Tools to support the self assessment of the performance of Food Safety Management Systems

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Introduction

Changes in food supply chains, health and demographic situations, lifestyle and social situations, environmental conditions, and increased legislative requirements have led to significant efforts in the development of quality and safety management systems in agribusiness and food industry worldwide (Ropkins and Beck, 2000; Efstratiadis, Karirti, and Arvanitoyannis, 2000; Jacxsens, *et al,* 2009a, Luning and Marcelis, 2009a). Nowadays, companies have implemented various quality assurance (QA) guidelines and standards, such as GMP and HACCP guidelines (like General Principles of food hygiene (Codex Alimentarius 2003), GFSI guidance document (GFSI (2007), and quality assurance standards (like ISO 9001:2008 (2008), ISO22000:2005 (2005), BRC (2008), and IFS (2007) into their company own food safety management system. The performance of such systems in practice is, however, still variable. Moreover, the continuous pressure on food safety management system (FSMS) performance and the dynamic environment wherein the systems operate (such as emerging pathogens, changing consumer demands, developments in preservation techniques) require that they can be systematically analysed to determine opportunities for improvement (Wallace, *et al,* 2005; Manning *et al,* 2006; Van der Spiegel *et al,* 2006; Cornier *et al,* 2007; Luning *et al,* 2009a). Within the European project entitled 'PathogenCombat-EU FOOD-CT-2005-007081' various tools have been developed to support food companies and establishments in systematically analysing and judging their food safety management system and its microbiological performance as basis for strategic choices on interventions to improve the FSMS performance. This chapter describes briefly principles of the major tools that have been developed and some others, which are still under still under construction.

Quality assurance evaluation grids

The wide range of quality assurance standards and guidelines commonly leads to difficulties for small and medium enterprises (SME) to select and implement them into their company specific Quality Management System (QMS) and or Food Safety Management System (FSMS). It is often hard for SME's to understand the detailed differences between various QA standards and guidelines and to judge the possible consequences of implementation, because they

not always have the necessary expertise, experience, and resources (e.g. financial, staffing capabilities) (Yapp and Fairman, 2006; Aggelogiannopoulos *et al,* 2007; Karipidis, *et al,* 2009). Therefore, quality assurance evaluation grids have been developed, which show the major differences between acknowledged QA standards and guidelines on distinct features. The QA evaluation grids may support companies in the agri-food chain to balance the benefits of implementing certain QA standards (and guidelines) against the efforts that are required. Moreover, it might serve as a compact overview of possibilities and consequences of implementing QA standards and guidelines when supporting companies to improve their own FSMS. The features that have been included in the grids are in table 1 summarised. For details the reader is referred to Kussaga and co-authors (2009).

Food Safety Management System Diagnostic Instrument (FSMS-DI)

Stakeholders (like government, branch organisations, customers, retail, etc) put demands on the design of a company's FSMS by requiring the implementation of certain (sets) of quality assurance (QA) standards and or guidelines. However, each company or establishment has a unique company-specific FSMS depending on how standards and guidelines have been translated into the own situation (Jacxsens, *et al*, 2009a; Luning and Marcelis, 2009a). Recently, a

Table 1. Features on which acknowledged QA standards and guidelines have been evaluated (modified from Kussaga et al, 2009b).

Features related to position of QA Standards and Guidelines	
Focus	QA standards and guidelines have been (are being) developed for different purposes, they may have a different focus (like, safety, quality, organisation).
Scope	Scope refers to the range and applicability of the standard or guideline, which can be restricted or broad.
Legislative Status	Legislative status refers to being compulsory or voluntary.
Combined	The feature combined implies if a standard or guideline is a primary one or is typically a combination of more standards/guidelines.
GFSI status	GFSI status refers to the benchmarking position of the Global Food Safety Initiative of the QA standard/guideline.
Acknowledgement	Acknowledgement of QA standards and guidelines indicates whether they are nationally (e.g. one country), regionally (e.g., the whole region/continent like Europe, Middle East), or worldwide recognized.
Features related to type of requirements of QA Standards and Guidelines	
Comprehensiveness	Comprehensiveness refers to the extent of detail of the requirements, requirements and to how they are in the document formatted.
Extent validity requirements	Extent of validity requirements refers to what degree demands are put on assuring that the system is really effective in practice.
Degree of organisational demands	Degree of organisational demands refers to what extent QA standard and guideline set requirements on typical organisational issues (like training of personnel, setting procedures).

