CONTAIN AND RESTRAIN INDIVIDUAL POUCHES DURING PROCESSING?
ARE TRAYS OR DIVIDER PLATES IN GOOD CONDITION WITH NO ROUGH OR SHARP POINTS THAT COULD PUNCTURE CONTAINERS?
CONTAINER COOLING
CONTAINERS ARE COOLED BY: Air Water Kernel Strategies Are Cooling:
TYPE OF VALVE ON COOLING WATER LINES:
WERE COOLING WATER LINES NOTED TO BE LEAKING?
WATER DRAINS
ARE SCREENS USED OVER ALL DRAIN OPENINGS TO PREVENT CLOGGING OF DRAINS?
IS THE DRAIN VALVE WATER TIGHT AND NON-CLOGGING?
OTHER CONCERNS AND OBSERVATIONS
PLEASE EXPLAIN ANY OTHER CONCERNS WITH THE OPERATION OF THIS RETORT SYSTEM: