Firm Name, City & State:	FEI Number:
Inspection Date(s):	FCE Number:
Investigators:	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

PROCESSING IN WATER IN DISCONTINUOUS AGITATING RETORTS (Retort Survey)

INSTRUCTIONS

This report covers batch-type agitating retort systems pressure processing in water with overriding air or steam. This includes the traditional rotating systems specifically covered under 113.40(e) as well as other axial and end-over-end processing systems covered by 113.40(j), "Other Systems."

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 to the EIR as an exhibit. Measure and verify retort plumbing – record on this form. Report all pipe sizes as inside diameter (ID). Refer to 21 CFR Part 113.40(e) and pp. 32-34 of LACF Guide, Part 2.

Before entering the interior of the retort, you must confirm with the firm that you are following the firm's Standard Operating Procedures designed to meet OSHA confined space requirements. If the firm insists that only plant personnel enter the retort, witness the measurement procedure and data collection. To obtain OSHA confined space information and safety procedures, see the confined space presentation on the FDA ORAU web site. If the firm is not aware of the OSHA confined space requirements or does not have a confined space program, DO NOT ENTER THE RETORT.

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

RETORT DESCRIPTION			
*CAN SIZE	COOKER CAPACI	ΓY STEF	PS/REEL
PROCESSING MODE			
Axia	End-ove	r-End 🗌	
the inspection.			
Co	OMPUTER CONTROLS		
DOES A COMPUTER CONTROL ANY OF THE RETORT FUNCTIONS?			
DOES THE FIRM HAVE DOCUMENTATION ON HAND WHICH INDICATES THAT THE COMPUTER SYSTEM HAS BEEN VALIDATED?Yes No			
EXPLAIN:			
OF THE COMPUTER FUN	ICTION?		······Yes 🗌 No 🗌
KEEPING COMPLY WITH	I 21 CFR PART 11?		Yes No N
	*CAN SIZE PROCESSING MODE Axial the inspection. CO ROL ANY OF THE RETORT UMENTATION ON HAND VAS BEEN VALIDATED? OF THE COMPUTER FUN	*CAN SIZE COOKER CAPACIT PROCESSING MODE Axial	*CAN SIZE COOKER CAPACITY STEF PROCESSING MODE Axial End-over-End the inspection. COMPUTER CONTROLS ROL ANY OF THE RETORT FUNCTIONS? UMENTATION ON HAND WHICH INDICATES THAT

Firm Name:		FEI Number:	
	AGITATION		
IS THE AGITATING RETORT OPERATED IN THE COMMENTS:	STILL MODE?		Yes 🗌 No 🗍
IF CRATES ARE USED, IS THE CRATE POSITION COMMENTS:	N CRITICAL TO THE COME-U	P AND/OR PROCESS?	Yes 🗌 No 🗍
HOW WAS IT DETERMINED? (FOR EXAMPLE, PR	IF CRATE POSITION HAS BEEN DETERMINED AS CRITICAL TO THE PROCESS, WHAT IS THE RECOMMENDED POSITION AND HOW WAS IT DETERMINED? (FOR EXAMPLE, PROCESS ESTABLISHMENT TESTS MAY HAVE DETERMINED THAT AN ANGLED CRATE POSITION RESULTS IN FASTER HEAT PENETRATION.)		
	PROCESSING WATE	R	
METHOD USED TO HEAT PROCESS WATER:			
A. Steam Injection into Process Water IF OTHER, EXPLAIN:	B. Heat Exchanger	C. Steam Spreader	D. Other
	WATER DRAINS		
ARE SCREENS USED OVER ALL DRAIN OPENIN COMMENTS:	IGS TO PREVENT CLOGGIN	G OF DRAINS?	Yes 🗌 No 🗍
IS THE DRAIN LINE VALVE WATER TIGHT AND N COMMENTS:	NON-CLOGGING?		Yes 🗌 No 🗌
	WATER DISTRIBUTION	N	
WATER DISTRIBUTION SYSTEM:			
Manifold Plate? Yes	□ No □ □		
Spray Nozzle Heads? Yes	□ No □ □		
Manifold Pipe? Yes	□ No □		
Other? Yes IF OTHER, EXPLAIN:	□ No □		
DESCRIBE HOLE SIZE AND DISTRIBUTION IN M.	ANIFOLD/SPRAY NOZZLES:		
HAVE HOLE SIZES BEEN ALTERED BY PRODUC COMMENTS:	OT OR MINERAL BUILD-UP?		Yes No
DOES THE FIRM HAVE A CLEANING PROGRAM COMMENTS:	FOR THE WATER DISTRIBU	TION SYSTEM?	Yes No

