NATIONAL FISHERIES INSTITUTE

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3548 5 AUG 25 P1:37

August 23, 2005

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2005N-0065
Risk Assessment on the Public Health Impact from Foodborne *Listeria monocytogenes* in Smoked Finfish; and Evaluation of Food Code Provisions that Address Preventive Controls for *Listeria monocytogenes* in Retail and Foodservice Establishments; Request for Comments and for Scientific Data and Information

Dear Sirs:
Enclosed is the Smoked Seafood Working Group's (SSWG) survey of industry practices, microbiological data, and copies of flow diagrams received from respondents. At the end of the survey we included some National Fisheries Institute's statistics on sales volume among small, medium, and large companies and percentages each devote to hot or cold smoked. We hope these will be helpful, though we realize the information is from 2000. To our knowledge this is the only information available on the subject.

Sincerely,

Barbara Blakistone

Barbara Blakistone, Ph.D.
Director, Technical and Regulatory Affairs

Enclosures

2005N-0065 SUP1

SMOKED SEAFOOD WORKING GROUP (SSWG)
SUMMARY OF SURVEY OF INDUSTRY PRACTICES IN PROCESSING
HOT AND COLD SMOKED SEAFOOD

Seven companies responded to our survey. One completed only the first part of the survey. Numbers in Q1 and Q2 include summaries of data sent by all 7 with plant by plant data.

1. How many pounds of smoked finfish (excluding shelf-stable products) do you produce yearly?
2. Of the pounds produced (Question1), please approximate how much is percentage of the total is distributed, as indicated below:

The tables below summarize of Questions 1 and 2.

Hot Smoked Products

Plant	Frozen Prepackaged Consumer Portions, *Retail*	Frozen Prepackaged Fillets, *Food Service & Retail*	Frozen Bulk Prepackaged *Food Service*	Refrigerated Prepackaged Consumer Portions, *Retail*	Refrigerated Bulk Prepackaged *Food Service*	Refrigerated Prepackaged Vac Pak, *Food Service*	Refrigerated Bulk no package, *Food Service*
Plant A 250,000 lbs.	0%	0%	2%	3%	20%	0%	75%
Plant B 1,232,958 lbs.	2%	8%	0%	73%	0%	14%	3%
Plant C 130,000 lbs.	95%	0%	3%	2%	0%	0%	0%
Plant D 100,000 lbs.	0%	0%	100%	0%	0%	0%	0%
Plant E 2,172,896 lbs.	0%	0%	0%	24.7%	35.9%	0%	39.4%
Plant F 808,595 lbs.	4.1%	0%	95.6%	0%	0%	0%	0%
Plant G 36,000 lbs.	0%	0%	14%	5%	67%	0%	14%
Total For All Plants 4,730,449 lbs.	3.8% 181,311lbs.	2.1% 98,637 lbs.	18.8% 886,957 lbs.	30.6% 1,448,664 lbs.	18.1% 854,190 lbs.	3.6% 172,614 lbs.	23% 1,085,650 lbs.

Approximately 25% of > 4.7 million pounds of hot smoked fish production is distributed frozen
Approximately 75% of > 4.7 million pounds of hot smoked fish production is distributed refrigerated

Cold Smoked Products

Plant	Frozen Prepackaged Consumer Portions, *Retail*	Frozen Bulk Prepackaged, *Food Service*	Refrigerated Prepackaged Consumer Portions, *Retail*	Refrigerated Bulk Prepackaged, *Food Service*	Refrigerated Bulk no package, *Food Service*
Plant A 0 lbs.	0%	0%	0%	0%	0%
Plant B 0 lbs.	0%	0%	0%	0%	0%
Plant C 323,600 lbs.	95%	3%	2%	0%	0%
Plant D 800,000 lbs.	5%	95%	0%	0%	0%
Plant E 4.2 million lbs.	4.5%	0%	37%	45.9%	12.7%
Plant F 856,595 lbs.	5.8%	92%	2.1%	0%	0%
Plant G 58,000 lbs.	15%	85%	0%	0%	0%
Total For All Plants 6,262,951 lbs.	9.5% 595,872 lbs	25.7% 1,607,075 lbs	25.3% 1,587,250 lbs	31% 1,938,704 lbs	8.6% 536,417 lbs

Approximately 35% of > 6 million pounds of cold smoked fish production is distributed frozen
Approximately 65% of > 6 million pounds of production of cold smoked fish production is distributed refrigerated

3. How are your frozen and refrigerated products packaged? Vacuum pack? Non-barrier film wrap? Pouches? Other? Check all that apply. Letters correspond to the plants in Questions 1 and 2. Note that companies may use multiple types of packaging.

	Vacuum Packed	**Gas Flushed Modified Atmosphere**	**Breathable Film or other oxygen permeable package**	**Air Packed in Bulk Containers**	**Pouches**	**Other, Please specify**
Hot smoked, frozen	B, C, D, E, F, G		A	A		
Hot smoked, refrigerated	B, C, E, F		A, B, E	A, B, E, G		Plastic tub-G
Cold smoked, frozen	C, D, E, F, G		G	G	G	
Cold smoked, refrigerated	C, E, F		E	E		

4. How many days shelf life do you set for your hot and cold smoked products? Please list shelf life for products which are distributed frozen and refrigerated.

