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Standard Norwegian fishmeal- and fishoil process

Heat treatment requirements

Halvor Nygaard

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Summary:

The present report is a consolidated version of former Nofima Report K-371, incorporating new kinetic data on thermal inactivation of IPNV (Nygaard and Myrmel, 2010). Report K-371 has been withdrawn.

The project was initiated by the Norwegian Seafood Federation (FHL) after a request from the Norwegian Food Safety Authority to define a standard Norwegian fish meal process and criteria to kill infectious agents present in wild fish and aquaculture fish.

The report summarizes inactivation data for *Enterobacteriaceae/Salmonella* and bacterial/viral pathogens of fish. Inactivation effects resulting from various temperature-time (T/T) combinations were estimated from available D-and z-values.

Wild fish should be processed according to the “fishmeal method” as outlined in Regulation (EC) 1774/2002. The minimum conditions proposed for heat treatment of wild fish are 70 °C/20 minutes which provides 100 LOG_{10} reductions of *Enterobacteriaceae/Salmonella*.

The minimum conditions proposed for heat treatment of aquaculture fish are 76 °C/20 minutes or other T/T combinations resulting in 3 LOG_{10} reductions of IPNV.

The report describes heat treatment at two alternative stages of the manufacturing process; in cooker and in indirect steam drier. For production of fishmeal, fulfilment of minimum conditions for heat treatment may be documented either in the cooker or in the steam driers. For fishoil production, inactivation has to rely on heat treatment in the cooker.

The report proposes conditions to be fulfilled in order to allow processing of category 3 materials from wild fish and aquaculture fish in the same processing unit.

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1 Background

The manufacturing of fishmeal and -oil for animal feed was formerly approved according to the Regulation of 26th mars 1999 no 416 relating to Fishmeal, Fish Oils, etc. Since October 2007 the production is regulated by Regulation of 27th October 2007 no 1254 relating to animal by-products not intended for human consumption which implements Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3rd October 2002 laying down health rules concerning animal by-products not intended for human consumption.

Annex V, Chapter III of Regulation (EC) 1774/2002 defines seven methods for treatment of animal by-products. Annex VII, Chapter II, paragraph 3 states that fishmeal must have been submitted to any of the processing methods or to a method and parameters which ensure that the product complies with the microbiological standards set in Chapter I, paragraph 10 with regard to *Salmonella* and *Enterobacteriaceae*.

Annex VII, Chapter I, Section C states that critical control points (CCP's) that determine the extent of heat treatment must be identified for each processing method and shall at least include particle size and temperature, pressure and duration of the heat treatment process or feeding rate to a continuous system. Minimum process standards shall be specified for each CCP. Also, there are requirements to monitoring equipment, record keeping and treatment of material that has not received the required heat treatment.

In January 2009, the Norwegian fish meal industry was encouraged by the Norwegian Food Safety Authority (NFSA) to define and document a standard fish meal process with criteria to inactivate infective agents of interest. NFSA intend, after risk assessment of the method, to apply it for audits and approval of establishments.

Nofima was engaged by the Norwegian Seafood Federation (FHL) to prepare a proposal for a description of a standard Norwegian fish meal process. FHL also appointed a project group with representatives for the fish meal industry. The group consisted of;

- Gunn Harriet Knutsen, Advisor Health and Quality, FHL
- Arve Hjelle, Quality Manager, Welcon AS
- Ola Dybvik, Factory Manager, Vedde AS
- Bent Inge Ulset, Technical Leader, Egersund Sildoljefabrikk AS
- Sverre Ugletveit, Quality Manager, Norsildmel AL
- Halvor Nygaard, Research Scientist, Nofima Ingrediens

2 Scope

The project group decided that description and documentation of the process should focus on heat treatment during the manufacturing of fish meal from wild caught and aquaculture fish. Consequently, the descriptions can have the same format as the pre-approved methods described in Annex V, Chapter III of Regulation (EC) 1774/2002. Additionally, arrangements to adequately separate the processing of wild caught and aquaculture fish should be described.

The minimum conditions proposed for heat treatment should be supported by scientific data. Establishments choosing to adopt the described methods will not have to validate the heat treatment process them selves, but can refer to the present report.

The minimum conditions should be integrated in each plants own check systems. Other steps of the manufacturing process must be described and hazard assessed by each individual establishment. Those steps shall maintain the hygienic standard obtained during heat treatment but must also take into account other aspects such as quality, economy, health, safety and environment. This is beyond the scope of the present project.

3 Definitions

D-value	D-value (decimal reduction time); the time needed at a certain temperature, to kill 90 % of a population
z-value	Z-value; the temperature increase needed to reduce D-value by a factor of 10
Validate	Check if process requirements are adequate to achieve a required effect
Verify	Confirm (by monitoring or other investigations) and obtain objective proofs that process requirements are met
IPNV	Infectious Pancreatic Necrosis Virus
SVCV	Spring Viraemia of Carp Virus
EHNV	Epizootic Haematopoietic Necrosis Virus
CCV	Channel Catfish Virus
CCP	Critical Control Point; a processing step where control measures can be applied in order to prevent, reduce or eliminate a safety risk
Own Check System	A mandatory quality ensurance system based on HACCP principles and focusing on food safety
HACCP	Hazard Analysis Critical Control Point

4 Legislation

4.1 Regulations in force

Regulation of 27th October 2007 no 1254 relating to animal by-products not intended for human consumption

Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3rd October 2002 laying down health rules concerning animal by-products not intended for human consumption

Commission Regulation (EC) No 811/2003 of 12 May 2003 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the intra species recycling ban for fish, the burial and burning of animal by-products and certain transitional measures

4.2 Repealed regulations

FOR 1999-03-26 nr 416: Regulation relating to Fishmeal, Fish Oils, etc. (provisions concerning meal and oil intended for animal feed is repealed)

FOR 2007-03-29 nr 511: Regulation relating to the intra-species recycling ban of animal protein (provisions concerning feeding of aquaculture fish with material from aquaculture fish is repealed).

5 Heat resistance of pathogens

5.1 Thermal inactivation of microorganisms

The heat resistance of microorganisms is described by D-values and z-values. D-value is the time required at a certain temperature to kill 90 % of the organisms being studied (1 Log_{10} reduction). z-value is the temperature increase needed to reduce the D-value by a factor of 10. When D-value and z-value for an organism is known, inactivation at any temperature can be predicted.

The relationship between D-values and temperature is expressed by Bigelow's equation (Bigelow, 1921):

Log Dx = (Ty – Tx)/z + log Dy

where Dx and Dy are decimal reduction times at temperature Tx and Ty, and z is temperature increase needed to obtain a ten-fold reduction of D-value. With Bigelow's equation, D-values can be estimated for other temperatures than those experimentally examined.

The heat resistance of microorganisms are influenced by the medium in which it is exposed to heat. Van Asselt and Zwietering (2005) collected 4066 published D-values for organisms involved in foodborne disease and linear regression was applied to obtain average D- and z-values. When comparing these overall data it was seen that most factors reported to have an effect on D-value are smaller than the variability of all published D-values. A limited number of factors that did have a significant effect on D-value were identified.

A high fat content protected bacteria against heat inactivation. An example is given in Table 1 (*Salmonella* spp. in chocolate). It is also known that low water activity protects against thermal inactivation.

5.2 Salmonella and Enterobacteriaceae

Enterobacteriaceae is a family of bacteria which includes several enteric pathogens such as *Salmonella*, *Klebsiella* and *E.coli*. Their optimum temperature for growth is approximately 40 ºC and maximum temperature 45 ºC. The bacteria are killed at temperatures above maximum temperature for growth. The killing rate increases with increasing temperature. The *Enterobacteriaceae* family is relatively homogenous with regard to heat resistance (ICMSF, 1996).

Table 1 Thermal inactivation of Salmonella and some other Enterobacteriaceae bacteria.

Organism	Matrix	Temp (°C)	D-value (min)	z-value (°C)	Reference
Enterobacter sakazakii	Tryptic Soy Broth	62,0	0,40 ± 0,08	5,60 ± 0,13	Iversen et al. (2004)
Enterobacter sakazakii	Infant Formula Milk	62,0	0,30 ± 0,12	5,80 ± 0,40	Iversen et al. (2004)
Klebsiella pneumoniae	Water	55,0	0,37 ± 0,05		Spinks et al. (2006)
E.coli O157:H8	Minced meat	62,8	0,26 – 0,47	5,30	Line et al. (1991)
E.coli K12	Liquid egg	60,0	0,22	3,95	Jin et al. (2008)
E.coli (ATCC 9637)	Chocolate milk	57,2	2,60		ICMSF (1996)
Serratia marcescens	Water	60,0	0,17 ± 0,01		Spinks et al. (2006)
Yersinia enterocolitica	Milk	62,0	0,15 – 0,19		ICMSF (1996)
Yersinia enterocolitica	Milk	58,0	1,40 – 1,80		ICMSF (1996)
Shigella sonnei	Water	65,0	0,05 ± 0,005		Spinks et al. (2006)
Salmonella senftenberg	Milk chocolate	70,0 – 71,0	276 – 480	18,90	ICMSF (1996)
Salmonella spp. [1]	Various	70,0	0,15	9,10	van Asselt et al. (2005)
Salmonella senftenberg	Various foods	65,5	0,56 – 1,11	4,40 – 5,60	ICMSF (1996)
Salmonella senftenberg	Pea soup	65,5	1,11	5,60	ICMSF (1996)
Salmonella tennessee	Milk	65,6	1,40	4,90	ICMSF (1996)
Salmonella enteritidis	Liquid egg	60,0	0,17	4,08	Jin et al. (2008)

D- and z-values for *Salmonella* (Table 1) are typical values obtained from scientific papers. The data indicate that at least 1 Log_{10} reduction of *Salmonella* is obtained at 65 ºC for 2 minutes. With a z-factor of 5,0, a temperature increase to 70 °C will give the same effect in 0,2 minutes (12 seconds). Furthermore, it can be calculated that 70 ºC for 20 minutes will result in 100 Log_{10} reductions for *Salmonella*.

The data in Table 1 indicate that *Salmonella* is somewhat more heat resistant than *Enterobacteriaceae* in general. Any specified combination of time-temperature will therefore result in more inactivation of those than of *Salmonella*.

The extreme resistance (high D- and z-values) encountered for *Salmonella* when heated in chocolate, is included in Table 1 even if it is considered to be of little relevance for heat treatment of fish.

[1] Average values based on 1141 single values).

Table 2 TT (Time-Temperature) combinations resulting in 7 Log_{10} reductions of Salmonella in various meat products (Data from FSIS, US., 2005)

Matrix	Fat content	Temperature (ºC)	Time (minutes)
Cooked meat, roast beef, corned beef	Not specified	60,0	12,0
Cooked meat, roast beef, corned beef	Not specified	65,0	1,5
Cooked meat, roast beef, corned beef	Not specified	70,0	Immediate
Poultry products (chicken, turkey)	1 %	60,0	25,2 - 28,1
Poultry products (chicken, turkey)	1 %	65,0	3,5 - 4,7
Poultry products (chicken, turkey)	1 %	70,0	0,4 - 0,7
Poultry products (chicken, turkey)	12 %	60,0	35,0 - 33,7
Poultry products (chicken, turkey)	12 %	65,0	5,4 - 6,2
Poultry products (chicken, turkey)	12 %	70,0	0,5 - 0,7

The data in Table 2 confirm that *Salmonella* is rapidly inactivated at 70 ºC. The data also show that fat is protecting microorganisms from thermal inactivation.

5.3 Bacterial pathogens of fish

Bacterial pathogens of fish are adapted to low and stable oscean temperatures and have low resistance to elevated temperatures. Many of them are killed at temperatures below 40 ºC. Unfortunately, few published data exists on the heat resistance of fish pathogenic bacteria (Table 3). D- and z-values which are needed to estimate the inactivation effect of other temperatures than those experimentally examined, are missing for most of them.

Table 3 Thermal inactivation of bacterial pathogens of fish

Organism	Strain	Matrix	Temp (ºC)	Effect	Reference
Aeromonas salmonicida	AS-SS70	Culture-med	50,0	ND[2] after 2,5 min	Whipple et al. (1994)
Mycobacterium chelonei	Bandon strain	Culture-med	60,0	ND[3] after 2,5 min	Whipple et al. (1994)
Aeromonas hydrophila		Not specified	60,0	D-value: 0,04 min	EC SCAHAW (2003)
Vibrio vulnificus		Not specified	48,0	D-value: 0,41 min	EC SCAHAW (2003)
Lactococcus garvieae	NCIMB 702927	Culture-med	60,0	2,0 log_{10} drop in 5min	Defra (2005)
Lactococcus garvieae	NCIMB 702927	Culture-med	60,0	3,3 log_{10} drop in 1h	Defra (2005)
Renibact. salmoninarum	NCIMB 1114	Culture-med	60,0	>5,7 log_{10} drop in 5min	Defra (2005)
Streptococcus iniae	NCIMB 702722	Culture-med	60,0	>4,1 log_{10} drop in 5min	Defra (2005)
Yersinia ruckeri	NCIMB 2194	Culture-med	60,0	3,9 log_{10} drop in 5min	Defra (2005)

[2] Not detected after specified exposure time. Start concentration was 1,4 x 10E8/ml
[3] Not detected after specified exposure time. Start concentration was 7,5 x 10E8/ml

Thermal inactivation studies of *R.salmoninarum, Y.ruckeri, A.salmonicida, V.anguillarum* and *V.salmonicida* demonstrated z-values in the range of 4 to 6, and D-values for the most resistant strains similar to that of *Y.ruckeri* in Table 3. (Nofima, unpublished data[4])

If it is assumed that the D-value for the most heat resistant of bacterial pathogens of fish is 1 minute at 60 °C and that z-value is 5, the effect of heat treatment at 70 °C for 20 minutes will be 2.000 Log_{10} reductions.

[4] Data is considered for publication and can not be cited in detail

5.4 Viral pathogens of fish

Few data on the heat resistance of viral fish pathogens have been published (Table 4). The available data rarely contain D-values or data that can be used to estimate D-values. No z-values were found. This lack of data was the motive for a recent study of thermal inactivation of IPNV (Nygaard and Myrmel, 2010).

Table 4 Thermal inactivation of viral pathogens of fish.

Organism	Matrix	Temp (ºC)	Effect	Reference
IHNV (RB-76)	Not specified	55	ND[5] after 30 sek	Whipple et al. (1994)
IHNV (Karluk Lake isolate)	Culture-med	38	>7 $\log_{10}$ drop in 2,3h	Gosting et al. (1981)
SAV (Salmonid alphavirus)	Culture-med	60	ND[6] after 1h	Graham et al. (2007)
SVCV (D120)	Culture-med	60	>5,7 $\log_{10}$ drop in 1h	Defra (2005)
SVCV (880062)	Culture-med	60	>4,7 $\log_{10}$ drop in 1h	Defra (2005)
EHNV (sheatfish)	Culture-med	60	>6,1 $\log_{10}$ drop in 1h	Defra (2005)
EHNV (562/92)	Culture-med	60	>5,2 $\log_{10}$ drop in 1h	Defra (2005)
CCV	Culture-med	60	>4,0 $\log_{10}$ drop in 1h	Defra (2005)
VHSV	Not specified	70	>3,0 $\log_{10}$ drop in 1min	EC SCAHAW (2003)
IPNV (Sp)	Culture-med	60	3,14 $\log_{10}$ drop in 1h	Defra (2005)
IPNV (Ab)	Culture-med	60	0,20 $\log_{10}$ drop in 1h	Defra (2005)
IPNV (970160)	Culture-med	60	1,02 $\log_{10}$ drop in 1h	Defra (2005)
IPNV (rainbow trout)	Culture-med	60	1,5 $\log_{10}$ drop in 20min[7]	Gosting et al. (1981)
IPNV (rainbow trout)	Culture-med	60	1,0 $\log_{10}$ drop in 160 min[8]	Gosting et al. (1981)
IPNV (ATCC VR299)	Culture-med	60	3,0 $\log_{10}$ drop in 30min[9]	MacKelvie et al. (1975)
IPNV (ATCC VR299)	Culture-med	60	1,0 $\log_{10}$ drop in 80min[10]	MacKelvie et al. (1975)
IPNV	Organic matter	65	>4,0 $\log_{10}$ drop in 1min	Fløgstad et al. (1991)
IPNV (VR-299)	Not specified	80	ND[11] after 10 min	Whipple et al. (1994)
IPNV (Sp)	Medium[12] pH 7	60	D value: 288 min	Nygaard and Myrmel (2010)
IPNV (Sp)	Medium pH 4	60	D value: 291 min	Nygaard and Myrmel (2010)
IPNV (Sp)	Medium pH 7	70	D value: 16 min	Nygaard and Myrmel (2010)
IPNV (Sp)	Medium pH 4	70	D value: 54 min	Nygaard and Myrmel (2010)
IPNV (Sp)	Medium pH 7	80	D value: 2,7 min	Nygaard and Myrmel (2010)
IPNV (Sp)	Medium pH 4	80	D value: 2,7 min	Nygaard and Myrmel (2010)

[5] Not detected after specified exposure time. Start concentration not specified
[6] Not detected after specified exposure time. Start concentration inverse LOG titre: 4-5
[7] 1. phase
[8] 2. phase
[9] 1. phase
[10] 2. phase
[11] Not detected after specified exposure time. Start concentration not specified
[12] Artificial medium w. 10,2 % water soluble protein

For IHN virus (Gousting and Gould, 1981), we could estimate z-value 6 ºC based on the provided inactivation data; $D_{28\,°C}$ = 180 minutes, $D_{32\,°C}$ = 30 minutes and $D_{38\,°C}$ = 6,2 minutes. Unfortunately, similar data for other viral pathogens of fish was not found.

IPNV is considered to be more resistant to heat and chemicals than other fish viruses (Schei and Torgersen, 1990, Christie and Hjeltnes, 1990, EC SCAHAW, 2003). IPNV is widely distributed in the marine environment. It has been demonstrated that IPNV survives passage in the gastro-intestinal tract of warm blooded animals like chicken, owl and mink (Eskildsen and Jorgensen, 1973). It has also been demonstrated that IPNV survive in water for long periods of time. In fresh water at 4 ºC, 99 % reduction in infectivity was reported after 12 weeks and that there were still activity left after 24 weeks (Desaultes and MacKelvie, 1975). Those properties may explain the wide distribution of IPNV in marine environments.

Several studies have demonstrated that thermal inactivation of IPNV is bi-phasic. Both phases follow 1. order kinetics. At 60 ºC and neutral pH, the first 30 minutes resulted in 3 Log_{10} reductions. It was followed by 1 Log_{10} reduction per 80 minutes (MacKelvie and Desaultes, 1975). In another study by Gousting and Gould (1981), 60 °C resulted in ca 1,5 Log_{10} reduction during the first 20 minutes and then 1 Log_{10} reduction per ca 160 minutes. 50 ºC resulted in ca 1,5 Log_{10} reduction during the first 40 minutes and then 1 Log_{10} reduction per ca 30 hours. According to EC SCAHAW (2003) information on thermal resistance of IPNV are conflicting.

In a resent study by Nygaard and Myrmel (2010), IPNV (serotype Sp) was heat treated in artificial media at pH 7 and 4. The inactivation curves were bi-phasic. The regression exponential curves (exposure time vs. Log_{10} IPNV titre) from which D-values were calculated, were mainly determined by data from phase 2 of the bi-phasic inactivation. When considering the total inactivation of a certain temperature-time combination, the rapid initial 0,7 Log_{10} reduction has to be added.

D-values obtained at 60 ºC were 4,8 hours irrespective of pH. At 70 ºC, D-values were 16 and 54 minutes in media with pH 7 and 4, respectively. At 80 ºC, D-values were 2,7 minutes, irrespective of pH. Z-values for heat treatment in media with pH 7 and 4 were 9,9 and 9,8, respectively. The regression exponential curves (temperature vs. Log_{10} D-value) showed that the exposure temperature must be approximately 1,6 °C higher at pH 4,0 than at pH 7,0 to achieve the same inactivation. The curve obtained at pH 4,0 was therefore used to make conservative estimates of thermal inactivation at both pH values.

5.5 Fungal pathogens of fish

Most of the fungi affecting fish are strictly aquatic and cannot survive outside an aquatic environment. They generally have low capacity to survive at low humidity, and their infectivity is rapidly lost at temperatures above 40 ºC (EC SCAHAW, 2003).

5.6 Parasites of fish

Parasites are generally more heat sensitive than bacteria and viruses and will be inactivated by treatments applied to kill those other pathogens. Although very little data are available for parasites of fish, the risk of their transmission to other fish or to humans is assumed to be low after heating to over 65 ºC and drying (EC SCAHAW, 2003).

6 Production of fishmeal and -oil

6.1 Raw materials

The raw material used for fishmeal and -oil production in the 1970's constituted roughly 70 % of the total Norwegian fish catches. By the turn of the century, this portion was reduced to approximately 50 %. To day, the amount of fish material processed annually is on the short side of 1 million MT.

Until the end of the 1950's, herring was the most important species. In the 1970's capelin dominated. Later, new species were exploited, such as blue whiting, sprat, Norway pout and sandeel. Mackerel and horse mackerel were important species in a period of time and in the 1990's NVG-herring fully returned.

To day, mackerel, horse mackerel and herring are mainly used for human consumption, but herring still represents an important resource as big amounts of by-products are supplied by food processing establishments.

Aquaculture fish and by-products from such fish has until now not been utilized by the fish meal industry. Legislation now allows feeding of aquaculture fish with processed animal protein derived from aquaculture fish, as long as it is not the same species.

6.2 Principal method of processing

Fish consists of three main components; fat-free dry matter, oil and water. The aim of the fish meal process is to separate those components as completely as possible.

The main stages of a traditional fish meal process are;

- Cooking to coagulate protein, liberate oil and inactivate microorganisms. (Fish is heat treated in one or more steps in indirect cookers with screw- or pump transport).
- Mechanical separation of the coagulate, yielding a solid and a liquid phase. (Liquid is separated from solid phase by strainer, press and decanter. Other separation techniques can be used).
- Mechanical separation of oil from press liquor and subsequent concentration of stick water. (Oil is separated by centrifuge and remaining stick water is concentrated by multi-effect evaporators. Other separation techniques can be used).
- Press cake, decanter sludge and stick water concentrate are mixed and dried. (Water is removed in one or more stages in indirect steam driers and/or hot air driers. Other drying methods can be used).
- Polishing of oil. (Impurities and water is removed in a special separator. The need for oil polishing depends upon machine arrangement and mode of operation).

The fish meal process is thoroughly described in Håndbok for Sildemelindustrien (Handbook for the herring meal industry) and in easily available sources such as FAO Fisheries Technical Paper 142 (FAO, Rome, 1986).

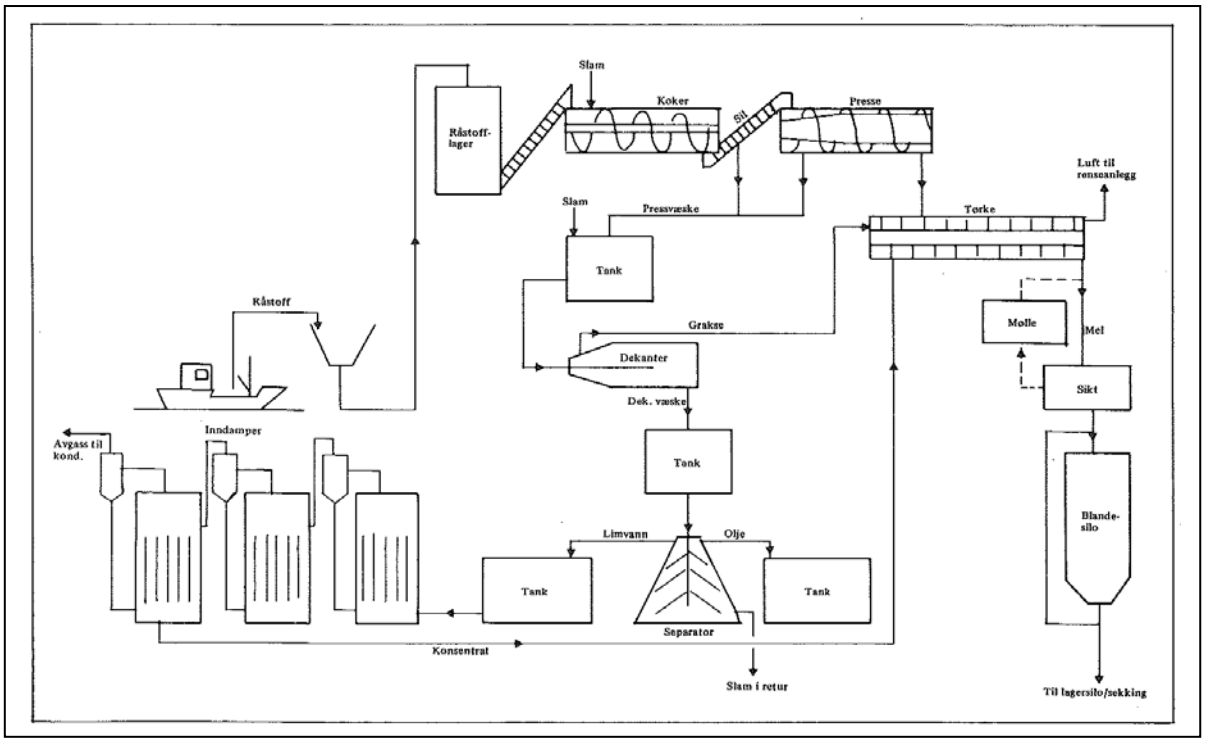

Figure 1 Flow diagram of typical fishmeal and oil plant. Illustration from "Håndbok for Sildemelindustrien".

6.3 Heat treatment in cooker

In the cooker, all incoming raw material is heat treated. A uniform, optimal temperature throughout the whole mass is of utmost importance for the whole functioning of the factory.

The most common practice is to cook the fish in a steam cooker, through which it is conveyed continuously. The cooker is designed as a cylinder having a steam heated jacket and a steam heated rotor, designed as a screw conveyor with hollow flights. Cooker may be connected to tanks allowing dosage of blood water or press liquor in order to facilitate heat transfer and flow through the cooker.

The optimum cooking conditions for a particular type of raw material must largely be established through practical experience. A precise time-temperature programme for the cooking process can therefore not be set up.

Cookers are commonly operated in order to ensure rapid heating of the fish mass to a temperature of about 95 °C. The proof of good cooking is good pressability leading to proper removal of press liquor and efficient recovery of oil. For some types of raw materials, (e.g. capelin), improved fat separation is achieved at considerably lower cooking temperature (70-

80 °C). Determination of cooking temperature must therefore take into account other aspects than merely hygiene.

According to FAO Fisheries Technical Paper no. 142 (1986), the walls of the fat cells are ruptured and the oil liberated before the temperature reaches 50 °C. Also, it has been demonstrated that coagulation of the fish protein is completed at about 75 °C and, furthermore, that the process is very rapid. Therefore there is very little, if anything, to be gained by heating the material beyond 75 °C or by using a long heating time.

The material is heat treated in the cooker at temperatures below 100 °C and at atmospheric pressure. The temperature of the raw material reaches its maximum at the cooker outlet and will thereafter gradually decrease. The distance between the cooker and strainer/press is generally short. Machines and conveyors are closed, thus limiting heat loss.

The duration of the heat treatment, i.e. the time span from temperature equalization in cooker to the press outlet is commonly close to 30 minutes and not below 20 minutes. The process does not allow residence time to be further reduced. Monitoring and documentation of residence time is therefore not required.

The core temperature obtained during heat treatment of animal by-products may be greatly influenced by particle size. However, fish material rapidly becomes tender as muscle proteins coagulate and it therefore fall apart when exposed to mechanical forces in cooker, strainer, screw-press and screw conveyors.

Due to experience, temperature of the fish material after cooker is quite homogenous and equal to the temperature of the liquid phase where temperature is actually measured. Reduction of particle size of fish material prior to cooking is not required to achieve uniform temperature throughout the material. Moreover, grinding of the fish may result in processing problems. As an example, formation of emulsions will severely impede oil separation.

6.4 Heat treatment in indirect steam dryer

The fractions containing fat free dry matter (press-cake, decanter-sludge and stickwater concentrate) are dried by evaporation of water. There are several types of dryers, but to day mainly indirect steam dryers and hot air dryers supply the demand for dewatering capacity in the Norwegian fish meal industry. Steam dryers are mostly used for pre-drying.

The indirect steam dryers used by the Norwegian fishmeal industry to day works on the following principle: the material to be dried is fed continuously into the drier and is dried in direct contact with steam heated discs. The heat is transferred from the steam to the pulp through the heating surfaces, and rotary agitation of the pulp promotes the heat transfer. The residence time in indirect steam driers is relatively long, generally 30-45 minutes, or even more than an hour for the biggest models. It has been experimentally demonstrated that the shortest residence time possible in a “Turbodisc” drier is approximately 20 minutes (documentation can be supplied).

A maximum steam temperature of 170°C corresponding to 6 atmospheres gauge pressure is most frequently used in steam dryers. Heat surfaces are continuously supplied with steam. Heat is transferred to the pulp in the whole length of the dryer. The heat transfer and the heat-surface temperature is almost constant. The fish particles rapidly attain a temperature close to the boiling point of water, provided that heat supply is sufficient and free water is present on particle surfaces. Pre-drying takes the water content down to 35-50 %.

Press-cake is crushed in screw conveyors after the press and additional grinding is therefore not necessary.

6.5 Heat treatment in separation process

The liquid coming from both the press and the pre-strainer is collected in a tank. An important prerequisite for efficient separation is high temperature, implying that the liquid is reheated to 90 - 95 °C before entering the centrifuges. This applies to sludge removal as well as to separation of oil and water.

The suspended solids are first removed in a horizontal centrifuge (decanter or desludger), while the separation of oil from stickwater takes place in a vertical disc centrifuge.

If the oil separators are operated with the aim to obtain as low fat as possible in stick-water, some emulsion will enter into the oil and it has to be refined in an oil polisher. Polishing is facilitated by using hot water, which extracts impurities from the oil and thus ensures stability during storage. The temperature of the feed should be maintained at about 95 °C, but not less than 90 °C.

6.6 Microbiological stability of finished products

Fishmeal

Microorganisms can survive but not multiply in fishmeal. The microbiological stability of fishmeal solely depends on its low moisture content. During handling and storage, finished fishmeal must be carefully protected against moisture from water leakages or water vapour condensation.

The water content of fishmeal is typical 6 % and maximum 10 %. 10 % water in fishmeal corresponds to an A_w (water activity) of approximately 0,60. Most bacteria require A_w above 0,95 corresponding to 30 - 35 % water in order to grow. Moulds are able to grow at lower A_w. According to experience, fishmeal containing up to 20 % water is microbiological stable but should still contain maximum 10 % for other reasons (flow properties, oxidation, etc.)

Fish oil

Microorganisms in pure fish oil can survive but not grow without addition of water. Since water and oil are not mixable, microbial activity always take place at oil-water phase boundaries.

Such conditions prevail in water/sludge deposits at the bottom of oil tanks. Fat degrading bacteria may be active at water-oil interfaces. They cause lipid hydrolysis with formation of free fatty acids. The fatty acids may be further degraded by β-oxidation. The effect is local, and more related to quality than to safety. As accumulated water at bottom of oil tanks are drained before blending and shipment of oil, the effect is hardly detectable in average samples.

Microorganisms are also active in emulsions with water and oil. Such emulsions are either oil-in-water emulsions (water is continuous phase) or water-in-oil emulsion (oil is continuous phase).

Microbiological stability of an emulsion is influenced by its physical structure. When oil is continuous phase, microbial activity is located in isolated water droplets. Microorganisms, except mould, can not spread from one water droplet to another through the oil matrix. Contrary, when water is continuous phase, microorganisms can spread freely through the water. Oil in water emulsions are therefore more vulnerable to microbial damage.

The content of impurities in fish oil is typical 0,1 % and maximum 0,5 %. Microbial processes causing damage of oil are uncommon. Presence of infective agents in oil, capable of causing fish disease, is unlikely considering the heat treatment in cooker and separation process. Proliferation of such organisms in an oil associated water phase is therefore also improbable.

7 Criteria for heat treatment

7.1 Characterization of category 3 by-products from wild fish

This material mainly consists of whole wild fish caught in the open sea for the purpose of fishmeal production and from fresh by-products from plants manufacturing fish products for human consumption. It can also contain wild fish suitable for human consumption but rejected for commercial reasons.

All known communicable fish diseases have its origin and its reservoir in the marine environment and hence wild fish can be carriers of fish pathogens. As fish moves freely in the sea and have big areas at its disposal, infection pressure is low and the concentration of infectious agents in wild fish is assumed to be low. Most of the known fish pathogens, including Infectious Pancreatic Necrosis virus (IPNV), Viral Hemorrhagic Septicemia (VHS) virus, Infectious Salmon Anemia (ILA) virus, *Aeromonas salmonicida* and *Vibrio anguillarum* have been detected in wild fish. Carrier animals without any symptoms are also commonly observed, i.e. fish which are infected and occasionally may spread the infection without showing clinical signs of disease (VKM, 2007).

7.2 Characterization of category 3 by-products from aquaculture fish

This material contains parts of slaughtered aquaculture fish which are fit for human consumption but are not intended for human consumption for commercial reasons. It also contains fresh by-products from aquaculture fish processed at slaughterhouses or processing establishments. Only aquaculture fish without any clinical signs of disease can be slaughtered and are fit for human consumption.

When the new Animal By-Products Regulation (EC) No 1069/2009 enters into force on 4 March 2011, also aquaculture fish that died from other causes than infectious diseases can be classified as category 3 materials.

Fish farming is intensive food production with high animal density and higher infection pressure than in wild stocks. Regarding risks to fish health, any fish either wild or farmed, can be infected by one or more disease agents.

There will be healthy individuals carrying both listed and non-listed as well as both known and unknown infective disease agents. Depending on the disease, the amount of infectious agents excreted is sometimes highest before clinical signs of disease are evident, other times opposite.

There are great differences regarding infectivity of a disease and the way it spreads within or between fish farms, depending of the properties of the infective agent, the immunity of the individual fish and the whole population and environmental factors like water temperature and ocean currents. It must always be taken into consideration that fish without clinical signs of disease, may still be infected regardless of the official animal health status of the farm it comes from.

7.3 Heat treatment requirements

Regulation (EC) 1774/2002 require that raw material for fish meal production must have been submitted to any of the processing methods or to a method and parameters which ensure that the product complies with the microbiological standards set in Annex VII, Chapter I, paragraph 10;

Salmonella: absence in 25 g: n = 5, c = 0, m = 0, M = 0

Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1 g

where:

n = number of samples to be tested;

m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m;

M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and

c = number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other samples is m or less.

Pathogens of fish represent a hazard when materials from fish are used for feeding of fish, in particular when the material originates from aquaculture fish (Chapter 7.2). If by-products from aquaculture fish shall be processed by the fish meal industry, the heat treatment must secure sufficient inactivation of the pathogens.

The requirements will be the same in the new Animal By-Products Regulation.

FOR 2007-03-29 no 511, Regulation relating to the prohibition of using proteins of animal origin for production animals, was laid down in Norway in 2007 pending Regulation (EC) 1774/2002 coming into force. In appendix 3, hygienization requirements were defined for materials from aquaculture fish used as feed for aquaculture fish: The method must be scientifically documented under adequate experimental conditions, to show minimum 3 $\log_{10}$ (99,9 %) inactivation of *Aeromonas salmonicida,* subsp*. salmonicida* and IPN-virus.

Appendix 3 was repealed in February 2009, after Regulation (EC) 1774/2002 had come into force in Norway. Still, it is a relevant reference to what can be considered as a sufficient inactivation effect for fish pathogens.

In a letter to the EU Commission dated 10.09.2010, the Norwegian Food Safety Authority proposed to include in the new Animal By-Products Regulation an requirement for IPN virus reduction of 3 $\log_{10}$ as a parameter that is relevant and appropriate for risk reduction when using fish by-products for fish.

7.4 Validation of thermal processes

When D- and z-values for a microorganism are known, inactivation of the same organism at any temperature-time combinations can be calculated. Inactivation effects for all micro-organisms of interest must be calculated and the processing conditions must be established with a view to obtain adequate inactivation of all agents.

A process where temperature and duration of heat treatment is determined on basis of relevant scientific data can be considered to be validated.

7.5 Temperature/time requirements for heat treatment

Residence time in process stages where the fish material undergoes heat treatment can be controlled only to a certain extent. Residence time in process stages (cf. chapter 6.3 and 6.4) where it is convenient to establish CCP for inactivation of infective agents is at least 20 minutes. The temperature in those same stages is at least 70 °C when the process is under control.

70 °C/20 minutes is proposed as minimum conditions for heat treatment of category 3 material from wild fish. This process results in 100 Log_{10} reductions of *Enterobacteriaceae/Salmonella* (Table 5) which should be more than sufficient to fulfil the requirements layed down in Annex VII, Ch. II, paragraph 3 of Regulation (EC) 1774/2002 (“the fish meal method”).

76 °C/20 minutes is proposed as minimum conditions for heat treatment of category 3 material from aquaculture fish. This process results in 3 Log_{10} reductions for IPNV, which is in line with former regulative requirements towards inactivation effect (Chapter 7.3). Table 5 also indicate alternative temperature-time combinations providing the same inactivation of IPNV.

Table 5 Estimated inactivation effect (Log_{10} reductions) resulting from proposed minimum conditions for heat treatment of wild fish (70 ºC/20 minutes) and aquaculture fish (76 ºC/20 minutes). For aquaculture fish is given alternative temperature/time combinations resulting in equal IPNV inactivation.

		Wild fish	**Aquaculture fish**			
Organism	Basis for calculations	70 ºC 20 min	76 ºC 20 min	80 ºC 7,1 min	85 ºC 2,2 min	90 ºC 0,7 min
Enterobacteriaceae *Salmonella*	D_{65}: 2,0 min Z-value: 5,0	**100**	1.600	3.600	11.000	35.000
Bacterial fish pathogen *Yersinia ruckeri*	D_{60}: 1,0 min Z-value: 5,0	2.000	32.000	71.000	220.000	700.000
Viral fish pathogen IHN virus	D_{38}: 6,2 min Z-value: 6,0		7 mill	11 mill	24 mill	54 mill
Viral fish pathogen IPN virus	D_{75}: 10,0 min Z-value: 9,8		**3**[13]	**3**	**3**	**3**

7.6 Methods for inactivation of infective agents

Regulation relating to Fishmeal, Fish Oils, etc (FOR 1999-03-26 no. 416) laid down minimum requirements for temperature in fish material at the cooker outlet. Provisions concerning meal and oil intended for animal feed have been repealed. Since October 2007, fishmeal production for feeding purposes shall comply with Regulation (EC) 1774/2002 which does not require that fish shall be heat treated at a specified stage of the process (in cooker) and neither defines specific temperature requirements.

Traditional fishmeal manufacturing implies heat treatment at several process stages (Ch. 6.3, 6.4, 6.5). In our view, indirect steam driers provide at least as safe and controllable heat treatment as cookers. Some plants will prefer to document fulfilment of the required heat treatment in steam drier instead of the cooker. Therefore, two optional methods for the inactivation of infective agents in a standard Norwegian fishmeal process have been described. The preferred method shall be treated as a CCP.

Whether the CCP for pathogen inactivation is established at the cooker or at the steam drier, all fish meal has actually been exposed to both processes at plants where steam driers are part of the manufacturing process. This implies an additional effect. Considerable additional inactivation is also obtained during warm up and cool down phases of both methods, since most pathogens of fish starts to die at temperatures well below 50 ºC.

Fish oil is heat treated in both cooker and separation process. Infective agents in fish are initially situated in water phase, but may be mixed into the oil phase at later stages of processing. Since inactivation data for fish pathogens in fat matrices are scarce, inactivation of pathogens in fishoil has to rely on heat treatment in cooker. The additional effect obtained

[13] The total inactivation effect includes the rapid initial 0,7 Log_{10} reduction

in the separation process (Chapter 6.5) could be substantial, but has not been quantified due to lack of data.

Heat treatment requirements for a standard Norwegian fishmeal and fishoil process can be expressed as follows;

Heat treatment in cooker:

Reduction:

1. Particle size of the fish material to be processed is sufficiently reduced during the transportation through cooker as a consequence of mechanical forces and textural change following protein coagulation.

Time and temperature:

2. After reduction and heating in the cooker, the fish material is transported through strainer and press. Residence time from end of cooker to press outlet is minimum 20 minutes. Temperature at cooker outlet must be high enough to ensure that temperature at press outlet is at least 70 ºC for wild fish. For aquaculture fish the temperature is at least 76 ºC.
3. The processing is carried out in a continuous system.

Note: Each plant shall determine what minimum temperature is required at cooker outlet to obtain required minimum temperature at press outlet. Temperature at cooker outlet shall be monitored and records kept. If requirement are not being complied with, appropriate action shall be taken.

Heat treatment in indirect steam drier:

Reduction:

1. Particle size of press cake is sufficiently reduced as a consequence of mechanical forces during transportation from press to steam drier. Decanter sludge and stick water concentrate are fine particulate.

Time and temperature:

2. Fine particulate presscake, decanter sludge and stickwater concentrate is feed into steam drier. Residence time in steam drier is minimum 20 minutes. Temperature of meal in the steam drier is at least 70 ºC for wild fish. For aquaculture fish the temperature is at least 76 ºC.
3. The processing is carried out in a continuous system.

Note: Temperature in meal at steam drier outlet shall be monitored and records kept. If requirement are not being complied with, appropriate action shall be taken.

8 Processing of material from farmed fish

8.1 Legal requirements

Regulation (EC) No 1774/2002 bans the feeding of animals with processed animal protein produced from animals of the same species, but allows a derogation when it comes to fish, after consultation with the Scientific Committee on Animal Health and Animal Welfare.

Regulation (EC) No 811/2003 Article 2 provides a derogation from this ban. It is allowed to feed fish with processed animal protein from fish of the same species, but not to feed farmed fish with processed animal protein produced from farmed fish of the same species.

Background for the derogation is that the Scientific Steering Committee issued an opinion on 17 September 1999 on the risk arising from the recycling of animal by-products as feed with regard to the spread of TSE to non-ruminant production animals. It also issued another opinion on 6 and 7 March 2003 on the feeding of fishmeal from wild fish to farmed fish and recycling of fish with regard to the risk of TSE. The Scientific Committee on Animal Health and Animal Welfare adopted an opinion on 26 February 2003 on the use of fish by-products in aquaculture. According to those scientific opinions, the potential risks from recycling fish may be reduced by fulfilling a number of conditions.

The conditions are given in Annex I to Regulation (EC) No 811/2003. Requirements are given concerning fish and animal by-products intended as feed for fish, and the records to be kept by processing plant. Among other things, the raw materials are to be handled and processed separately from the material that is not allowed used for this purpose and it shall be processed to a standard that ensures a microbiologically safe product. Furthermore, daily records of all raw materials received and of all fishmeal produced must be kept.

The new Animal By-Products Regulation 1069/2010 together with the new Implementing Regulation enters into force 4. March 2011.

8.2 Processing of wild and aquaculture fish with separation in time

Fish meal or fish oil produced from wild fish must be kept separate from fish meal or fish oil produced from aquaculture fish and when necessary also separated on the basis of species when the raw material comes from farmed fish. It requires a separation at reception and storage of raw materials, processing, packing and storage of the finished products. Such a separation can be either physical in the form of separate facilities or separate lines, or in time. Establishing of separate facilities is considered to be too expensive.

The project group suggests that material derived from category 3 aquaculture fish can be processed in the same processing plant as wild fish. Companies that want to take advantage of the opportunity to process material from farmed fish must implement arrangements that prevent unintended use of the products. Inadvertent use could be made by contamination or misidentification.

An acceptable solution as judged by the industry will be to flush the whole production line by processing wild fish at normal capacity for 1 hour, following any processing of aquaculture fish. The resulting products shall be labelled as the same batch of fishmeal produced from aquaculture fish (with indication of species). 1 hour production at the Norwegian factories corresponds to 10-15 tons of finished product.

The industry believes that such a "flushing" of machinery and transport equipment will ensure adequate hygienic separation between the different productions. It will also be the most efficient and the only practically feasible cleaning method. An arrangement as outlined above will enable the fish meal industry to take care of category 3 material from aquaculture fish in a beneficial way with regard to environmental considerations and community interests.

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