Failure Mode and Effect Analysis (FMEA) as a decision support tool within a quality information system in pork production chains.

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Abstract

Recent norms of retailer organisations, chain oriented quality programmes, the new ordinance of the German government concerning the hygiene of food (Lebensmittelhygieneverordnung) and of course the EU regulation 178/2002 demand the implementation of self-control and hazard control techniques in terms of Hazard Analysis and Critical Control Point (HACCP) systems of agrofood industry. Such an analysis of course includes a risk analysis. These demands and regulations require a stronger inclusion of the production process in systems of quality assurance. The Failure Mode and Effect Analysis (FMEA) seems to be an appropriate tool to enable animal health services to support farmers to fulfil these requirements. On the level of advisory services a computer aided FMEA tool which includes elements of the HACCP concept is tested. The tool allows to document efforts made to meet the claims of quality assurance and simultaneously provides gathered knowledge in form of a knowledge data base supporting the advisory service to solve concrete problems on farm. The paper describes how to assemble such a system for the Salmonella problem in pig farms.

Introduction

Recent norms of retailer organisations, chain oriented quality programmes, the new ordinance of the German government concerning the hygiene of food (Lebensmittelhygieneverordnung) and of course the EU regulation 178/2002 demand the implementation of self-control and hazard control techniques in terms of the Hazard Analysis and Critical Control Point (HACCP) system of the agrofood industry. Relating to the supplier chains for meat and meat products this means to include the process of animal production in the process of quality assurance. While in the converting companies lead of experiences in quality methods have been made, there is a lack of those at the level of animal production. The establishment of those chain oriented systems may be an appropriate operational field of the Failure Mode and Effect Analysis (FMEA) in the pork production chain. The conception of this tool of preventive quality assurance is similar to the HAACP system. However the FMEA is wider composed. A combination of the two techniques FMEA and HACCP seems to be promising. To optimise the application of hazard control techniques a method manual which combines those two techniques was developed (Schmitz and Petersen, 2004). Such a “mixed” FMEA-HACCP concept is provided here.

FMEA method

In the range of industrial production the FMEA is an established part of quality mangement as a tool of preventive quality assurance. The FMEA helps to implement a closed quality control loop by providing gathered expert knowledge. This can be used for planning as well as for executing processes (Pfeifer, 1996).

The FMEA intends to detect potential sources of error and their consequences on quality characteristics as early as possible. So consecutively disturbances can be anticipated (Pfeifer, 1996). Because of this it is essential that the FMEA has to be customer oriented from the first

step of production. Therefore all possible consequences of a self-inflicted failure for all succeeding chain members has to be considered.

Three important contents of the FMEA are:

- structered failure analysis including an analysis of the causes and effects,
- risk assessment based on the analysis mentioned before,
- use of the results of risk assessment to carry out an optimisation of process or concept (Edenhofer and Köster, 1991).

This aspects show that the FMEA is in fact part of a HACCP analysis. Within such an analysis the FMEA takes the parts of failure/ hazard analysis, risk assessment and it provides the actions to deal with the revealed failures and hazards.

The knowledge needed to run the FMEA in an efficient way is distributed to many persons. Therefore a team with members from every step of the process of interest should be formed. The team members contribute their knowledge as experts. The discussion in the FMEA team is prepared and presented by an experienced moderator. The moderator has to encourage the other team members e.g. QM representatives and other experts to examine the process of interest very critically. And of course the moderator has to encourage the other members to be self-critical. This in addition to efficient preparation of the FMEA determines the FMEA´s success.

To initiate a FMEA the following steps should be taken. The first step is to fix the analysis´ limits. Then the process is structured and standards are assigned. In step 4 and 5 the failure analysis is done and a FMEA form established. The achieved FMEA´s results are filled in a FMEA form to guarantee documentation as well as systematics and clarity. Step 6, risk assessment, is done by calculating a risk priority number (RPN). The RPN is calculated by using three variables describing the probability of the failure to occur (occurrence ,O), the severity (S) of the potential failure mode on the process and the probability to detect the failure (detection, D). Normally an assessment number ranging from 1 (no risk) to 10 (high risk) is used to describe these three variables. To facilitate assessment verbal explanations are assigned to the different values. The RPN is calculated by multiplying the values of the three variables O, S and D. The value of the RPN gives a hint whether optimisation is urgently required. Risk assessment needs a lot of supporting data to be done exactly. Optimisations (step 7) are carried out according to the following principles:

- Strategy amendment to exclude the cause of failure or reduce the severity. This means to restructure the system.
- Increase of the strategy reliability to minimise the occurrence of the failure´s cause
- More effective detection of the failure cause.