	Days Refrigerated (% of total production)	**Days Frozen (% of total production)**
Hot Smoked	45 (Plant F; air or vac not specified)	365 (Plant F; air or vac not specified)
air packed	21 (Plant A); (98%)	days not specified; (2%) (Plant A)
	35 (72%) (Plant B)	
	14 (13%) (Plant E)	
	14 (fish, 14%) (Plant G) and 56 (salad, 72%) (Plant G)	
vacuum packed	52 (28%) (Plant B)	180 (80%) (Plant G)
		365 (25%) (Plant C)
		365 (100%) (Plant D)
	14-35 (21%) (Plant E)	
		180 (14%) (Plant G)
Vac packed with sodium nitrite		365 (25%) (Plant C)
Cold Smoked	30 (Plant F; air or vac not specified)	365 (Plant F; air or vac not specified)
Air packed	14 (8%) (Plant E)	
Vacuum packed	30 (ca.5%) (Plant D)	1 yr (95%) (Plant D)
	21-30 (55%) (Plant E)	21-60 (3%) (Plant E)
Vac with sodium nitrite	90 (0%) (Plant C)	365 (20%) (Plant C)
		180 (80%) (Plant G)
Vac without sodium nitrite	30 (54%) (Plant E)	30-60 (2%) (Plant E)
		365 (80%) (Plant C)
	21 (9%) (Plant E)	30 (2%) (Plant E)

Plant D noted that some percent of cold smoked is sometimes converted at Retail to refrigerated. D recommends once refrigerated to store at 38F or less with a 30 day (unopened) shelf life.

What is the basis for the shelf life (time) (e.g., company research on time to spoilage, literature, buyer's specifications, long-standing company practice, etc)? Please list the primary criteria first followed by any others that apply.
Most companies responded that in dating their products they had done some research either themselves or by a contract lab and/or followed long standing company practices. Company A said their dating followed state and federal (?) regulations. (WI law is 21 days for an air and vacuum pack. MI law is 35 days for an air pack and 40 days for a vacuum pack.)

5. Is your plant using or evaluating any technology or additives to reduce, eliminate, or control microbes like *Listeria* spp. in raw materials? Yes____ No_____ If yes, Check all that apply

___ ozone ___ acidified chlorite ___nisin ___steam pasteurization

___ sodium/potassium lactate/ sodium diacetate ___ electrochemical treatment

___ chlorine dioxide ___ liming (calcium hydroxide) ___ CPC(Cecure™)

___ Other (specify)_____

- Nisin-containing ingredient system (maltodextrin, cultured dextrose, sodium diacetate, egg white lysozyme, and nisin) (Plant E)

Tested on hot smoked seafood salads. 1 log reduction of *Lm*. Brief shelf-life studies also conducted. Treatment not currently implemented. Price prohibitive.

- Sodium/potassium lactate/sodium diacetate (Plants B and E)

Tested on cold smoked salmon at brine/cure step. Not currently implemented as strong flavor had a negative effect on quality. (2 companies mentioned trying this with similar results.)

- Liming

Used to treat raw whole Atlantic salmon. Soaked prior to raw processing. Currently used on a limited basis in cold smoked. (Plant E)

A second company (Plant F) reported using this treatment and found it cost effective and a benefit to food safety. This same company also uses chlorine dioxide as a dip after liming and before splitting and finds its usage expensive but effective in *Lm* control.

- Sodium hypochlorite (Plant C)

Dissolved in the process water and used on raw headed and gutted (H&G) and raw fillets for cold and hot smoking at thawing, splitting, and trimming steps. Cost effective.

- Citro bio (Plant C)

For cold smoked fillets. Applied prior to drying and after fat line removal.

- Lime;Ozone (Plant D)

Raw H&G washed in lime or washed with ozone. Somewhat effective.

- Chlorine Dioxide

Used to wash H&G fish prior to splitting for cold smoked and some hot smoked. Plant F's experience: "We use as a secondary barrier against LM. We use this as a fish wash dip after the liming process and before splitting the fish. An evaluation has been done on 13 raw un-limed H&G fish that had *Listeria* species present. Soaked the fish for 60 sec in the chlorine dioxide at 40 ppm. During this 60 sec, the belly cavities were washed thoroughly with chlorine dioxide solution, and we had zero *Listeria* spp. present. This process and chemical usage is quite expensive, but we are extremely satisfied with the results." Plant G has used this chemical too; no details available.

- Plant D is testing a proprietary lactobacillus extract spray.

(Plant G gave no further information beyond Q5.)

6. Does your plant have a formal sanitation program? Yes___ No___

All 6 companies responded affirmatively.

7. Do you have specific sanitation procedures for *Listeria* spp. control? Yes___ No___

Five (5) out of 6 companies said they had a directed sanitation program for *Listeria* spp.

8. How often do you do a complete clean-up of equipment?_____

5/6 companies said they cleaned daily, and 4 of these said they broke down the equipment completely. One (1) said they cleaned weekly or after each use.

9. Are there any plant areas for which you have particular concerns regarding sanitation? Do you have sanitation issues with certain types of equipment? Please describe.

Targeted pieces of equipment or areas that were mentioned: Slicers (Company F mentioned either spraying chlorine dioxide over the slicers at the end of the sanitation shift until the morning pre-op or, if environmental sampling showed any bacterial counts on equipment or product contact surfaces, breaking down equipment and heating at 300 F for 35 min in their smoke ovens. Larger equipment is shrouded and steamed.); skinner (Company D modified equipment until sanitation could be properly controlled.); splitting machines; smoking racks, floor stress mats (Company F now soaks them in chlorine dioxide at 150 ppm without drying.); drains and drain coverings (Company F uses iodine blocks in the drains and plugging the drains and soaking them with 200 ppm chlorine.); tubs. Plant E noted concerns in food contact areas that involve complex equipment and parts that are not always constructed with sanitary parts, e.g., use of rubber or other absorbent materials that can be difficult or impossible to sanitize. Company F uses chlorine dioxide spray during processing day on cart wheels, doors, smoke racks, pallet jacks, etc.

10. Do you conduct employee training programs? ___ Yes ___ No

All 6 companies responded that they had training programs.

11. What type of training programs do you conduct and how often?

Type of Employee Training (Check All that Apply)		**How often do you conduct this type of training (e.g. for new employees, once per year, twice per year etc.)**
Sanitation procedures		
Employee Hygiene		
Cross Contamination Prevention		
Specific *Listeria* spp. control procedures		

Plant A responded that employee training is "covered under our own HACCP plan." (It seems they misunderstood the question.)

Plant B said training is given to new employees, once a year for regular employees, and after inspections with corrective actions. No specific training on *Listeria* spp. control.