Firm Name:	FEI Number:
HOW DOES THE FIRM ENSURE THAT WATER FLOW IS CONSTANT?	
Visual Checks Yes No	
Water Flow Measurement Yes No	
Flow Meter Yes No	
COMMENTS:	
HOW OFTEN IS WATER FLOW CHECKED?	
WHAT IS THE WATER FLOW RATE?	
DESCRIBE THE PROCEDURE TO ENSURE WATER FLOW IS MAINTAIN	ED:
PROVIDE THE WATER FLOW METER MODEL NUMBER AND LOCATIO	N:
AT WHAT POINT DOES WATER ENTER THE RETORT WATER DISTRIB	UTION SYSTEM?
Back Top Yes No	
Back Bottom Yes No	
Front Top Yes No	
Front Bottom Yes No	
Center Yes No	
Multiple Yes No COMMENTS:	
EXPLAIN THE WATER DISTRIBUTION SYSTEM:	
DESCRIBE THE WATER RETURN SYSTEM:	
ARE WATER RETURN INLETS SCREENED?EXPLAIN, IF NECESSARY:	Yes
IS THE PROCESSING WATER REUSED?	Yes No
IF WATER IS REUSED DURING THERMAL PROCESSING, WHAT IS THI	ERECIRCULATION RATE?

Firm Name:	FEI Number:
WHAT IS THE CAPACITY OF THE WATER PUMP (GPM/LPM)?	
IS WATER FLOW IDENTIFIED AND CONTROLLED AS A FACTOR CRITICAL COMMENTS:	TO THE THERMAL PROCESS? Yes No
ARE WATER FLOW PROBLEMS HANDLED AS PROCESS DEVIATIONS? . COMMENTS:	Yes No
DURING THE INSPECTION, WAS THERE ANY EVIDENCE OF LOW WATER COMMENTS:	R FLOW? Yes No
COOLING WATER S	UPPLY
IS PROCESSING WATER USED TO COOL CONTAINERS DURING THE CO	OOLING CYCLE? Yes No
IF WATER IS INTRODUCED FROM AN EXTERIOR SOURCE DURING COCIS THE WATER COOLING LINE EQUIPPED WITH A CHECK VALVE?	
INDICATING MERCURY-IN-GLASS THE	RMOMETERS (113.40(e)(1))
IS THE RETORT EQUIPPED WITH AT LEAST ONE MERCURY-IN-GLASS (I	MIG) THERMOMETER? Yes No
IS THE RETORT EQUIPPED WITH A TEMPERATURE INDICATING DEVICE THAN A MIG THERMOMETER?	·
IF YES, DESCRIBE THE INDICATOR:	
ARE SCALE DIVISIONS EASILY READABLE TO 1°F (.5°C)?	Yes No 🗌
NO. OF DEGREES F OR C/IN. OF GRADUATED SCALE:	(TEMP. RANGE MUST NOT EXCEED 17°F (8°C) PER
DATE LAST TESTED FOR ACCURACY:COMMENTS:	
STANDARD USED FOR THE TEST:	
NAME AND TITLE OF PERSON WHO PERFORMED TEST:	
IS THE LAST TEST DATE IDENTIFIED ON THE THERMOMETER?	

Firm Name:	FEI Number:
DESCRIBE THE FIRM'S ACTIONS REGARDING MIG THER	MOMETERS THAT WERE OUT OF CALIBRATION:
IS THE MERCURY UNDIVIDED? (A THERMOMETER THAT HAS A DIVIDED MERCURY COLUBE ADJUSTED TO THE STANDARD SHALL BE REPAIRED COMMENTS:	IMN OR THAT CANNOT
WHEN MIG THERMOMETERS ARE FOUND TO BE PROVIE TEMPERATURES, DOES THE FIRM EVALUATE PRODUCTS DESCRIBE THE FIRM'S PROCEDURES:	DING READINGS ABOVE THE ACTUAL S PRODUCED USING THOSE THERMOMETERS? Yes
IS THE THERMOMETER LOCATED WHERE IT IS EASY TO (SHALL REQUIREMENT) COMMENTS:	READ ACCURATELY? Yes No
THE SENSOR BULB IS LOCATED IN THE(SHALL REQUIREMENT) COMMENTS:	Retort Shell , or External Well
IS THE MERCURY THERMOMETER USED AS THE REFER (SHALL REQUIREMENT) COMMENTS:	ENCED INSTRUMENT DURING PROCESSING? Yes No
TEMPERATUR	RE RECORDER (113.40(e)(2))
TYPE OF TEMPERATURE RECORDERIF OTHER, EXPLAIN:	
(GRADUATIONS ON THE TEMPERATURE RECORDING DE OF THE PROCESSING TEMPERATURE. EACH CHART SHA	ENTS OF PART 113.40(e)(2)?
IS THE TEMPERATURE CHART ADJUSTED TO AGREE AS THE KNOWN ACCURATE MERCURY-IN-GLASS (MIG) THEF (SHALL REQUIREMENT - NOTE ANY DIFFERENCE BETWEE AND WHICH READING IS HIGHER.) COMMENTS:	

