MASTER THESIS
MSC MANAGEMENT OF TECHNOLOGY
FACULTY OF TECHNOLOGY, POLICY AND MANAGEMENT
DELFT UNIVERSITY OF TECHNOLOGY

Building A Safety Management System For Infectious Disease Outbreak Control In the Netherlands

An Exploratory Study

Wei Zhu
4123131

Graduation Committee:

Chairman: Prof. dr. Ben Ale
Section Safety Science Group

First supervisor: Dr. ir. Floor Koornneef
Section Safety Science Group

Second supervisor: Dr. Mark de Bruijne
Section Policy, Organisation, Law & Gaming

External supervisor: Dr. Jim van Steenbergen
Rijksinstituut voor Volksgezondheid en Milieu

[Intended to be left blank]

Abstract

This thesis explores to build a Safety Management System for infectious disease outbreak control in the Netherlands. Q-fever and Salmonella were two major disease outbreaks in the past decade. The outbreak management were criticised for ineffective implementation of control measures, and the magnitude of the outbreaks increased by years. Although they were not as contagious and lethal as pandemics such as SARS, but the well-being of the people were threatened. Moreover, the two outbreaks did not end well: relevant actors had fallen victim to last-minute remedies which cost a large proportion of their properties. RIVM (National Institute of Public Health and Environment) has initiated a project to investigate the past outbreaks, aiming at a clearer understanding of the complexity of the situation back in time during the outbreaks, and calling for strategies for improving the outbreak management system in the country.

The research project started with studying four evaluation reports on Q-fever and Salmonella. Phase I of the research focused on reconstructing chains of events, which led to root causes analysis of unwanted events. Fact reconstruction tool *Event and Conditional Factors Analysis+* (ECFA+) was used to analyse the two cases. Significant events were picked from the resulted ECF chart, and underwent *Cause Change Control Analysis* (3CA), out of which work controls/protective barriers and root causes of the significant events were obtained. Results of ECFA+ and 3CA were revised within the project team with the attendance of an expert from RIVM.

Phase II of the research focused on system building and discussion. A *Risk Management System* (RMS) for outbreak control and a companion *Business Process Model* (BPM) were constructed to address the controls or protective barriers identified in the 3CA analysis. *Organisational Learning* (OL), as an embedded process in a risk management system, was mapped to the RMS, and then barriers to organisational learning were discussed.

After a focus group discussion, recommendations were given in terms of a guideline of gap analysis for the safety management system, as well as how to tackle the barriers to organisational learning in the system for outbreak control.

This exploratory study attempted to combine incidents investigation tools (ECFA+3CA), using abductive reasoning as a base to formulate explanations for the occurrence of unwanted events and to build a safety management system preventing such occurrence. The resulted RMS steps and business process model added systemic perspectives to the infectious disease outbreak control management in the Netherlands.

Keywords: infectious disease, outbreak management, incidents investigation tools, safety management system (SMS), risk management system (RMS), organisational learning (OL).

Acknowledgements

This master thesis project started five months ago and I felt that I was greatly challenged for three reasons: 1) the project has a very limited timeframe of four months; 2) the theories that I was about to apply on the case study and their connections with the social science research methodologies that I learned were very unclear to me in the first two months; 3) all the four important evaluation reports for the case study were in Dutch. Therefore it definitely astounded me at the beginning.

However, people kept coming to my "rescue" when I was faced with each of the above problems.

First, I would like to thank Ms. Assia Yabba from VU who did oral translation of essential information in the Dutch reports, and spent the time together with me doing the ECFA+ and 3CA analysis. Without you the maze-like ECFA charts would have been impossible. Another big "thank you" goes to my first supervisor Floor Koornneef, a dedicated researcher in safety science, spent hours giving me private lectures about safety management system and trained me in the use of ECFA+. Jim van Steenbergen, my external supervisor from RIVM, has the magic to turning long and dry research topics into joyful and intriguing topics for discussion during every project meetings. Also I want to thank you for your time and efforts in gathering experts for the focus group session for the project.

I would like to sincerely thank Mark de Bruijne from POLG section for lending me great assistance in reviewing every little detail concerning methodologies and logic issues in my thesis; and Professor Ben Ale, for the extra insights beyond what I came up and guided me to reflect on the power of the methodologies.

I will also never forget the help from friends that ever supported me. My special thanks to Ms. Ellen Jagtman, my graduation coordinator, without you I could not have gone this far from the first day I was put on this project. And Ms. Hanaa El Hilali, my dear Dutch language teacher, your enthusiasm and invigorating laughter during every Dutch lesson made my reading Dutch reports less tormenting when Ms. Assia was not around!

Last but not the least, I would like to thank the focus group at CIb/RIVM who took hours out of their life to help improve the SMS process model: Aura Timen, Rob Riesmeijer, Mariken van der Lubbe, Marieke Timmer, and Valentina Di Gregori. Thanks to you all for lending me support in the final phase of the project!

Delft, July 2012

Wei Zhu

Contents

Chapter 1 Introduction

1.1 Background Information

Outbreaks of epidemic diseases threaten not only the wellbeing of people, but the productivity of a society. There have been large disease outbreaks around the world, *e.g.* Mad Cow Disease in UK, SARS in China Mainland and Hong Kong. Some of them were successfully controlled while some lasted long enough to damage the competitiveness and economy of the nation. In the Netherlands, Q-fever and Salmonella have been two troubling disease outbreaks in the past decade, and were out of control at their times - control measures were implemented but the magnitude of the outbreak was still out of control. They were not as contagious and lethal as some of the other diseases such as SARS, but the wellbeing and productivity of the infected were nonetheless damaged. Moreover, in the previous two outbreaks, the effectiveness of the control measures has criticised to be limited, and some actors involved had fallen victim to last-minute remedies which cost a large proportion of their properties. RIVM (National Institute of Public Health and Environment) initiated a project to investigate the past outbreaks, aiming at a better understanding of the complexity of the outbreak control management and improvements for outbreak control.

This chapter will give an overview of Q-fever and Salmonella outbreaks and control measures in the Netherlands between 2006 and 2010, as a result of preliminary study of the past evaluation reports prior to the kick-start of the research project.

1.1.1 Q-fever outbreaks in the Netherlands

A zoonosis is an infectious disease that can be transmitted from animals to humans. Q fever is such a disease that is caused by the bacteria Coxiella burnetii, which is common in a wide range of wild and domestic animals. Large human infection outbreaks have been associated with small ruminants such as sheep and goats. The infection could lead to fever, pneumonia, and/or hepatitis. Clinical patients diagnosed by PCR(Polymerase Chain Reaction) are considered as confirmed cases. The first outbreak of Q-fever was notified by a general practitioner from a rural village in the province of Noord-Brabant (Karagiannis, et al., 2007), and it in the Netherlands broke out every year from 2007 to 2009. Each time the outbreak became larger in scale than that of the previous year, and spread to areas farther from rural areas and farms. The majority of notified cases took place between week 18 and 24, while in 2009 the situation was the worst: even after week 33 the number of notifications remained high in every following week until 2010. In 2007 and 2008, the confirmed cases are located in the south of the Netherlands, but in 2009 the incidence of Q fever expanded to almost the whole country (Hoek, et al., 2010).

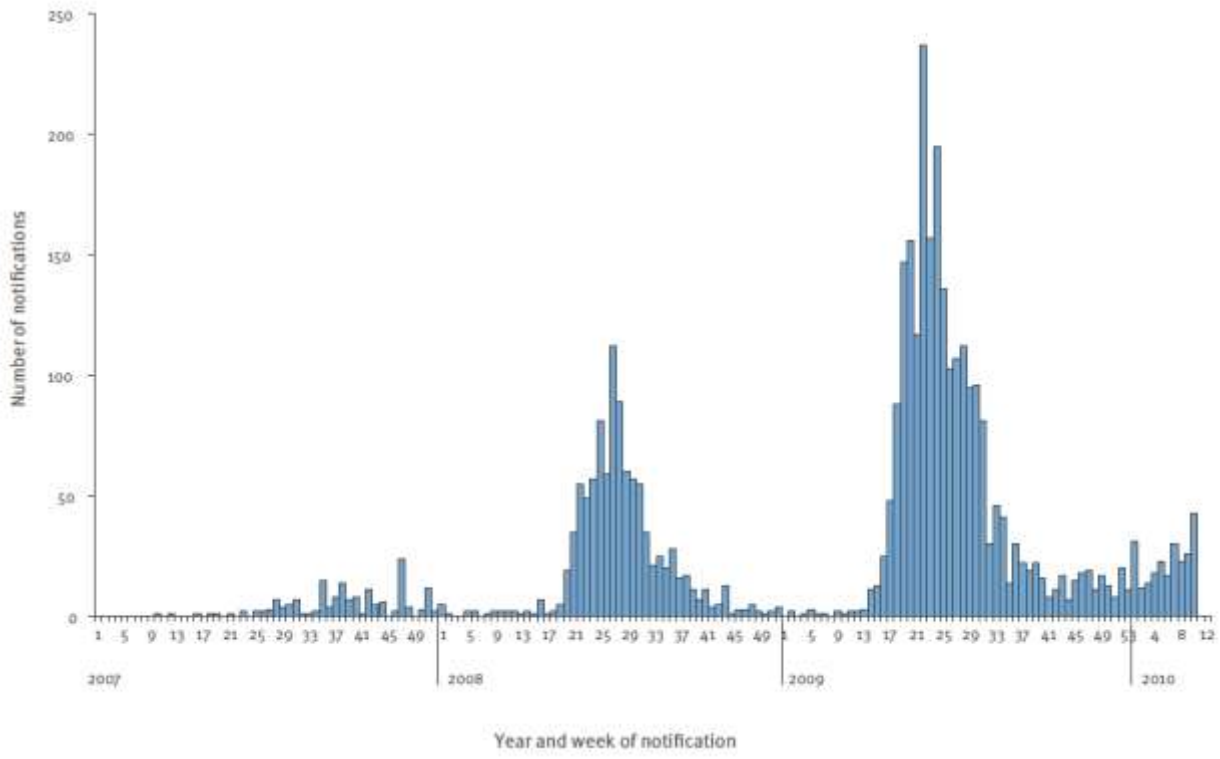


Figure 1.1 Q-fever notifications by year and week (W. van der Hoek 2010)

After the first outbreak in 2007, an informal agreement was made that the veterinary and the public health sectors would exchange information on farms with newly diagnosed animal cases of Q fever, so that faster response and control measure became possible. The larger outbreak in 2008 urged the formation of an outbreak management team, and a mandatory notification scheme was recommended and implemented by the Dutch Ministry of Agriculture and the Ministry of Health. Under this notification system, farmers and veterinarians have to report symptoms compatible with Q fever. Besides, visitors and certain farming activities were restricted in the next three months after the detection of Q fever at the farms (Scimmer, et al., 2008).

From February 2009, a nationwide hygiene protocol for professional dairy goat and sheep farms was announced mandatory. Veterinarians, physicians, and the public were informed through targeted mailings, publications and media. From October 2009, bulk milk monitoring has become mandatory for farms with more than 50 dairy goats or sheep, and PCR test was used to detect if the milk from the farms were positive, so that a notification of Q fever could be made. The result of research showed that humans living within 2-kilometre radius of the farm had a much higher risk of contracting Q fever than those living more than 5 kilometres away. Based on this result, a new policy was made to communicate the risk: when a dairy goat or sheep farm appears positive in Coxiella burnetii test for the first time, all inhabitants living within 5-kilometre radius of the farm will receive a letter informing them of the Q fever-positive farm. But the letter does not give advice, only allows people to make their own decisions (Hoek, et al., 2010). Although all these intensive monitoring and control measures were taken, Q fever still remains to be a major public health problem in the Netherlands, and is expected to remain a significant problem over the coming years.

1.1.2 Salmonella outbreak in the Netherlands

Salmonella Typhimurium is a family of Gram-negative bacteria that can cause gastroenteritis in human. From 2000 to 2005, cases caused by a rare phage type STM DT7 of it were only observed from 0 to 16 per year in the Netherlands. From Jan 2006, the number of cases significantly increased: by the end of the year more than 200 confirmed cases nationwide were confirmed. From July 2006, all cases with S. Typhimurium cultured at regional laboratory were reported to MHS (municipal public health service). MHS also dispatched an information leaflet to all GPs, paediatricians, and child health centres to inform them of the outbreak and requesting specimens for testing of all suspected cases.

It was not until November 14th 2006 when hard farmhouse cheese was confirmed as the source of contamination. At the same time COKZ (Netherlands Controlling Authority for Milk and Milk Products) initiated several control measures, which resulted in the destruction of all cheeses produced between November and April available at the farm or wholesalers. From May all cheeses produced must undergo test for Salmonella before approved for sale; all cheeses with positive test results would be destroyed. Moreover, improvement projects for cheese production were implemented. What is interesting is that from the end of November to Jan 22 2007 the milk for cheese production was pasteurised, after which the use of unpasteurised milk was revived again but under the supervision of COKZ, yet no Salmonella in cheese was observed since then (Duynhoven, et al., 2009).

Yet in 2009 another Salmonella outbreak occurred across the country. This outbreak was lesser in scale (23 cases between October and December), but was caused by eating raw or undercooked beef products as was suggested by epidemiological investigation. However, the result of trace-back investigation was quite limited because of small sample size and a 10-day delay between the onset of illness and laboratory tests. Relevant research concluded that there were no better control measures than promoting consumer awareness of the potential hazard of eating raw or undercooked meat, especially for children who were more vulnerable to the infection (Whelan, et al., 2010).

1.2 Theoretical Relevance

The "safety management system for outbreak control" as the unit of analysis of this paper, as one functional part of healthcare system, contains multiple actors not only from the healthcare system itself, but also from agricultural food production system. In order to avoid the same mistakes which delayed the control activities or mitigated the effectiveness of control measures, the system must have a working process which enables the system to undergo self-improvements overtime. To achieve this, the actors in the system must learn as an organisation - in a sense that it is not enough for each actor to learn their own lessons from past risk events, but such learning must be organised in a way that it is made clear for the organisation 1) what is there to learn, 2) by whom certain lessons should be learned, and 3) that the lessons learned can be retrieved in time when needed. In addition, although learning from operational surprises in a system takes place through people (actors) in it, contextual knowledge in terms of resources and processes within the system must be well understood in the evaluation of the system. In this way, the lessons learned can be translated into goals in new situations and one can give judgment on whether the system is ready, in terms of

people, resources and process in every step of the working process, to realise these goals under risk-based decision making.

Since organisational learning is an embedded process in Risk Management System, which is the core of a Safety Management System, barriers to organisational learning could compromise the effectiveness of a safety management system. Our preliminary studies on the evaluation reports indicated that similar issues concerning the same role in outbreak control, for instance the leading actor, persisted, pinpointing to a possibility that the organisation failed to learn from what had happened before. The incapability to learn from past lessons not only results from a particular actor being the "obstacle" to learning, but also from the lack of a matching procedure to make sure the "operational surprise" reaches those who play the role of a learning agency in the system. Therefore, organisational learning theory will be the other theory to apply in this project.

1.3 Research Questions

Having delineated the research problem, a main research questions was formulated and further decomposed into 6 sub-questions.

Main research question:

How can “the national infectious disease outbreak control system” be improved in such a way that the spread of infectious disease can be more effectively controlled?

To answer the main research question, we will first use sequencing tools in conjunction with root cause analysis to identify possible factors that could have mitigated the control measures in two past disease outbreaks, and then apply theories and principles on Safety Management System and Organisational Learning to reconfigure the network of disease outbreak control in the Netherlands, addressing all the root causes identified in the previous steps. Following this basic framework, we decomposed the main research question into six sub-questions.

Sub-questions:

1. What were the chains of events like during the Q-fever and Salmonella outbreaks? (Chp 2)
2. What are the root causes of the ineffectiveness of the infectious disease outbreak management in the Netherlands? (Chp 3)

Sub-question 1 is meant to guide us to understand the events during the two disease outbreaks in the country; question 2 is answered by performing root cause analysis, aiming to help us understand the situations in the network of actors and to formulate explanations for the mitigated effects of control measures during the two outbreaks.

3. What should a Safety Management System for Outbreak Control manage? (Chp 4)
4. How would a Safety Management System work for disease outbreak control? (Chp 4)

To apply theories and principles on Safety Management System, we will first answer sub-questions 3 and 4 to re-define the network for disease outbreak control in the Netherlands from a systemic

perspective, namely to reconfigure the actors and the working progress intertwined in the network under a Risk Management Model.

5. How are Organizational Learning and Safety Management System related? (Chp 5)
6. How can the system for outbreak control be improved in a way to facilitate outbreak management in future? (Chp 6)

Sub-questions 5 will guide us into the depth of exploring the learning aspects of in the system. By identifying the barriers to organisational learning, we further look into the possible factors that may compromise the system that was built in previous steps, which will finally lead to our recommendations in Chapter 6.