Plant C said sanitation and employee training is given quarterly with cross-contamination prevention and specific *Listeria* spp. control training given on hire date.
Plant D said all new employees get all training mentioned. Otherwise all programs are given quarterly.
Plant E said sanitation training is given twice a year. Other training programs are given once a year to regular employees.
Plant F said all programs are given to new employees and annually for all employees.

12. Do you conduct any microbiological testing related to *Listeria* (e.g., tests for *Listeria* species or *L. monocytogenes*)?

Yes, all 6 companies do environmental monitoring.
Plant A said 2X per year. B said 4X per year. C said 1X per week. Plants D and E said 2X per week. Plant F monitors 1X per week and once a month by a third party.
Yes, all do product testing.
Plant A tests 4X per year. B tests 4X per year and upon customer request. Plant C tests weekly. D tests 1X per month. E tests 2X per week. F tests 4X per week and 1X per month by a third party.

Are you willing to provide microbiological data?

Number of *Listeria* spp. (or *L. monocytogenes*) positive product samples/total samples tested for a specific period of time (specify organism, product, e.g., 2 cold-smoked salmon positive for *Listeria* spp. out of 97 total samples tested over 18 months, one of which was *L. monocytogenes*):

Number of *Listeria* spp. positive environmental samples/total tested for a specific time period (35 *Listeria* spp. positive out of 520 samples over 12 months)

Plant B data is in attached file.
Plant C data showed 0 cold-smoked salmon positive for *Listeria* spp. out of 8. 9 *Listeria* spp. positive environmental samples out of 24 over 6 months; none was *Lm.*
Plant F data: From 01/15/05 to 07/07, a total of 85 finished samples were analyzed by a third party. Of these, 2 were positive for *Lm.* During the same time frame, 72 environmental samples were tested by a third party of which 1 was positive for *Lm.*

National Fisheries Institute statistics on the hot and cold smoked industry (prepared in December, 2000)

- 50 small companies with <$1 million in sales
- 43 medium companies with $1-8 million in sales
- 16 major companies with $8 million in sales

- Among the small companies, 80% process hot smoked and 20% process cold.
- Among the medium companies, 70% process hot smoked and 30% process cold.
- Among the large companies, 40% process hot smoked and 60% process cold.

Hot Smoked Mixed Species Testing

Date	Analysis	Species	Lbs	Cook Time/Temp	Brined	Salt/Nitrite Injected	Lot No.	Result
10/30/2003	Lm	Chum Vac Pac	4,300	30 min @ 145 F		yes	4309	Lm Neg
	Lm	King Salmon	500	30 min @ 145 F		yes	4309	Lm Neg
	Lm	Chum Salmon	4,300	30 min @ 145 F		yes	4309	Lm Neg
	Lm	Lake Whitefish	2,310	30 min @ 145 F	yes		4309	Lm Neg
	Lm	Lake Trout	500	30 min @ 145 F	yes		4309	Lm Neg
	Lm	King Salmon	500	30 min @ 145 F	yes		4309	Lm Neg
	Lm	Chub/Cisco	1,240	30 min @ 145 F	yes		4309	Lm Neg
12/30/2003	Lm	Lk WF Chunks	120	30 min @ 145 F	yes		4342	Lm Neg
	Lm	Chum Salmon	700	30 min @ 145 F		yes	4342	Lm Neg
	Lm	WF Dressed	2,310	30 min @ 145 F	yes		4342	Lm Neg
	Lm	Carp	165	30 min @ 145 F	yes		4342	Lm Neg
	Lm	Chum Vac Pac	4,300	30 min @ 145 F		yes	4342	Lm Neg
3/11/2004	Lm	Chub/Cisco	1,240	30 min @ 145 F	yes		4397	Lm Neg
	Lm	Sable/Black Cod	50	30 min @ 145 F	yes		4397	Lm Neg
	Lm	Whitefish Chunks	120	30 min @ 145 F	yes		4397	Lm Neg
	Lm	WF Dressed	2,310	30 min @ 145 F	yes		4397	Lm Neg
	Lm	Rainbow Trout	50	30 min @ 145 F	yes		4397	Lm Neg
	Lm	Chum Vac Pac	4,300	30 min @ 145 F		yes	4397	Lm Neg
6/24/2004	Lm	WF Dressed	2,310	30 min @ 145 F	yes		4457	Lm Neg
	Lm	Chum Vac Pac	4,300	30 min @ 145 F		yes	4457	Lm Neg
	Lm	Chub/Cisco	1,240	30 min @ 145 F	yes		4457	Lm Neg
	Lm	Atlantic Salmon vac pac	100	30 min @ 145 F		yes	4457	Lm Neg

Hot Smoked Mixed Species Testing

Date	Analysis	Species	Lbs	Cook Time/Temp	Brined	Salt/Nitrite Injected	Lot No.	Result
9/22/2004	Lm	Chum Vac Pac	4,300	30 min @ 145 F		yes	4501	Lm Neg
	Lm	Chum Pcs.	700	30 min @ 145 F		yes	4501	Lm Neg
	Lm	Chum Chunks	850	30 min @ 145 F	yes		4501	Lm Neg
	Lm	Lake Trout	500	30 min @ 145 F	yes		4502	Lm Neg
	Lm	Chub/Cisco	1,240	30 min @ 145 F	yes		4502	Lm Neg
	Lm	WF Dressed	2,310	30 min @ 145 F	yes		4502	Lm Neg
1/3/2005	Lm	Lake Trout	500	30 min @ 145 F	yes		4557	Lm Neg
	Lm	King Salmon	500	30 min @ 145 F	yes		4557	Lm Neg
	Lm	Chum Salmon	700	30 min @ 145 F	yes		4557	Lm Neg
	Lm	Sable/Black Cod	50	30 min @ 145 F	yes		4557	Lm Neg
	Lm	WF Dressed	2,310	30 min @ 145 F	yes		4557	Lm Neg
		Totals	51,225					