Firm Name:	FEI Number:	
(A MEANS OF PREVENTING UNAUTHORIZED MANAGEMENT STATING "ONLY AUTHORIZED	HORIZED ADJUSTMENTS?Yes No CHANGES IN ADJUSTMENTS SHALL BE PROVIDED. A LOCK OR NOTICE FROM PERSONS ARE PERMITTED TO MAKE ADUSTMENTS," POSTED AT OR NEAR THE FANS OF PREVENTING UNAUTHORIZED CHANGES.)	
IS THE CHART DRIVE TIMING MECHANISM AC IF NO, EXPLAIN:	CCURATE?Yes	
IS THE RECORDER COMBINED WITH A TEMP AS A RECORDING/CONTROLLING INSTRUME COMMENTS:	ERATURE (STEAM) CONTROLLER TO FUNCTION NT? Yes No	
	TEMPERATURE CONTROLLER	
HOW IS TEMPERATURE CONTROLLED IN THI Recorder Controller COMMENTS:	ERETORT? CAM Controller	
REPORT THE MANUFACTURER, MODEL, TYF	PE AND SIZE OF THE AUTOMATIC STEAM CONTROL VALVE:	
IF THE TEMPERATURE (STEAM) CONTROLLE SYSTEM HAVE AN ADEQUATE FILTER TO AS: (AIR OPERATED TEMPERATURE CONTROLLE) FILTER SYSTEMS TO ASSURE A SUPPLY OF COMMENTS:	SURE A SUPPLY OF CLEAN, DRY AIR? Yes No RS SHOULD HAVE ADEQUATE	
	COME-UP PROCEDURE	
DESCRIBE THE FIRM'S PROCEDURE TO BRIN TEMPERATURE AND NUMBER OF STEPS:	IG THE RETORT UP TO PROCESSING TEMPERATURE. INCLUDE TIME,	
CAN THE FIRM DOCUMENT ALL STEPS OF THE COMMENTS:	HE COME-UP PROCEDURE?Yes No	
DOES THE FIRM IDENTIFY PROCESS COME-U	JP STEPS AS CRITICAL ON THE PROCESSING FILING FORMS? Yes No	
,	ON THE PROCESS FILING FORM WHEN THEY HAVE BEEN IDENTIFIED AS CRITICAL STHE CASE WHEN THE GENERAL METHOD IS USED TO CALCULATE THE ${\sf F}_{{\sf o}}$.)	
AIR PURGE		
IN SOME SYSTEMS, AN AIR PURGE (VENT VAINTO THE PROCESSING VESSEL; IS AN AIR F	LLVE) IS USED TO ENHANCE WATER ENTRY PURGE VALVE USED ON THE PROCESSING VESSEL?Yes No	