If the FMEA reveals that optimisation has to be done it has to be defined who has to do which of the recommended actions by when. This is also entered on the FMEA form. After performance of the recommended actions a risk assessment is carried out again. Risk priority numbers which had an effect on the decision are calculated again. A comparison of the two RPNs (previous and improved state) allows a final result assessment and the assessment of the relationship between achievable improvement and utilised effort. The reassessment of the risk after implementation of the recommended actions gives an estimation of the remaining risk of certain failure´s occurrence. Depending on this result the team decides whether the chosen actions were successful or whether additional actions are necessary. (Stamatis, 1995)

The application of FMEA software tools proved to be useful in different industrial branches. There are three main advantages:

- The FMEA establishment is systematised.
- The entered FMEA knowledge will be saved onto a knowledge database and can be used again.
- The effort of the establishment is reduced by the optimisation of the teamwork and by the falling back upon information already entered by means of search helps. (Schmitz and Petersen, 2001)

Adaption of the FMEA - concept to farm level

Referring to Noordhuizen and Frankena (1999) a quality-management instrument at farm level should satisfy two basic requirements:

- it should provide the advisory service or the individual farmer with clear and simple procedures for elimination and control of disease risks on the farm,
- it should enable the farmer to prove the execution of these procedures to a third party for herd-health certification and health insurance purposes.

Welz (1994) demonstrated the possibility to adapt the FMEA concept to animal production. In his study he used the FMEA to reveal interferences of product and process quality resulting from animal diseases on farm level.

In the following a FMEA like approach for prevention and reduction of Salmonellosis in pig production is given. In pig production the problem of Salmonella is to be considered from two different angels. On the one hand problems in production and economical losses resulting from Salmonellosis during the production period, on the other hand the endangering of human health due to Salmonella contaminated pork-products (Waldmann and Plonait, 2001). Steinbach and Hartung (1999) assume circa 20% of human Salmonellosis in Germany to be caused by consumption of Salmonella contaminated pork-products. Referring to van Altrock and co-authors (1999) and Meyer (2004) circa 10 % of tested fattening pigs showed a positive test result. This indicates that there is a need for supporting tools to solve this problem.

In literature several possible sources for the introduction of Salmonella in pig producing farms are described. The most important sources are:

- purchase of piglets and gilts (Lo Fo Wong et al. 2004, Berends et al. 1996),
- purchase of feed (Hartung 2003, Lo Fo Wong et al. 2002),
- biotic and abiotic vectors (Meyer 2004, Letellier et al. 1999).

Each of these aspects include a lot of different subaspects. Also the transmission of Salmonella within a farm is influenced by a lot of factors. The most important are listed below:

Table 1: Factors with influence on the transmission of Salmonella within a farm

factor	author
hygiene status and farm hygiene	Berends et al. 1996
hygiene lock	Lo Fo Wong et al. 2004
all in and all out	Lo Fo Wong et al. 2004
cleaning and disinfection	Lo Fo Wong et al. 2004
disposal of dead animals	Letellier et al. 1999
farm management	
farm size	van der Wolf et al. 2001
pig density in pens	Funk et al. 2001
pen separation	Lo Fo Wong et al. 2004
floor design	Meyer 2004
manure mangement	Belœil et al. 2004
feeding system	Lo Fo Wong et al. 2004, van der Wolf et al. 2001, van Schie and Overgoor, 1987
addtion of organic acids to feed or drinking water	van der Wolf et al. 2001a
number of attending persons	Meyer 2004
other infections within the herd	Belœil et al. 2004, Wills et al. 2000, Møller 1998
concomitance of parasitic diseases	van der Wolf et al. 2001

Each of these factors is associated with a number of different characteristic values which may even interact. A lot of these factors especially those which refer to the spreading of Salmonella within a herd/farm apply for every step of pig production (farrowing, fattening). So to keep the FMEA clear and to be able to use the gathered knowledge preferably on different types of farm, the following seven system elements were created in Workgroup Computing System SCIO™ FMEA System (PLATO AG, Lübeck):

- production process/ husbandry,
- cleaning and disinfection,
- pest control,
- water,
- feedstuff/ feeding,
- hygiene of environment,
- hygiene of staff.