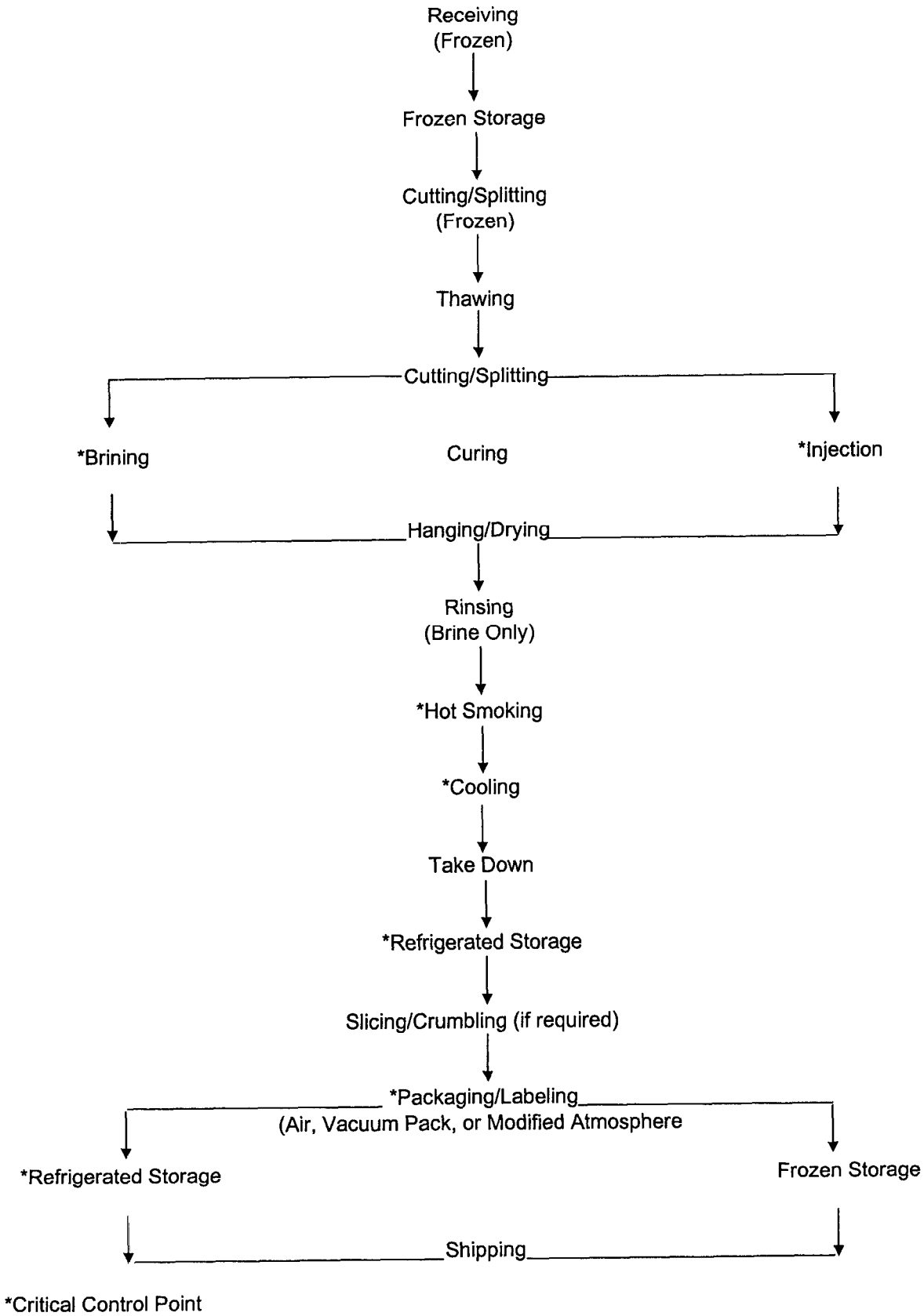
Hot Smoked Coho Salmon Crumbles

Date	Analysis	Species	Lbs	Cook Time/Temp	Brined	Salt Injected	Lot No.	Result
9/24/2003	Lm	Coho Salmon	3,200	30 min @ 145 F		Yes	3260	Neg
11/14/2003	Lm	Coho Salmon	3,200	30 min @ 145 F		Yes	3309	Neg
12/10/2003	Lm	Coho Salmon	3,200	30 min @ 145 F		Yes	3337	Neg
12/18/2003	Lm	Coho Salmon	3,200	30 min @ 145 F		Yes	3344	Neg
3/11/2004	Lm	Coho Salmon	3,200	30 min @ 145 F		Yes	4065	Neg
4/7/2004	Lm	Coho Salmon	3,200	30 min @ 145 F		Yes	4091	Neg
5/7/2004	Lm	Coho Salmon	3,200	30 min @ 145 F		Yes	4119	Neg
7/30/2004	Lm	Coho Salmon	3,200	30 min @ 145 F		Yes	4203	Neg
8/30/2004	Lm	Coho Salmon	3,200	30 min @ 145 F		Yes	4231	Neg
9/15/2004	Lm	Coho Salmon	3,200	30 min @ 145 F		Yes	4252	Neg
12/6/2004	Lm	Coho Salmon	3,200	30 min @ 145 F		Yes	4329	Neg
1/3/2005	Lm	Coho Salmon	3,200	30 min @ 145 F		Yes	4357	Neg
2/14/2005	Lm	Coho Salmon	3,200	30 min @ 145 F		Yes	5033	Neg
3/29/2005	Lm	Coho Salmon	3,200	30 min @ 145 F		Yes	5075	Neg
4/22/2005	Lm	Coho Salmon	3,200	30 min @ 145 F		Yes	5103	Neg
		Total	48,000					

Frozen headless, dressed fish are thawed, split into fillets and ready for injecting brine. Fish are injected with salt, water, then hot-smoked and processed through mincer that removes skin and bones. Product is sold frozen in 20-pound boxes.

