**SUBJECT:**

**Listeria Program for Smoked Salmon**

**Notes:**

**The FDA contact for this EOL is Frank MacKeith, HFS-585**

**Tel No. 202-2054045**

**This EOL is in effect indefinitely.**

THE DIRECTORATE
OF FISHERIES

Food and Drug Administration
Office of Seafood
1110 Vermont Avenue, N. W.
Washington, D.C. 20005

May 22, 1996

EXCHANGE OF LETTERS BETWEEN U.S. FOOD AND DRUG ADMINISTRATION THE NORWEGIAN DIRECTORATE OF FISHERIES REGARDING THE CONTROL OF LISTERIA MONOCYTOGENES IN SMOKED SALMON PRODUCED IN NORWAY EXPORT TO THE UNITED STATES.

In the enclosed documents we have outlined a program on which the Norwegian control of L. monocytogenes in smoked salmon would be based. The program has been prepared after previous consultations with the FDA. It should satisfy FDA entrance requirements and should thereby the need for the routine FDA collection of samples for Listeria monocytogenes analysis in smoked salmon from Norway.

It is our intention to implement the program as soon as we receive a confirmation on this from Food and Drug Administration.

We look forward to your reply.

/s/
Aksel Eikemo
Director General
Department of Quality Control

/s/
Geir Vaiset
Chief Inspector
Department of Quality Control

Notes:

May 22, 1996

# BASIS FOR EXCHANGE OF LETTERS BETWEEN THE FOOD AND DRUG ADMINISTRATION AND THE NORWEGIAN DIRECTORATE OF FISHERIES REGARDING THE PREVENTION OF *LISTERIA MONOCYTOGENES* IN SMOKED SALMON

## I. PURPOSE

The mutual goal of the United States Food and Drug Administration (FDA) and the Norwegian Directorate of Fisheries is to provide safe smoked salmon and provide assurance that:

a) Norwegian procedures can assure that smoked salmon shipped to the United States (U.S.) is produced under condition designed to detect *Listeria monocytogenes* and exclude product which contains this organism.

b) The program implemented by the Norwegian inspecting agency will be consistent with the provisions of this document.

c) The results of these procedures are acceptable to the FDA.

Documentation of these steps would provide the FDA with assurances that could affect its decisions on U.S. sampling and examination of entries when shipped directorate from Norway to the U.S. These steps include a safety control system that is equivalent to or the same as the Hazard Analysis Critical Control Point (HACCP) preventive system of hazard control. Verification that no detectible *Listeria monocytogenes* is present in the product and the processor is operating in accordance the Smoked Salmon HACCP Program should normally satisfy FDA entrance requirements. This Norwegian government program should avoid the need for routine FDA collection of samples for *Listeria monocytogenes* analysis. However, this program will not exempt smoked salmon from normal U. S. entry procedures a the prerogative of the agency to exercise its regulatory responsibilities.

## II. DEFINITIONS

For the purpose of the exchange of letters the following terms are defined.

### ANALYSIS FOR *LISTERIA MONOCYTOGENES*

All analyses for *Listeria monocytogenes* will be conducted using current procedures as outlined in the Food and Drug Administration Bacteriological Analytical Manual (BAM). In all cases references to the BAM will be the most recent edition and or version of the procedure

Notes:

available. The analyst may analyze individual subs (portions or composite multiple subs (portions) following BAM instructions. Alternatively the Nordic committee on Food Analysis (NMKL) method No. 136, 1990. "*Listeria monocytogenes* detention in food" may be used. Each analysis will be validated by use of appropriate controls.

## ANALYZING LABORATORY

The laboratories performing such analyses shall be official Norwegian Government laboratories or European Standards (EN-4500 series) certified laboratories capable of performing *Listeria monocytogenes* analyses.

## ANNEX

An Annex is an attachment(s) to this document that contain specific program information.

## LISTERIA MONOCYTOGENES NEGATIVE

The absence of detectable *Listeria monocytogenes* for all samples is required. The identification will be based on criteria outlined in the BAM or NMKL. method No. 136, 1990. The absence of detectable *Listeria monocytogenes* from these samples does not guarantee absence of *Listeria monocytogenes* from the lot.

## LOT

A lot is the quantity of smoked salmon produced by one processor at the same plant during a period of not more than 14 consecutive days. A lot is all production for shipment(s) destined for the U.S.

It is final product and identified by unique code traceable to the processor and the dates of production.

## PROCESSOR

A processor means any person engaged in commercial, custom, or institutional processing of smoked salmon for inclusion under this program.

## PRODUCTION PERIOD

A production period is a designated length of time during which product is produce. It is not to exceed 14 consecutive days.