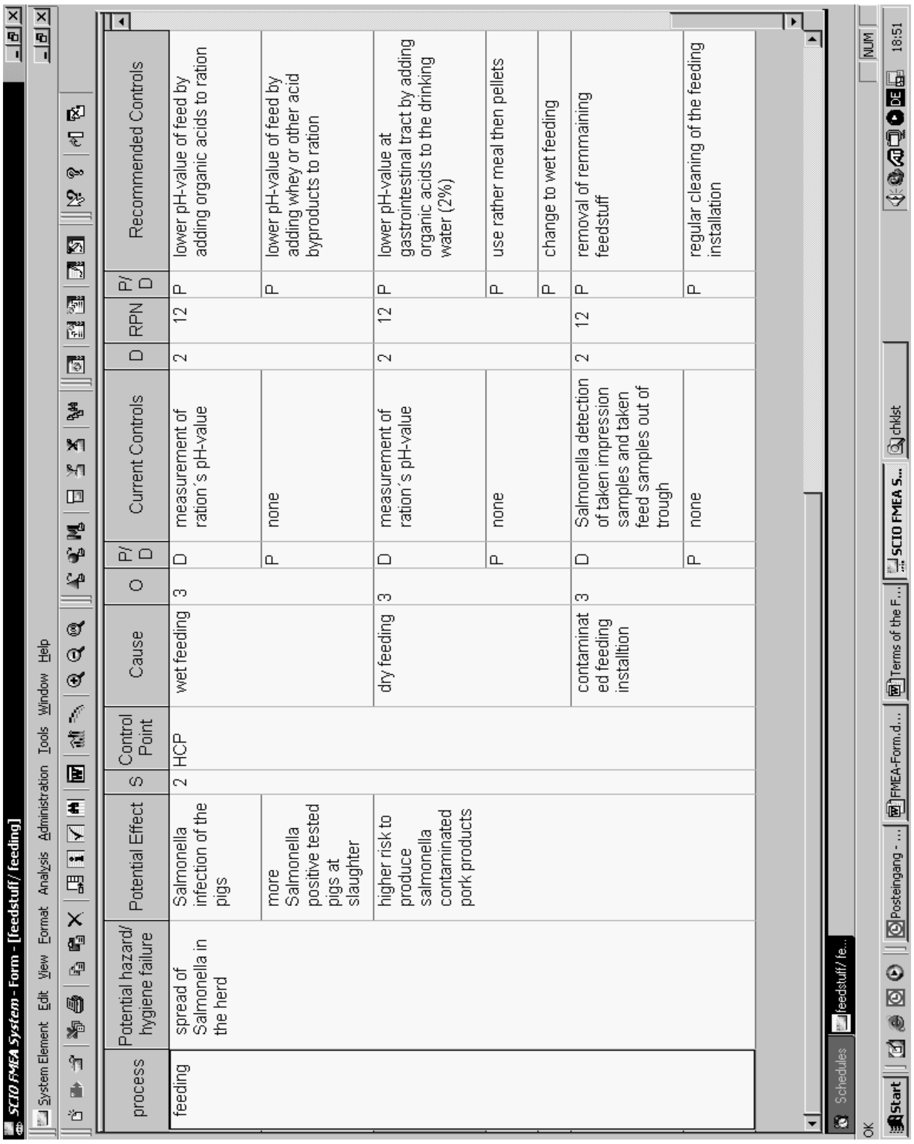
For each of these system elements a FMEA form was established by checking literature for possible risk-factors concerning introduction and spreading of Salmonella associated with the

system element of interest. To create the FMEA form the following steps were executed and the following corresponding questions put forward:

- listing all steps concerning the production process
- determination of potential hazards/failures
  question: Which hazard or hygiene failure can be caused by this production step?
  Which hazards or hygiene failures are occured at this production step in the past?
- determination of the effects
  question: What are the effects of this hygiene failure on the animals?
  What are the effects of this hygiene failure on the farm´s Salmonella status?
  What are the effects on the next production step?
  What are the effects on the consumer of pork products?
- search for potential causes for each hazard/failure
  questions: Searching for the causes in the surroundings of man, machines, environment, material, method, management or measurement.
- listing possible actions to avoid the hazard/failure (precautionary and checking actions)
  question: What can be done to avoid this hazard/hygiene failure?

The kind of questions indicate that the chosen approach is not just FMEA based but also contains elements of the HACCP concept. Some of the chosen column headings reflect this,too.