Plant B

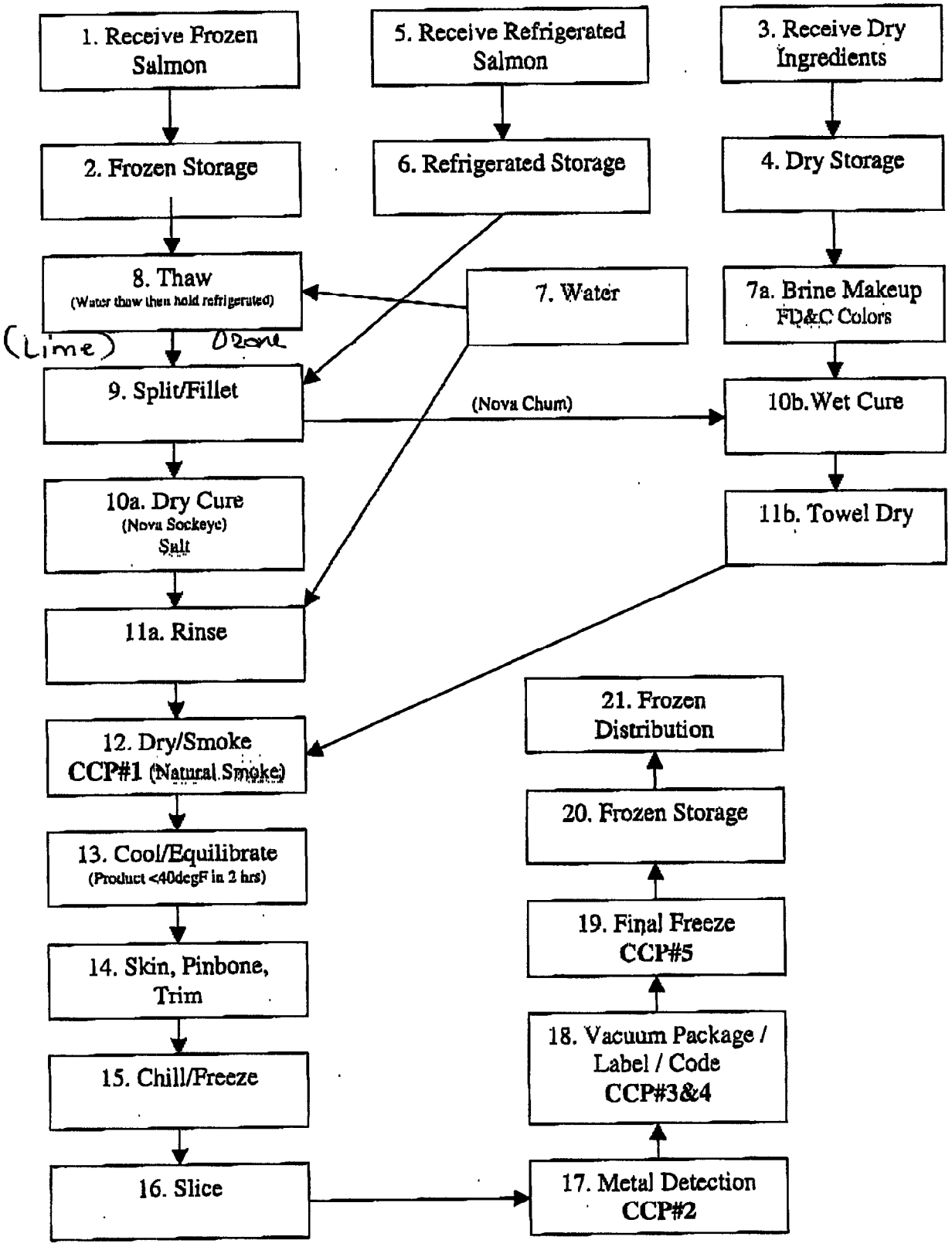
General Process Flow Chart For Hot Smoked Fish Products