Notes:

## SAFETY CONTROL SYSTEM

A safety control system is a multi-art program implementing a preventative system of hazard control to ensure the safe preparation, packing and holding of smoked salmon produced under this program. It is equivalent to or the same as HACCP principles for preventing safety hazards.

## SUB (portion)

A sub (portion) is a single unit of product collected for analysis. The sub (portion) may be taken from a larger unit or consist of the entire unit.

## SAMPLE

A sample consists of one or more subs (portions) of product collected under an agreed upon sampling plan. Subs (portions) that are collected by an official designated by the Norwegian Directorate of Fisheries shall result in an official sample. The sample shall be aseptically collected, transported and stored in a manner which maintains its integrity. The sample will represent a lot that was produced during production period. The sample can consist of subs (portions) from in-process or product and quality assurance controls.

## SAMPLING PLAN

A sampling plan is the written instructions describing how, when, where and why sample is collected. The purpose of the sampling plan is to verify that the process safety control system is working properly. The sample shall be collected in a manner consistent with current FDA practices. This includes adjusting the number of subs (portions) collected to correspond to the type of analytical method used and purpose of the sample. The sampling plan may be modified based on compliance with the processors safety control system success at excluding *Listeria monocytogenes* and compliance with government regulations.

## SMOKED SALMON HACCP PROGRAM

The Smoked Salmon HACCP Program is the Norwegian plan under which action is taken to meet the requirements of this document.

Notes:

## III. PROCEDURE

The Norwegian Directorate of Fisheries will ensure that the smoked salmon produce during the production period is fit for human consumption, the processor is operating under an effective safety control system, the processor is under government inspection, and that all lots of product, under this program are produced during periods from which verification samples are negative for detectable *Listeria Monocytogenes*.

Shipment to the U.S. will be permitted under the following conditions:

A) The norwegian Directorate of Fisheries will permit shipment of product produced during a production period during which *Listeria monocytogenes* is not detected.

B) The processor is required to implement an effective safety control system which is equivalent to or the same as HACCP principles for preventing safety hazards and an effective sanitation program. The Norwegian Directorate of Fisheries will document that the safety control system produces a safe product.

C) The Norwegian Directorate of Fisheries will document that the processor is in compliance with the requirements of this program, safety control system is implemented, and the product is produced accordance with Norwegian "Quality Regulations relating to Fish and Fishery Products" and "Hygiene Regulations for the Productions a Sale/Distribution, etc. for Foodstuffs" regulations.

D) The Norwegian Directorate of Fisheries will assure that the product does not contain detectable *Listeria monocytogenes* through verification sampling and by evaluating processor verification results.

E) The Norwegian Directorate of Fisheries will assure that the sample analysis for *Listeria monocytogenes* will comply with procedures identified in Part II of this document.

F) The Norwegian Directorate of Fisheries will permit shipment of smoked salmon produced during an identified production period and which have no unresolved sample results or other issues pending.

G) The procedures and directives contained in each Annex and other appropriate Norwegian regulations will be followed.

H) The Norwegian Directorate of Fisheries will require that all shipment of smoked salmon to the U.S. shall be identified and marked with the dates of production or a unique code traceable to the processor and the dates of production.

Notes:

I) The Norwegian Directorate of Fisheries will submit a list of processors participating in the Smoked Salmon HACCP Program to the FDA Office of Seafood in accordance with Annex A and Update the list as necessary.

J) Issuance of an export certificate will be the Norwegian Directorate Fisheries final verification that the processor and product meet the Smoked Salmon HACCP Program requirements. Upon request expert certificates shall be presented to the appropriate Food and Drug Official.

k) The Norwegian Directorate of Fisheries will include the following information on the export certificate for each lot of smoked salmon exported to the U.S.

1) Product Name:

2) Name and address of the processor or his current Norwegian Directorate of Fisheries registration number (register of approved plants);

3) Affirmation that the processor operated in compliance with provisions of this document during the period during which the covered product was produced;

4) Lot number which will identify the dates of production or the production period (not more than 14-days) or unique code traceable to the processor and the dates of production;

5) Number and size of containers in lot;

6) Analytical results of the test for *Listeria monocytogenes* (laboratory work sheets and method should be provided upon request) for the production period during which the sampled product was produced;

7) Date of certificate;

8) Name and stamp or seal of the authorizing official.

Notes:

May 22, 1996

## ANNEX A- NORWEGIAN DIRECTORATE OF FISHERIES

REGULATIONS GIVING THE AUTHORITY FOR SUPERVISION AND CONTROL

1. "Quality Regulations relating to Fish and Fishery Products" laid down by the Ministry of Fisheries 1 July 1986 pursuant to the Act of 28 May 1959 relating to quality control of fish and fishery products and the Royal Decree of 8 April 1960 with subsequent alterations, latest alteration 10 November 1995.