Table 1. Features on which acknowledged QA standards and guidelines have been evaluated (modified from Kussaga et al, 2009b) (continuation).

Features related to Certification of QA standards	
Scope of certification	Certification scope refers to what the certification process covers.
Gradation in certification	Differences in gradation refers to fact that QA standards vary in the way certification requirements can be fulfilled.
Frequency	Frequency of certification refers to how often certification audits must be by third parties carried out.

diagnostic tool has been developed using a techno-managerial research approach to consider both technological factors and people behaviour in the performance of food safety management systems (Luning and Marcelis, 2006, 2007, 2009b). The tool is called "food safety management system diagnostic instrument" (FSMS-DI). The FSMS-DI is a tool that enables a systematic analysis and assessment of a company's unique food safety management system independent of the QA standards and or guidelines that have been implemented (Luning et al, 2008, 2009a, b, c; Jacxsens et al, 2009c). The instrument consists of **comprehensive lists** with sets of indicators to analyse respectively which core control and core assurance activities are addressed in the company specific FSMS, which major contextual factors could affect FSMS performance, and to analyse the microbiological safety performance of the system. Moreover, the FSMS-DI encompasses **grids** to assess respectively **levels** of control and assurance activities (i.e. more or less advanced), contextual **situations** (i.e. more or less 'risky') wherein the FSMS has to operate, and the microbiological **safety level**. For each indicator, to assess core control or assurance activities or food safety performance, four different levels have been described (i.e. 0, 1, 2, and 3 representing a low, basic, average, and advanced level respectively). Similarly, for each indicator, to assess contextual factors, three different risk levels have been described (i.e. 1, 2, and 3 representing low, moderate and high-risk context respectively).

The elements of the FSMS-DI are summarised in figure 1, it starts with introductory questions followed by defining a representative production unit for which a QA manager can do the self assessment (part I). Part II includes the indicators and grids to assess the major contextual factors 'product characteristics', 'process characteristics', 'organisational characteristics', and 'chain environment characteristics'. Part III is for assessment of the core control activities 'design of preventive measures', 'design of intervention measures', 'design of monitoring systems', and 'actual operation of control measures', whereas the core assurance activities 'setting system requirements', 'validation', 'verification', and 'documentation and record-keeping are covered in part IV. Part V includes the indicators (called the Food Safety Performance Indicators FSPI) and grids to assess 'internal' and 'external food safety performance' (Jacxsens *et al*, 2009c). The assumption behind the FSMS-DI is that companies operating in a high-risk context (due to highly risky product and

PART I: introductory section for Food Safety Management System (FSMS)	
A. Introduction questions	(1 -11)
B. Selection of Representative Production Unit (RPU) for self-assessment	(12-20)
PART II: assessment of contextual factors	
A. Assessment of product characteristics	(A1-3)
B. Assessment of process characteristics	(B4-6)
C. Assessment of organisation characteristics	(C7-13)
D. Assessment of chain environment characteristics	(D14-17)
PART III: assessment of core safety control activities	
E. Assessment of preventive measures design	(E18-23)
F. Assessment of intervention processes design	(F24-27)
G. Assessment monitoring system design	(G28-34)
H. Assessment of operation of preventive measures, intervention process and monitoring systems	(H35-41)
PART IV: assessment of core assurance activities	
I. Assessment of setting system requirements activities	(I42-43)
J. Assessment validation activities	(J44-46)
K Assessment of verification activities	(K47-48)
L Assessment of documentation and record-keeping to support food assurance	(L49-50)
PART V: assessment of food safety performance	
M. EXTERNAL Food Safety Performance	(M51-54)
N. INTERNAL Food Safety Performance	(N55-57)