The created FMEA form is a table with 22 colums (figure 1 and 2). In the first column the process of interest is entered. The second column contains the potential hazards or rather the "hygiene failures". The potential effects of these failures are listed in the next column. Then an assessment of failures´ severity (S) is done. The next column shows your decision whether this aspect is a controlpoint or not. Then failures´ causes are assembled. Next step is to assess failure´s probability to occur (O). The result of this assessment is entered in the column. In the next column the decision is made whether the current applied control to deal with the failure is precautionary or checking. Then the current control is entered. In the next column a assessment of the probabillity to detect the failure (D) is given. The risk priority number (RPN) is calculated automatically by the software according to the values for S, O and D. The problem of risk assessment is discussed beneath. The next two columns contain the recommended controls to deal with the failure and the specification of this actions in terms of their precautionary or checking character. Then is entered who has to carry out this action by when. The finally chosen and performed action and their character is displayed in the following columns. Finally risk assessment is done again by adapting the values for S, O and D according to the taken actions. Until now the forms are filled with data collected by literature research. When the FMEA is used at farm level it is possible to add new processes steps to the system elements. Also the current applied actions have to be added to the FMEA at the farm. This is simply to be done because the software allows you to fall back on all actions detected during literature research.



process	Potential hazard/ hygiene failure	Potential Effect	S	Control Point	Cause	O	P/ D	Current Controls	D	RPN	P/ D	Recommended Controls
feeding	spread of Salmonella in the herd	Salmonella infection of the pigs	2	HCP	wet feeding	3	D	measurement of ration´s pH-value	2	12	P	lower pH-value of feed by adding organic acids to ration
		more Salmonella positive tested pigs at slaughter					P	none			P	lower pH-value of feed by adding whey or other acid byproducts to ration
		higher risk to produce salmonella contaminated pork products			dry feeding	3	D	measurement of ration´s pH-value	2	12	P	lower pH-value at gastrointestinal tract by adding organic acids to the drinking water (2%)
							P	none			P	use rather meal then pellets
											P	change to wet feeding
					contaminat ed feeding installtion	3	D	Salmonella detection of taken impression samples and taken feed samples out of trough	2	12	P	removal of remmaining feedstuff
							P	none			P	regular cleaning of the feeding installation

Figure 1 Screenshot of the used FMEA form. This screenshot displays only the half FMEA form. The rest is shown in figure 2.