Firm Name:	FEI Number:	
HAS TIMING OF THE AIR PURGE VALVE (TIME OPEN) BEEN IDITO ADEQUATE TEMPERATURE DISTRIBUTION IN THE RETOR		
COMMENTS:		
HEATED PR	OCESS WATER	
IS WATER PRE-HEATED IN A SEPARATE VESSEL PRIOR TO PR	ROCESSING?Yes No	
IS THE WATER TEMPERATURE OF THE PRE-HEATED WATER CRITICAL TO TEMPERATURE DISTRIBUTION IN THE RETORT? COMMENTS:	Yes No	
DESCRIBE THE TEMPERATURE REQUIREMENTS FOR PRE-HE	ATED WATER:	
DID THE FIRM MEET THE REQUIREMENTS FOR PRE-HEATING EXPLAIN:	WATER DURING THIS INSPECTION?Yes No	
RETORT PLUMBING A	AND EQUIPMENT ISSUES	
WHEN WAS THE LAST MAJOR OVERHAUL OR MAINTENANCE COMMENTS:	PERFORMED ON THE RETORTS?	
MAINTENANCE IS PERFORMED ON CRITICAL EQUIPMENT (RE SURVEY IS NOT REQUIRED BY THE REGULATIONS, BUT IS CO	MMONLY USED TO DOCUMENT THAT A FIRM'S PROCESSING AT THE SYSTEM MEETS THE SAME CRITERIA (VALVE TYPE, STEAM	
COMMENTS:		
DO THE BOILERS SUPPLY SUFFICIENT STEAM TO THE RETOF SUPPLYING STEAM TO THE RETORTS, ESPECIALLY WHEN MC COMMENTS:	RTS? IS THERE SUFFICIENT PRESSURE IN THE HEADER PIPE DRE THAN ONE RETORT IS BEING VENTED SIMULTANEOUSLY?	
TEMPERATURE DISTRIBUTION		
HAVE TEMPERATURE DISTRIBUTION STUDIES BEEN PERFOR IF SO, WHO CONDUCTED THE STUDY, WHAT PROCEDURES W		
IS THERE DOCUMENTATION SUCH AS A RETORT DIAGRAM AND PARAMETERS USED TO VALIDATE THE TESTS?	Yes No	
(FOR AN EXPLANATION OF TEMPERATURE DISTRIBUTION, SEE FOR CONDUCTING TEMPERATURE DISTRIBUTION STUDIES IN COMMENTS:		

Firm Name:	FEI Number:
DATE OF LAST TEMPERATURE DISTRIBUTION STUDY:	
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMI COMMENTS:	ED ON EACH INDIVIDUAL RETORT? Yes No
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMS COMMENTS:	ED ON EACH CONTAINER SIZE? Yes No
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORM CONTAINER TYPE? (E.G., GLASS, METAL, PLASTIC)	
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH PRODUCT OR PRODUCT TYPE?	Yes No
HAVE TEMPERATURE DISTRIBUTION STUDIES BEEN PERFORM THE EFFECTS OF TEMPERATURE DROPS DURING COME-UP A REPORT RESULTS:	
ARE PARTIAL LOADS PROCESSED IN THE FIRM'S RETORTS? . COMMENTS:	Yes No
ATTAINMENT OF TEMPERATURE DISTRIBUTION IN THE RETORI THESE FACTORS COULD NECESSITATE A NEW TEMPERATURE IF A CHANGE HAS BEEN MADE IN THE THERMAL PROCESSING	AFFECT TEMPERATURE DISTRIBUTION? Yes No CONTAINER SIZE AND MANY OTHER FACTORS CAN AFFECT THE SEE PP. 21-22 OF LACF GUIDE, PART 2. A CHANGE IN ANY OF DISTRIBUTION STUDY AND POSSIBLY A NEW VENT SCHEDULE.
RETORT CRA	TES AND RACKS
DESCRIBE THE RETORT CRATES: DIMENSIONS: NUMBER OF HOLES: SIZE OF HOLES: LOCATION OF HOLES: CRATES/BASKETS NOT USED	
COMMENTS:	

Firm Name:	FEI Number:
ARE CONTAINERS POSITIONED IN THE RETORT AS SPEC COMMENTS:	IFIED IN THE SCHEDULED PROCESS? Yes No
ARE DIVIDERS, TRAYS, RACKS OR OTHER MEANS OF POAND EMPLOYED TO ENSURE EVEN CIRCULATION OF HEAT COMMENTS:	SITIONING FLEXIBLE CONTAINERS DESIGNED ATING MEDIUM AROUND ALL CONTAINERS?
ARE DIVIDER PLATES USED? DESCRIBE THE NUMBER OF HOLES AND DISTRIBUTION II	Yes No DIVIDER PLATES:
IS THE SAME TYPE OF DIVIDER PLATE USED FOR ALL CO	NTAINERS?Yes No N/A
ARE CONTAINERS PROCESSED WITHOUT DIVIDER PLATE COMMENTS:	ES? Yes No
LARGER CONTAINER MAY OCCUR WITH PRODUCTS DES	E ARE POSITIONED ONE INSIDE ANOTHER TO REPRESENT A MUCH IGNED TO STACK ON STORE SHELVES (E.G., TUNA, SARDINES). Yes No RS?
WAS CONTAINER NESTING EVALUATED AS PART OF THE COMMENTS:	PROCESS ESTABLISHMENT? Yes No
WHICH OF THE FOLLOWING CONTAINER TYPES ARE PROMETAL CANS Glass Jars COMMENTS:	OCESSED? Pouches Rigid Plastic
DOES THE FIRM PROCESS MORE THAN ONE CONTAINER LIST ALL CONTAINER SIZES: METAL CANS GLASS JARS POUCHES RIGID PLASTIC IF MORE THAN ONE CONTAINER SIZE OR TYPE IS PROCE	
FOR POUCHES, ARE TRAYS ADEQUATELY DESIGNED WIT AND RESTRAIN INDIVIDUAL POUCHES DURING PROCESS COMMENTS:	TH POCKETS TO CONTAIN ING? Yes No