2. "Hygiene Regulations for the Productions and Sale/Distribution etc. for Foodstuffs" laid down by Royal Decree of 8 July 1983 pursuance of The Food Act of 1-- May 1933 No. 3, latest alterations of 6 April 1995. By Royal Decree of 29 April 1988 the Directorate of Fisheries is granted authority to make individual decisions and to carry out supervision in pursuance of these Hygiene Regulations.

REQUIREMENTS FOR PROCESSOR APPROVAL

Production plants fulfilling the quality and hygiene regulations, are listed in The Director General of Fisheries Register for Approved Plants for Fish and Fishery Products. The Directorate of Fisheries will grant a special approval to processors that are in accordance with this document before entering this program. The plant shall have a documented safety control system sanitation plan, sample collection procedure and corrective action procedures. When requested, the results of stipulated checks, measurements or observation for these items will be made available to the Norwegian Directorate of Fisheries. These documents shall be kept in a record keeping system for at least 2 years.

Before entering into this program, the processor has to take a 300 gram sub (portion) of in process or finished product from each days production for a week. Composite the subs (portions) into one (1) sample an analyze for *Listeria monocytogenes*. Negative analytic results are required to enter the program.

The requirements for entering this program are the same for seasonal or intermittent processors.

Notes:

ANNEX A-NORWEGIAN DIRECTORATE OF FISHERIES CONTINUED

CONTROL

Facility inspections and official sampling provide verification that the processor is in compliance with this document. Processor files, records and registration documents are kept in a record keeping system that is accessible to the Norwegian Directorate of Fisheries. The Directorate of fisheries will perform less frequent inspections and verification sampling as a history of processor compliance is established.

EXCLUSION FROM THIS PROGRAM

If *Listeria monocytogenes* is detected the processor will be ordered to affect corrections. The processor will be excluded from this program until compliance with the Smoked Salmon HACCP Program can be demonstrated.

The Directorate of Fisheries will verify that the processor is operating in accordance with the document.

The plant can be readmitted into this program after successful completion of the Directorate of Fisheries verification inspections and negative analytical results.

Notes:

May 22, 1996

# ANNEX B- PROCESSOR REQUIREMENTS

The processor must develop an effective HACCP plan.

The plant shall fulfill the requirements in accordance with the requirements described in Annex A. The plan, procedures, and registrations shall be in accordance with Norwegian regulations, and structured in accordance with the Manual of Own Checks System based on HACCP.

When HACCP is implanted in a plant approved under this program, the requirements described in this document will become a part of the processor's Own Check System based on HACCP.

Samples taken in accordance with Annex C will be included as part of the processor's verification procedures.

The following is mandatory in Norwegian Regulations:

**Own Check Based on HACCP in the Norwegian Fishing Industry**

**Activities and System Documentation in the Plants**

## I. Plant Organization

1. Background information about the plant.
2. Organization chart.
3. Description of organizational responsibilities.
4. Plant for Own Check/HACCP training of personnel.
5. Name and address of laboratories used for analyzing control samples.
6. Information about production volumes, numbers of employees, deep-freezing capacity and volume of deep-freeze storage facilities.

## II. Official Regulations

1. List of official regulations which the Own Check-system is referring to

## III. Products and Production Processes

1. List of finished products with description of products, packaging materials, and labels.

Notes:

2. For each separate product group.

   2.1 Flow sheet.
   2.2 Operating description.
   2.3 A Critical Control Point Analysis (CCP - analysis sheet).

3. For each Critical Control Point document (CCP - sheet) listing:
   a) Control point (Marked on the flow Sheet).
   b) Hazard to be controlled.
   c) Critical Limits.
   d) Preventative measures.
   e) Control methods, frequencies and responsible person.
   f) Corrective actions.
   g) Name or No. of registrations form(s).

4. All instructions and registration forms used for control at the Critical Control Point.

**IV. Cleaning Plan**

**V. General Hygiene and Building Control Plan for the Plant.**

**VI. Procedure for Recall of Products and Procedure for Dealing with Customer Complaints.**

**VII. Description of how the Own Check Documents and Control Forms are Handled and Filed.**

**VIII. Description of Routines for Internal Revision and Updating of the own Check System.**

Notes:

May 22, 1996

# ANNEX C- SAMPLE PLANTS and ANALYSIS

The use of product sampling and microbiological analyses can help verify that the producer safety control system is effective.

## PROCESSOR

Each sampling plan must be individually evaluated because each establishment location its safety control system and product compliance with government regulations is unique Each sampling plan will be evaluated by the Norwegian Directorate of Fisheries.

## NORWEGIAN DIRECTORATE OF FISHERIES

Each sample plan will be based on processor compliance with the Smoked Fish HACCP Program.