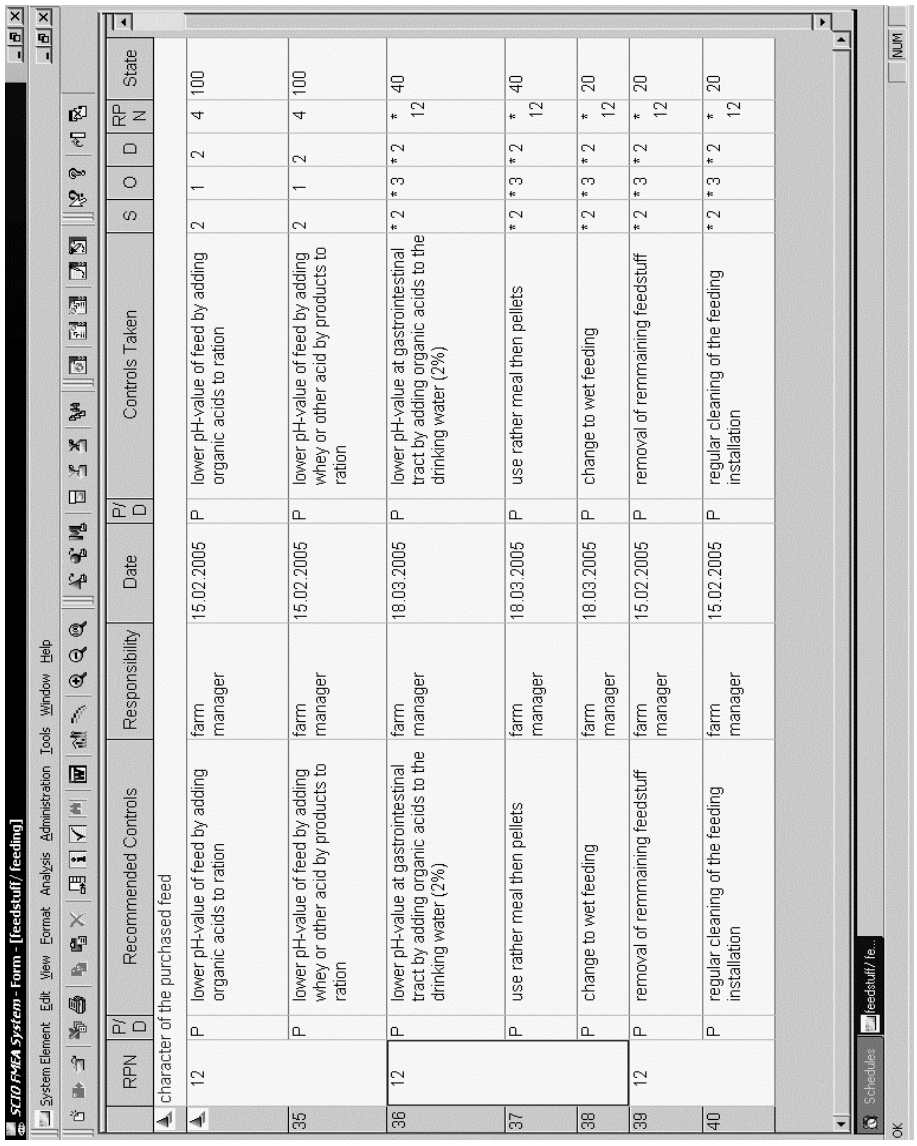


Figure 2: **Sequel to figure 1**

As mentioned before the problem of risk assessment is in agriculture distinctive. While in other sectors e.g. automobile industrie there is a lot of data allowing exact risk assessment, in agriculture there is not so many data because of a lack of documentation, until now. But the introduction of quality programmes such as QS (Quality and Security) for example improved documentation and therefore the amount of available data. But still it is very difficult to give an assessment for a failure´s probability to occur, to be detected or its severity. As mentioned above normally an assessment number ranging from 1 to 10 is used to describe these three variables. In small food processing businesses positive lead of experiences were made with assessment numbers only ranging from 1 to 5. In this model for Salmonella introduction and spreading assessment numbers ranging from 1 to 3 were determined. Because of the limited numbers of experiences this scale was chosen. If on road tests reveal the need for adjustment it can easily be done by means of the used software tool. The following evaluation patterns were fixed:

To determine the severity of a failure Odd´s ratios (OR) (which are known from literature) for intoduction or spreading of Salmonella on a farm were used as an ancillary tool (table 2). The borders chosen may be adapted by further investigations.

Table 2: Evaluation pattern for failure´s severity (S)

evaluation pattern	OR	evaluation
High: A cardinal failure occurs which leads to a very fast spread of Salmonella within the whole herd. Because of this in all probability a higher percentage of Salmonella positive pigs at slaughter is to be expected. This arises the risk of Salmonella contamination of pork products while slaughter and will lead to a degradation of farm´s Salmonella status.	> 2	3
Medium: The spread of Salmonella in the herd is supposable, but may be unique to batches. The percentage of Salmonella positive pigs at slaughter may arise.	> 1	2
Low: An influence of the failure on the Salmonella situation on the farm is improbable.	≤ 1	1

Table 3 shows the evaluation pattern for failure´s or cause of failure´s probability to occur (O). The data for frequency are adopted from a project carried out with small food processing businesses.

Table 3: Evaluation pattern for failure´s probability to occur (O):

evaluation pattern	Frequency	evaluation
High: The cause of failure´s occurrence is almost inevitable. Failure´s occurrence in a large quantity is very probable.	> 2 %	3
Medium: The cause of failure may occur in some cases but the process is controllable.	< 2%	2
Low: Failure´s occurrence is improbable. It was not (it was rarely) detected at similiar processes.	< 0,5%	1

In table 4 the evaluation pattern for failure´s or cause of failure´s probability to be detected (D) is shown. Here as well the frequencies are adopted from the project with small food processing businesses.

Table 4: Evaluation pattern for failure´s probability to be detected (D):

evaluation pattern	Frequency	evaluation
Low: It is almost impossible to detect the failure or the cause of failure. It is a matter of hidden failure.	< 90 %	3
Medium: A detection of the failure or of its cause is possible by investigations with ancillary tools like pH-value measurement or bacteriological or serilogical investigations of taken samples.	> 95 %	2
High: It is very easy to detect the failure or its cause by visual, manual investigation or by computer supported control (e.g. climate computer). It is a ostensible inspection criterion.	> 98 %	1

Chain oriented using of the FMEA based knowledge database

The following figure 3 makes a proposal how to use the FMEA within a chain oriented approach to minimise the risk of Salmonella contaminated pork products. The gathered expert knowledge is used to run self-control systems within the chain. By doing this an enhancement of the database and the methods may be achieved.