Figure 1. Overview of elements of food safety management system diagnostic instrument.

processes, less supporting organisational conditions, highly vulnerable and depend chain position) need to have an advanced FSMS (i.e. based on precise information, scientifically underpinned, critically analysed, procedure-based, systematic, and independent) to realise a predictable and controllable food safety performance. In a moderate-risk context an average FSMS is expected to be sufficient to realise a good FS performance, while in a low-risk context even a basic FSMS would be adequate to realise a good FS performance (Luning *et al*, 2009c). At the other hand, a good FS performance is an indication for a well functioning FSMS (Jacxsens, *et al*, 2009c). Figure 2 illustrates this assumption. The FS performance can be analysed by using the food safety performance indicators (Jacxsens *et al*, 2009c) and can be measured by experiments using the microbial Assessment Scheme (MAS) of Jacxsens and co-authors (2009b) (Section 4).

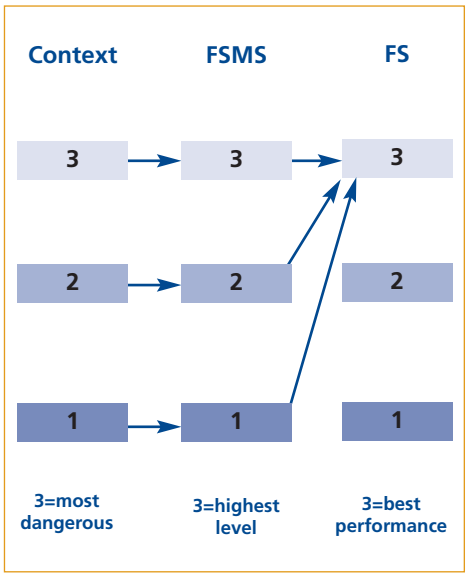

Figure 2. Principle assumption behind the research work of tools to measure the performance of Food Safety Management Systems.

The FSMS-DI has been tested and validated in pre-tests and a pilot study with 15 food producing companies in the area of dairy, pork, beef & lamb, and poultry products. Moreover, the instrument has been slightly adapted and applied in the catering sector (50 food service establishments) in Spain (Chinchilla, 2009). Recently, the 'paper based' instrument has been transformed to a 'web based' application, i.e. **the FSMS self assessment tool**. This self assessment tool is now used for a quantitative study to assess food safety management systems in dairy, pork, beef & lamb, and poultry companies in Europe. For details about the diagnostic tool, the reader is referred to Luning and co-authors (2008, 2009 a, b, c), Jacxsens and co-authors (2009c), and the Pathogen Combat website (www.pathogencombat.com).

Microbiological Assessment Scheme (MAS)

As previously stated, the actual microbiological performance of FSMS in practice is still variable (e.g. Cormier *et al,* 2007; Manning *et al,* 2006; Tsalo *et al,* 2007). In fact, attention has been shifted from implementing QA standards to better understanding the performance of an FSMS (Doménech *et al,* 2008; Luning *et al,* 2008; Stringer and Hall, 2007) and various audit tools have been developed to determine performance towards certain QA standards (e.g. Wallace *et al,* 2005; CIES, 2007; Cormier *et al,* 2007). However, these audit tools basically check on compliance to the set requirements, for instance, during internal or external auditing (Van der Spiegel *et al,* 2005), whereas the FSMS-DI focuses on crucial control and assurance activities (not linked to specific QA standards). Although, the FSMS-DI can give an indication about the microbiological safety performance, it gives restricted insight in the actual microbiological performance.