1.4 Theoretical Framework

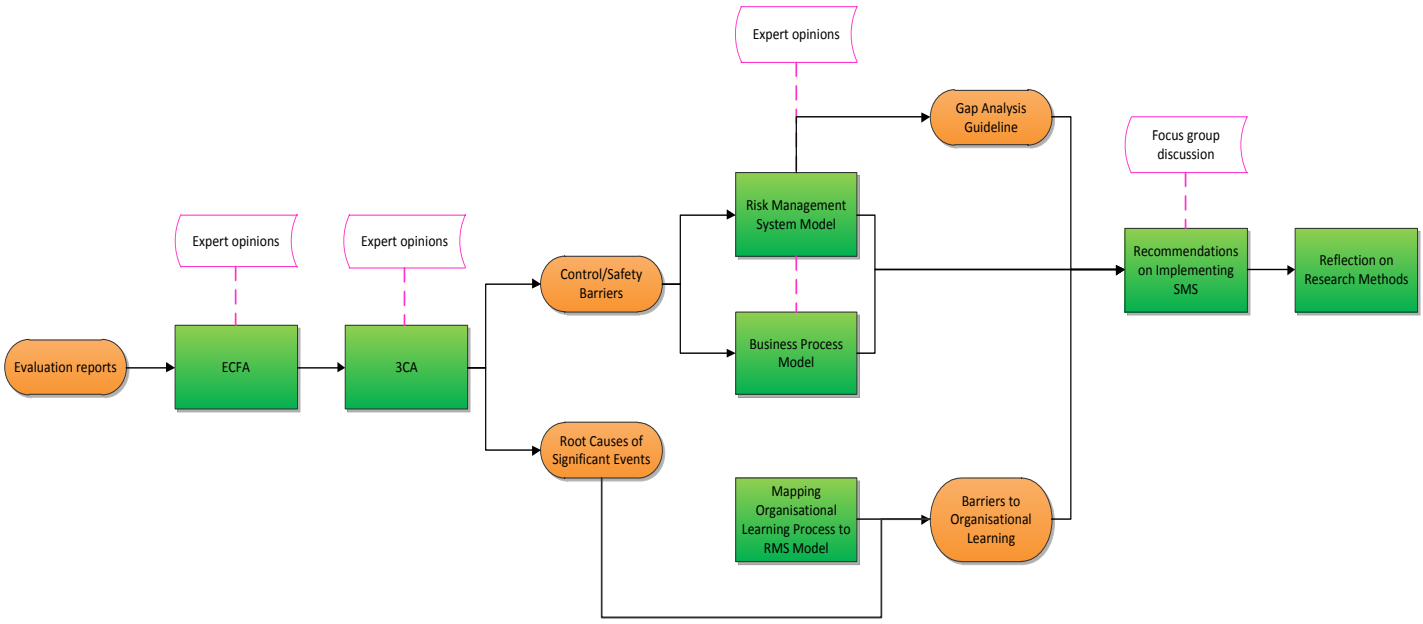


Figure 1.2 Theoretical Framework

The whole research project is based on four evaluation reports on Q-fever (Commissie van Dijk, 2010) (RIVM, 2007) (Jeeninga, Vos, Bon-Martens, & Sande, 2008)and Salmonella (Isken, Roorda, Kok, Kaur, Ouwerkerk, & Stenvers, 2008). Phase I of the research aims to understand the cases, rebuild chains of events, and analyse root causes. Fact reconstruction tool *Event and Conditional Factors Analysis+* (ECFA+) was used to analyse the two cases. Significant events were picked from the resulted ECF chart, and underwent *Cause Change Control Analysis* (3CA), out of which work controls/protective barriers and root causes of the significant events were obtained. Results of ECFA+ and 3CA were revised within the project team with the attendance of an expert from RIVM. This concludes phase I of the research, and research questions (1-3) were answered in the process.

Phase II of the research focuses on system building and discussion. A *Risk Management System* (RMS) for outbreak control and a companion *Business Process Model* (BPM) were constructed to

address the control/safety barriers identified in the 3CA analysis. Functions of the system were described and a guideline for gap analysis was created applying the principles in the ICAO Safety Management Manual. *Organisational Learning* (OL), as an embedded process in a risk management system, was mapped to the RMS, and then barriers to organisational learning were discussed. On the grounds of the mapping from OL to RMS, barriers on the learning aspect of the system are translated into recommendations on improving the safety management system for outbreak control. In phase II remaining research questions (4-6) were answered.

1.5 Investigation Tools

This research is a typical problem-analysing research (Verschuren & Doorewaard, 2010). Specifically, the research aims to identify past and current situation of the national safety management system for outbreak control, delineating with relevant theories in social science, and finally compare with desired situations and give recommendations. The research starts with the investigation of past Q-fever and Salmonella outbreak cases using modelling tool "ECFA+", followed by Root Cause Analysis tool "3CA". The investigation process will be under pre-defined protocols, and the qualitative analysis of root causes will be done by the researchers and discussed in project meetings.

1.4.1 ECFA+

ECFA is short for Events and Conditional Factors Analysis, and was firstly established as a standalone tool for accident investigation by Buys and Clark in 1995 (Buys & Clark, 1995). EFCA serves three main purposes in investigations: (1) To assist the verification of causal chains and event sequences; (2) To provide a structure for integrating investigation findings; (3) To assist communication both during and on completion of the investigation.

ECFA+ is an improved investigation technique prepared by Noordwijk Risk Initiative Foundation (Kingston, Jager, Koornneef, Frei, & Schallier, 2007). The "+" stands for testing rules as in another sequencing tool STEP (Sequential Timed Event Plotting). The aim of applying testing rules is to test the validity of the resulted diagram, making sure that it is a true reconstruction of the some incidental chain of events under the enabling conditions. Rules and principles of ECFA+ are detailed out in the ECFA+ manual and thus will not be repeated here.

1.4.2 3CA

3CA(Control Change Cause Analysis) is an investigation tool developed by Noordwijk Risk Initiative (Kingston, 2002). It is also a method for root cause analysis, and is able to help investigators gain insights and useful findings quickly. The aforementioned ECFA+ focuses on re-establishing sequenced events, while 3CA takes the analysis of root causes further on the basis of the results of ECFA+. The 3CA method digs further into the contextual facts and decision-making procedures, taking cultural and managerial control systems into account. This method also encourages and keeps reminding the investigator not to guide themselves into "counterfactual reasoning", meaning that the investigator tends to over-focus on what an actor did not do so that the reasoning would become biased. Such "preoccupation" can block gaining insights that come directly from what the actors actually did in the past.

In practice, the critical events as well as the conditions accompanying them will be selected through discussions during project meetings. Then 3CA will be used to explain the difference between actual and expected performance regarding the chosen events, specifically focusing on the original logic of the actors acting that way, the existence of "cultural pattern" for actual performance, and what processes in the system could have prevented the expected performance from being the case. From the analysis on the critical events, root causes of the difficult situations in the system under investigation can be identified, and the causes are actually barriers to organisational learning - they could take the form of a barrier that makes an operational surprise not notified, or result in strong resistance to changes due to prevailing norms and values for some actors.

1.6 Safety Management System (SMS)

A Safety Management System is a business management system for the purpose of managing safety elements in an organisation's work process. SMSs have been adopted by several industry sectors, such as aviation (Koornneef, Stewart, & Akselsson, 2010), maritime (IMO, 2002) and railway industry (Canada Department of Justice, 2001). We quote a more general definition of "system" and "safety" by Thomas A. Smith (Smith, 2010):

> "SYSTEM is defined as interdependent components working together in a cooperative manner to accomplish a purpose. SAFETY means to be free from harm when working in a system."

In ICAO Safety Management Manual, an analogy is made between an SMS and a toolbox (ICAO, 2009).

> "An SMS is the toolbox, where the actual tools employed to conduct the two basic safety management processes (hazard identification and safety risk management) are contained and protected. What an SMS does for an organisation is to provide a toolbox that is appropriate, in size and complexity, to the size and complexity of the organisation."

The manual also points out that safety management is not one managerial process within one organisational unit; rather, it covers all of the operational activities in the entire organisation in a continuous, active manner: an SMS is a constant, never-ending operation that aims at maintaining and improving safety levels that are in proportion to the organisation's strategic objectives and supporting core business functions.

In a research project, Floor Koornneef *et al* emphasized that SMS principally consist of a Risk Management System (RMS) and a Safety Assurance process (Koornneef, Stewart, & Akselsson, 2010). The RMS is conceived as an aspect system with functions, actors, supporting processes and connecting data streams. The authors also proposed a RMS embedded with an organisational learning process, which will be introduced in the next sub-chapter.

1.7 Organisational Learning Theory

1.7.1 Organisational Learning

According to Argyris and Schön, organisational learning refers to an organisation acquiring, processing, and storing information content. There are three components in this definition: a learning product (information), a learning process, and a learner. However, organisational learning does not take place itself - it must be organised and implemented to be effective. Also, an organisation learns through people, and learning should be embedded in the organisation rather than some extra operation (Koornneef & Hale, 2004). A single- and double-loop organisational learning model is shown in Figure 3.

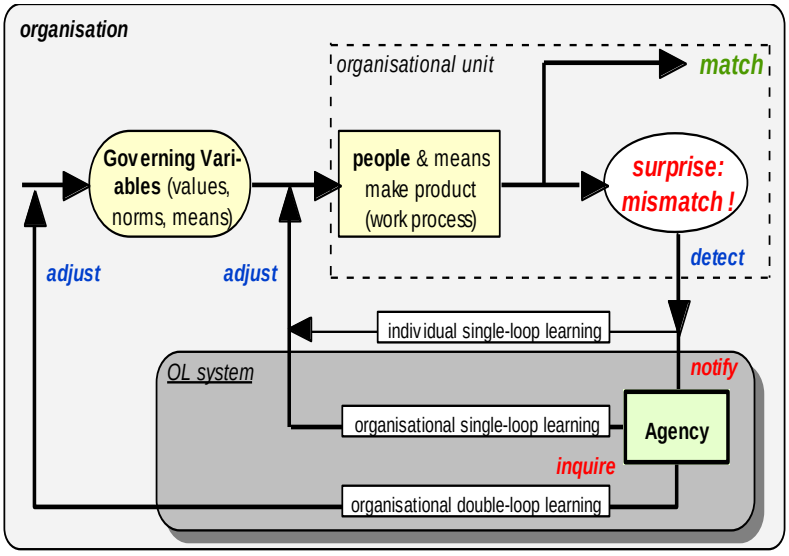


Figure 1.3 Organisational single- and double-loop learning processes (Koornneef & Hale, 2004)

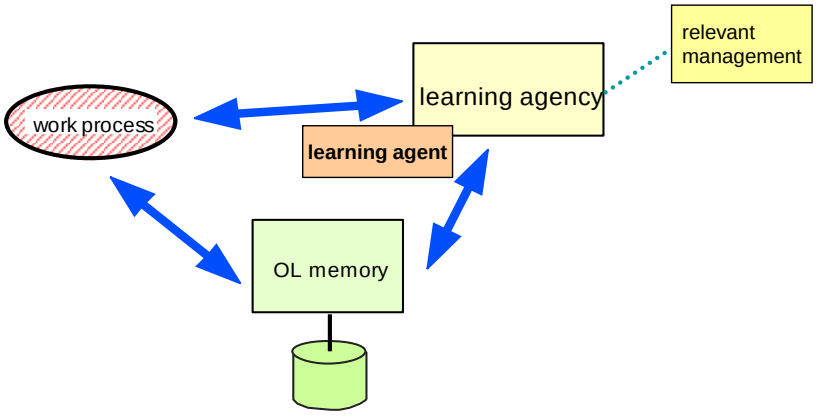


Figure 1.4 Basic model of a system for organizational learning (Koornneef, Hale, & Dijk, 2005)

Theory of action is an important notion in the concept of organisational learning. Floor Koornneef outlined **Theories of action** as existing imperatives, which can be formulated as,

IF intent=consequence **C** in situation **S THEN** do action **A.**

Theories of action take two forms, *espoused theories* and *theories-in-use*. **Espoused theories** are *explicitly* given in operations. **Theories-in-use** are *tacit and implicit*; they are not "given" but play a role in shaping people's behaviours and choices in operations, they are governing variables that people adopt when dealing with threatening problems or situations in organisations.

Within an organisational unit, work process operates under both implicit and explicit "theories of action" in the form of routines, priorities, and actions, the activities and consequences are "known" under this setting. When an operational surprise occurs which is a mismatch compared to the expected outcome, individual learning takes place first (individual single-loop learning). But individual learning will not settle such a mismatch thus organisational learning will not happen, unless a relevant learning agency is notified of this issue. Organisational Single-loop learning is tactical modification of the work process within the span of control of the first line manager, who is advised by a designated learning agency. However, there are occasions when lower tier of management cannot adjust the working process to solve the mismatch. Only with the intervention of governing variables such as norms and values, the "theory-in-use" can be adjusted, new espoused theories are formed, thus the actual outcome will match with what was expected, which signifies that organisational double-loop learning has happened.

Argyris and Schön also proposed Model I and Model II organisational learning associated with two different types of theories-in-use. **Model I theories-in-use** behaviour hinders change and has governing variables such as striving to be in unilateral control, maximising winning and minimise losing, minimising the expression of negative feelings, and being rational. **Model II theories-in-use** welcomes change and emphasize openness and mutual respect, and has governing variables such as free and informed choice, internal commitment to the choice and constant monitoring of its implementation, and being concerned with others. It is recommended that Model I learning should be avoided or shifted towards Model II learning, if productive organisational learning is desired. A mature system for learning from incidents requires an organisation to operate with Model II (Koornneef F., 2000).

1.7.2 Operational Readiness

One crucial approach to organisational learning is to get knowledge on the "operational readiness" (Kingston, Frei, Koornneef, & Schallier, 2007), which is about "creating an organisation that places ***the right people*** in the right places at the right times, working with ***the right hardware*** according to ***the right procedures and management controls***". The operational readiness model (simplified) is illustrated in Figure 1.5.

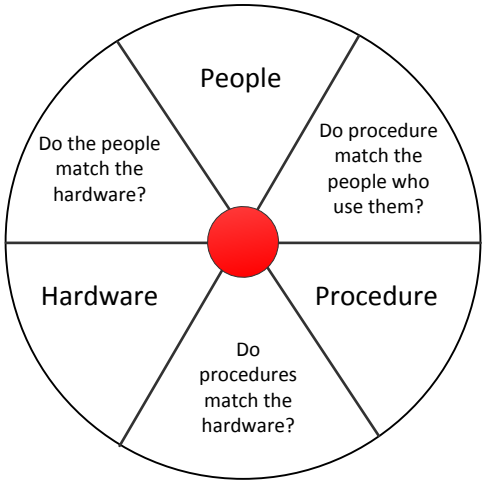


Figure 1.5 Simplified Nertney Wheel

The three elements ***People, Plant, Procedure*** in the model can be adapted to different types of organisations even without a physical plant - the Plant is replaced with "***hardware***" or "***means***", representing the infrastructure and technologies, and Procedure replaced with "***software***", representing the process management of the non-manufacturing system. The model depicts that the intended work process (the "bull's eye") can only by achieved if all the ingredients (people, hardware, software) and the interfaces between them are coordinated and tuned. Also it is noteworthy that each sub-category of the ingredients should be aligned to its "neighbour" sub-categories in order for the organisation to achieve "readiness". Take the second level of the personnel system. If the personnel are not trained properly to evaluate the equipment system or they do not understand the detailed procedures, the three blocks do not align each other on the same level and the "bull's eye" will be off the centre. In this case, the system is said to be not ready and unstable. In the organisational learning process in Figure 1.3, if people, means, work process and their interfaces are not aligned, neither organisational single- nor double-loop learning will be accessible. Note that this operational readiness model is a philosophy behind the system theories (SMS and OL), not a tool used to quantitatively "measure" the alignment of the elements and interfaces.

Chapter 2 Events and Conditional Factors Analysis (ECFA+)

2.1 Research setup

ECFA+ for Q-fever and Salmonella cases in the Netherlands are based on various post-crisis reports, documentaries, and experts meetings. Sources are shown in Figure 2.1 below.

Q-fever outbreak reports	RIVM: Eindrapport evaluatie Q-koortsuitbraak in Noord-Brabant 2007
	GGD: Evaluatie Q-koorts uitbraak 2007 in de GGD-regio Hart voor Brabant
	Commissie van Dijk: Van verwerping tot verheffing – Q-koortsbeleid in Nederland 2005-2010
	Eurosurveillance: Large ongoing Q-fever outbreak in the south of the Netherlands
	Eurosurveillance: Q-fever in the Netherlands: an update on the epidemiology and control measures
Salmonella outbreak reports	Epidemiol. Infect. : A prolonged outbreak of Salmonella Typhimurium infection related to an uncommon vehicle: hard cheese made from raw milk
	RIVM:

Figure 2.1 Sources on which ECFA+ are based

ECFA+ is a team-based iterative process. According to the ECFA+ manual, the team needs to be selected to include the right mix of disciplines and experience relative to the incident to be investigated. We started with a team of two investigators (one in management field and the other in medical field) reading into the evaluation reports. Over a month, weekly meetings were held with an expert in safety science methodology and an expert from RIVM (also the project contact). The ECF chart resulted from the previous round of facts reconstruction is reviewed by both experts during project meetings or on personal basis. During the meetings the event chains were reviewed in terms of both method and logic, queries were checked with or answered by experts, and then the any correction or new information from the discussions were incorporated into the new ECF charts. Such feedback loops took place at least 4 times for each case to have a final ECF charts in this project, until the team feels it is sufficient to move on to root cause analysis.