Notes:

October 15, 1996

Mr. Aksel Eikemo
Director General, Department of Quality Control
The Directorate of Fisheries
P.O. Box 185
N-5002 Bergen
Norway

Dear Mr. Eikemo:

This will acknowledge our receipt of both your May 22, 1996 letter concerning the control of Listeria monocytogenes in Norwegian smoked salmon that is intended for export to the United States and the description of the proposed Norwegian smoked salmon HACCP Program (Program) that will provide this control.

Please understand that because of the limited information at hand concerning implementation of your HACCP Program, we consider the Food and Drug Administration (FDA) action described in this letter to represent an interim measure of cooperation with Norway in response to your welcomed effort to ensure that hazards from L. monocytogenes in Norwegian smoked fish that is to be exported are controlled. Because the scope of this exchange of letters is limited to control of L. monocytogenes, we do not consider this to constitute a Memoranda of Understanding (MOU). However, your Program may very well form the basis for a future MOU.

FDA will consider the success of the Program in setting the rate at which the agency will examine Norwegian smoked salmon that is offered for entry into the United States (U.S.) and that is identified as being from processors that participate in your Program. While we are impressed with your efforts, and thus will consider examining such fish at a lower rate than would otherwise be the case, any change in examination rate is contingent upon a determination by FDA that the Program is effectively controlling L. monocytogenes in Norwegian smoked salmon, as shown by the results of our analyses at the port of entry. Therefore, we do not intend to make an immediate change in the examination rate of Norwegian smoked fish. Nor can we specify how long it will take, or how many Norwegian entries that FDA will need to examine to establish that your Program is effective in controlling L. monocytogenes in smoked fish. We will keep you informed of the progress of our review.

Notes:



Recognize that in addition to an examination for L. monocytogenes, Norwegian smoked fish will remain subject to examination for other attributes to determine whether it complies with the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, and the regulations that implement them. As is the case with entries from other countries, smoked fish found in violation of U.S. regulations will be detained in accordance with FDA published procedures. Shipments from a processor whose smoked fish has been previously found in violation may be subject to detention without physical examination by FDA. Should this situation arise in the case of smoked fish that are subject to the Program, the Norwegian Directorate of Fisheries may request removal of a processor's product from detention without physical examination after submitting a report to the FDA office of Seafood that establishes the cause of the violation and provides verification that appropriate corrective actions have been taken to prevent future violations.

One technical point that is of some concern to us is that your Program states that a "lot" can consist of up to 14 consecutive days of production, and that the lot is linked to sampling and analysis of product by the Norwegian government for the purpose of verification. The definition of a "lot" that FDA has generally used in food MOU's states that a lot will consist of production from a definite period of time not exceeding one day, and this limitation is linked to product identity and traceability when a recall is necessary. This is an important difference that could become an issue during future MOU discussions.

In order to avoid confusion, Norway may wish to revise the language of the Program to refer to the 14-day period as something other than a "lot." Two possibilities would be to call it the "sampling verification period" or the "production period for verification." On the other hand, if Norway wishes to retain the term "lot" for purposes of this exchange of letters, we are taking this opportunity to clarify in this letter, from the U.S. standpoint, that the term "lot" as used in your Program refers to the interval between samples that are taken for analysis by the government of Norway for the purposes of verification, and that the interval spans more than one day of production. Should Norway's L. monocytogenes testing program be the subject of an MOU between our countries, FDA would expect that a term other than "lot" will be used to refer to the products that are subject to a 14-day verification interval.

It is not clear from section III (A) of the Program whether the processing environment must be free of L. monocytogenes, or whether only the product needs to be free of L. monocytogenes. From the U.S. standpoint, it is the intent of the Program to control L. monocytogenes in the finished product, and that an effective sanitation program, in accordance with section III (B) of the Program, needs to include control of L. monocytogenes in the processing environment.

Notes:

We noticed that several words in Annex B of the Program were crossed-out when it was received. Mr. Birger Larsen of the Royal Norwegian Embassy assured Mr. Thomas Latt of the FDA Office of Seafood, in a telephone conversation, that the crossed-out words are not a part of this exchange of letters and will not alter the Program. Based on that telephone conversation, we accept Mr. Larsen's assurance that the cross-outs will not alter te Program.

It is our understanding that the Norwegian Directorate of Fisheries and FDA's Office of Seafood will maintain communication regarding product detention, sampling, and changes in regulations, policies, and procedures that may affect the Program. Either party may terminate the exchange of letters 30 days after mailing written notification to the other party.

We look forward to continued cooperation between our two countries on issues of mutual interest. Please find the enclosed Program revised as agreed.

Sincerely yours,

/s/
Fred R. Shank, Ph.D.
Director
Center for Food Safety
and Applied Nutrition