SUBJECT:

Certification Program for Listeria in Cheese

Notes:

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

Tel. No. 202-205-4045

This EOL is in effect indefinitely.

Currently: Mr. Claude Chereau, Counselor for Agriculture

EXCHANGE OF LETTERS

Mr. Ralph Ichter
Agricultural Attache
Embassy of France
4101 Reservoir Road, N.W.
Washington, D.C. 20007-2173

Dear Mr. Itchter:

This responds to the December 19, 1986, letter from Mr. Philippe Caradec of your staff to Mr. Thomas D. Gardine of FDA's Center for Food Safety and Applied Nutrition. Enclosed with Mr. Caradec's letter was the most recent (December 1986) revision of the proposed plant and product certification program for Listeria testing in soft-ripened cheese and goat cheese made from pasteurized milk.

I have reviewed your government's current proposal and have determined that it adequately addresses the concerns we have raised during previous discussions regarding a Listeria certification program. I believe that it represents a strong program with a high likelihood of success. Therefore, I am prepared to initiate the program at the earliest possible date.

One point that was not addressed specifically in the proposal, which I believe needs clarification, is the status of certified plants whose products are found to be Listeria-positive during an FDA analysis. We believe an FDA-positive result should require suspension of a firm's certification. If not, how would a positive FDA result be treated and what corrective actions would be mandated?. Please feel free to contact either my staff or personnel at the Center for Food Safety and Applied Nutrition if you wish to discuss this issue further. If you believe it necessary, we are prepared to meet with you and your staff to finalize any remaining details. We anticipate receiving the list of certified plants under the Listeria certification program in late January 1987 as indicated in Mr. Caradec's letter.

We at FDA believe that the proposed program will have a major impact on lowering, and eventually eliminating, the incidences of Listeria contamination of French cheese imported to the United States. We recognize the commitment of resources necessary for the implementation of a program of this type and want to thank all of those individuals, both here in Washington and in France, who have devoted so much effort to developing this program and helping us to combat a matter of serious public health concern.

Sincerely yours,

John M. Taylor
Associate Commissioner
for Regulatory Affairs

Notes:

Mr. John M. Taylor
JAN 21, 1987

You indicate that your agency is prepared to initiate this program at the earliest possible date. After consultation with the French Ministry of Agriculture, it appears that instructions could be given to the field offices in France so that our Regional Veterinary Services would start implementation of the program in late January. Instructions would be worded so that revised Certificates (including Listeria Certification) would be issued only for shipments intended to arrive in the US not earlier than February 1st, 1987.

I would greatly appreciate it if you could inform me as soon as possible whether such a time frame is compatible with FDA's administration procedures.

Your January 16, 1987 letter calls for clarification of the status of certified plants whose products are found to be Listeria-positive during an FDA analysis. After consultation with representatives of the French Ministry of Agriculture, it appears that such a finding could only be recognized as a "non-official positive result" by the French authorities and would therefore be handled as described in paragraph 2.1.3. of the December 18, 1986 document:

> (Quote)
> 2.1.3. Action in the case of positive result for a non-official analysis.
>
> When a control performed under the authority of the company is not in accordance with set standards, an official control will be performed as described in 1.2.
>
> If the result of the official control is not in accordance with set standards, the certification will be fully suspended (see 2.3.1.) and will have to be re-certified under the procedure described in 2.3.2. (Note that plants for which certification has been suspended will not be allowed to export to the United States until re-certified.)
>
> If the result of the official control is in accordance with the set standard (Absence of Listeria in 25g) the Company will be required to perform a Listeria analysis for each lot intended for export, as well as to conduct an investigation of the cause of the observed contamination. Modifications will have to be performed in accordance with the conclusions of the investigation. After 20 consecutive negative results and only after evaluation by the Milk and Dairy Product Bureau of the Ministry of Agriculture confirms the appropriateness of the modifications performed in the plant to prevent contamination, certification will be fully re-established.

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Only at that time, will the sampling rate be reduced to one analysis per week performed on the composite of five cheeses sampled during one day of production.