2.2 Selection criteria for events and causal relations

The amount of qualitative data contained in the original four reports (three for Q-fever and one for Salmonella) is enormous; also there are unclearly narrated events or messages because the reports did not use structured facts sequencing tools during their investigation. As a result, before applying ECFA+ procedures, it is essential to develop criteria for identifying relevant events and conditions, and to make the criteria "take roots" in the investigator's mind before performing the analysis.

Investigators using ECFA+ as a sequencing tool must always be careful about how to select appropriate events that are specific to the incident under study and how to formulate the events based on the linguistic rules prescribed in the ECFA+ manual. However, due to the fact that the actors in the network under investigation are organisations, the "actions" performed by actors may not be as accurate and clear in literal meaning as in more "tangible" accidents such as a train crash

or fire outbreak. For example, a typical description of an event in a chemical leaking accident may be "Operator A smells the chemical" and "Operator A rotates valve 13", the actions of which are concrete and "visualisable" in investigator's mind. Let's take "LNV makes vaccination for goats obligatory" as an example in our case. "To make something obligatory" does not sound as a concrete and visualisable action as in the chemical leaking incident. Nevertheless, "to make" is still a transitive verb, and together with its objects, it still qualifies as an action which contributes to the observed consequences – vaccination as a control measure to become obligatory since the decision was announced. Therefore, apart from the linguistic rules, we think it is necessary to emphasize following rules and criteria we used to select events for facts reconstruction.

1) An "event" must be of very short duration. "GGD does research on Q-fever" does not qualify as an event because "doing a research" as a lasting action will take weeks to months; while "GGD starts doing research on Q-fever" qualifies as an event because "to start" is an immediate action, although it is not tangible.
2) In an "event", the object of has to be able to be affected by the verb, and possible influences shall impact future events. Take the same example in 1). "GGD does research on Q-fever" does not qualify as an event, because the verb "to do" is meaningless and cannot affect the quality, time, or any other properties of the object "research" so as to have an impact on the outcome of the sequence of events. On the other hand, "GGD starts doing research on Q-fever" qualifies, because clearly WHEN and HOW it "starts" doing the research matters and affects the quality, time, *etc*. of the research as well as future decision-making in the outbreak.
3) Conditions that are obvious and presumed to be known to "everyone" are not mentioned. For example. "One responsibility of GGD's is to do research on epidemics" does not need to be mentioned as a condition for "GGD starts doing research on Q-fever".
4) A valid "event" in this study should have an impact on communication among actors OR decision-making process, the two of which directly influences the effectiveness of outbreak control measures. From the past evaluation reports, hundreds of facts can be transcribed into "events" conforming to ECFA+ rules, but only the ones that impact the outcome of outbreak control are our targets for this analysis, which serves as inputs for discussions on the organisational learning and safety management system in subsequent chapters of this thesis. For example, "The director of LNV attends a press release" may not be a valid event for analysis because it does not affect the outcome of outbreak control if the press release elicited no reaction from stakeholders or citizens; it would be only a message in the report. Otherwise, it would become an event for the analysis nonetheless.

The past reports on the outbreak cases were mostly written in chronological order. It is a most common way of presenting facts, but it also leads to an unsorted "mixture" of critical events, relevant but non-contributing messages to evaluative purposes, and disconnection between causal relationships. The investigators must firstly filter the information based on above-mentioned rules and criteria, and grasp three elements, namely the actors, the resources they own, and their working procedures, in order to discuss all the stakeholders involved in the outbreak control further from a systemic view. In this sub-chapter, we will firstly look into the results of our ECFA+,

discuss "what happened" during the outbreaks, and lastly conclude the chapter with insights which serves as a base for root causes analysis in the next chapter.

2.3 Results and discussion

2.3.1 ECFA+ for Q-fever outbreak control

Overview

Data from the three Dutch reports and three English reports cover 3 years (May, 2007-May, 2010). Q-fever was first officially signalled by GGD in June, 2007, when a significant increase in the number of confirmed and probable Q-fever cases was observed. No control measures were taken until June, 2008, before which relevant stakeholders held conferences and discussions while GGD HvB was tasked to investigate Q-fever in terms of case definition, its spread, and possible sources. The events during Q-fever outbreak can be divided into two categories/phases: source tracing (May, 2007 – Sep, 2007) and acting (Jun, 2008 – May, 2010). Corresponding events and relations to be analysed below are marked with reference numbers (K1 – Kn) in red boxes on the ECF chart for quick reference.

Points of interests during Q-fever outbreak: source tracing

1. Delayed discussion and decision-making in response to crisis signals (K1). When GGD reported confirmed Q-fever cases on Jun 11, the number of increased infections in human was already alarming: total cases in week 21 are about four times that of week 20 (both weeks were in May, 2007). Yet no formal meeting that responded to such anomaly was held until Jul 11, which was one month later. It is also interesting to find that on Jun 21 GGD reported hundreds of patients with lung infections (probable Q-fever cases), but it was until about 20 days later a formal meeting organised by LCI/RIVM was held. Whether the warning is a direct cause or condition of the meeting, a meeting of stakeholders to discuss the situation was probably so late as to miss opportunities to generate reacting options. Also in the report by Commissie van Dijk it is mentioned that one aim of the meeting was to encourage cooperation between parties, and this information makes us to doubt that back in 2007 the network of stakeholders in healthcare were ready facing such crisis.
2. After the meeting on Jul 11, crisis level was announced by the mayor to be raised to level 2 (K2). It is not known to us from the data what are the criteria for raising crisis level and what actions for stakeholders should be taken at each crisis level. According to the *Crisis Management Plan for Infectious Disease* (Crisisbestrijdingsplan Infectieziekten) published in 2007, a couple of actions could have been taken at specific crisis level. Yet clearly the plan was not used as documentation with regulating power to decision-makers. Another meeting on Jul 19, which is a follow-up meeting of the one on Jul 11, concluded three points that seemed to have released the tension for the stakeholders: 1) the outbreak was past its peak time given no new patients emerged in the past 3 weeks; 2) how Q-fever impact humans is not clear so it is better to keep quiet; and 3) OMT says Q-fever is curable by treating the subject with antibiotics. What is confusing to an investigator here is that the tension in the situation seemed to be alleviated, but there was no change in the crisis level given the above conclusions. The only active action to be executed after the meeting was an investigation in

the spread, source, etc. of Q-fever by GGD. However, some actors realised that GD giving incomplete information on the outbreak was a problem, yet the decision of the meeting was only to let LNV "commission" GD to provide management information to CIb under privacy, which was proved to be ineffective as can be seen later in the document.

3. After the meeting concluded on Jul 19, GGD received new tasks: to investigate the spread and sources of Q-fever, and to establish new case definitions (K3). It took GGD about two months to conduct the research, and to result in a geographical map which was shown to the OMT. Spending time collecting and analysing data takes time, and what GGD did in the two months was obviously necessary. However, we find how OMT reacted to the new information interesting: after the meeting on Jul 19, OMT and other stakeholders agreed that the epidemic was no longer a threat, and intended to keep silent to the public about the outbreak. But when VWA showed the geographical map as the result of their investigation to OMT in September, a month with few new Q-fever cases (Karagiannis, et al., 2007), OMT concluded that the Q-fever was still a threat. Obviously it would have made more senses if OMT had insisted Q-fever being threatening in July or August, during which there were more new Q-fever patients than in September. We argue that the decisions in point 2 in conjunction with the fact that OMT giving inconsiderate advice caused the delay of all actions for outbreak control as well as the possibilities for improve readiness for future risks.

Points of interests during Q-fever outbreak: control measures

4. It was until December 2007 when the stakeholder began to ponder options to get ready for possible outbreak during the coming lambing season in 2008 (K4). That was also a "confusing" period for the stakeholders involved in the case, because they have to face several uncertainties. First, evidence for Q-fever outbreak being a consequence of abortion waves on the farms in Hart voor Brabant was not concrete. This was to a large extent due to the lack of authorised or enforced monitoring of the suspected farms in the area, as well as the fact that GD did not share information on the whereabouts of infected farms. Second, the Crisis Management Manual for Infectious Disease did not define response scheme if stakeholders outside the healthcare system are involved. In fact, the outbreak of Q-fever was highly suspected to be linked with dairy farms, which dictates the involvement of stakeholders in the agricultural sector is inevitable. Thus these information led us to believe that such uncertainty was one of the reasons why the Ministry of LNV was made the leader of the crisis management network so late, that actions that could have been taken earlier in order for the situation to be understood, such as why the investigation on the cause and effect of animal abortions on the farms and Q-fever were delayed so much. Third, in October when OMT advised to make reporting suspected Q-fever outbreak on farms obligatory, there were contradicting viewpoints concerning whether actions could be taken with partial information. And it was until December when the Ministry of LNV decided to intervene in order to get information from GD. We think that the above three factors had increased the level of uncertainty in the network of the stakeholders involved. We will discuss this further in Chapter 4 in the barrier analysis before 3CA.
5. Advice and preparation of vaccination plans (K5&K6). There are two events worth discussion: the time when OMT suggests vaccination (K5) and the readiness of the vaccines

(K6). Vaccination is a rather commonplace preventive method against infectious disease, regardless of to human or animals. Moreover, the Crisis Management Manual for Infectious Disease Version 1.0 was written in March 2007, much ahead of the date when OMT suggested vaccinating goats and sheep on the farm (the end of July 2008). Plus such vaccination already existed at that time, though available in another European country, which makes the delay of the proposal even a feasibility study of vaccination hard to expect. On the other hand, evidence from discussion with an expert in this project shows that the supply of the vaccines against Q-fever was in shortage before 2009, and it was probably why it could not be enforced on all the farms in the region. However, according to the CvD report and inputs from RIVM experts, the supply of the vaccine became abundant in at most 6 months' time (until Apr 2009). To summarise, the "storyline" of vaccination reflects two issues: 1) Crisis Management Manual was not in much of a position as a reference to make decisions; 2) the resource aspect of a control measure was not thoroughly investigated before it was advised.

6. Delay of all other control measures in 2008 and 2009 (K7). The beginning 3 months of 2008 and 2009 were very similar in terms of the number of Q-fever notification, the rising of proposals and the implementation of outbreak control. Q-fever accompanies the abortion waves during lambing season, which started from late March to April. According to Figure 1.1, there were few cases of Q-fever prior to the lambing season in both years, during which not any other control measures were implemented, except for the enforcement of vaccination in late 2008. In the report by Commissie van Dijk, there is almost no clear description of what the main stakeholders did during the 3 months which would exert influence on major control measures, only sending letters to express opinions on certain possible control measures. Before Oct 2008, when LNV recommended voluntary vaccination, the outbreak of Q-fever had already been quite alarming. What is hard to believe is that when vaccination could not be enforced right away during the outbreak in 2008, other control measures were not considered timely as contingency plan except for the ban on moving manure. Note that there exists a unique economy of manure business in the agriculture sector, so it is fully logical to pay attention to such a profitable farm business as a potential source of hazard that might be overlooked. However, hygienic practices and quarantining are two of the most common control measures for infectious disease. So by intuition it is more logical to think of and implement the warranted measures like disinfection and quarantining first, and then turn to the less common ones like the manure issue. The way the prioritisation of different control measures was handled in 2008 and 2009 was confusing.
7. The last point in the case of Q-fever outbreak concerns a delayed advice on early detection and a possible omission in the implementation of mandatory PCR test (K8). Polymerase Chain Reaction (PCR) is a very responsive technique to identify early infection in samples. It is unknown why PCR was proposed as a possible diagnostic method for early detection. Despite the uncertainty of source back in 2007, 2008 could have been a right time to explore the possibility of accelerating the diagnosis method for case confirmation in the Hart voor Brabant area. Since LNV had taken charge in 2008 and announced mandatory vaccination, the goat and sheep farms in the area must have been confirmed somehow as

the source of infection, at least to the network of stakeholders involved. Therefore, CIb as the main force in OMT could have done research in terms of methods for early detection in 2008, not a year later. However, one possible omission in the policy implementation might have mitigated the expected effect. After the obligatory bulk milk PCR test was announced, unknown number of farms did PCR test abroad secretly and if the samples were positive, the animals from which the samples were taken were hidden away from being tested by the regional PCR programme. There is no statistics on the consequences of this event in the reports we own in our research, but this move of the farms in the area created a new hazard of letting go of Q-fever infected animals.

2.3.2 ECFA+ for Salmonella outbreak control

Overview

The outbreak of Salmonella Typhimurium infection in 2006 was much smaller in scale than the Q-fever outbreak. It is technically different in nature because the infection was not transmitted one another or from animals, but due to the consumption of hard cheese made from raw milk. Therefore the acting stakeholders in this case are also different than the previous case. The facts reconstruction was mainly based on the evaluation report by RIVM. The study of outbreak control of S. Typhimurium infection shows that a lot more time was spent on source tracing in proportion to the time spent on implementing control measures. If the 2nd week of October 2006 was considered as the milestone of the completion of source tracing, then implementing control measures by COKZ on the source farm only took three months as opposed to nine months for source tracing. Corresponding events and relations to be analysed below are marked with reference numbers (S1-Sn) in red boxes on the ECF chart for quick reference.

Points of interest during Salmonella outbreak: source tracing

1. The privacy issue of GD and farms during source tracing (S1). Given the GD's protective manner in the Q-fever case, what interested us first was again GD's reporting behaviours from February to May 2006. In Feb GD was the first to find S. Typhimurium on Farm A, but GD did not report the findings to RIVM. Actually this may not be as surprising as it sounds for two reasons: first, S. Typhimurium infection mostly affect children, in fact, most parents would just let the children stay home and the young patients usually recover overnight; second, S. Typhimurium is a broad name for many variants distinguished by phage types, and it is far from alarming to detect one of the subtypes of the bacteria in manure samples. It is also possible that GD at that time was not informed of the identification of the rare phage type 561 during the 2nd week of Feb. Regardless, GD chose to deliver S. Typhimurium-positive beef sample to RIVM for testing when they discovered the same bacteria the second time in 2006 (E20 in ECFA+). However, after LIS/RIVM confirmed the same phage type in the sample as in the patients and VWA established links from Farm A and the increased number of patients, GD began to show protective attitude towards Farm A – in May GD killed the 4 cows in secrecy after the samples from them were confirmed to be infected with Salmonella, and in November 12 more Salmonella-positive cows were also killed (COKZ was already monitoring Farm A then). Both actions impeded effective source tracing or control measures in the case, although the number of cows killed was not great.

2. The second point of interest concerns the method for analysing samples during source tracing (S2). VWA was one of the acting stakeholders in the Salmonella case. VWA has its own facilities for microbiological research, and it is capable of conducting research in identifying certain microorganisms. However, based on the information we get from the RIVM report, VWA gained negative testing results for five times in occasions when GGD's survey pointed to a suspected source, and three times on Farm A, which had been suspected to be the source farm for eight months (Mar-Oct), until LZO/RIVM intervened and repeated VWA's testing methods to prove the false-negative results on Farm B. Therefore we posted a query concerning VWA: why did VWA not deliver samples to LIS or LZO for parallel testing during its monitoring on Farm A?

Points of interest during Salmonella outbreak: control measures

3. The last point of interest includes two parties: the dairy company (Farm A) and COKZ, the law enforcer and authority for dairy product quality control (S3). Dairy Farm A had an 8-month record of being the suspect of the Salmonella outbreak case. There were multiple evidence pointing the source to Farm A, such as the detection of S. typhimurium ft. 561 by GD and LZO, also the fact that Farm B was a buyer of hard cheese from Farm A made the possibility more evident. Yet Farm A finally quitted the research for two possible reasons: 1) most testing on the farm by VWA showed negative results (even LZO failed once, C20 in the ECFA chart) while only one test by LZO on Aug 2nd 2006 was positive; and 2) After cleaning and disinfecting the cheese factory (E37 in ECFA chart), LZO's test shows negative results. On the other hand, as the national authority of dairy product quality control, COKZ was not called in to investigate Farm A at an earlier date, until Farm A refused to cooperate in the source tracing. This will be further discussed in the barrier and 3CA analysis in Chapter 4.

2.4 Chapter Conclusion

We have obtained Event and Conditional Factors charts from this analysis, which can be found in Appendix II at the end of the thesis. We also selected and presented in total 11 "points of interests" in the analysis, which were marked in the ECFA charts and which will go further into root cause analysis in the next chapter. These points of interests are summarised in Figure 2.2 below.