*Critical Control Point

COLD SMOKED, FROZEN, VACUUM PACKED NOVA STYLE SALMON PROCESS FLOWCHART

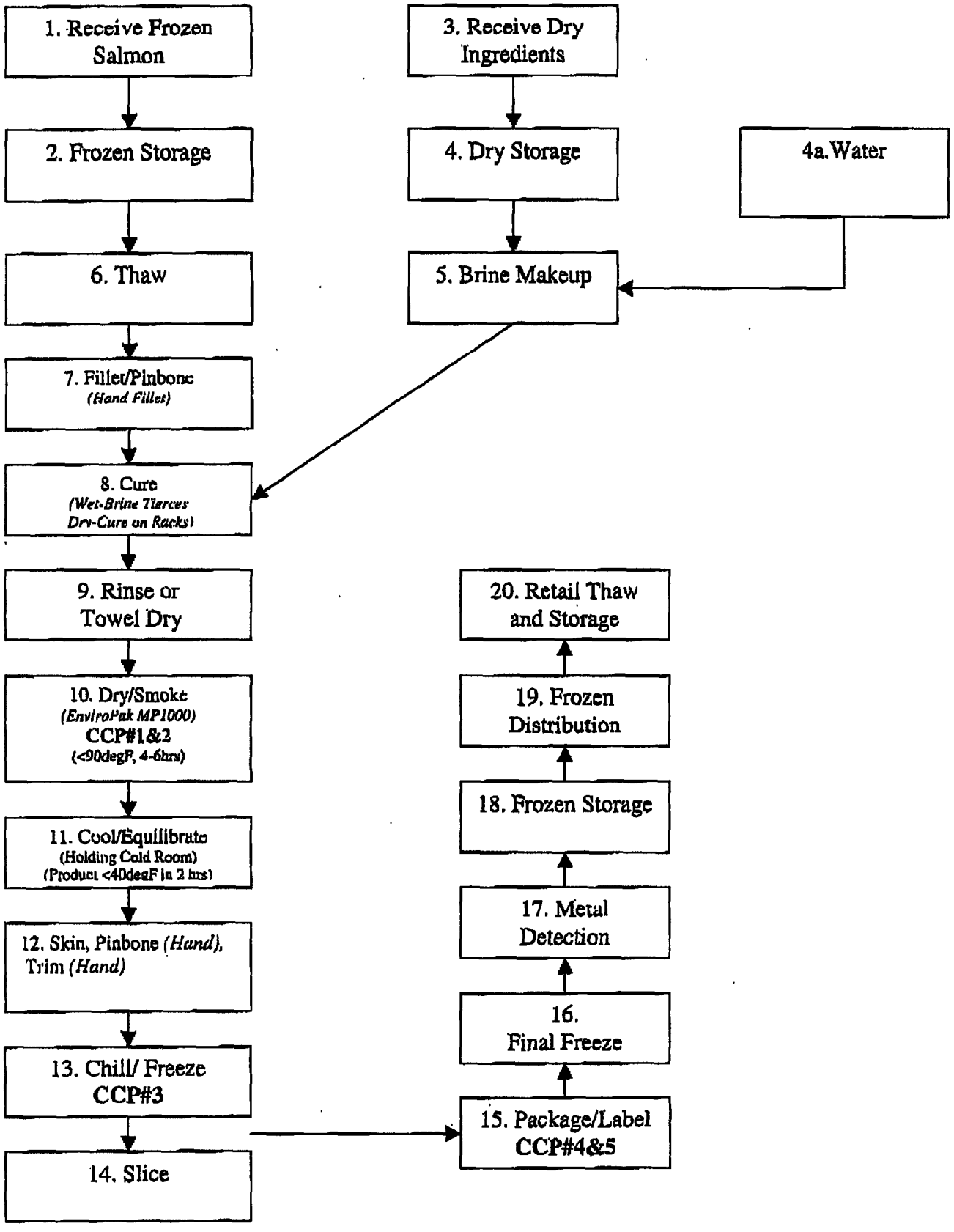
Plant D



Revised: 6/23/04

Plant D

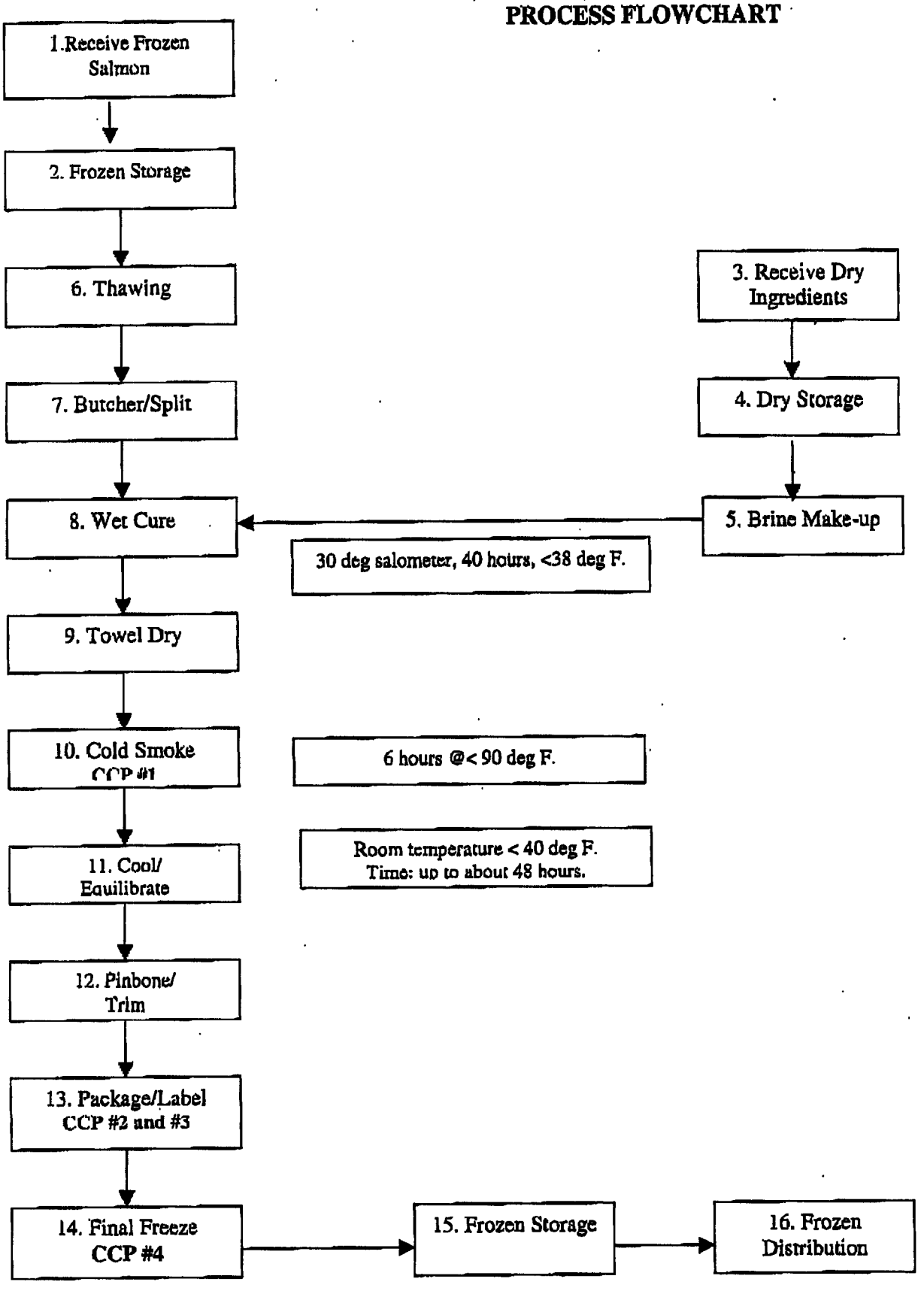
COLD SMOKED, REFRIGERATED, VACUUM PACKED NOVA STYLE SALMON PROCESS FLOWCHART