(Unquote)

I would greatly appreciate receiving your opinion on the appropriateness of this procedure to address FDA's concerns on this matter.

I hope that the information provided in this letter clarifies the remaining details mentioned in your letter. However, should you or FDA's staff have any questions on this issue, please feel free to contact either myself or Mr. Phil Caradec of my Staff. Should you feel that a meeting is needed to finalize this agreement, I would be glad to arrange for one at your convenience.

Sincerely yours,

Ralph Ichter
Agricultural Attache

Currently: Mr. Claude Chereau, Counselor for Agriculture

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Feb. 6, 1987

Ralph Ichter
Agricultural Attache
Ambassade De France Aux Etats-Unis
4101 Reservoir Road, N.W.
Washington, D.C. 20007-2173

Dear Mr. Ichter:

This replies to your letter, dated January 21, 1987, concerning the Plant and Product Certification Program for Listeria Testing in Soft-riperied Cheese and Goat Cheese which I informed you, in my letter of January 16, 1987, that FDA was prepared to implement.

Due to the need to prepare and issue new instructions to all FDA field offices, we anticipate that we will be in a position to fully initiate the new program on February 15, 1987. While this does not coincide with the February 1, 1987, date indicated in your letter for the arrival of shipments from France produced under the new program, we will attempt to handle entries under the new program, arriving before February 15, 1987, on a case-by-case basis. This procedure should keep any disruption to a minimum.

You indicate, in response to my inquiry, that, under the program, FDA findings of Listeria-positive shipments would be treated in the same

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manner as a Listeria-positive plant control sample that is not confirmed by French government analysis. That is, the plant would be required to investigate the potential cause of the problem and to perform Listeria analysis for each lot intended for export for a minimum of 20 consecutive shipments.

Frankly, we would have preferred that a Listeria-positive result obtained by FDA be treated as an "official" positive under the program and result in the suspension of a plant's certification. While this interpretation will not affect our acceptance of the program, you must realize that FDA reserves the option to initiate action, including the automatic detention of cheese from individual plants in the program, when FDA laboratory results find the cheese produced by these plants to be violative.

I believe that all outstanding questions regarding the program have now been resolved. A copy of the instructions issued to our field offices concerning the implementation of the program will be forwarded to your office as soon as it is finalized.

Sincerely yours,

John M. Taylor
Associate Commissioner for
Regulatory Affairs

The ACRA is currently Mr. Ronald G. Chesemore

January 21, 1987

Mr. John M. Taylor
Associate Commissioner
for Regulatory Affairs
Food and Drug Administration
Rockville, MD 20857

Dear Mr. Taylor:

Thank you for your letter dated January 16, 1987 informing me of your acceptance of the December 86 proposal for the Plant and Product Certification Program for Listeria Testing in Soft-ripened Cheese, and Goat Cheese made from Pasteurized Milk. I am pleased that, through close cooperation of all parties involved in the development of this Proposal, the concerns of the FDA have been thoroughly addressed.

Under separate cover, I am sending today a copy of the list of plants certified by the French Ministry of Agriculture, to both the Center for Food Safety and Applied Nutrition and to FDA's Import Operations Director. This list includes two types of plants:

1/plants for which certification has been granted for all micro-organisms

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and substances covered by the certification program developed by the French Ministry of Agriculture including determination of possible contamination by Listeria:

2/plants for which certification for Listeria has not yet been granted, but which are still certified under the former certification program not including Listeria testing. Under the terms for the proposal you agreed upon and only during an interim period which will not exceed one year after the effective date of this new program, such plants will be allowed to export to the United States provided that each shipment of cheese is accompanied by a report establishing that the specific lot exported to the US has been tested for the presence of Listeria and that no contamination has been detected.

Please note that, following a request originating mainly from the American Cheese Importers Association, the plant identification codes are considered confidential by this Embassy. However, the list of approved plants, not including identification codes, is considered a public document. Therefore, I would appreciate it if the plant identification codes provided to FDA could be considered as confidential information and not be released to a third party.