ECFA ref.	Event chain summary	Reason to be chosen as 3CA candidate events
K1	Formal meeting of stakeholders were late.	Stakeholders supposed to be in a sensory network of hazard detection should be proactive. Delayed communications before and during an outbreak is undesirable.
K2	OMT gave late advice and the advice was inconsistent with the changes in crisis level.	Documentation in crisis management is not clear; OMT did not seem to be functional as it should be at that time.
K3	OMT gave late advice because evidence showed up late.	The fact that OMT's advice and judgement on the situation was inconsistent with the real situation in terms of number of patients.
K4	Disagreement on source of infection; Lack of contingency plan; Obligatory case reporting was pending.	Uncertainties could come from the infection itself or lack of documentation on accountabilities or responsibilities. The latter suggests a systemic approach in outbreak management is missing.

K5	Vaccination was not considered earlier as a most common control measure.	OMT's role was to give advice on control measures, but was there a procedure that regulates OMT to give advice in time?
K6	Supply of vaccines was not enough until LNV wanted to make it obligatory.	A resource scarcity problem when implementing control measures.
K7	Other control measures came in late as advice given by OMT.	OMT's role was to give advice on control measures, but was there a procedure that regulates OMT to give in-time, concrete and feasible advice?
K8	PCR test as an early detection method was investigated not at an earlier time.	Testing methods that were already proven was not considered as a tool for early detection.
S1	GD chose not to report earlier findings of S. Typhimurium to RIVM.	GD as one important actor in the sensory network in case of zoonosis chose not to communicate hazards.
S2	VWA applied wrong testing method during source tracing.	Hazard investigation requires the right technical knowledge. False-negatives due to technical error make the hazards undetected and remain.
S3	COKZ was called in not earlier in the source-tracing.	Why not the right acting stakeholder at the right time?

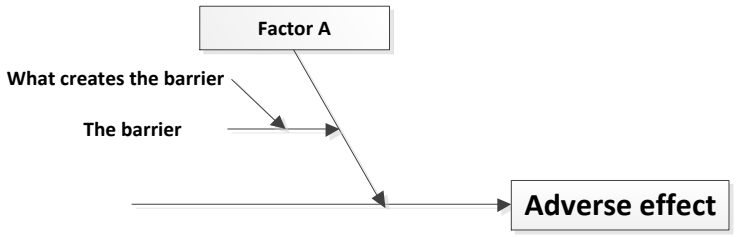
Figure 2.2 Summary of ECFA+ results

Chapter 3 Control Change Cause Analysis (3CA)

3.1 Research Setup and Key Concepts

3CA is also a team-based, iterative process. We used the ECF charts which were revised according to extra evidence from literature or experts at least 4 times to choose the 11 "points of interests" which were believed to have a greater impact on the results of outbreak control. The selection of these significant events were totally qualitative and highly subjective, based on discussions among the project team and expert opinions. After at least 4 rounds of iterations, we have resulted 3CA form-A in Appendix III at the end of thesis. Before we dig into discussions, we will first clarify several key concepts we used in 3CA form-A setup.

1. "Change"
   A significant event chosen from ECFA+ is an event that was supposed to happen in another way, with a different quantifiable attributes, or at a different magnitude. The difference between the actual and expected events is called a "change" in 3CA form-A language.
2. "Adverse effect of change"
   Adverse effect of change is the consequences that change has resulted in. This is discussed between analysts and reviewed by experts outside the team.
3. "Barriers"
   The term "barriers" in 3CA language is emphasized as "implicated", meaning that investigators should "nominate any control or barrier that they think may have been relied upon or that could have been useful". It requires brainstorming and revision by external experts to increase validity.
4. Root causes shown in fishbone diagram



Before root causes are discussed, barriers are identified in 3CA form-A columns (1-4). The barriers and what result in the barriers are shown at the ends in the fishbone diagram. Then such barrier was attributed to a certain factor chosen from *organisational, cultural, managerial, administrative and legal* as a label, then the factor and why the barrier was attributed to this particular factor was presented as the root causes of such an adverse effect on outbreak management. The root cause analysis, in 3CA form-A columns (6-8), was also revised by experts outside the team for several rounds and then finalised in the thesis.

3.2 Results and Discussion

3.2.1 3CA for Q-fever outbreak control

Critical Events (CE) and Barrier Analysis

CE1 Farmers do PCR tests abroad in secrecy (E29)

On Oct 10th 2009, LNV announced new mandatory PCR test for bulk milk. After this announcement, unknown number of farmers did PCR tests for their animals (goats and sheep) abroad. The animals showed positive results were hidden from the official PCR test in the infected area. The subject of the official PCR test was the bulk milk tanked on the dairy farm. It is unknown what actions were taken to the farms if its milk fails the test, yet a most possible assumption is that the suspected farm will suffer from economic losses from either the sales even destruction of the milk, or evacuation of the animals. By hiding the infected animals would make detecting the exact number of infected animals impossible. We propose three barriers implied in this change.

1. The farm-owners' decision - to do the PCR tests for their own animals with a third-party institution.
2. Supervision from LNV, the enforcer of this new regulation, which was not comprehensive as such to ensure all the animals could be found should the bulk milk failed the test.
3. International regulation during time of crisis, which was incomplete at that time.

CE2 GD reveals partial postcode of the infected area (E4)

The outbreak of Q-fever in Netherlands originated from dairy goats and sheep, and GD was the one who knew about the whereabouts of the infected farms in Hart voor Brabant area. There were already hundreds of patients with lung infections in Jun, and GD attended the first meeting on July 11 so they should have known the possible connection between the outbreak among humans and the infection on the farms. Therefore it is apparent that GD decided not share the information on farms after one week, reporting with 2 digits of the postcodes of the farms only. There are two possible barriers implied.

4. Obligation of providing relevant information about potential hazards during time of crisis.
5. Financial or other forms of compensation for stakeholders at disadvantageous position.

CE3 OMT gives vague advice on hygiene protocols (C34)

The advice on hygiene protocols from the OMT was vague. We give two arguments for this event as a critical one: 1) OMT was composed of experts and specialists from epidemiology and microbiology, led by CIb/RIVM with four laboratories specialised in infectious disease control, so "investigating the hygiene status on the farms" does not sound like expert opinion with professionalism and it lacks details as for the decision-maker (LNV) to consider as a plausible measure. 2) In fact, hygienic practice issue is commonly known as first priority no matter in food industry or microbiology and epidemiology. It is surprising that the hygiene protocol was not brought up in 2007; even when the supply of the vaccines was not abundant in Oct 2008, there was no concrete action on the improvement of hygiene protocol on farms. We found three possible barriers in this critical change.

6. Obligation of OMT as the crisis management team to give considerate and concrete advice which is subject to evaluation and criticism.
7. Guidelines that regulate what aspects of a hazardous factor or scenario the OMT must give advice to.
8. Supervision of "risk-bearing areas" on the dairy farms, which leads to incomprehensive consideration in the time of crisis.

CE4 OMT gives late advice on control measures (C19, C32, C34, E24)

At least four advices on control measures from OMT were arguably late. 1) Vaccination was firstly advised on July 30, 2008. The cost of buying large quantities of vaccines could have been much lower, and also the slack time of producing the vaccines could have been during 2007 or 2008 before the regulation could be enacted. 2) The first time when the hygienic status was suggested as a problem was July 31, 2008, which was not only one year later than the outbreak occurred, but the real action taken upon this suggestion was four months later. 3) The quarantine of the animals was proposed by OMT on May 11, 2009. Similar to hygienic issue, quarantining suspected subjects, humans or animals, is one of the most common control measure, yet it was proposed two years later when the situation almost lost control. 4) PCR as one newer but warranted method for early detection of infectious disease should have been proposed and researched for specifications for the Q-fever case. The barriers for this change are:

9. Guidelines that regulate the OMT to exhaust options for infectious disease control.
10. Supervision within or from outside OMT to coordinate advices from OMT and the implementation by decision-makers.

CE5 OMT gives inconsistent information (E10, C11)

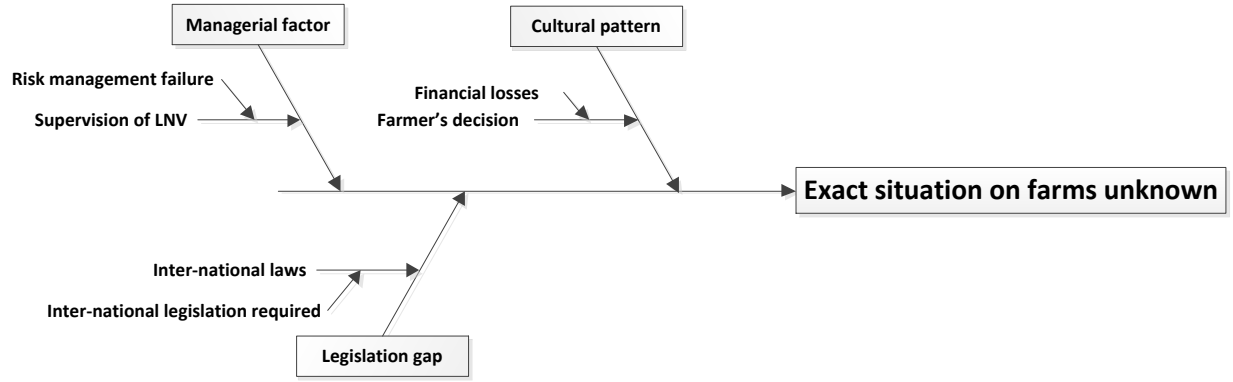
On Jul 19, 2007, OMT was formed during the second meeting organised by LCI/RIVM. As one conclusion of the meeting, OMT stated that Q-fever was rare and were curable, while two month later seeing the geographical map made by GGD OMT concluded that Q-fever was still a threat. OMT is the crisis management team and consists of experts from four laboratories under RIVM. It is unclear to us as investigators whether there should have been another announcement about the decrease of crisis level, but the changing opinions of OMT during the two months are probably "mixed information" to all the stakeholders: there were fewer patients in September than in July, but OMT gave a late signal that the Q-fever was still a threat, and was then tasked to investigate further. The barrier for this change is:

11. Supervision within or from outside OMT to check the validity and logic of arguments, conclusion, and advice as information given to other stakeholders.

Root Cause Analysis

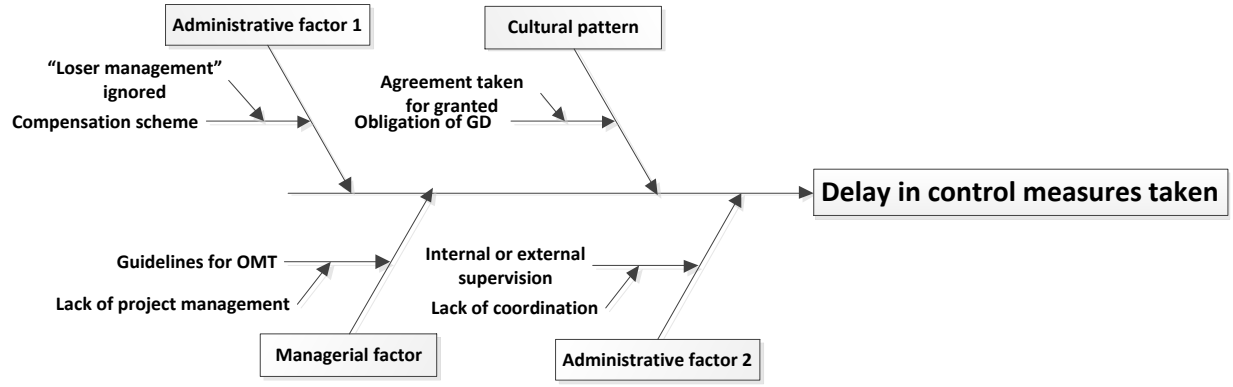
Twelve root causes are formulated using Form A of 3CA analysis. The 3CA chart can be found in Appendix III to this thesis. Column (7) in the chart contains the 12 root causes. In this sub-chapter we will present and discuss the root causes in "fishbone" diagrams.

Adverse Effect 1: Exact situation on infected farms unknown



As private business entities, it is the farmer's "natural instinct" to avoid financial losses by any means possible. And because of this norm, farmers tend to "keep to themselves" rather than "make noises" about matters that may harm their interests. If the farmers did not hide the infected animals, once the bulk milk on their farms turned out to be positive in PCR test, there would have been control measures taken against their animals – economic losses would have been inevitable in 2009. This is identified as the possible cultural pattern in this change. On the managerial aspect, LNV was not experienced in such zoonosis outbreak management before; also they did not foresee the deceptive act of farmers in advance. This is a risk that LNV as a "manager" in the network should manage beforehand, and we pinpoint this as a failure of risk management so that the effectiveness of the monitoring the situation was compromised. Last but not the least, there was a "grey area" in EU laws that allowed such hazardous action to be performed, and the institution who conducted the tests for farmers were not held responsible. This is identified as a legislation gap on international scale.

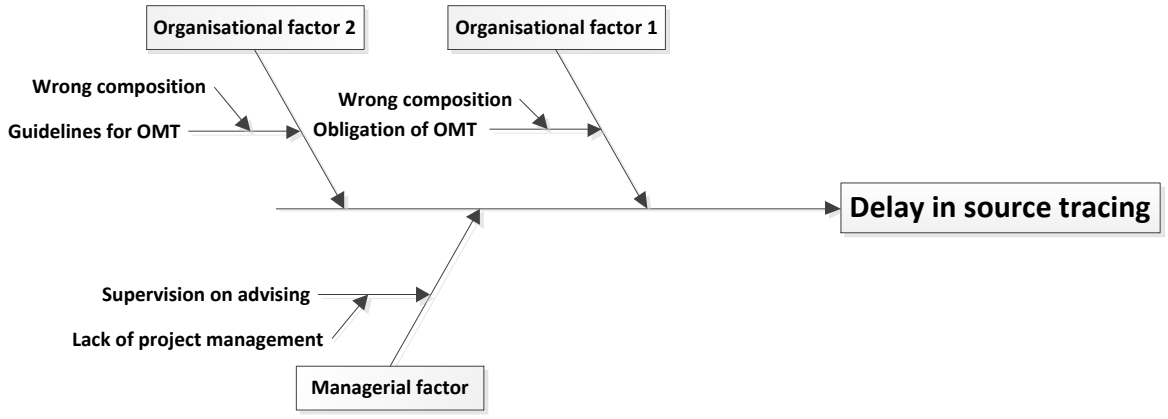
Adverse Effect 2



This adverse effect was attributed to two critical events: the protective behaviour of GD and the late advices given by OMT. The cultural pattern is this diagram refers to the belief in GD that they would share information and report to the government as is described on GD's website – it was apparently taken for granted that GD would cooperate. There were two administrative factors concerning supervision. First, as far as process management is concerned, in other words, the management of decision-making process, there are winners who gain power or fortune as well as

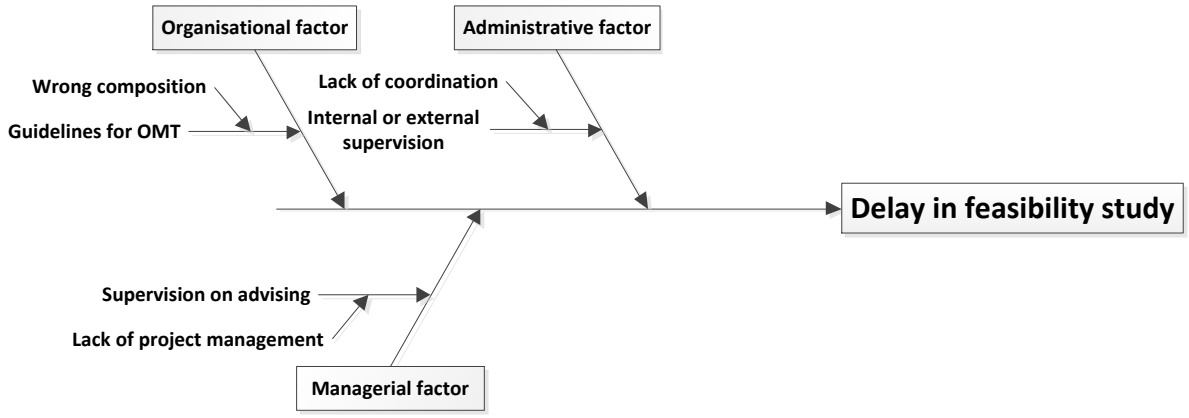
losers who lose powers or fortune. If no compensation schemes are planed beforehand, potential losers may exit the decision-making rounds and refuse to cooperate in future. We argue that GD chose not to share complete information not only for the sake of privacy of farmers, but also for the purpose of protecting their own network with the farmers as their only clients. The second administrative factor is about OMT. OMT, led by CIb/RIVM, gives advice on control measures as one actor in the network. However, there was no internal or external coordinator to help coordinating advices from the expert team and the implementation by the leader. Besides, the lack of project management is probably the fourth root cause of the delay. Preliminary and feasibility study must be planned using project management approach in every nationwide event. Without the feasibility of control measures being researched, source tracing and investigation could be either late to start or late to conclude.