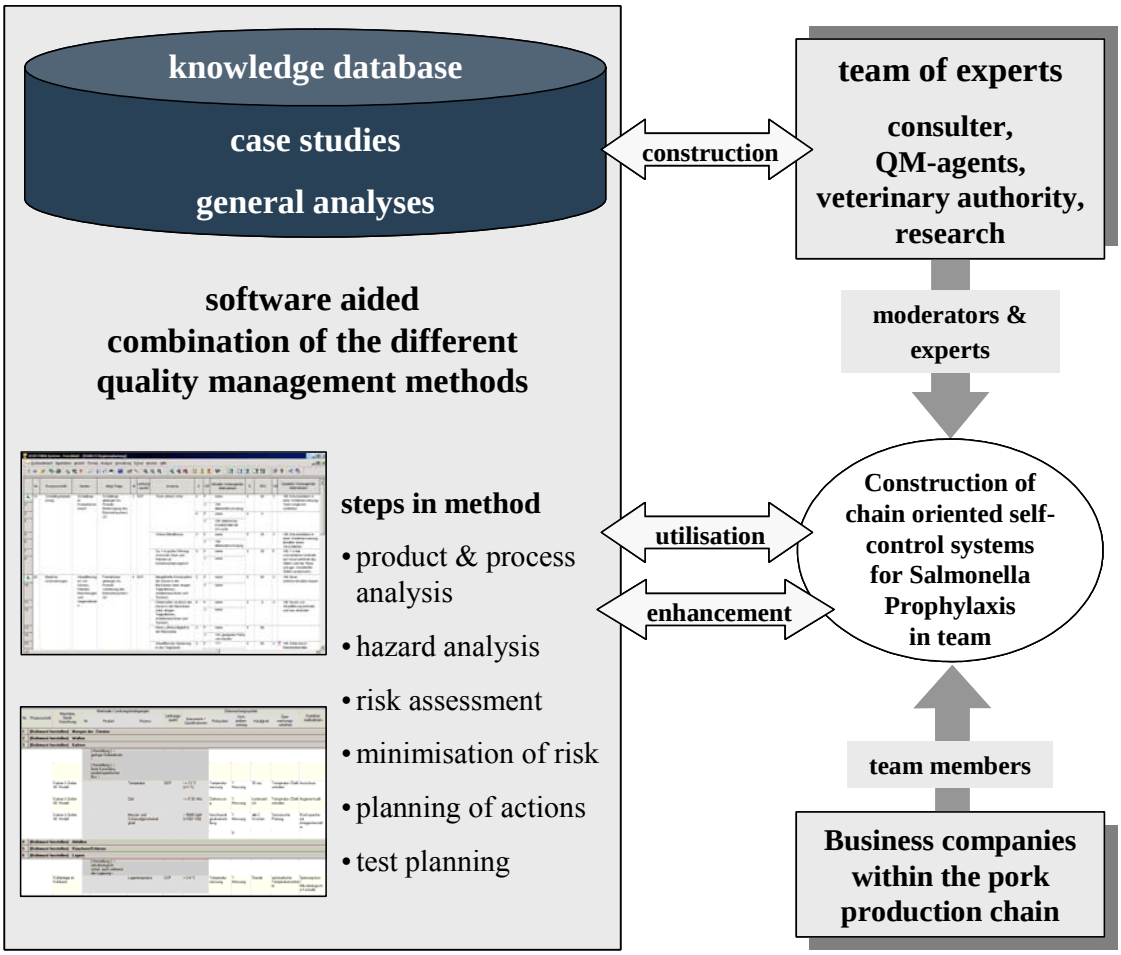


Figure 3: Using the FMEA in a chain oriented approach

Conclusion

A computer-aided FMEA system can be very helpful to run risk analysis within complex processes. The complete documentation of the analysed processes enables to arrange knowledge data bases. This helps to solve concrete problems in a very effective way. Due to the FMEA´s structure those data bases provide clear and simple procedures for the elimination and control of disease risks on farm. Furthermore the FMEA allows to prove the execution of these procedures for health certification and health insurance purposes according to the demands of EU-regulations and distributive trade. Therefore the FMEA seems to be an appropriate tool to support quality information systems in pork production chains. Now the theoretically approach has to be validated by tests with advisory services.

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