Revised: 12-18-03

Plant D

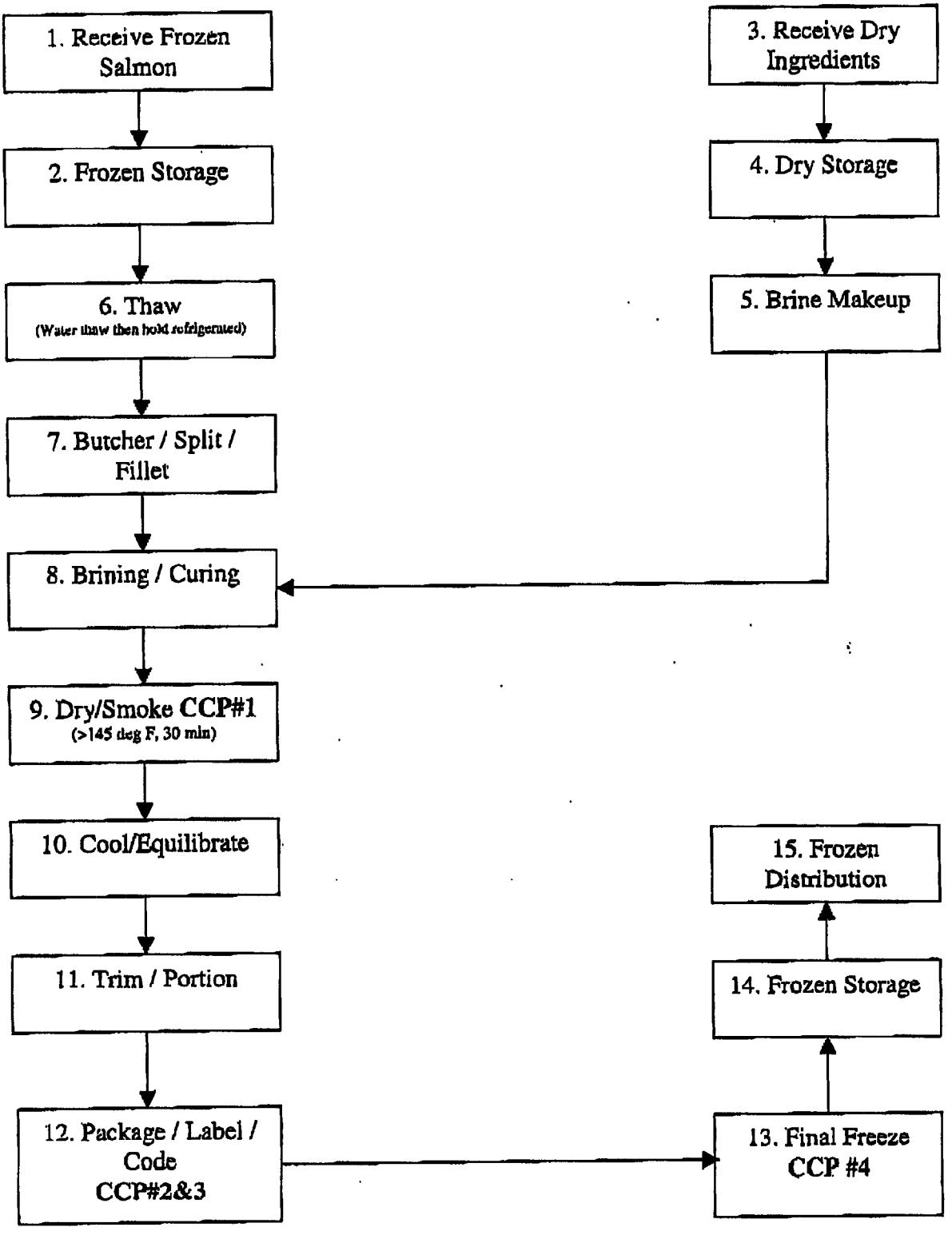
COLD SMOKED, FROZEN, VACUUM PACKED, SUSHI SALMON
PROCESS FLOWCHART



Date: 3/24/04

Plant D

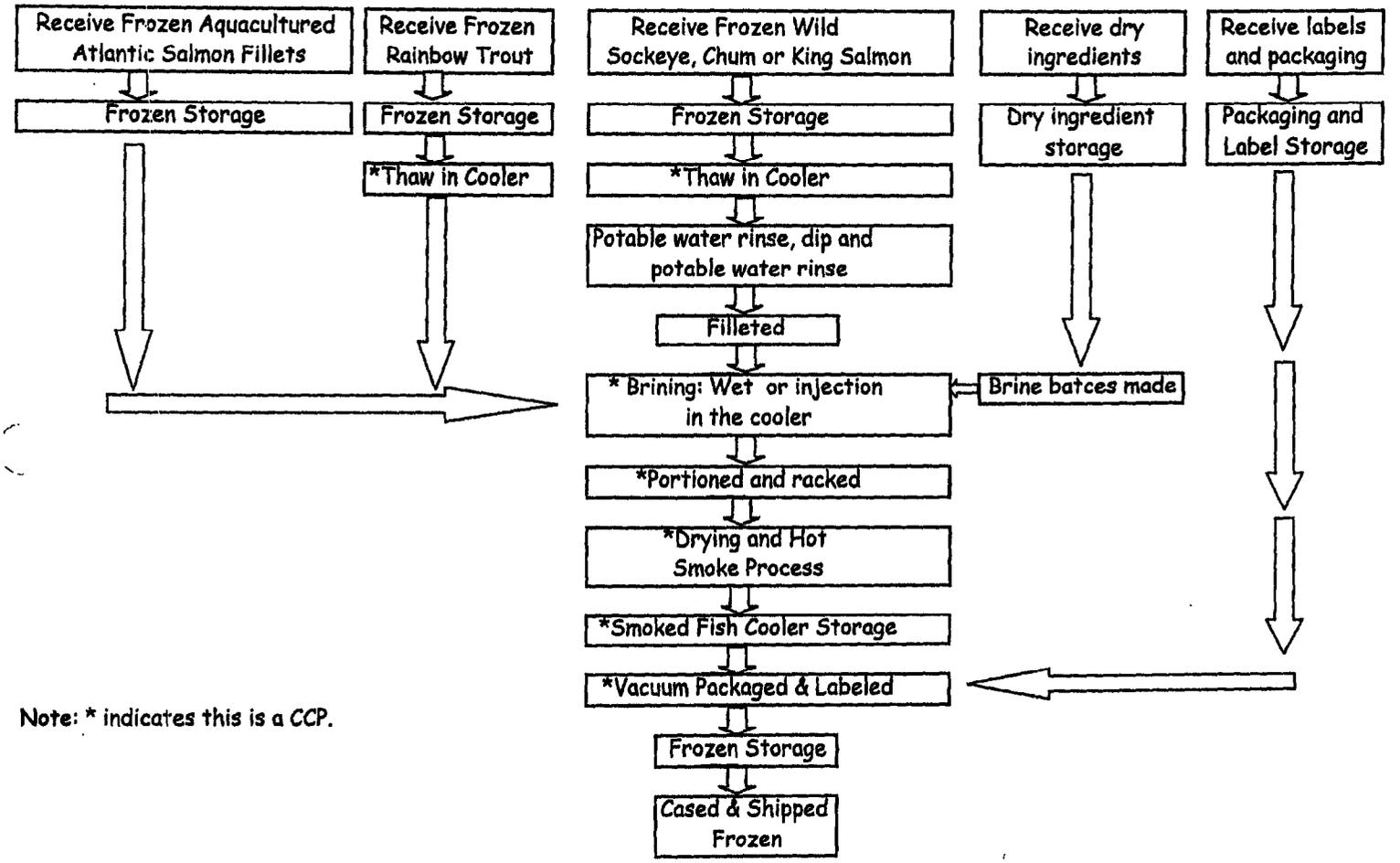
HOT SMOKED, FROZEN, VACUUM PACKED SALMON OR TROUT PROCESS FLOWCHART