Adverse Effect 3



Microorganisms could be transmitted via many channels, and this has made the source tracing of infectious disease always a difficult and time-consuming step. One root cause of this delay lies in the composition of the OMT – it is a consortium of technical experts, specialists, and four laboratories. As researchers, conflicts in opinions are completely normal because of the different backgrounds and field of expertise. OMT requires a coordinator team or management team composed of representatives on the policy-makers' team, so that the validity and constructivity of OMT can be evaluated against guidelines specially made for them. Similarly, another root cause is the lack of a project approach to regulate and manage effective feasibility study of any advice given by OMT. This will be further discussed in the next adverse effect. As for hygiene practices on the dairy farms, it is normally considered as the first priority when investigating sources of infection. The late advice on such an obvious candidate cause is most likely due to lack of supervision from a project management, defining what, how, when, where and why for this advice to be heard by LNV.

Adverse Effect 4



Every control measure against hazards in an infectious disease outbreak would definitely cost money to assess and then implement. Assessment of control measures are essential and should be treated as manageable sub-projects, which has to be managed in terms of breakdown of works, budget control, quality control, success criteria, etc. in order to give constructive advices in time, on budget, and within scope. Without supervision, it is hard to get consistent expert opinions which the policy-makers rely on. The rest two factors, organisational factor and administrative factor, have already been discussed in adverse effect 2 and 3.

3.2.2 3CA for Salmonella outbreak control

Critical Events and Barrier Analysis

CE6 GD reveals information too late (E18, E20)

Feb 23, 2006 was the first record of finding Salmonella Typhimurium in RIVM's report. It is unknown (although unlikely) if GD knew how about the phage type of the bacteria, but the fact that GD chose not to report their findings on Farm A drove away the opportunity of linking the presence of Salmonella on farms to the evidence from earlier notifications in January. This is similar to the protective behaviour of GD's in the Q-fever case 2007. We think the barrier is:

1. Obligation to notify relevant stakeholders during crisis.

CE7 VWA calls in COKZ too late (E43)

COKZ has been the official authority in charge of regulating the production of all dairy products in the Netherlands; also it could act on behalf of the government in setting criteria for quality control in the dairy industry. According to the RIVM report, COKZ was called in to join the research in Oct 2006, which was about seven months later since dairy Farm A became a suspect in the outbreak case. Seven months was a shocking number compared to the nine months waiting time from the start (in Feb) to the implementation (in Nov) of control measures as soon as COKZ kicked in. A possible barrier in this change could be:

2. Knowledge on the network of stakeholders to VWA decision-makers, which was incomplete or forgotten during the time of crisis.

CE8 VWA tests samples with faulty method (E25, E17, E14, E11)

VWA and LZO have two different experimental settings to test the cheese samples: they used different quantities of samples (5 times' difference) in their own testing methods. VWA used 25 grams of cheese sample in their tests, but LZO used 5 times as much in their tests. It is obvious that the difference in the quantity of the samples dictates the concentration of bacteria cells in the sample, which further affects the sensitivity of the experiments. We speculate that the sensitivity issue could be a reason why VWA got negative test results in most cases. Testing bacteria in food is not only dictated by the quantity of the sample, but by the number of parallel experiments. According to the European Commission Regulation 2073/2005 (valid from Jan 2006), for cheese, butter, and cream made from raw milk, 25 grams of 5 samples should be tested, and none should be positive for the samples to pass the test (Duynhoven, et al., 2009). VWA did not conform to this rule either. The barriers for this change are:

3. Professionalism of experimenters in acting stakeholders.
4. Knowledge on technical standards for identifying hazards, which was unfamiliar to the acting stakeholder.

CE9 VWA decides not to act on Farm A (E25)

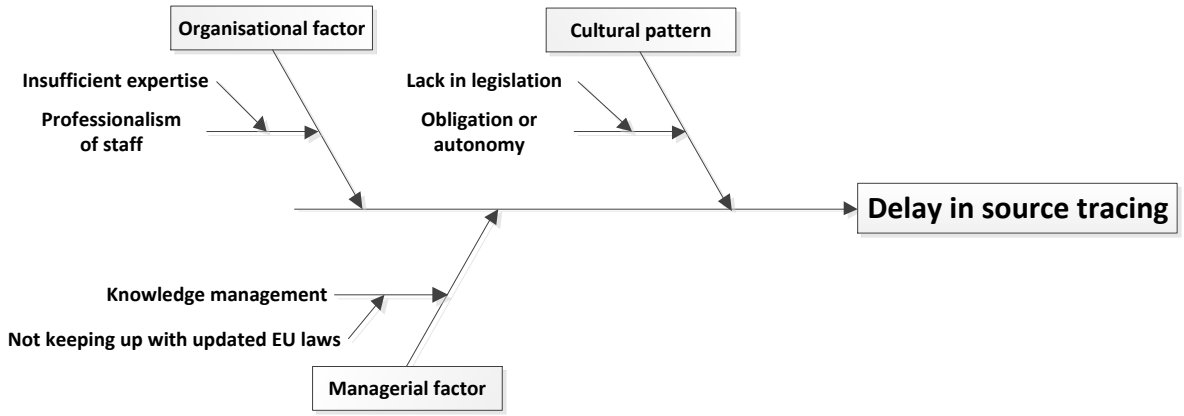
The first time when Farm A was put on the suspect list during source tracing was in the first week of April 2006. VWA's tests on the samples taken from the farm turned out to be negative. But VWA decided not to take control measures on Farm A. According to EU law, authorities should take precaution against food security and infectious disease outbreaks even though solid proof is lacking. Thus the barrier for this change would be:

5. Knowledge on relevant EU laws to VWA decision-makers during and before crisis.

Root Cause Analysis

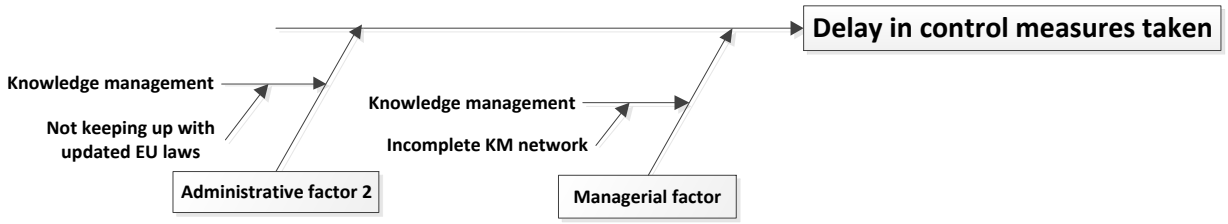
Twelve root causes are formulated using Form A of 3CA analysis. The 3CA chart can be found in Appendix III to this thesis. Column (7) in the chart contains the 12 root causes. In this sub-chapter we will present and discuss the root causes in "fishbone" diagrams, describing how our judgments are justified.

Adverse Effect 1



In the case of Salmonella outbreak, source tracing was the major problematic area. GD's issue was the same cultural pattern as in the Q-fever case. We want to add that GD's issue was a persistent one since the Salmonella outbreak happened before Q-fever. But however, the continuity of the same problem to the next case in a row suggests a learning issue, which will be discussed in Chapter 7 with more details. A notable cause of the delay in source tracing is the professionalism of the staff on the research team of VWA. As the authority in food and consumer sector, VWA really should not have ignored the sensitivity of experiments, and also on the other hand should be held responsible for not keeping up with newly enforced EU laws as the one in charge.

Adverse Effect 2



The root causes here are two-fold but both attributed to issues in the knowledge management practices of VWA. First, there were early opportunities for VWA to take control measures on Farm A, but VWA chose not to act. We assume that VWA was not aware of the precautionary principle, which is part of EU laws. Additionally, owing to the fact that no evidence in the reports could prove that VWA involved COKZ in one of the meeting until October, we hypothesized that VWA did not take COKZ into consideration until every attempt to prove Farm A being the source farm failed in vain (Farm A eventually refused to cooperate with either LZO or VWA). A possible explanation to this is that VWA emphasized internal knowledge sharing, communication and exchange of opinions, but ignored those from external sources.

3.5 Chapter Conclusion

In this chapter we have identified the barriers that are implicated in the significant events during the two outbreak cases, and then analysed the root causes of the adverse effects that the significant events had on the outbreak management. Figure 3.1 below summarises the various factors labelling the root causes, which will serve as the bases on which a process model for a risk management system will be built in Chapter 4. Also the table below indicates which work control barriers could be explained by the root causes and under the influence of factors.

Factors	Root causes of adverse effects	Barriers # in 3CA
Organisational factors	Wrong composition of OMT, Insufficient personnel with technical expertise	6, 7; 14
Cultural factors	Fear of financial losses, Agreement between actors taken for granted	1; 12

Administrative factors	Lack of "Loser management", Lack of coordination among actors, Not keeping up with EU laws updates	5; 13; 15, 16
Managerial factors	Risk management failure, Project management failure, incomplete knowledge management network	2, 8, 9; 10, 11; 13
Legislation related factors	Inter-national legislation gap, Lack of or late legal actions	3; 4

Figure 3.1 Summary of root causes of adverse effects

Chapter 4 Safety Management System for Outbreak Control

4.1 Introduction to SMS

Our investigation into the Q-fever and Salmonella cases pinpoints barriers to the success of control measures, which implies the working processes in the network still have difficulties dealing with nationwide disease outbreak. According to the actor network shown in Appendix I, it is merely a "network" with links between the stakeholders with regard to communication, and sometimes such links can be rather weak according to our 3CA conclusions. Such instable and ambiguous relationships in the actor network do not facilitate investigation of hazardous sources or decision-making in crisis management as can be inferred from van Dijk report on Q-fever and RIVM report on Salmonella. In this chapter, following the practice of applying safety management in other industries, we will attempt to apply its principles on the network under investigation in this project, and to define a safety management system for infectious disease outbreak control by illustrating a system model and a corresponding business process model.

A safety management framework consists of twelve elements (ICAO, 2009) which are categorised into four building blocks:

1. Safety policy and objectives
   1.1 Management commitment and responsibility
   1.2 Safety accountabilities
   1.3 Appointment of key safety personnel
   1.4 Coordination of emergency response planning
   1.5 SMS documentation
2. Safety risk management
   2.1 Hazard identification
   2.2 Safety risk assessment and mitigation
3. Safety Assurance
   3.1 Safety performance monitoring and measurement
   3.2 Change management
   3.3 Continuous improvement of the SMS
4. Safety Promotion
   4.1 Training and education
   4.2 Safety communication

There exists no such a structured SMS for outbreak control in the Netherlands, but according to the fact re-construction and root cause analysis, we can see that certain activities required for SMS functions already existed, so some basic functions of a safety management system have already been at work in some organisations. Safety Management System consists of Safety Risk Management System and Safety Assurance Process. Risk management system is the core of a safety management system. Our study in this project is explorative, thus integrating safety assurance process into an SMS is not within the scope of this research project. So in this chapter we shall define an RMS for infectious disease outbreak control in the Netherlands in terms of purpose, functions, boundaries and interfaces, as a blueprint of the safety management system.

4.2 System Description

According to ICAO Safety Management Manual, an SMS is characterised by three features: *systematic, proactive, and explicit* (ICAO, 2009). An SMS is *systematic* because safety management practices are pre-determined and should be applied throughout the organisation (throughout the network of organisations as defined in our case). An SMS is also proactive because the hazard identification and safety risk control and mitigation must be planned before an outbreak actually happens. An SMS is explicit because all the safety management activities are documented and accessible to anyone in the organisation(s). Writing a *system description* is the first step for the development of an SMS. Before the risk management model is built, we will describe the system in terms of purpose, functions, boundaries and interfaces.

4.2.1 The purpose of the system

Fending off the threat of incoming infectious disease outbreak cannot be executed well unless the stakeholders with their resources are coordinated in such a status that the control measures are implemented in a way to minimise losses. Therefore the safety management system for infectious disease outbreak control aims to facilitate the prevention of infectious disease or minimising the loss suffered from undesirable hazardous scenarios during any epidemic through continuous improvements made to the system itself.

4.2.2 The system's functions

Based on the information about what was done during the two outbreaks described in the evaluation reports, an SMS for infectious disease outbreak control should include **six core functions** in order to tackle the practice of outbreak control:

1) Detection of hazards. Herein hazards refer to sources of an infection, such as patients, animals, harmful microorganisms and their possible transmission routes, all of which could directly lead to a disease outbreak if not controlled with certain measures. The hazards discussed here are "technical" source of the outbreak, which are identifiable by diagnostic methods. Figure 4.1 is a list of normal categories of hazards that the system could confront or generate from within.

Examples of hazards
- Patients (local, international) - Infected animals (wild, domestic) - Infected produce (food, plants) - Specific microorganisms (bacteria, virus that cause infectious disease) - Transmission of harmful microorganisms (food, airborne, body contacting) - Unrecognised infection source such as medical staff that work with patients
Detection: hospital diagnosis, health surveillance projects, veterinarians, etc.

Figure 4.1 Typical hazards that would result in outbreak

2) Notification of hazards. The above-mentioned hazards must be communicated within the shortest time possible to a designated stakeholder in the system network in order for all other corresponding stakeholders to act or to be coordinated accordingly.
3) Investigation of the risk event and possible causes. This function of SMS deals with safety risk assessment and the outcome is used to generate risk mitigation options. Tools for

investigations into the hazards incorporate not only the use of technical methods such as epidemiological research and statistics tools for *risk assessment*, but also the use of formal investigation methodology such as event and conditional factors diagrams, barrier analysis, and root cause analysis for uncovering *operational failure*.

4) Implementation of control measures to mitigate the hazards. This function refers to decision-making stage in the risk management process; also change management is required should certain system factors impede the implementation of the selected control measures. The latter is further elaborated as to intervene in the existing working process in order to remove the systemic barriers which reduce the effectiveness of control measures.
5) Monitoring of the implemented control measures as well as the system functionalities. The SMS should also have a function of monitoring the implemented controls, making sure the corresponding stakeholders are actually carrying out the plan as stipulated. The monitoring function also tries to discover "resilient" or newly emerged hazards and to generate continuous safety data. A higher level function of monitoring is to adjust the configuration of the SMS so as to maintain operational readiness. In other words, the monitoring function also provides feedback to high-level safety policies and objectives, so that they can be adjusted in time to be in line with the changing system and its environment.
6) Evaluation of outbreak management. This function of the system aims to evaluate the working process, control measures taken, and the implementations during the outbreak, giving every stakeholder both feedback, especially feedback that are specific to that stakeholder, so as to improve the preparedness of the system against future threats.

4.2.3 The system's boundaries and interfaces

The source of infectious disease could stem from infected food, animals, or patients, thus the proposed SMS for infectious disease outbreak control includes various stakeholders that belong to four different sectors as indicated in Figure 4.2. For a reference to detailed description of responsibilities, see Appendix I.

Research organisations (GGD, RIVM, and hospital laboratories) are actors that are tasked with identifying and communicate the hazards to different stakeholders in the system. They will have to work with other actors, for example, GD in case of infections on farms, hospitals for wider pandemics, to update and communicate the safety data in the system. Also these research organisations are responsible for contacting and advising the ministries and authorities for possible control measures, which are then coordinated and implemented by these national legislators. The ministries and authorities not only intervene when proposals from learning organisations are presented, but they also appoint members to the outbreak management team (OMT), which are composed of mainly researchers and specialists from the research organisations and others depending on the situation. Last but not the least, the boundaries of the system goes beyond national level in case external stakeholders can affect the effectiveness of outbreak control: in case of an international outbreak, the connections between the national SMS and research institutions, governments, and specially WHO would come to the surface.