In practice, food processing companies commonly use microbial testing of final products to assess if their products meet food safety criteria (e.g. ICMSF, 2002; Legan, 2001). These criteria are set by different stakeholders or regulatory bodies (like EU and/or country regulations and/or customers' requirements), but can also be used to guide the evaluation of a manufacturing process to define preventive actions (Kvenberg and Schwalm, 2000; Martins and Germano, 2008). However, no procedure to systematically evaluate the microbiological performance of a FSMS was yet available. Therefore, the **Microbial Assessment Scheme (MAS)**

tool has been developed to support a systematic analysis of microbial counts to assess the current microbial performance of an implemented FSMS.

The MAS tool is a procedure that defines the identification of critical sampling locations (CSL), the selection of microbiological parameters, the assessment of sampling frequency, the selection of sampling method and method of analysis, and finally data processing and interpretation (figure 3).

Based on the MAS assessment, microbial safety level profiles can be derived, indicating which microorganisms and to what extent they contribute to microbiological safety for a specific food processing company. A microbial safety level can be classified from 1 to 3, where level 3 reflects a good performance (legal criteria or guidelines are respected, no improvements are needed –current level of FSMS is high enough to cover this hazard), level 2 corresponds with a moderate performance (legal criteria or guidelines are exceeded, improvements need to be made on a single control activity of the FSMS) and level 1 represents a poor performance (legal criteria or guidelines are exceeded, improvements need to be made on multiple control activities of the FSMS). The sum of the levels is resulting in the microbial food safety level profile. The principle behind the MAS tool is that low numbers of microorganisms and small variations in microbiological counts imply a well functioning FSMS (Jacxsens *et al*, 2009b).

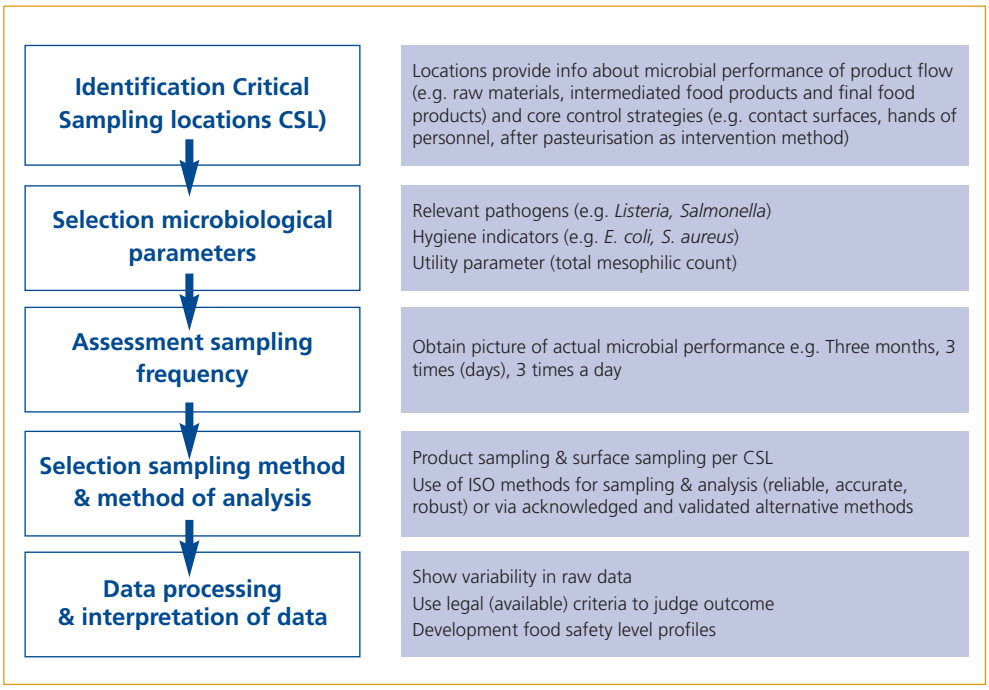

Figure 3. Steps of the MAS scheme (modified from Jacxsens et al, 2009b).

A MAS scheme will differ depending on the production processes and food type that are addressed in the specific company. MAS-schemes have been specified for microbiological analyses in respectively poultry, dairy, beef & lamb, and pork companies. Depending on the product and production processes, specific microorganisms have been selected to indicate respectively safety (e.g. *Listeria monocytogenes*, *Salmonella* spp, *Campylobacter*), hygiene indicators (e.g. *E. coli* and *Enterobacteriaceae*, *Staphyloccocus aureus*), and overall performance (total aerobic count). Data provided in-depth insight in microbiological counts in product flows (both raw materials, intermediate, and final products), contact surface areas (like at critical cutting areas, knives, conveyor belts, etc), and people (hands and gloves).

The detailed MAS data provide insight in *which* indicator microorganisms exceed limits and at *which* critical locations, but also reveals the *extent of variation* in microbiological counts. The microbial safety level profiles give an immediate insight in the room o improvement and or which microbiological parameters. These profiles can also be used to compare the microbiological performance of different companies with the same type of production processes and food products as benchmarking tool. As such, microbiological problems in a sector can be identified, independent of the type of company. The food safety performance indicators (FSPI) have been analysed on their indicative value by comparing data with the extensive MAS data for nine European companies. (Jacxsens *et al*, 2009c). The food safety performance diagnosis can be a useful tool to have a first indication about the microbiological performance of an operational food safety management system.

For more details the reader is referred to Jacxsens and co-authors (2009a, 2009c), and Sampers and co-authors (2009), and Kussaga and co-authors (2009b).

MAS analysis method selection tool

Different authors recommended the use of microbial testing to evaluate critical control points (e.g.), to evaluate procedures for Good Hygienic practices (GHPs) and Standard Operating Procedures (SOPs) (e.g. Brown *et al,* 2000; Swanson and Anderson, 2000; Kvenberg and Schwalm, 2000; Gonzalez-Miret *et al,* 2001; Cormier *et al,* 2007; Martins and Germano, 2008). The MAS-scheme can support food safety experts in systematically designing a tailored scheme to asses the microbiological performance of implement ted food safety management systems (Jacxsens *et al,* 2009b). According to the MAS protocol appropriate methods for sampling and analyses of pathogens and other micro-organisms (to indicate hygiene or total performance) need to be selected. In the current MAS protocol, the authors refer to the use of internationally acknowledged sampling and analysis methods according to ISO standards. However, nowadays a wide range of methods to sample and or analyse micro-organisms (and specifically pathogens) are existing or have been recently developed. Each method has its own specific characteristics, which may affect the choice of a certain method.

Therefore a **MAS analysis method selection tool** has been developed, which can aid in the process of decision-making regar-

ding selection of microbial analysing methods in specific situations. A comprehensive review of literature regarding different enumeration and detection method was performed. Based on this review specific method characteristics were determined that have used as a parameter in the selection tool. The major characteristics on which the methods have been analysed are shown in table 2. Moreover, a decision tree was made that allows classifying the MA that needs to be performed. The decision tree is based on a techno-managerial point of view.

Regarding the selection tool it should be noticed that no method exist that is a 100% sensitive, 100% specific, that can be performed in real-time and that is completely without costs. All methods have advantages and disadvantages. The challenge is to select the method that fulfils the most of the characteristics of the ideal method in a specific situation. Advantages of a method should be optimally exploited and the disadvantages should be recognized. The selection tool can aid in finding the most appropriate method for a specific situation in need of microbial analysis.

Table 2. Some examples of characteristics on which microbiological methods have been evaluated as basis of the MAS method analysis selection tool (modified from Jasson et al, 2009).

Characteristics	Brief description
Alternative method	An alterative method is a method of analysis that demonstrates or estimates, for a given category of products, the same analyte as is measured by using the corresponding reference method. This alternative method can be proprietary or non-commercial and covers an entire analysis procedure, that is, from the preparation of samples to the test results either as such or may include references to other procedures in order to be complete. The alternative method exhibits attributes appropriate to the user' needs, e.g.: speed of analysis and/or response, ease of execution and/or automation, analytical properties, miniaturisation or reduction of cost
Time	Total time to result is the time needed from sample until counting results or presence/absence result (confirmation not included)
Matrix	Food matrix. A method should be applicable for the food matrix of interest
Validation certificate	Users of commercially available kits (proprietary methods) need guarantees regarding the performance of these kits. Validation of alternative methods is a process that determines if an alternative method can obtain the same analyte as is measured by using the corresponding reference method
Type of microbial parameters	Multi-functionality of the method regarding different microorganisms

For details about the MAS analysis method selection tool, the reader is referred to Jasson *et al*, (2009).

Improvement roadmap for FSMS

After companies have analysed their system by using the self assessment tool FSMS-DI alone or in combination with MAS, they have detailed insight in the *levels* at which they execute their core control and assurance activities (ranging from absent, low, medium to high (= level 3). They also have an idea about the typical contextual *situation* wherein their system has to operate (ranging from highly, to restricted and not vulnerable, ambiguous and uncertain (situation 3-1) moreover, they have an indication about the (actual) microbiological performance. As previously, stated the principle behind the diagnosis is that companies that operate in a more risky context (i.e. more vulnerable, ambiguous and uncertainly) require a more advanced (high level) FSMS to be able to realise and ensure safety requirements (Luning *et al*, 2009b). If the assessment data reveal food safety levels below 3 (Jacxsens *et al,* 2009b,c) and this is perceived as a problem, then a company could first consider those core control and assurance activities that are at level 1 (is associated with aspect, like not scientifically underpinned, general, not structured, incomplete, not independent) or at level 0 (absent, not used, unknown), to consider possible interventions in the FSMS to improve the performance. However, one can also consider those contextual factors that are allocated in situation 3, to identify possible interventions in the contextual situation, which are commonly long-term interventions (like changing production process, increasing competence level of operators, improving information system, enhancing supplier relationships, etc) (Luning and Marcelis, 2009a; Luning *et al*, 2009c).

To support the improvement process, generic roadmaps have been made showing how to go through the different steps of an improvement process The systematic approach is based on the principles of the food quality relationship model (food quality = f (food behaviour, human behaviour), the food quality management decisions grid, and the principles of improvement processes (Luning and Marcelis, 2006, 2007, 2009a, b). The basic steps of an improvement cycle are: 1) map problem area, i.e. collecting information and documentation, 2) analyse problem area: i.e. identification of causes and effects, and 3) redesign: i.e. development and implementation of solutions as depicted in Figure 4.

Improvement processes are characterised by a gradual nature, it is a step-by-step ongoing process. Depending on the starting situation, improvements can vary from simple measures to reduce variation in products and decision-making on the short term, to changes in the infrastructure on the long-term. Using the food quality relationship we have defined three levels of increasing improvement efforts, i.e. a) changes in product and people behaviour, b) changes in technological and decision-making process conditions, and c) changes in the technological and organisational infrastructure. After each improvement cycle the new situation should be reassessed in order to judge the effect of the improvement. Subsequently, the new situation must be assured (Luning and Marcelis,

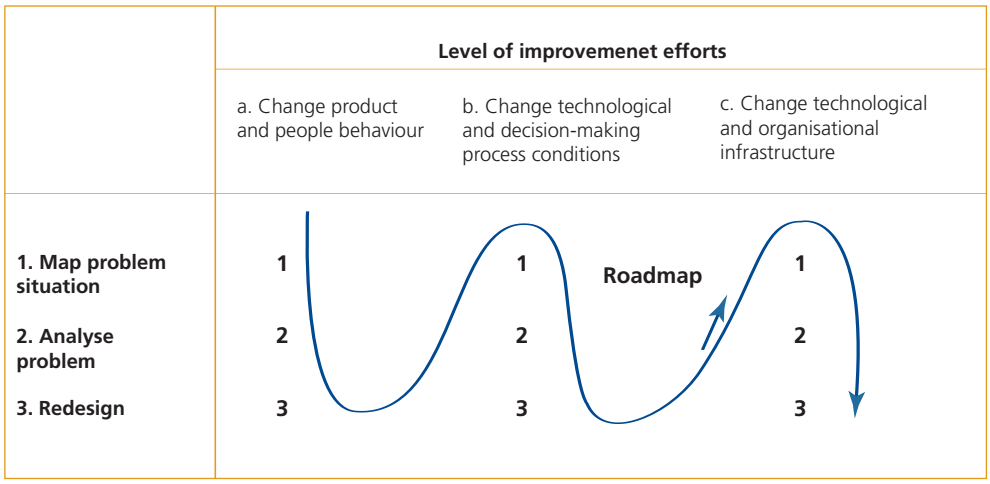

Figure 4. Generic approach to develop roadmaps.

2009). Using above approach, an example of a roadmap has been elaborated indicating typical activities that could be done by food companies when they want to improve problems with aw materials, table 3 shows typical activities in the three improvement steps for the different levels of improvement. The activities are a selection of information gathering, analyses methods, and improvement measures addressing both technological and managerial issues to demonstrate how food companies can systematically improve their FSMS. Companies have to select themselves which tools, techniques, and methods are most suitable for their own situation.

The principle of generic roadmaps for improvement will be further in the near future (Luning *et al,* 2009c).

Additional supporting tools

Data from the pre-tests and pilot studies indicated that validation and verification activities but also design of sampling plans are still not yet well worked out in practice. Protocols have been developed to support companies in improving their validation and verifications activities, and a protocol to improve design of sampling plans.

To support companies in improving their FSMS they need to have access to information, knowledge, and experience about these tools. In this perspective, a food safety management **support system** has been developed to provide in a systematic way information about control and assurance principles, supporting tools (like new enumeration, detection and monitoring techniques for pathogens, new intervention techniques and methods, protocols and procedures on sanitation, validation, verification, microbial assessment, etc), principles and structure of acknowledged quality assurance standards and guidelines, and legislative requirements.

The FSMS support system is available via the Pathogen Combat website (www.pathogencombat.com).

Table 3. Typical activities in the improvement steps for problems with 'Raw materials'

	a. Change product and people behaviour	b. Change technological and decision-making process conditions	c. Change technological and organisational infrastructure
1. Map problem situation: gathering information	Gather materials information, like rejections, incidence reports, complaints, microbial load products, % realised inspections	Gather process condition information, like storage temperatures, complaints, actual availability of and compliance to procedures, actual availability of materials and supplier information	Gather information on storage facilities and suppliers, like microbial load walls and floors, supplier performance, communication problems, quality system performance
2. Analyse problems: methods and tools	Use basic statistic tools, and brainstorming for analysing structural deviations	Use CCP analysis, risk analysis, Total Productive Maintenance, and literature analysis	Use CCP analysis, hygienic design methods/principles, risk analysis, predictive modelling, and literature analysis
3. Redesign: improvemen t options	Possible measures for improvement: change corrective actions, change inspection frequency, change frequency of recording data, change instructions, intensify supervision	Possible measures for improvement: change incoming material inspection, change storage temperature control, change corrective measures, change procedures, training, intensify support quality department, intensify information supply	Possible measures for improvement: building conditioned storage rooms, change suppliers, intensify supply chain requirements, change supplier agreements, change organisational responsibilities

Final considerations

It is evident that an implemented FSMS in a company in the agri-food chain must be seen as a dynamic system, which needs to be frequently analysed, judged, improved, and tailored to the actual and changing situation with respect to the control and assurance activities and the contextual factors affecting the performance of the company's unique FSMS. The FSMS self assessment tool in combination with the FSMS support system (including all relevant tools developed in PathogenCombat, useful guidelines, legislative requirements, scientific knowledge) can be used to search for knowledge, information and tools to analyse, judge, and improve an implemented FSMS.

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