Plant F

Species included:
Sockeye
Atlantic
Chum
Kings
Rainbow Trout

HOT SMOKED FLOW CHART



Note: * indicates this is a CCP.

Signature Of Company Official: Diane M. Mill

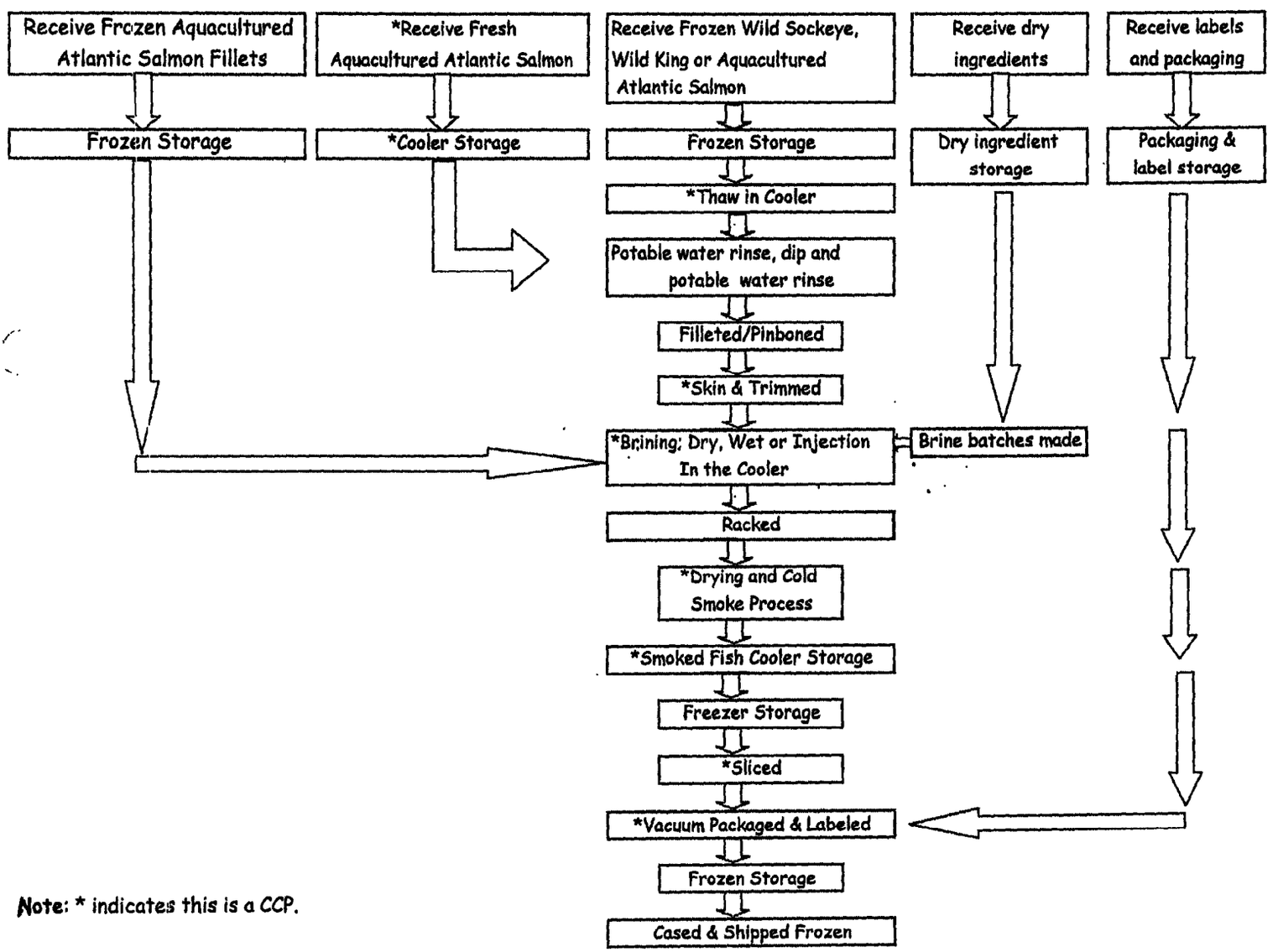
Date: 3-2-04

Document:htflow.xls
Revised: 02/27/04
Initials:TH

Plant F

Species included:
Atlantic
Sockeye
Kings

COLD SMOKED
FLOW CHART



Note: * indicates this is a CCP.

nature Of Company Official: Daniel Miller

ıte: 11-Oct-04

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