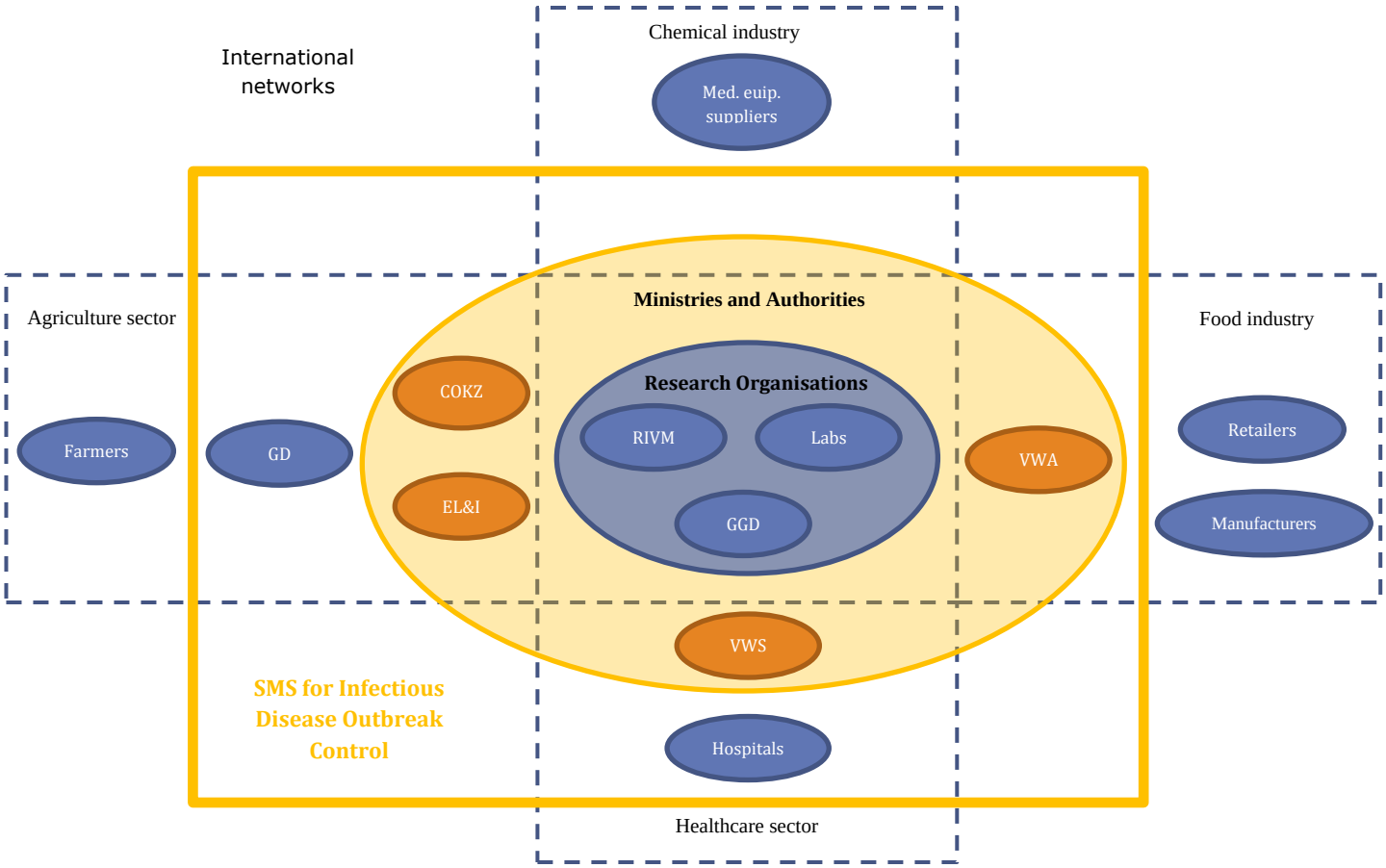


Figure 4.2 Organisations in the safety management system for infectious disease outbreak control

The links between the organisations in the system are less strong in the "normal mode", a status in which the system is not threatened by infectious disease, but at least maintaining good communication, timely feedback, and information sharing throughout the layers in the system. In the next sub-chapter the different system modes will be elaborated.

4.3 Risk Management System (RMS) and Business Process Model (BPM)

After describing the functions and boundaries of the system, we propose an RMS for infectious disease outbreak control, and allocate responsible stakeholders to each function in the model as shown in Figure 4.3. This RMS was inspired by the SIRA RMS in the HILAS project (Koornneef, Stewart, & Akselsson, 2010), and adapted to the context of infectious disease outbreak control.

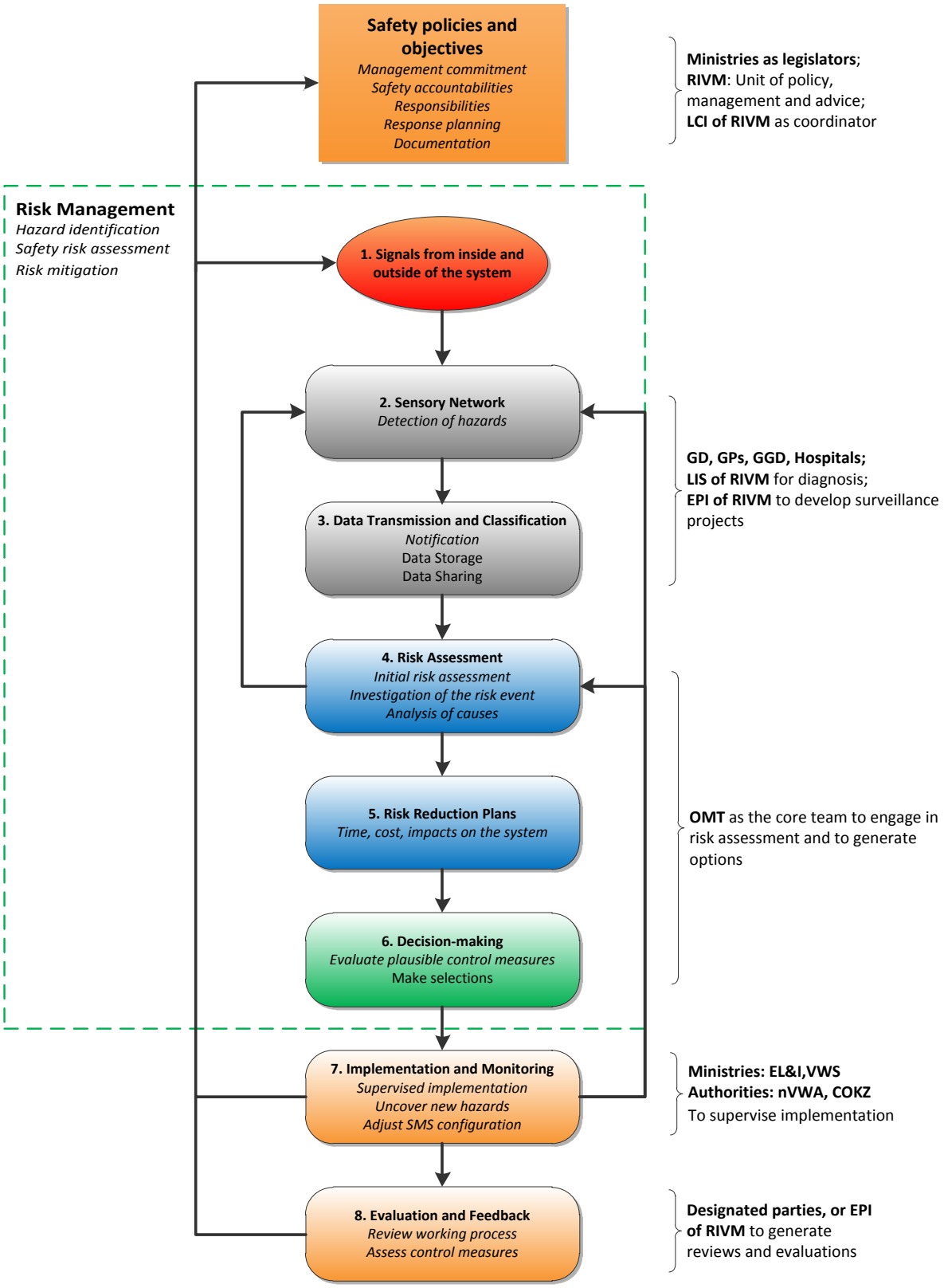


Figure 4.3 RMS for infectious disease outbreak control in the Netherlands

RMS steps and BPM steps

The functional blocks of the RMS should be accompanied by a business process model (BPM), which shows more details of the functions of RMS in terms of process steps, sub-processes, stage gates, etc. Appendix IV is a blueprint of the business process of the proposed RMS for outbreak control. The steps and stage gates in the BPM chart were created on the basis of existing working processes confirmed with a focus group at RIVM and of the discussions on the control/safety barriers identified in the 3CA analysis in Chapter 4.

1. Signals from inside and outside of the network

Signals of a potential outbreak could be created from the operations within the national network of signalling organisations. For example, it could be from the regular surveillance projects conducted by RIVM, hospitals participating the projects, or GGD in cases of normal diseases, or veterinarians in cases of zoonosis. Examples of signals could be quantitative data telling unexpected increase in the number of patients or sick animals in a period, like a week. In this step, preparedness for picking up signals needs to be defined and communicated before implementation in terms of accountabilities (who is responsible for reporting), reporting threshold (whether a "surprise" qualifies as a signal), and the "radar" (who shall be informed of the signal).

2. Sensory network

Sensory network functions as the "risk radar" for the system. The signals are "picked up" by actors in the sensory network with technical knowledge and capable of generating epidemiological/immunological/microbiological diagnostic reports (by LIS/EPI). The system switches into a "reactive detection mode" in which these reports are stored in a Safety Data Centre for future retrieval. But if existing knowledge on the hazards borne by the source of the signal is not sufficient, then the hazard level is qualitatively considered as high and sensitivity of the signalling should be increased (e.g. lower the reporting threshold since higher preparedness are required), and also the system switches to an "exploratory detection mode" in which stakeholders on different levels will be notified, and some initial control measures can already be taken against common symptoms, although the cause of the infection may not be the same as known hazards. Note that sometimes it may be required both modes be activated. All information regarding these process steps will be recorded in the data centre as safety data.

3. Data transmission and classification

Step three is the data transmission and classification stage, where the safety data gained from the sensory network and all later steps is stored in a "Safety Data Centre for Outbreak Control", which is maintained by a dedicated team specialised in knowledge management. Safety data includes reports on surveillance projects, investigations on infection cases, surveys, evaluation reports, etc. The dedicated team is responsible for managing incoming data and notifying all relevant stakeholders of the renewed safety data. The relevance of any particular stakeholder is pre-defined based on predicted scenarios; if necessary, extra stakeholders will be contacted by the "Signaleringoverleg" during or after the initial risk assessment. Also this safety data centre serves

as the “organisational memory”, a key component in the organisational learning model, which was described in Chapter 1.7.1.

4. Risk assessment

The risk assessment stage is divided into three sub-processes: initial risk assessment, risk investigation, and analysis of causes. The initial risk assessment is conducted by LCI or “Signaleringsoverleg” (literally “signalling council”), who review the safety data on a weekly (for human infections) or monthly (for zoonosis) basis, and will initiate the inquiry process with the new safety data and historical records concerning the hazard. The result of initial risk assessment will lead to a stage gate decided by the Director of CIb: whether the signal reaches an alarming level as to trigger “crisis management mode”, or if not, stakeholders go back to the status of “monitoring” at normal times, but the risk assessment result goes to the safety data centre.

In the “crisis management mode”, the Director of CIb decides whether to call for Outbreak Management Team (OMT). The composition of OMT is subject to change based on different contexts. The OMT exists as a non-active group of experts and specialists in various research organisations known as “response team” at normal times; once the crisis management mode is triggered, based on our conclusion in root cause analysis, project management personnel are suggested to be included in the OMT to guide the generation of investigation plans, risk investigation, and analysis of causes under investigation protocols (technical standards) and methodologies (ECFA, etc). The process steps also include a quality check on the investigation plans. If additional expertise is required, new experts will be added to the outbreak management team.

5. Risk reduction plans

Generation of risk reduction plans could happen on two levels: strategic and tactical level. Following the result of risk analysis in the previous step, if the causes of the hazard had been in effect in historical outbreak and so effective control measures are registered in the safety data centre, tactical risk treatment options can be generated on the basis of historical records; if the causes of the risk never existed or are vague at the moment, then strategic risk treatment options should be generated first (by BAO, Bestuurlijk Afstemmingoverleg) in order to decide in which the “direction” the risk treatment plans should be going. For example, when the source of an infection is still uncertain, a strategic direction should be made: whether removing the possible carriers of the disease would be more effective, or limiting entry into the infected area would be a better direction for generating specific control options. Either way, an organised feasibility study conducted by specialists together with proper decision-makers should be in place to investigate the feasibility of the tactical risk reduction plans in terms of time, cost, and impacts on the system.

6. Decision-making

The decision-making step refers to the selection of proposed control measures. The steps concerning the decision-making function also happen at a strategic level and a tactical level, but both are essential. In strategic decision-making, involved ministries have to inspect the three systemic elements (human, hardware, software) and their interfaces are aligned for a proposed control measure adjusted before a tactical decision can be made. If the systemic elements are not

aligned, for instance, there being organisational or political barriers or scarcity issue in the supply of equipment, then these elements of the system must be adjusted first before making a tactical decision. After a tactical decision-making, it is possible to face legal barriers during the implementation. Although technically legal barriers can be overcome if intervened by ministries, whether making a new law to secure the implementation of a control measure is the best option at the time is more complicated than this linear process, and it requires an organisational double-loop learning process to happen. This will be discussed further in Chapter 5.3.

7. Implementation and monitoring

The implementation of selected control measures should be under the supervision of nVWA or Health Inspectorates depending on the situations. This is because control measures may 1) bring financial or human resource-related changes (possibly a burden) to the affected stakeholders, 2) generate new hazards by adopting new technology, and 3) require organisational changes in the system to make it successful. Once resilient hazards or residual risk generated during implementation are identified, a new risk assessment-mitigation procedure will take place until the risks meet the acceptance criteria.

8. Evaluation and feedback

In the evaluation stage evaluation reports on every aspect of the outbreak management are generated. Evaluations of the outbreak control are also subject to investigation methodologies such as event and conditional factors analysis. Feedback are sent to involved stakeholders, safety documentation are updated if there have been systemic changes during the process. The evaluation reports are also collected into the safety data centre.

4.5 Chapter Conclusion

A Safety Management System (SMS) is a Risk Management System (RMS) with Safety Assurance Process. In this chapter we delineated the Safety Management System without the latter, so a Risk Management Model accompanied by a Business Process Model (BPM) as a prototype of SMS for outbreak control in the Netherlands is resulted (Appendix IV). The SMS model's core functions are Detection, Notification, Investigation, Implementation, Monitoring and Evaluation. The process model was created to specify the actors and work processes based on the results of ECFA+ and 3CA analysis in previous chapters, and then corrected after a focus group discussion at RIVM with experts in relevant areas. The resulted BPM shows before, during and after an outbreak control how the outbreak management activities are organised in a way to realise a systematic, proactive, explicit and self-improving safety management system. Recommendations on making improving certain outbreak management activities based on existing processes will be elaborated in Chapter 6.1.1.

Chapter 5 Organisational Learning and SMS for Outbreak Control

5.1 Introduction

During the HILAS project, the SIRA (Systems Integrated Risk Assessment) model for airlines has been redesigned and enhanced by applying principles of Organisational Learning. According to the researchers in the project, an organisational learning system is embedded in the integrated risk assessment model. In the research on the SMS for outbreak control, we attempted to apply a similar approach to correlate organisational learning principles with the risk management system (RMS) proposed in Chapter 4.

Since the RMS is built on the grounds of a multi-actor network rather than an archetype of a single organisation, some assumptions must be made before the transition of key-concepts in the mapping.

Assumption 1

The Safety Management System for Outbreak Control in the Netherlands consists of multi-actors from different sectors (Figure 4.2), and the system is assumed to be a collective organisation with those actors as its "divisions". The connections between the "divisions" are loose in "normal mode" before and after an outbreak, and become strong during an outbreak.

Assumption 2

Every actor in the system is an organisational unit per se, performing its own tasks as described in the business process model (Appendix III) within the spectrum of norms and values set by the system's management tier.

Assumption 3

The collective organisation wants to learn and to integrate the OL process. A learning agency has been designated by the management tier and commissioned with the task of detecting operational surprises through single- and double-loop learning processes.

Assumption 4

Every organisation in the system clearly understands the need for delivering the message of an operational surprise to the learning agency.

5.2 Mapping Organisation Learning to SMS

Key functions and components in organisational learning are mapped to the RMS presented in the previous chapter. Results are shown in Figure 5.1.