Firm Name:	FEI Number:
ARE TRAYS OR DIVIDER PLATES IN GOOD CONDITION WITH POINTS THAT COULD PUNCTURE CONTAINERS?	
COMMENTS:	
PRESSU	RE CONTROL
ARE PRODUCTS PRODUCED USING OVER-PRESSURE? IF YES, WHAT OVER-PRESSURE IS ACHIEVED?	Yes No
IS THE RETORT EQUIPPED WITH A PRESSURE GAGE? COMMENTS:	Yes No
IS A MEANS PROVIDED FOR INTRODUCING COMPRESSED A AT THE PROPER PRESSURE AND RATE? COMMENTS:	
IS THE PRESSURE IN THE RETORT CONTROLLED BY AN AUT (SHALL REQUIREMENT) COMMENTS:	TOMATIC PRESSURE CONTROL UNIT? Yes No
IF A PRESSURE GAGE IS PRESENT ON THE RETORT COOKE IS IT GRADUATED IN DIVISIONS OF 2 LBS. OR LESS?	Yes No
DESCRIBE THE LOCATION WHERE COMPRESSED AIR OR ST	EAM ENTERS THE RETORT:
IS COMPRESSED AIR USED FOR OVER-PRESSURE HEATED TO INTRODUCTION INTO THE RETORT?	
IS A DIFFUSER USED ON THE COMPRESSED AIR ENTRY LINI RAPID MIXING OF THE AIR IN THE RETORT ATMOSPHERE? COMMENTS:	
HAS THE POINT WHERE AIR ENTERS THE RETORT BEEN IDE AS A COLD SPOT IN THE RETORT?	
EXPLAIN HOW PRESSURE IS CONTROLLED IN THE RETORT:	

Firm Name:	FEI Number:
HAS OVER-PRESSURE BEEN IDENTIFIED AS CRITICAL TO THE COMMENTS:	IE THERMAL PROCESS? Yes No
ARE PRESSURE DROPS CONSIDERED PROCESS DEVIATION WHY OR WHY NOT? (AND ANY OTHER COMMENTS)	S? Yes No
RETORT SPEED	TIMING (113.40(e)(5))
IS THE ROTATIONAL SPEED OF THE RETORT SPECIFIED IN T	THE SCHEDULED PROCESS? Yes No
(<u>SHALL</u> REQUIREMENT) COMMENTS:	
IS THE ROTATIONAL SPEED OF THE RETORT ADJUSTED, AS TO ENSURE THAT THE SPEED IS AS SPECIFIED IN THE SCHE (SHALL REQUIREMENT) COMMENTS:	NECESSARY, EDULED PROCESS? Yes No
IS THE ROTATIONAL SPEED OF THE RETORT AND THE PROC	CESS TIME RECORDED FOR EACH RETORT LOAD PROCESSED?
PROCESS TIME	Yes No
ROTATIONAL SPEED	Yes
(<u>SHALL</u> REQUIREMENT)	
IF NO, IS A RECORDING TACHOMETER USED TO PROVIDE A	CONTINUOUS RECORD OF THE SPEED? Yes No
(<u>SHALL</u> REQUIREMENT) IF NO TO THE ABOVE 2 QUESTIONS, HOW DOES THE FIRM M OF EACH RETORT LOAD PROCESSED?	ONITOR AND RECORD THE RETORT SPEED AND PROCESS TIME
OTHER COMMENTS:	
DOES THE FIRM HAVE A MEANS OF PREVENTING UNAUTHOR (SHALL REQUIREMENT – A LOCK OR NOTICE FROM MANAGED DEVICE WHICH PROVIDES A WARNING THAT ONLY AUTHORIZED IS A SATISFACTORY MEANS OF PREVENTING UNAUTHORIZED COMMENTS:	MENT, POSTED AT OR NEAR THE SPEED ADJUSTMENT IED PERSONS ARE PERMITTED TO MAKE ADJUSTMENTS,
EXPLAIN HOW THE RETORT ROTATIONAL SPEED IS MONITO	RED AND RECORDED:
OTHER CONCERNS AND OBSERVATIONS	
EXPLAIN ANY OTHER CONCERNS WITH THE OPERATION OF	THIS RETORT SYSTEM: