

The feed borne outbreak of Salmonella Tennessee in Finland in the spring of 2009

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Contents

Summary	3
Background	4
Control of Salmonella in animal feed	4
Structure of the Feed Control in Finland.....	6
Sampling for Salmonella and laboratory investigations	7
The Rehuraisio feed mill.....	7
Guiding documents developed by Evira.....	8
Salmonella own control at Rehuraisio	8
Audits carried out at Rehuraisio feed mill in 2007 and 2008 by Evira	9
Summary of the S. Tennessee outbreak presented in a report by Rehuraisio, 29.6.2009.	9
Decisions by the Evira´s feed control unit regarding Rehuraisio	10
Salmonella monitoring at farm level by Evira and ETT	11
ETT activities during the outbreak	12
Audits carried out by Evira in April 2009.....	13
Considerations.....	13
Control strategy and crisis management	13
Salmonella Tennessee in the feed mill.....	15
Possible reasons behind the outbreak.....	16
HACCP-program at Raisio.....	17
Proposal by the working group	17
Relevant questions to be asked	18

Summary

The primary objective of the investigation was to evaluate the reasons behind the feed borne outbreak, primarily from a scientific point of view, where Salmonella Tennessee was detected in several layer and pig farms in SW Finland in the early spring of 2009. The report is based on documents provided by Finnish authorities, ETT, the feed business operator and stakeholders involved and also information provided during a field trip in Sept. 2009.

Based on the provided information my opinion is that Finland has implemented a Salmonella control for feed that in most cases is working very well. The authorities, ETT and the feed business operators all have their responsibilities in the work. An important aspect is that the co-ordination between the official control carried out by the authorities, ETT and the quality control by the feed business operators is well coordinated.

In the risk assessment the main focus of the salmonella control of feed is put on the control of raw materials (esp. risk materials), rather than the finished feed. The collected evidence showed that the reason for the outbreak was a persistent infection with S. Tennessee in the feed mill environment.

Because to the efficient control of feed raw materials in Finland, where salmonella contaminated materials are prevented from entering feed mills, a preparedness for situations when salmonella is detected inside feed mills was to some extent lacking. What measures to take in order to control and prevent a situation when salmonella was detected in the feed mill did not seem to be clear for the feed business operator or for the authorities. An improved control of the feed manufacturing process would prevent further outbreaks.

My understanding of the outbreak is that there was no real preparedness for a feed-borne Salmonella outbreak by authorities, ETT or by the feed company. When the outbreak started contingency plans developed for other disease outbreaks were to some extent used however, a crisis management organization that immediately could take up the work did not seem to be in place. The impression is that a successful crisis management organization was, however, developed at an early stage of the outbreak where ETT and Evira together with the feed business operator were coordinating the activities. An impressive tracing activity was rapidly organized by ETT, authorities and different stakeholders that successfully managed the situation at farm level.

Background

The investigation was initiated by the Finnish Ministry of Agriculture and Forestry (mmm.fi) and an agreement was made with the National Veterinary Institute (SVA), Uppsala, Sweden to carry out the work. Professor Per Häggblom, SVA was appointed as investigator. The primary objective of the investigation was to evaluate the reasons for the large feed borne outbreak of Salmonella Tennessee in layer and pig farms in SW Finland in the early spring of 2009. Due to the extended time period when the feed could have been infectious more than 600 farms were sampled for feed contamination and faecal samples were collected from more than 800 farms.

According to the directives of the investigation a critical evaluation of the measures taken by the feed business operator, authorities and other organizations should be carried out. Primarily, the investigation should focus on the series of events in the feed mill that made the feed infectious, however, the investigations and control measures carried out at farm level and by the feed distributors should also be evaluated. Suggestions and /or modifications in the Finnish salmonella control program for feed are welcomed in the report. A maximum of three weeks can be used for the investigation.

The report is based on documents provided by Finnish Food Safety Authority Evira, Ministry of Agriculture and Forestry, Rehuraisio Oy, Eurofins Laboratory and the Association for Animal Disease Prevention in Finland (ETT).

Oral and visual information was provided during the field trip from August 31 to Sept 4, 2009 and the closing meeting Nov 27, 2009. Detailed questions were raised in e-mails or by phone to Evira, Ministry of Agriculture and Forestry, ETT and Rehuraisio Oy.

Control of Salmonella in animal feed

The European Center for Disease Prevention and Control (ECDC) and the European Food Safety Authority (EFSA) reported 151 995 human cases of salmonellosis in 2007 in the 27 EU Member States, being an incidence of 31.1 per 100 000 population which makes salmonellosis the second most important zoonotic infection. It is generally agreed, however, that the number of human cases are seriously underestimated and also underreported.

Because of the special guarantees granted to Finland and Sweden in the EU with regard to Salmonella strict control measures and are important to maintain for the entire food chain also in the future.

As reported in the EFSA opinion on "Microbiological risk assessment in feeding stuffs for food producing animals" (2008) salmonella is considered a major hazard in feed. In regions where the endemic situation in food producing animals is well controlled, such as the Nordic countries, salmonella contaminated feed is considered one of the major sources for introducing Salmonella into food producing animals. In regions with a higher prevalence the relative importance of feed as compared to other sources of

Salmonella may be somewhat lower. Because of the difficulties of detecting low levels of salmonella in feed underreporting of feed contamination occurs widely.

The feed industry has an important role of ensuring a safe feed production. In EC Regulation 1831/2003 on Feed Hygiene it is indicated that “Feed business operators shall put in place, implement and maintain permanent written procedures based on HACCP-principles”. In addition to HACCP effective GMP and GHP procedures should also be implemented by the feed operator. Because of the poor hygienic design of most feed mills a salmonella control program should contain several independent activities in order to successfully control the hygienic risks in the premises.

It is well recognized that moist heat can effectively decontaminate feed materials and compound feed from Salmonella if sufficiently high temperatures and treatment times are used. A prolonged conditioning time using steam may under certain conditions compensate for a lower temperature during the processing. Efficient GHP/GMP-procedures must in all situations be in place in order to carefully monitor the production and prevent recontamination of the final product after the decontamination.

The risk for recontamination after a heat-treatment is clearly illustrated in soybean meal, being one of the more frequently contaminated ingredients according to EFSA. The reasons for the high level of contamination may usually be explained by recontamination after the heat treatment at the site of production where salmonella multiplies in e.g. the warm and moist feed coatings (dust) in pellet coolers or conveyers.

Chemical treatment of feed may, under certain conditions, offer an alternative means of protection compared to heat treatment.

Limited information is available on the actual concentration of salmonella in feed materials or the risks associated with a particular level of contamination. Efficient sampling plans and isolation methods for salmonella in feed are important instruments in any control program for feed. Mechanical sampling is the most often used method.

When a sampling plan for Salmonella is designed the uncertainty of the sampling is to a large extent depending on how the bacteria are distributed in the lot. An uneven distribution of Salmonella will require a large number of samples in order to reach the same level of confidence. It is well recognized that a large number of increments must be taken in order to increase the confidence in results that are reported to be negative (“salmonella free”).

Empirical information indicate that fine particles and dust, probably because of the large surface area, are more likely to be contaminated by Salmonella. For that reason the sampling of dust in filters or in other equipment in the processing line of a feed mill is a valuable indicator of Salmonella in an environment.

The low level of contamination of most feed materials reveal that the methods used for isolation of Salmonella in feed must be sensitive enough. Presently, it is not possible to quantify the risk that infectious levels of Salmonella in feed would remain undetected with the present sampling plans and isolation methods. It is unfortunately

not uncommon for salmonella infected feed to be identified by positive samples in e.g. poultry flocks and subsequently traced back to the feed supplier.

Structure of the Feed Control in Finland

The Feed Act 86/2008 regulates the quality, safety and traceability of animal feed in Finland in order to protect animal health and the quality of food stuffs of animal origin.

The EU feed-legislation is fully implemented in Finland and the Ministry of Agriculture and Forestry is responsible for the overall guidance of the feed legislation.

The Food Safety Authority (Evira) has several different responsibilities in the official feed control such as planning, steering, developmental work and also implementation of control measures.

The customs authority carries out supervision of the import and export of feed in Finland.

Authorization of feed inspectors and laboratories for official investigations are covered in this legislation. Evira's responsibility is to develop the multiannual control plan according to §42 in (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

In addition Evira carries the responsibility to develop annual control plan for the feed production according to the risk classification of the different operators. Evira also has the authority to carry out audits at feed business operators and according to §21 of the Feed Act 86/2008 a feed business operator must immediately notify Evira of non-compliance in issues related to feed safety.

According to the national decree (MMM 712/2008) it is stressed that feed operators must inform Evira 24 h before import of feed (materials) according to §9 and §10. It is also stressed that feed business operators must inform Evira without delay of non-compliance regarding issues related to feed safety. Furthermore Evira must be notified immediately if salmonella is detected in feed raw materials, final products or in the production environment. According to a leaflet from Evira, distributed to feed business operators 29.01.2009, the laboratory carrying out salmonella analyses must without delay forward the isolated strains to Evira in Kuopio for typing. The responsibility of the feed business operator to report any observations related to feed safety is clearly stated in the leaflet. Observations should be submitted to Evira by phone, e-mail or directly to the senior feed officer appointed to the feed plant.

Evira plays several different roles in the Finnish feed control from decision making to giving advice to the industry, carry out NRL-work, making up reports of inspections, approving laboratories for official Salmonella analysis and controlling feed business operators according to feed hygiene regulation (EC) 183/2005, authorizing feed inspectors etc. Different departments within Evira are responsible for the different tasks, however the main work in the feed area is carried out by the feed section having 12 employees. Authorized inspectors (45) carry out sampling and make inspections of transportation and inspectors at the Employment and Economic Development Centres (30) make farm controls.

ETT has together with feed business operators drawn up a so called "Positive list". Producers and importers who carry out voluntary salmonella control for feed for production animals in their import are approved to stay on the "Positive list". Feed business operators who are on the list are required to implement quality control programs and hygienic standards also including transport and storage of feed.

Sampling for Salmonella and laboratory investigations

Sampling for salmonella in the feed sector is carried out in the official sampling by Evira as well as in quality control plans by the feed operators.

According to the Feed Act 86/2008, with a reference to (EC) 183/2005, feed business operators are obliged to implement a quality control system also including a HACCP-program for their operation. A strict liability of the feed operator is laid down in the legislation.

Data from an inquiry sent out by Evira to feed operators, summarizing the sampling for salmonella in the feed sector for food producing animals reveals that more than 36 000 samples in 2008 were analyzed in the feed business operators own quality control programme. A total of 47 positive samples were identified where the majority (79 %) of positive samples was from either the production line or the processing and storage areas. Five feed operators reported positive samples from the processing lines and six operators from the processing/storage areas. Salmonella was not detected in transport vehicles (1 250 samples). Two positive samples were detected in feed materials of plant origin out of approximately 14 000 samples of compound feeds and feed materials. Out of 231 inquiries sent to the feed business operators 208 (90%) were returned.

Laboratories carrying out official salmonella investigations must be approved by Evira. There are eight approved laboratories using modifications of the ISO 6579- method. These laboratories and the methods used for salmonella analysis are accredited and the feed business operator may use these laboratories or other non-approved laboratories in their own control. Evira's method for salmonella analysis in feed samples are carried out according to the method ISO 6579:2002/Cor. 1:2004(E) modified. A prolonged enrichment time is used for chemically or thermally treated samples or strongly dehydrated samples compared to the ISO-method. Additional Buffered Peptone Water is used for feed samples with a strong swelling capacity. Rehuraisio use the approved Eurofins' laboratory in Raisio which use an ELISA method in the own control for salmonella.

The Rehuraisio feed mill

The feed mill is the largest in Finland and produce feed on several production lines for ruminants, pigs, poultry and fish. The mill has seven pellet lines (P1-P7) and two extruder lines for fish feed. The feed mill is using fish meal for certain feeds and also produce medicated feeding stuffs. In the official control of the feed mill, according to Evira's risk based control program annual audits are carried out. The last audit before the

outbreak was in April 2008. Besides audits, authorized feed inspectors carry out sampling of the feed mill.

Guiding documents developed by Evira

According to guiding document REHU 801/1 Evira has developed instructions how to implement HACCP principles in feed mills following (EG) no 183/2005 and also Codex Alimentarius. In this instruction detailed information about HACCP-principles are described with the purpose to control the most important risks in feed production. The required documentation of the HACCP-system is described as well as the selection of critical control points.

In another guiding document, REHU 12817/1, the sampling frequency of imported risk materials are described in the official sampling. In this report "imported" means import from the EU or third countries. The sampling plan for e.g. soybean meal is one official sample/50 tons. A consignment of 2000 tons of soybean meal will generate (a maximum of) 40 samples. Guiding document REHU 12708/2, describes the procedures to be used for the sampling of feed incl. sampling for microbiological contaminants. In the guiding document, REHU 12720/1, a description is given how the control of salmonella in imported feed materials should be carried out. Salmonella positive samples from imported feed, analyzed in the feed business operator's own quality control plan will also form the basis for decisions of prohibition by Evira according to this document.

Salmonella own control at Rehuraisio

According to the legislation Rehuraisio carry out own control of Salmonella in raw materials, the feed mill environment and in finished feed. Samples are presently analyzed at the Eurofins' laboratory in Raisio. According to Evira, Rehuraisio have reported their Salmonella findings in the feed mill environment during the control audits. Salmonella were not detected in any samples of finished feed. Occasionally positive samples were detected in the production environment for the last 15 years with S. Tennessee or other serotypes. A total of 3520 samples were investigated in 2008 from raw materials, storage, production environment, transportation and finished feed. S. Tennessee was isolated in 7 environmental samples in the feed mill 2008 from the quality control program carried out weekly.

In a document dated 25.04.2008 the feed operator's quality assurance regarding Salmonella is presented. The most essential factor is to control salmonella in the raw materials. A program describing how to reduce the risks with potentially contaminated ingredients is presented, measures which seem to be very similar to what is prescribed in the official control. For the monitoring of the feed processing the implementation of HACCP is described particularly the cleaning of the feed mill. Specifications about the sampling for salmonella in feed products are described in protocol HYGNA TOU.XLS. When salmonella is detected in the samples the document refers to another document "management of a divergent product" and also some general measures to be initiated. If salmonella is detected in a finished feed Evira, ETT, the provincial veterinarian and the customers must immediately be informed. In the

document HACCP-analysis (05.10.07) a risk analysis of the different steps in the processing of feed is carried out. The relative risks are classified into four different categories according to the probability and severity of the risks.

Audits carried out at Rehuraisio feed mill in 2007 and 2008 by Evira

Documented audits at the Raisio feed mill were carried out by Evira before the outbreak in 2007 and 2008. During these audits several different aspects of the feed manufacturing was covered. In 2007 Rehuraisio was audited against the requirements of the feed hygiene regulation. In the auditing report several aspects were covered including implementation of the HACCP-system. Cleaning and disinfection of the feed mill was discussed and some remarks were made by Evira. It was concluded that salmonella in the feed mill was not a significant problem according to the results from the quality control program and for that reason the cleaning of the feed mill, as was done until 2005, was not prioritized, however, the normal cleaning of production lines were still carried out. Salmonella was not detected in previously contaminated areas. *S. Tennessee* was, however, detected in environmental samples from storage area for raw materials (intake pit and conveyer). In protocols from audits by Anticimex information about increased problems with mice were reported in 2007 and additional inspections were for that reason made by Anticimex.

Rehuraisio was again audited against the requirements of (EG) No 183/2005 in April 2008. According to the protocol the results from salmonella investigations of imported feed ingredients did not give rise to any concern. A point was made by Evira that the results of the HACCP-inspections should be presented and also updated.

According to Rehuraisio's quality control program *S. Tennessee* was isolated a few times from environmental samples (floors) near line P7.

Summary of the *S. Tennessee* outbreak presented in a report by Rehuraisio, 29.6.2009.

In the afternoon Friday, Feb. 27th Evira reported to Rehuraisio that *S. Tennessee* and *S. Typhimurium* were isolated from three layer farms. Monday, Mar. 2nd, Rehuraisio identified the layer farms as customers. Rehuraisio initiated sampling of the layer feed and other finished feeds that were manufactured on P7. Extra samples were also collected from the production line in the mill. For safety reasons the company decided to stop P7 in the evening of Mar. 5th. Friday, Mar. 6th, the Rehuraisio management was informed about the situation. Saturday, Mar. 7th, Rehuraisio received information from the laboratory about positive results among the samples collected Mar. 2nd. A meeting was held at Rehuraisio the Mar. 7th and contacts were also taken with Evira about appropriate measures. ETT and the provincial veterinarian were also informed. Rehuraisio informed the 26 layer farms that had received feed which could be contaminated with salmonella where the farms were asked to replace the feed with new feed that Rehuraisio supplied.

The same evening, Mar. 7th Evira announced in their press release on their website that salmonella were detected in samples of finished feed from the Rehuraisio feed mill and also that the production was banned. Also, Rehuraisio sent out a press release about the positive results and the measures that were taken by the company. The Rehuraisio management team continued to have daily meetings during the outbreak. It is mentioned in the summary that 3 520 samples were collected in 2008 in the own control program.

Mar. 9th, Evira banned production on line P7 in a written decision.

Mar. 10th, Salmonella was detected also in pig feed produced on P7 and the same day Rehuraisio decided to close the feed mill for cleaning and disinfection for two days.

Mar. 12th, Rehuraisio reported to Evira that all investigated samples (approx. 200) were negative from the trace back investigation of raw materials, processing environment, etc. The plan was to restart the feed mill the same night with the exception of P7. The other production lines were sampled with 2x10 samples before restart as official sampling. Simultaneously, the sampling of potentially infected farms was extended to all farms that received feed from P7 for a certain period. On April 17th was the ban of P7 removed by Evira and conditions before the re-start of P7 were defined. The commercial feed production was taken up April 27th.

May 15th, was P7 stopped again due to suspect Salmonella in samples from the cooler. Delivery of already manufactured feed was banned to customers. A total of 257 samples were collected from finished feed produced on P7 (27.4 – 15.5) all being negative for Salmonella. On May 18th, it was decided by Rehuraisio to make a major revision of the production line and a re-start was planned for Sept. 2009.

Decisions by the Evira's feed control unit regarding Rehuraisio

Evira received information Feb.27th about salmonella in faeces samples from 2 layer farms which confirmed the initial results. Mar. 1st, two days after were sampling carried out of feed at the layer farms and Mar. 3 rd Evira asked Rehuraisio for loading samples of the layer feed used by the farms. In a total of 9 feed samples salmonella was not detected, which is not surprising because of the low number of samples. Mar. 6 th were PFGE- results available showing identical clones of salmonella from layer and pig farm.

On Mar. 9th, 2009 production on P7 was banned in a written decision by Evira as well as the marketing of feed produced on this line due to the positive findings of S. Tennessee in layers and pigs. According to Evira an oral ban was, however, given already Mar. 7th and in the press release from Mar. 7th a ban of feed production on P7 was included. In the Rehuraisio document from June 29th it is mentioned that line P7 was closed down in the evening of Mar. 5th as a safety measure. In addition a recall of feed, produced on this line was decided by Evira. Rehuraisio was asked to deliver a report to Evira about the situation and what actions that were taken by the company.

Mar. 10th, Evira made an audit at Rehuraisio and also Mar. 23th. Mar. 24th an extended ban was decided by Evira particularly dealing with the recall of feed for the period 12.12.2008-10.03.2009.

On Mar. 25th Rehuraisio presented a plan for re-start of P7 in five steps. April 3rd, Evira made a request to further specify the plan before re-start. A completed plan was presented by Rehuraisio April 15th and an audit was carried out by Evira April 17th .

In a decision, signed April 17th after the audit, was the ban of feed production on P7 removed after Evira had received information from Rehuraisio about the cleaning and disinfection of P7 and also auditing of the feed mill.

The ban to produce feed on P7 was re-introduced May 18th by Evira after information from Rehuraisio that Salmonella was again isolated from the production line (pellet cooler and outlet pipe from pelleting machine) May 16th and 17th. The line was stopped by Rehuraisio May 15th and loading of already produced feed was prohibited.

Salmonella monitoring at farm level by Evira and ETT

Evira started to distribute information from Rehuraisio 9-10.03.2009 to the provincial authorities dealing with farms that had received potentially infected feed to allow sampling of animals and feeding systems. Information was also directed to operators of layer farms.

During the outbreak Evira continuously supplied provincial as well as municipal veterinarians with information about the sampling situation. An initial problem was the quality of information provided by Rehuraisio about their customers, a situation that delayed the sampling. During the outbreak Evira and ETT worked closely together in order to solve new situations coming up and were e.g. collaborating in training activities of veterinarians about sampling and cleaning methods. An important aspect when data became available was how to interpret the sampling results obtained from the large number of farms.

The clearance sampling, after cleaning and disinfection of a farm, was carried out in close contact between ETT and Evira. A summary of actions related to farms and food inspections carried out by Evira was presented in a report dated 31.08.2009. A list of developmental activities is presented in the document with the overall purpose to prevent similar out-breaks in the future. Instructions were sent out from Evira about the sampling of layer farms (D110 22§) and pig farms. Evira continued to give instructions to the local authorities about sampling of feed and faeces and also organized training events with ETT. Clearance sampling protocols for infected farms were adopted from plans developed by ETT.

Activities linked to food safety were also summarized in the report (Evira HYGI). A new instruction was developed by Evira how to label eggs from salmonella positive farms and also other instructions.

A large number of salmonella analyses were carried out at Evira and also at local approved laboratories. Feed samples were analysed at Evira and also most of the faecal samples from layers. Faecal samples from pigs were mainly analyzed at other laboratories than Evira. A total of 972 samples from 605 farms (feed samples) were investigated as well and other samples. Forty positive feed samples were identified. Investigations of farm animals were from 842 farms (faecal samples) and 213 environmental samples (dust from layer flocks). Additional samples, faecal and environmental (feeding systems), were investigated from pig farms by the industry. From a total of 30 layer farms and 10 pig farms were positive faecal samples isolated. Positive samples from the feeding systems were detected in 20 pig farms and 5 layer farms. A total of 422 isolated salmonella strains from layers, pigs, feed and environmental samples were identified as *S. Tennessee* by Evira in Kuopio. About 60 isolates from feed and samples from farms were further analyzed using Pulse Field Gel Electrophoresis (PFGE) with identical results.

ETT activities during the outbreak

Feb. 27th was ETT informed about the salmonella positive findings regarding two layer farms. Mar. 5th ETT arranged a meeting for feed suppliers, egg packaging companies and other stakeholders about the outbreak. Mar. 6th, was ETT informed by the slaughter house about the positive lymph node sample from a pig farm. Mar. 7th Rehuraisio called ETT and informed about the findings of *S. Tennessee* in feed from line P7. Mar. 10th was Rehuraisio removed from the "Positive list". ETT continued to organize several crisis management meetings with authorities and other parties involved where concrete actions to be taken were agreed on.

ETT made audits to Rehuraisio Mar. 23rd and April 7th, 2009. According to the ETT report (23.03.09) *S. Tennessee* positive environmental samples was new information for them as it was only reported to Evira previously. Observations by ETT on P7 indicated several details where the hygiene in the mill could be improved. In the report several observations were made in relation to the hygienic conditions in the mill and ETT suggested a number of points to be improved. An important observation that was made was the construction work going on in the feed mill in Dec. 2008 when line 8 was removed. It is well known that construction work going on in a feed mill is an increased risk for Salmonella in the environment.

ETT was seriously involved with the tracing of *S. Tennessee* at the farm level. ETT coordinated the tracing work by the industry during the outbreak, for example the sampling of the feedingsystem at farms and voluntary trade and animal movement restrictions. Several guidelines were prepared by ETT in Mar. 2009 about sanitation methods for pig and layer farms. The expert from ETT also made 80 farm visits, took over 5000 samples and made sanitation plans for 30 farms during the outbreak. ETT were also involved in work with the sampling of the different partners incl. the mobile mixers in the feed chain. Protocols were developed for the sanitation of storage silos for feed at the farms. Other protocols covered the clearance sampling of feed storage facilities at the farms. Detailed instructions were also developed for cleaning and disinfection of the animal units at layer and pig farms. Daily consultation was given to

the farmers, municipal veterinarians and other parties by phone or e-mail during the outbreak. Rehuraisio was re-introduced on the "Positive list" April 21st.

Audits carried out by Evira in April 2009

Additional information was requested by Evira 03.04.2009 before the start-up of P7 in order to secure the feed production. In the audit April 17, report dated May 8, 2009 the inspection focused on measures taken by Rehuraisio in order to re-start P7. Several details in feed mill were inspected, e.g. the physical separation of P7 in relation to other production lines. In the new P7- line the temperature should be 75°C with a retention time of 10-15 s, according to Rehuraisio. A remark was made about the earlier system of open conveyers for the fish feed production. In the report it was mentioned that the visiting staff from other companies are now better informed about the importance of a good hygiene in the mill.

Intake air to the cooler was presently taken from outside the mill, as a temporary solution, and permanently it will be taken from the roof of the mill.

In the report information from Rehuraisio reveals that all samples collected after the cleaning and disinfection operations were negative for salmonella. The sampling plan for the processing line was audited and some remarks were made by Evira that samples from filters of extruder lines also should be included.

The restart of P7 was discussed in detail e.g. the inclusion of SalCurb in wheat bran in the first batch going through the line. It was estimated by Rehuraisio to include Sal Curb in feed produced on P7 for one month. Some concerns were also raised regarding the use of SalCurb, whether the product may interfere with the laboratory analysis. From the first batch of feed 2x10 official samples should be investigated in both Evira's and Eurofins' laboratories.

Considerations

Control strategy and crisis management

In an outbreak evaluation many different questions are relevant to discuss, however, I have tried to focus on the most important aspects according to instructions for the investigation which mainly deal with the reasons behind the outbreak. My opinion is that Finland has implemented a Salmonella control for feed that in most cases is functioning well. The co-ordination between the official control carried out by the authorities and the quality control by the feed business operators is a prerequisite for a successful outcome.

The salmonella situation in the feed sector is reflected in data presented in the Evira enquiry from 2008 where no positive samples were detected in finished feed for food-producing animals.

The documents about the official feed control, provided by Evira, are generally clearly written, updated and cover relevant aspects of the control. Guidance documents and meetings by Evira give support to the feed industry for implementation of the legislation. The feed control is separated in official control carried out by Evira and the feed operator's quality control program.

In the risk assessment of salmonella contamination in the feed chain the main focus is put on the control of raw materials (esp. risk materials) used for compound feed rather than finished feed. The strategy is preventive and will effectively reduce the risks for introduction of salmonella into the feed chain at an early stage. The strict control of raw materials will also reduce the risks for salmonella contamination of the feed mill environment coming from raw materials. All available data support the opinion that it is essential to prevent contamination of the feed mill premises that in turn may cause re- or cross-contamination of the finished feed. Investigations from other countries have shown a close correlation between salmonella serotypes detected in feed mills environments such as coolers/dryers and in e.g. broiler farms. Conditions where salmonella may grow and multiply (suitable temperature and moisture) are available in most feed mills, and must be eliminated.

In most cases the level of salmonella contamination in feed raw materials is low, a fact that stresses the need for sensitive sampling and isolation methods as all sampling plans for salmonella are accompanied by a certain degree of uncertainty (Figure 1).

My opinion is that a successful salmonella control program for feed, because of the inherent difficulties in monitoring a rapid production process, detecting low levels of bacteria and the poor hygienic design of most feed mills, must rely on different preventive control mechanisms. In addition the feed is usually distributed to the farmer before the analytical results are available. In a robust control system the different parts will complement each other and if one control measure would fail it is important to have other control mechanisms in place. A combination of sampling and other control measures, are for that reason essential to include.

My understanding of the recent case is that there was no real preparedness for the large feed-borne Salmonella outbreak by authorities, ETT or by the feed company. In the available documents I was not able to see information about already developed contingency plans for zoonoses outbreaks or a crisis management organization that could be used. The impression, from reading the documents, is however that a successful crisis management organization was developed at an early stage of the outbreak and Evira was the authority coordinating most of the activities. The Evira website was used extensively for dissemination of information from the authority.

Provincial and municipal authorities, laboratories, ETT, Rehuraisio etc, were very soon involved in the work to sample the farms that had received potentially infected feed. Evira (HYGI) supplied information to provincial veterinarians, food companies, slaughter houses, layer farms etc. The Ministry took an active part during the outbreak and had a close dialogue with Evira, primarily. Evira also showed flexibility in increasing the laboratory capacity for salmonella analysis very soon after the outbreak started.

Access to and the flow of information is essential in outbreak situations and should also be covered in a crisis management organization. The information provided does, however, not give a detailed picture of the different responsibilities in the crisis management organisation. Several similar questions related to contingency plans are discussed in a report (31.8.09) by Evira.

Salmonella Tennessee in the feed mill

The repeated findings of *S. Tennessee* in the Rehuraisio feed mill became known to the management when the data about infected farms became available. The first meeting in the crisis management organization was Mar. 7 where contacts were established with Evira.

What measures to take when there are suspicions of persistent infections in a feed mill environment did not seem to be very clear for the company or for the authorities, primarily because similar situations did not occur before. The general comment is that the procedures Rehuraisio followed with the aim to eradicate the contamination inside the feed mill was obviously not sufficient in the present situation.

The feed mill has several production lines and the available information support the conclusion that salmonella was restricted to P7 where the feed concentrates for pigs and layers were produced. According to the information provided the thermal treatment on P7 was carried out at a lower temperature compared to the other production lines, a fact which could have contributed to the outbreak.

On P7 a "central aspiration system" was operating where the dust particles from the line were collected in a separate silo and the material was then reintroduced on the line before the thermal treatment. When the silo was emptied, after the outbreak, several positive samples were isolated. The filter on P7 was by mistake not included in the quality control program of the feed business operator.

S. Tennessee was isolated from the production environment in the feed mill several years ago for the first time and the most likely source of infection would be contaminated ingredients such as soybean meal. The conclusion is that the feed mill carried a stationary contamination with *S. Tennessee* for an extended period of time, which was not detected in the monitoring program of the feed business operator.

According to information from Rehuraisio, annual cleaning of the entire feed mill premises was carried out until 2005. Details about the cleaning procedure that was used are not provided, such as which parts of the feed mill that were cleaned or the methods being used. My opinion is that regular and careful cleaning operations are important preventive measures in order to control salmonella in a feed mill. Particular focus should be directed to areas where the risks for contamination are considered to be high and areas where multiplication of *Salmonella* may occur. It is also important to use cleaning (without water) and disinfection procedures that are proven to be effective. Where moist feed occur on the production line it is important to carry out a careful cleaning when, e.g the production is stopped for the weekends. Similarly, problems with moisture on floors etc inside the feed mill must be avoided. It seems

like no cleaning of the pellet press was carried out on P7 before the weekends which may have contributed to the build-up of infection on the production line.

In information provided by Evira it was mentioned that the plant will be closed March 10 at 15.00 and the sanitation is planned to take two days. It is not clear if the intention was to clean and disinfect the entire feed mill, however, from experience it is not possible to carefully clean a feed mill in only two days. A careful mechanical cleaning takes several days followed by contact spraying of the equipment using preferably formaldehyde or glutaraldehyde and in addition fogging of the premises.

If Salmonella is detected in environmental samples from the feed mill an investigation should immediately be carried out with the purpose to find out which part of the mill that is infected. Such an investigation is particularly important if the same serotype is detected repeatedly and it is then essential to find out if the strains are identical.

There is always a risk that persistent salmonella infections in feed mill environments will sooner or later result in contaminated finished feed!

Possible reasons behind the outbreak

The exact reasons behind the outbreak are not easily revealed by essentially reading documents from the outbreak. However, the fact that S. Tennessee was re-isolated from a dust sample from the cooler after the sanitation work was completed reveals that the source of contamination inside the feed mill was not identified in the initial investigation.

In the protocols from the quality control monitoring by Rehuraisio it can be found that S. Tennessee was isolated from one sample out of 21 samples (sweepings) Nov. 5, 2008. S. Tennessee was isolated from the floor close to the pelleting machine on P7.

The same week 24 samples were collected from truck loads, all being negative and one negative sample from ingredients.

In end of Jan. 2009, two samples with S. Tennessee were isolated from the loading samples produced on P7. Feb. 10-13, five positive samples were isolated and Feb. 17-22 six salmonella positive samples were detected and the week after were three positive samples detected. It should be noted that those loading samples were analyzed after Mar. 7, 2009, however, the data show that line P7 was heavily infected in the beginning of 2009. During the same period the monitoring of the feed mill environment including the production line did not detect S. Tennessee.

S. Tennessee identified in November 2008, close to the pelleting machine and the cooler, indicated a situation where salmonella occurred in vital parts of the feed mill. The risk to introduce S. Tennessee into the cooler/dryer, situated after the heat treatment, seemed to be high, particularly since the cooler/dryer was taking large amounts of air from inside the mill. The type of cooler that was used on P7 is well known for harboring salmonella infections and is difficult to clean and disinfect properly. "Bacteriological temperatures" (~37°C) are always present on some surfaces

inside a cooler and “inoculation” may occur either from the cooling air or from feed that passed the pelleting machine. Simultaneously, large amounts of water are removed during the drying process and condensation may occur on cold surfaces.

In my opinion it is essential to immediately make a thorough investigation of the feed mill environment including the processing line to make sure that no other part of the premises are infected after positive samples are detected in the monitoring. According to protocols from the own-control the monitoring of the feed mill environment was not increased considerably in Nov. – Dec. because of the isolation of *S. Tennessee*.

Data from the PFGE- investigations show that the strains of *S. Tennessee* isolated in 2008 and in 2009 were identical (clonal) with strains isolated in 2003, 2004 and 2005 which prove that the feed mill was harboring a stationary infection with *S. Tennessee* rather than being continuously exposed to contaminated raw materials.

HACCP-program at Raisio

From the Raisio HACCP-documents definitions of the critical control points were made. The presence of *Salmonella* in the production environment is rated $5 \times 10^=$ significant, while e.g. the cooler /dryer is rated $5 \times 5^=$ limited risk. In my opinion the dynamics of potential growth of salmonella and the fact that the cooling process occurs after the heat treatment was not adequately considered in the HACCP-plan. The microbiological aspects should, in my opinion, be considered more seriously in the HACCP-plan. Raw materials, if positive for salmonella, usually contain a low number of salmonella bacteria/g and this level will not increase unless growth will occur.

Proposal by the working group

In a translation of the proposal (Chapter 7) by the working group (mmm 2009:10), dealing with sampling of raw materials and the feed mill environment, certain modifications of the legislation are proposed. If the number of samples from raw materials will be increased, according to the proposal, the information below will indicate how the probability of accepting a lot as salmonella free will be modified.

As illustrated(Fig. 1), the International Commission on microbial specifications for Food (ICMSF) have developed so called operation characteristic (OC) curves expressing the risks associated with a sampling plan. Depending on the level of infection, the risks for accepting a positive lot varies depending on the sample size (= number of increments). If 2 % of the lot is contaminated with salmonella the probability of accepting the lot as salmonella free is 65% if 20 samples are collected while if 40 or 80 samples are collected the probability is 45 or 20%, respectively.

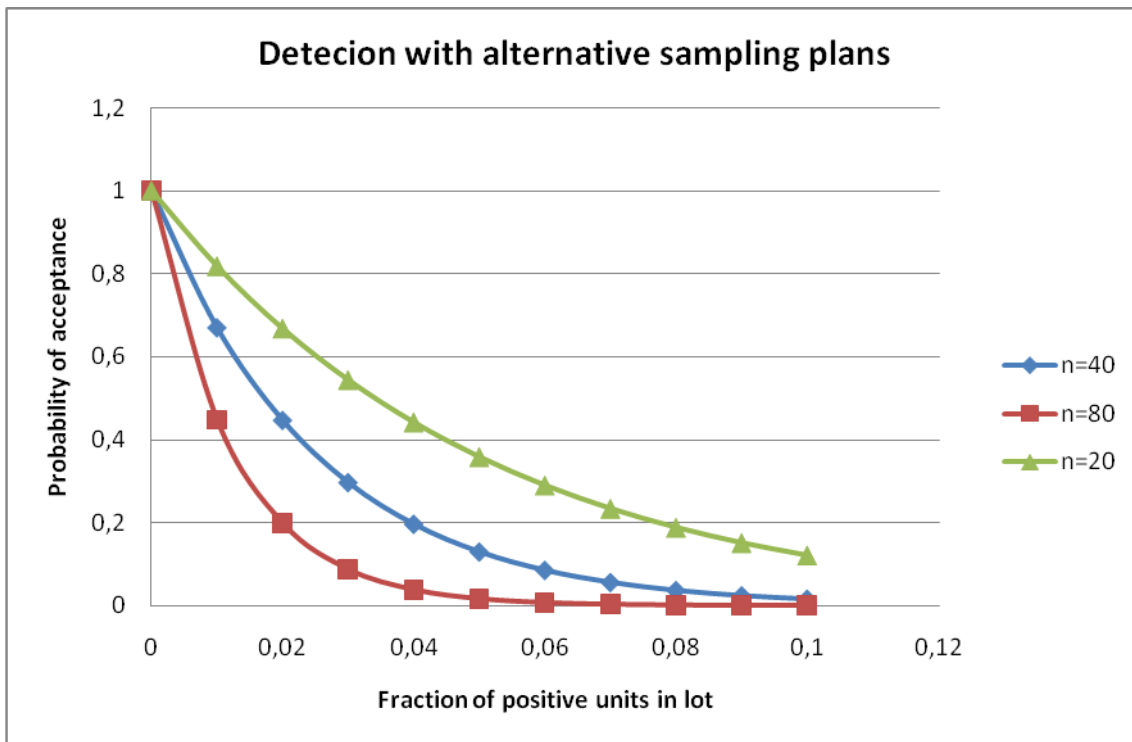


Figure 1. OC curve showing the effect of sample size (= number of increments) on the probability of detecting salmonella, based on calculations using the ICMSF model. X-axis, true fraction contaminated with salmonella. Y-axis, probability that batch is classified as salmonella free (%).

The figure illustrates the difficulties of actually proving the absence of salmonella in a batch based on sampling. Using automated sampling procedures it is possible to increase the number of increments from a feed batch considerably without increasing the work load. To my knowledge though, automatic sampling has so-far only been used for careful monitoring of finished products.

The objective of environmental monitoring in feed mills is to verify absence of Salmonella inside the feed mill and also that the production lines are not infected. Samples should be taken from environments where the risk for contamination is considered to be high (moisture and suitable temperature). If positive samples are detected in the monitoring process it is essential to immediately carry out an investigation.

A careful physical separation of the production line from the feed mill environment is another important precaution. Due to the monitoring of raw materials it is not likely that highly infectious raw materials ($>10^3/g$) will be used for the feed manufacturing. Temperatures between 75-80°C is used in Sweden with a conditioning time of < 1 min. Higher temperatures during pelleting may contribute to increased problems with condensation during cooling/ drying.

Relevant questions to be asked

1. Could the feed-borne outbreak have been avoided considering the information that is now available after the outbreak?

Most likely, if a careful monitoring of the production line by the feed business operator would have been in place and if more thorough actions would have been taken when positive samples were isolated inside the feed plant. This kind of work is often tedious and require a systematic approach. It should also be mentioned that from similar situations elsewhere the experience is that it may sometimes be difficult to detect a low level of infection in finished feed.

2. Could the tracing work to find contaminated farms have started earlier?

From the information provided I think the lag time when the tracing work began, after initial indications, could have been shortened if, i) the initial laboratory results would not have been delayed, ii) the information from Rehuraisio about customers would have been updated, iii) an available coordinated contingency plan by Evira and ETT to coordinate all stakeholder involved would have been in place, iv) information about the distribution network through the mobile feed mixers would have been more readily available.

3. Were all contaminated farms detected?

The sampling plans used at farm level would reveal if the feed area or the animals was contaminated/ infected. The time span for potentially infected feed from Dec. 12 – Mar. 10 was relevant.

4. Were the methods used for cleaning and disinfection at farm level adequate?

Most likely, however, I think it is essential to make sure that the disinfectants used also have a documented effect at low temperatures.

5. How was cleaning and disinfection of line P7 carried out?

Some mistakes were obviously made as salmonella was re-isolated after the re-start. The cleaning/disinfection procedures used should be carefully looked at.

6. Were the measures implemented at suspected holdings adequate in relation to food safety issues?

I think relevant measures were taken.

7. Were the laboratory methods used during the outbreak adequate?

I believe so, however, I think it would be essential to verify that the temperature during pre-incubation is ok when large numbers of samples are put into the incubators.

8. Any comments about the audits made by Evira?

From the protocols I can see that many different aspects related to feed production and safety are covered during the one day audits. Matters related to salmonella

prevention/contamination in a feed mill are often complicated and require time and experience.

9. Any proposals for the future?

With the aim to improve the safety of finished feed when similar situations occur in the future, the feed industry, ETT and authorities should secure that expertise is readily available to support the tracing work in the feed mill premises.