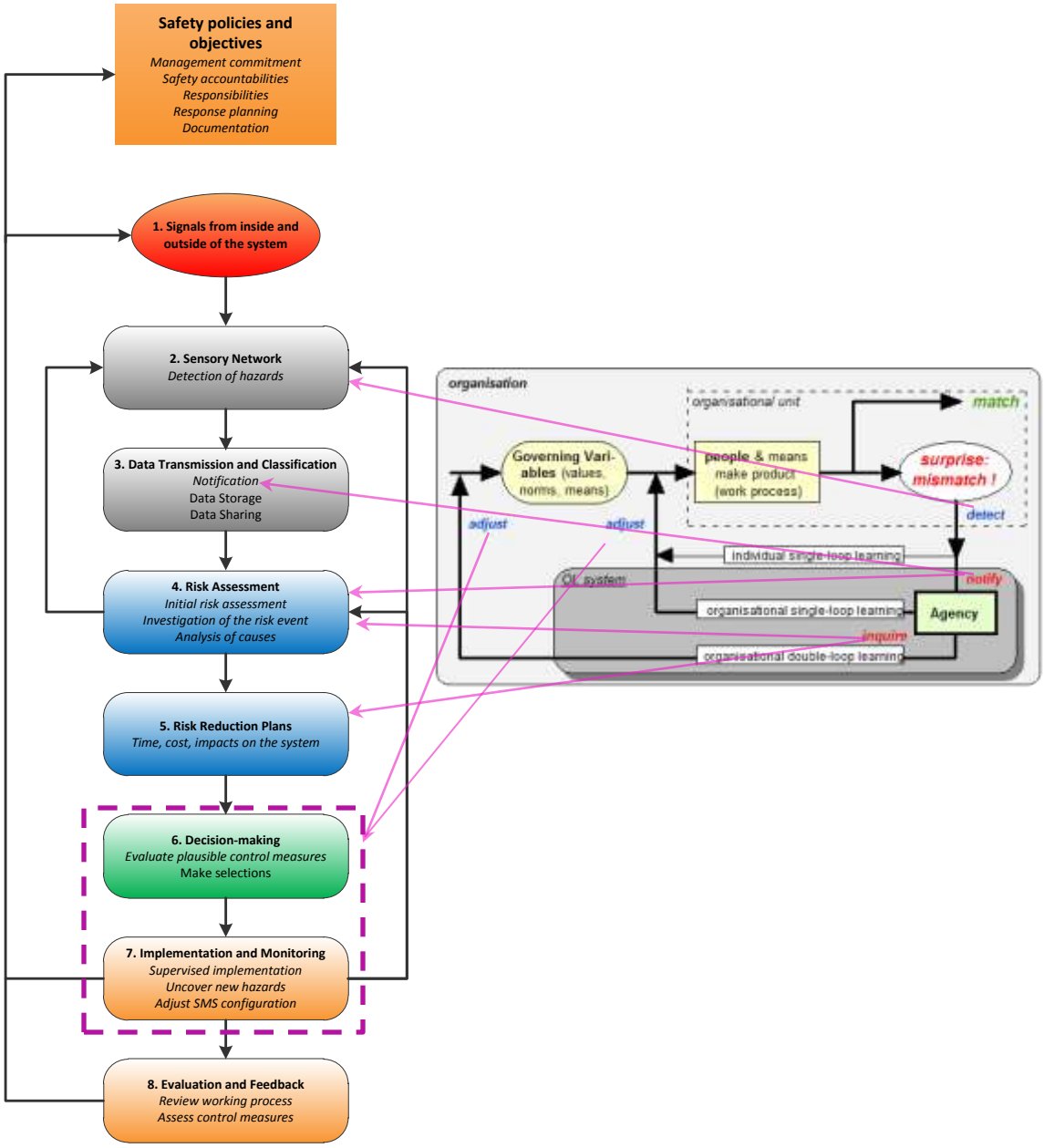


Figure 5.1 Mapping organisational learning to RMS steps for outbreak control

In the RMS Step 1, performance data, "signals" in RMS language, are generated from every organisation (referred to as "shop floor") in the system in their daily operations. The data could take various forms, ranging from formal communication channels such as research reports (i.e. reports from laboratories) and surveillance data from surveillance projects, to less formal channels such as communication through telephone or emails by individual family doctors.

In step 2, the trigger signals from the individuals, whether inside or outside the SMS, are detected by the Sensory Network (the "risk radar"). With hazard's source, spread, and transmission channels uncertain and differ from case to case, learning would require a much different learning agency

setup than the case of a regular disease in terms of the expertise, funds, investigation process, etc. within the learning agency.

The RMS Step 3 and 4 both incorporate the "notify" function in organisational learning, which is different from the SIRA model in the HILAS project. In Step 3 in our RMS, the system function "notification" should already kick in based on our system design: safety data for outbreak control, namely anomalies reported by agents in the sensory network, are input into the "data centre", accessible to the "Signaleringsoverleg", who could instantly start working on the data and assess the situation upon notification. Thus the initial risk assessment closely follows and according to the results of the assessment, decisions are communicated to relevant stakeholders in the system: if the situation is urgent, all relevant stakeholders in the system will be notified, and the system switches to a crisis management mode. Since the "Signaleringsoverleg" always exists, it is considered as an ad-hoc learning agency at this conceptual level.

The "inquire" function in organisational learning can be mapped to Step 4 and 5 in the RMS. Investigation of the risk event starts with checking organisational memory (the Safety Data Centre) for historical records on the outbreak management team composition and the disease itself. Checking on the historical records of the reported disease could help rule out unnecessary inquiry processes. In this phase of crisis management, OMT as an expansion of the original "Signaleringsoverleg" has taken the role of learning agency. The role of learning agency is constant before, during and after an outbreak control "cycle". Although composition of OMT also varies from case to case, adding personnel to the original learning agency does not change the responsibilities of the agency, only to enhance the sensitivity of the sensory network after crisis management mode is triggered.

The "adjust" function in organisation learning is functional in RMS Step 6 and 7, where decision-making and implementation take place. In Chapter 4.3, we discussed the difference between tactical and strategic decision-making in the business process model. They also make a difference if mapped to the organisational learning system. Tactical decision-making only concerns daily operations, and decisions can be implemented without adjusting governing norms and values in the organisation (single-loop organisational learning). An already proved control measure can be implemented without hindrance. In contrast, if a control measure which has never been implemented in similar situations before, or is impossible to implement unless new leadership, laws and regulations are in place, then these governing variables must be changed accordingly first, a process we call double-loop organisational learning. Last but not the least, in the latter case regime of the system are affected, so strategic decisions always result in new safety data which must be updated in the safety data centre – organisational memory in the language of organisational learning.

The above description clarifies how organisational learning is embedded in the risk management system for outbreak control. We can see that a complete loop of organisational learning process in the RMS with all the functions, actors and activities. However, this could mean something else: if the organisational learning process is blocked or part of the process made impossible, the RMS will also have issues. In the Chapter 5.3, we will identify barriers to organisational learning process on the basis of the two case studies in this thesis.

5.3 Potential Barriers to Organisational Learning in the SMS

Before we discuss possible blockages that may impede organisational learning, how are the key concepts in the Organisational Learning theory are represented in the outbreak control system must first be made clear. Figure 5.3 below is a table summarising the concepts being "translated" into units/activities and whether the concepts already took an "ad hoc" form back then during the outbreaks, meaning that some particular units/activities during the two outbreaks are analogous to certain concepts in the theory of Organisational Learning.

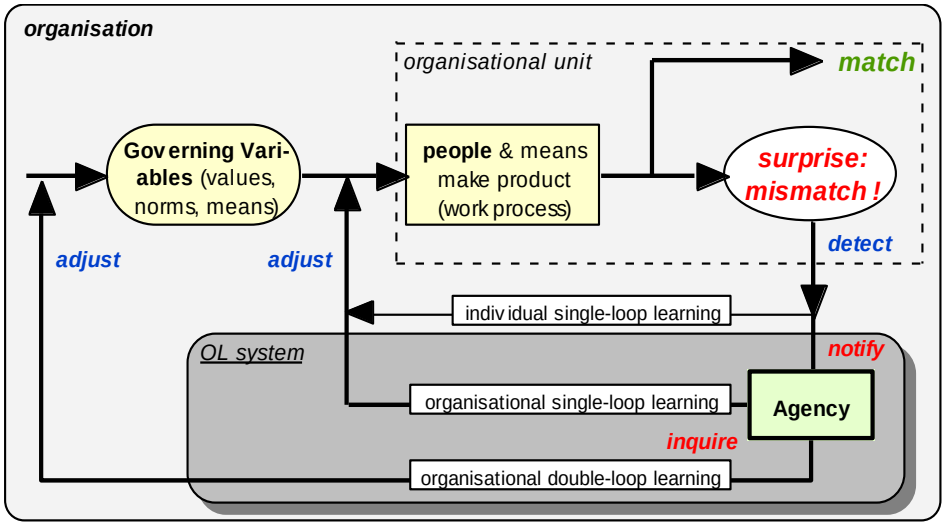


Figure 5.2 Organisational Learning concepts after Argyris (Koornneef & Hale, 2004)

OL concepts	Representation in the outbreak control system	"Ad hoc" concepts in the system[1]
Mismatch	Sudden increase in the number of patients/animals showing the same symptoms, which is unusual than expected at the time being	Yes.
Learning agency	The organisation(s) responsible for investigating the sources of infections and giving advice to decision-makers	Not in Q-fever case; In salmonella case it is VWA+GGD+RIVM.
Organisational memory	A "Safety Data Centre" which stores and distributes data on the mismatches, and is updated by the Learning Agency with newly acquired safety data. The concept of "safety data" entails both the updates on investigations during an outbreak and lessons learned after the outbreak. There is actually an OSIRIS system in existence but mainly used as a system for storing data gained in on-going surveillance projects.	Yes, but the concept vaguely exists but the OSIRIS was not paid too much attention.
Single-loop learning	The Learning Agency can work with the decision-makers at "*shop floor*" level, i.e. management of a farm company or a hospital, to change how that	Yes, but unsuccessful and received criticism. RIVM, GGD and hospitals help each

[1] The information in this column was provided by the contact from RIVM.

	particular organisation work in order to keep the outbreak under control; There is no need to involve decision-makers of more power such as the Ministries. For instance, some control measures *on farm/hospital level* can already be taken in response to some common symptoms showing on patients. This does not require the intervention of external power.	other and see if the outbreak can be kept under control without involve the Ministries, when the threatening level of the outbreak is concluded to be minor by "Signaleringoverleg".
Double-loop learning	The Learning Agency cannot influence the organisations at "*shop floor*" level, because it is impossible to change the current work process without changing the governing norms/values. For instance, when the economic concern of farm companies is dominant, it would be very difficult to implement control measures which would cause financial problems for the companies. In this case, the governing value is the "financial matter", and whether this should be put behind the value "elimination of the outbreak" is a decision not to be made by the Learning Agency, but by the government during crisis times.	Yes, but not efficient: OMT as the "learning agency" did not give concrete and timely advice to decision-makers during Q-fever outbreak; VWA did not think of COKZ as a critical actor in the dairy industry and failed to influence Farm A in the Salmonella case.
Detect **Notify** **Inquire** **Adjust**	As in the discussion in Chapter 5.2 about the functions' mapping to one another.	Yes.
Governing variables	Norms and values that are dominant for the empowered Ministries during an outbreak to make strategic decisions (refer to Chapter 4.3, and Chapter 5.2, strategic decision-making). Strategic decisions, such as whether one interest/value should be placed over another, are vital in outbreak management, and political or organisational changes to the system are considered or required.	No. Not openly discussed during Q-fever and Salmonella outbreaks.
Work process	Report lines and arrangement of operations according to prescribed responsibilities and "job routines".	Yes, but not quite clear. This is one of our explanations to the delay of crucial meetings and control measures.

Figure 5.3 Translation of Organisational Learning concepts into "ad hoc" units/activities

The barriers under discussion are hereby defined as "*factors that create blockage in the above-mentioned OL concepts in the outbreak control system*". Such barriers are often related to intangible norms and values, the Governing Variables in OL language, and thus are not readily noticeable by technical specialists and experts or not openly discussed. As we have discussed in Chapter 5.2, outbreak management requires a prescribed double-loop learning process in cases where the governing norms and values have to be changed in order to overcome certain safety or control barrier in the implementation phase. Argyris and Schön differentiate between Model I and Model II theories-in-use. Model I theories-in-use are tacit and shape people's behaviours, minds and

decisions in such a way that changing norms and values hardly ever happen, or the need of such changes become unrecognised. In contrast, people working under Model II theories-in-use are aware and in favour of changes in norms and values when necessary, thus double-loop learning can be realised. Hence "Model I theories-in-use" and its influence on the material network of stakeholders in the SMS are defined as "barriers" to organisational learning. Kingston summarised 20 obstacles to organisational learning (Koornneef, Stewart, Akselsson, & Ward, 2009). These barriers are critical to the success of implementing an SMS, and thus they must be in the back of the management's mind and avoided or kept at minimum level at all costs. We used his research as a base, identified some common barriers, and expand the list with new barriers supported by theories of organisational learning and sense-making in organisations. In the discussions below, we will describe what the barriers are in essence, what impacts they have on organisational learning process and the SMS, and examples from the Q-fever or Salmonella cases will be quoted if needed.

7.3.1 Structural barriers to Organisational Learning

Structural barriers refer to a mismatch between the demand for certain resources needed for learning and the misplacement or deficiency of such resources. Herein the resources is meant by technologies adopted in the working process, or information required for activities. In the model of Operational Readiness, this is the "Plant (hardware) element".

1. *Specialists own the message*
   In the RMS we proposed in this project, specialists are the earliest message owners before an outbreak. It is dependent on them to make the detection of "surprises" and "shocks" so that certain modes of operation can be triggered. Therefore it is dangerous in a safety management system to have the messages "clenched tight" in specialists' hands. Specialists owning the message can be owing to an unsuitably high reporting threshold or a set of resilient norms and values of the message owners that prevent them to do so. An example in the case studies is that the veterinarian company did not share information on infections until it became obligatory (Q-fever case) or the company itself bypassed by an authority (Salmonella case).
2. *Not keeping up with technical standards*
   Having up-to-date knowledge on technical standards is indispensable for the system of outbreak management. Since such factor can affect many processes and roles in the system, for example, the detection of signals in the sensory network or an acting learning agency investigating technical aspects of the outbreak, technical standards should be part of the safety data centre, or renewed in the organisational memory for retrieval, and also old standards should be eliminated in time to avoid misuse or confusion. Losing track of changes in technical standards is considered as a blocker to individual or organisational single-loop learning.

7.3.2 Managerial barriers to Organisational Learning

"Managerial barriers" is used here as a category of barriers that result from the "Process (software) element" and the "People element" in a system. We identified three such barriers from the case studies, and think they must be avoided in the construction of a new system for outbreak control from a learning perspective.

1. *Accountability issues of actors*
   To answer one of the research questions regarding how to reconfigure the actors in outbreak management, we proposed a RMS and a business process model for it. Reconfiguration of the actors would not work out unless the working processes are clear to all organisations included and interfaced in the system. To achieve this, as in the guidelines we created for gap analysis for the system, accountabilities of key safety personnel must be clarified and communicated, documentation must also be checked in every function block in the safety management system. As we have discussed in last session, "Signaleringsoverleg" as a pre-phase OMT and OMT itself during outbreak, the learning agency in the organisational learning process, would require their accountabilities and responsibilities re-defined. This is in general terms a regulation for the learning agency: they are the key persons in organising learning within the system, and organisational learning will not happen if the learning agency fails to deliver "what to learn" and "how to learn" to the management due to learning within the agency group fails first. Therefore, incomplete or ambiguously defined accountabilities is a barrier to organisational learning.
2. *Poor relationship management between actors*
   Relationship management refers to 1) maintaining links with other actors, and 2) managing potential "losers" in outbreak management. First, weak links between actors makes an actor "forgetful" in their operational activities. In the case of Salmonella outbreak, nVWA was one of the investigators, who were in the place of learning agency had organisational learning process been there. As we discussed in Chapter 3 before, nVWA did not realise COKZ could have been the actor who could be quick and effective to deal with a dairy product problem. Therefore, it is important that all links be strengthened between the actors we identified in the safety management system. Second, actors who tend to lose, most commonly in financial terms, would take a defensive stance in communication, which could make supervision and monitoring of control measures difficult to manage. Examples are farm A refusing cooperation in the Salmonella case and farmers doing PCR behind the scene in the Q-fever case. According to Argyris and Schön, Model II theories-in-use behaviour is characterised by openness and mutual respect (Koornneef, Stewart, Akselsson, & Ward, 2009). In outbreak management, openness can be an issue when negotiations are inevitable during both the decision-making and implementation phase. Detection of signals would be in problem if fear of losing in negotiations becomes the blocking power on the operational level of the system.

7.3.3 Barriers regarding sense-making issues

Sense-making in an organisation, or a system embedded with inter-connected organisations, such as the SMS we discussed in this thesis project, is one less often mentioned concept but with impacts in the organisational learning process. Karl E. Weick defines sense-making (Weick, 1995).

"… is about such things as placement of items into *frameworks*, *comprehending*, *redressing surprise*, *constructing meaning*, *interacting in pursuit of mutual understanding*, and *patterning*."

Organisational learning is through people in the organisation, and in all four functions of the organisational learning process – detect, notify, inquire, adjust – the actors that are involved must go through at least one of the above processes in the definition of K. E. Weick's. For example, the

"detect" and "notify" function are mapped to the RMS "sensory network" and "data transmission & classification". In middle of working processes, people engaging in signalling and detection must face questions like "Is this normal?" or "What should this be reported as?" etc. In the "inquiry" process, OMT as the learning agency must also filter/classify/re-construct the information they acquire from different resources. Particularly, at decision points when control measures must be chosen or implemented, decision-makers must try to assimilate the whole lot of information that are mostly technical or others not within their particular expertise, then paint themselves a picture and make a decision. Therefore, the way sense-making is handled is crucial to organisational learning. We identified two noteworthy points from the case studies and think they could create barriers in organisational learning process.

1. *A process could be rendered endless*
   Risk management on one level is to "manage the unknown". When facing the threat of an outbreak, even if it is a known disease, the source of the infection is uncertain, the consequences of the infection in human are uncertain, and sometimes the uncertainty of confirming the sources confuses the actors in charge of implementation. Organisations in the safety management system must face such uncertainty all the time – before, during and after an outbreak, and a lot of efforts are usually put in reducing the uncertainty. The problem is that often too much time is invested in trying to reduce the uncertainty, and "this often backfires and uncertainty increases" (Weick, 2002). Weick points out that uncertainty is one occasion for organisational sense-making (Weick, 1995). The stakeholders in the SMS for outbreak control face this uncertainty problem just as well: in the Q-fever case whether the farms were the source of the infection was in dispute even after control measures were taken on the farm; in the Salmonella case nVWA did not take actions on Farm A because of lack of considerations on EU laws and evidence pointed to various source, although farm A was "highly suspected". Compared with the SARS outbreak control in Canada (Health Canada, 2003), the Q-fever and Salmonella outbreak control in NL are far less responsive or effective than that of CA, who was even facing greater level of uncertainty since SARS was completely an unknown disease at that moment. One can argue that the fatality of SARS is much higher than Q-fever or Salmonella, which made the situation so urgent as for actions to be taken as fast as possible, but the time and opportunities wasted in waiting for more information to make senses about the situation are substantial in both Dutch cases, which resulted in delay of tactical decision-making to mitigate impacts on the infected farms. Therefore, endless waiting for more information is a barrier to double-loop learning, in a way that the governing values cannot be changed in time to implement changes in the working process – the organisation is in the danger of getting stuck in *Model I* learning.
2. *Senses can be shaped by theories-in-use*
   Theories-in use are tacit rather than explicit. Theories-in-use exist in working processes in a way that drives the people in it to behave without clear guidelines. When facing surprises and shocks, people unconsciously "quote" the theories-in-use to generate interpretation. Like Argyris observed "Every theory-in-use is a self-fulfilling prophecy to some extent. We construct the reality of our behavioural worlds through the same process by which we construct our theories-in-use" (Weick, 1995). Thus theories-in-use may come to the surface and are transformed into espoused theories, which are explicit and concrete, when the

particular theories-in-use no longer seem to be appropriate. Reflections in outbreak management in NL reveals: when clear working processes or accountabilities are lacking, actors in the network would have to take extra-long time to make sense about various issues, financial, political, procedural, etc. until a worsened situation urges them to setup new espoused theories. A generic example is at an early stage of an outbreak, certain prerequisite steps or policies are missing and are suspended in arguments, this way decision-makers are not able to implement certain control measure (e.g. obligatory reporting issue in Q-fever case), but when the outbreak loses control, the missing elements become in place within a few days. In fact, effective control measures can be delayed or ruled out by the management or learning agency due to sense-making constrained by theories-in-use that are no longer appropriate, but the stakeholders are still blindfolded by them and stuck in *Model I* learning. Here making senses out of this limited "space" would become a barrier to double-loop learning in the system.

7.4 Chapter Conclusion

In this chapter we have mapped key functions in the OL process to the RMS we proposed for this project. Through the mapping it is known to us that in what way organisational learning is embedded in a risk management system against epidemical hazards, and therefore contributing to the safety management system for outbreak control. We also pinpointed how can organisational learning concepts be "translated" into the actual units/activities in outbreak management, and then identified three categories of barriers (structural, managerial, and sense-making related) which could impede either single- or double- learning and thus compromise risk management practices in outbreak management. Recommendations on learning aspects will be given in Chapter 6.1.2.

Chapter 6 Recommendations and Reflections

6.1 Recommendations

6.1.1 Recommendations: gap analysis guidelines for the SMS

The SMS for outbreak control has three systemic components: Human component, Hardware component, and Software component. Human component refers to how each stakeholder should react according to their pre-specified responsibilities before, during, and after an outbreak. Hardware component refers to the physical resources that have to be made available to take precautions or fight against disease outbreak, which includes, for instance, medical equipment, vaccines, and medications, etc. Software component refers to working procedures, documentation, training and learning to guide actors involved to interact with the system's functional blocks.

Gap analysis is essential in developing an SMS, and is usually conducted under the guidance of a checklist of the required components for the system to work. It has two objectives: the first is to identify mismatches in the interfaces between the system functional blocks, the second is to identify whether certain elements of the aforementioned three system components (human, hardware, software) are absent. A safety management system is composed of a risk management system (RMS) and a safety assurance system. The latter is another system which is not the concern of this thesis. However, since we have also identified and discussed the system barriers, namely the missing or misplaced system factors in the 3CA analysis, it is vital to create guidelines not only to complement the RMS but as a reference for the management to set safety policy and objectives as well. The below guidelines are created as **recommendations (1-8)** for the SMS for outbreak control, following the guide in ICAO Safety Management Manual (ICAO, 2009).

Safety policy and objectives

1. Management commitment and responsibility

This element should define the making, the scope, and the status of the safety policy regarding outbreak control. **Relevant ministries** (depending on types of outbreak) and the **Unit of Policy, Management and Advice of RIVM** are the assumed responsible parties. Following items must be examined to make sure no aspects of the element are forgotten:

- which actors are involved in making the safety policy and objectives in different outbreak scenarios;
- a formal process to develop safety policy and objectives;
- whether the crisis management policy reflects organisational commitment for each stakeholder in the system;
- that reporting procedures between stakeholders within or cross sectors are pre-defined;
- which operational behaviours are unacceptable;
- whether safety policy and objectives made are communicated throughout all the stakeholders (organisations)in the system;
- that the safety policy and objectives are periodically reviewed, updated, and distributed among the stakeholders.

2. Safety accountabilities

This element specifies how accountabilities are managed in the SMS, which is supposedly stipulated at ministry level at early stage of developing an SMS. Below recommendations are to address the **control barriers (6, 7, 9)** in **3CA analysis**, regarding the lack of guidelines for OMT's advice during outbreak control. Items that need checking are:

- whether there exists an Accountable Executive who , irrespective of other functions in his own organisation, has the ultimate responsibility and accountability, on behalf of the system, for the implementation and maintenance of the SMS;
- that the Accountable Executive has full control of the financial resources required for all the operations concerning outbreak control;
- that the Accountable Executive has full control of the human resources required for the all the operations concerning outbreak control authorised by relevant ministries;
- whether the system has identified the accountabilities of all members of management, irrespective of other functions in their own organisation, as well as employees, with respect to the performance of the SMS;
- whether safety responsibilities and accountabilities documented and communicated to all the organisations in the system;

3. Appointment of key safety personnel

This element is meant to be a checklist of key safety personnel. To implement an SMS, each organisation should have at least one person trained with knowledge on the SMS. Following items should be examined:

- whether each organisation in the system has appointed a qualified person to oversee the system elements of the SMS within the organisation itself and the safety communication between connected organisations;
- whether the safety authorities, responsibilities and accountabilities of personnel at all levels of the system clearly defined and documented in all modes of the system (at different crisis level).

4. Coordination of emergency response planning

This element helps check the availability of emergency response planning, which should cover:

- whether every organisation have an emergency response/contingency plan appropriate to the size, nature and complexity of the organisation;
- whether the emergency response/contingency procedures are coordinated with other organisations in the system that it must interface with;
- whether every organisation have a process to distribute and communicate the coordination procedures to the personnel involved in such interaction.

Safety risk management

5. Hazard identification

This element is in the **RMS step 1-3**, with functions of signalling, identification, and safety data transmission. **"Signaleringsoverleg" and Outbreak Management Team (OMT)** are the assumed responsible stakeholders. Following items should be taken into consideration to identify system vulnerabilities:

- whether the stakeholders in the sensory network understand and are committed to the signalling obligation (to address **control barrier (4) in 3CA**);
- whether the resources are available and functional which guarantee that the signals as well as safety data can be received by relevant stakeholders within the shortest time possible;
- that the response reports from the sensory network are delivered to the right level of management and are then sufficiently reviewed;
- that feedback is given to the signalling stakeholders timely that their reports are received and analyses of the reports are communicated;
- that the stakeholders who are tasked to carry out technical diagnosis and develop surveillance project are proactively ready for identifying hazards;
- that the stakeholders who are tasked to monitor and analyse the working procedures are in place and proactive in identifying possible blockers;
- whether the responsible staffs are well-trained to process safety data from signalling stakeholders;

6. Safety risk management and mitigation

This element is in the **RMS step 4-6**, addressing risk management and mitigation strategies. **Outbreak Management Team (OMT)**, headed by **CIb of RIVM**, is the assumed responsible party. Below recommendations address **barriers (6, 7, 9, 10, 11) in 3CA**. Following items should be registered in gap analysis:

- that the responsible stakeholders are following a developed and formal process (quantitative and qualitative risk assessment) that ensures analysis, assessment, and control of the safety risks;
- that as many hazards, consequences, and risk factors as possible for every different scenario of outbreak are articulated, documented, and understood by relevant stakeholders;
- that a structured process for the analyses of the safety risks associated with the consequences of identified hazards, expressed in terms of probability and severity of occurrence, is in place;
- that the criteria for different risk management strategies (take, treat, transfer) are articulated and well acknowledged;
- that the Outbreak Management Team (OMT) has concrete risk mitigation strategies prepared within the shortest possible timeframe;
- that the risk mitigation strategies advised by the OMT are revised by authorised parties before decision-making;
- that all risk management activities during an outbreak are documented and communicated to all the organisations in the system.

Monitoring and improvement to the SMS

7. Change management

This element concerns managing the changes that have to be made to the system elements (human, hardware, software). Change management is included in the **RMS Steps 6-7** and relevant ministries/authorities/inspectorates are held responsible. Following items need to be checked:

- whether a formal process to identify changes within the system which may affect existing working processes and the effectiveness of control measures;
- whether an implemented control measure are working as intended and whether there are factors that would compromise the control measure (to address **barrier (2, 3, 8) in 3CA**)
- that the sub-process of change management analyses the essential systemic changes;
- that successful change management generate retrievable documents which are stored in the safety data centre;

8. Continuous improvement to the SMS

This element concerns the "maintenance" of the SMS and is not shown as a step in the RMS, since it is part of the Safety Assurance System. However, processes are needed for such a purpose to make sure the SMS is being improved overtime before a formal safety assurance system is built. Items that need to be checked are:

- whether the system has appointed key personnel to go through a formal process to identify the causes of substandard performance of the SMS;
- whether the system has established a mechanism to eliminate or mitigate the causes of substandard performance of the SMS;
- that the a process for the proactive evaluation of facilities, documentation and procedures is in place;
- that a process for the proactive evaluation of an organisation's performance during an outbreak is in place;
- that evaluation reports are documented and communicated to all the organisations in the system.

6.1.2 Recommendations: organisational learning

Since organisational learning processes are embedded in the safety management system, blockers to learning processes will render the SMS less effective or result in delay in action. Our recommendations regarding organisational learning are centred on three principles: 1) making improvements on existing elements that enable organisational single- and double- loop learning; 2) avoiding potential barriers to organisational learning and overcoming existing barriers, so that the system for outbreak control does not stuck in *Model I* learning mode. The four recommendations below are grounded on the conclusions of root cause analysis using 3CA as the tool (barriers numbered 1-16 in Appendix III).

1. Set up "organised learning" in the SMS system, formalise all the ad-hoc organisational learning elements (Figure 5.3), and make the concept of organisational learning explicitly known to the actors of the system because it is integrated into the risk management system.

2. Create or build upon existing communication network a Safety Data Centre, which serves as 1) a "vault" for storing signals of potential outbreaks, relevant legal information and technical standards, finished diagnostic reports, used control measures during past outbreaks, and updates on the investigation of hazards during outbreak control; 2) the "organisational memory" for lessons learned during and after an outbreak management cycle, lessons generated by the learning agency which is active during the outbreak management. The safety data or lessons learned are retrievable by all stakeholders any time. This recommendation is to counter **barriers (14, 15, 16) in 3CA** analysis, the root causes of which indicate that the learning agency is not aware of the crucial information so that opportunities for acting early are missed.

3. The learning agency must have complete knowledge on the stakeholder network available so that who should be contacted and called in, once required, is clear to the learning agency designated for the outbreak control. This recommendation is to address **barrier (13) in 3CA,** which prevents the timely addition of a crucial actor that is able to influence the outbreak control. Such knowledge should be stored in the Safety Data Centre, and must be checked by the learning agency before "inquiry" and updated after a possible "adjustment".

4. Governing variables in the outbreak management must be recognised by the learning agency and management tier as early as possible to facilitate early strategic decision-making. In case of an organisational double-loop learning is needed, meaning that governing variables must be modified or changed in priority, the options for changing in values or prioritising one value over another should be open for discussion. The ad-hoc learning agencies in the two outbreak cases were not trained with principles of organisational learning. In the context of outbreak control, diagnostics and source tracing are only two forms of "inquiry" performed by the learning agency; when organisational double-loop learning is required, theory-in-use should be identified and assessed by the learning agency, and coping strategy should be then made and communicated to the higher-tiered management, so that strategic decision-making can be made as early as possible prior to tactical decision-making. For the learning agency, failure to notice or to openly discuss tacit theories-in-use that is blocking the double-loop learning may add to the time waiting for more but unnecessary learning. This recommendation addresses **barrier (1, 5, 12) in 3CA**, which implies that important trade-offs must be made between several governing variables (e.g. finance, wellbeing, etc) on strategic level of outbreak control management. If the governing variables associated with certain stakeholders' interests are in contradiction with the intended governing variables, then they should be brought to the table for discussion rather than let them get ruled out or procrastinated.

6.2 Reflections on Methodologies

6.2.1 The use of ECFA on "non-traditional" type of incident investigation

ECFA is a sequencing tool used for incidents investigation. The "incidents" is a general term for "unwanted events". The method has been applied in investigating typical accidents, such as fire outbreak, car crashes, chemical plant accidents, etc. Evidence can be collected from interviews with witnesses, objects at the accident spot, newspaper articles, etc, and used by the investigators to reconstruct chains of events. Followed by barrier analysis and root cause analysis, the investigators

can develop hypotheses about control/safety barriers and possible causal factors regarding the accidents.

During the ECFA+ practices, we found ourselves faced with challenges concerning evidence collection:

1) Both the Q-fever and Salmonella outbreaks ended years ago (2 years for Q-fever and 5 for Salmonella);
2) There are few evaluation reports on the two outbreaks available, and other sources like documentaries or news articles are far from resourceful to contribute to facts reconstruction;
3) The "incident" or "unwanted events" in our case differs from traditional ones such as a car accident or personal injuries; it is "unwanted events that mitigate the effectiveness of outbreak control management", which is more abstract and associated with more non-technical factors than regular accidents.
4) The rules and formats stipulated in ECFA guidelines are optimised to describe events and conditions for more "traditional" type of accidents as mentioned in the beginning, and we found it hard to sort out useable information in the reports that can be formulated into events and conditions in "ECFA languages";

In an attempt to tackle the challenges, we took following measures:

1) Focus on the events that are "transitional", meaning that they can influence the next event(s) in the chain(s) they are positioned, in the meanwhile keeping a journal of the events that we are not sure at the moment whether they play a role in the chains or chains to be made;
2) Organise the "storylines" (chains of events) according to the different control measures (for the Q-fever case) or progress in source tracing (for the Salmonella case). The reason for this is that during the Q-fever outbreak the problem had always been which control measures to take and when and how to implement against an outbreak out of control, while during the Salmonella outbreak the problem was the ineffectiveness of source tracing despite the impact of the disease was of a lesser scale;
3) Make use of a multi-disciplinary project team to improve the internal validity: consult an expert on investigation methods for feedback on facts reconstruction, and consult an expert from RIVM for the selection/addition of events and conditions mentioned above as well as revision of "storylines"; Also, we found that 3CA as a tool of root cause analysis does not require adaptation to be applied on a non-traditional case distinguished from normal accidents, and it worked surprisingly well: following the analysis sequence "adverse effects – implicated control barriers – root causes", it is found that many of the barriers and root causes discussed with the method were in accordance with what had already been discussed and improved in the network of outbreak control in the Netherlands. Moreover, revision with the multi-disciplinary team pointed to new evidence for unconfirmed causal relationships in the ECF chart and updated our root cause analysis, both of which will serve as valuable references for future studies on the case.

To summarise, applying ECFA on post-event incidents which differ from normal accident subjects can be a good challenge for it creates difficulties in re-organising the data from evidence and transcribing them in ECFA languages, but this can be countered by, in a multidisciplinary team, setting up case-specific criteria, iterating the facts reconstruction and revising the root cause analysis to gain new insights in the causal relationships. It is noteworthy that an important lesson we learned from applying the combination of the two methods is that such application on this "non-traditional" type of incidents investigation can be time-consuming: the 3CA analysis could have started earlier in this research project to speed up the iteration cycle. In other words, investigators can initiate similar projects with ECFA for facts reconstruction first, but then 3CA could go with iterations of ECFA in parallel which not only contributes to improving the internal validity of both activities but to speeding up the research cycle.

6.2.2 ECFA+3CA in comparison with grounded theory methodology

The inspiration of making comparison with grounded theory originated from the time when we revise the presentation of overall research framework. In fact, during the early ECFA+ and 3CA practices on the case of outbreak control, we already began to circulate from facts reconstruction to root cause analysis and again back to written or oral evidence for several rounds. When the project was near the end, we became more familiar with the use of the two investigation tools, and once we "looked back" at the whole process, we found that the combination of ECFA and 3CA used in our project seemed to have the same methodological vibe as that of grounded theory. We made a comparison between the two (sets of) methodologies and showed it in Figure 6.1.

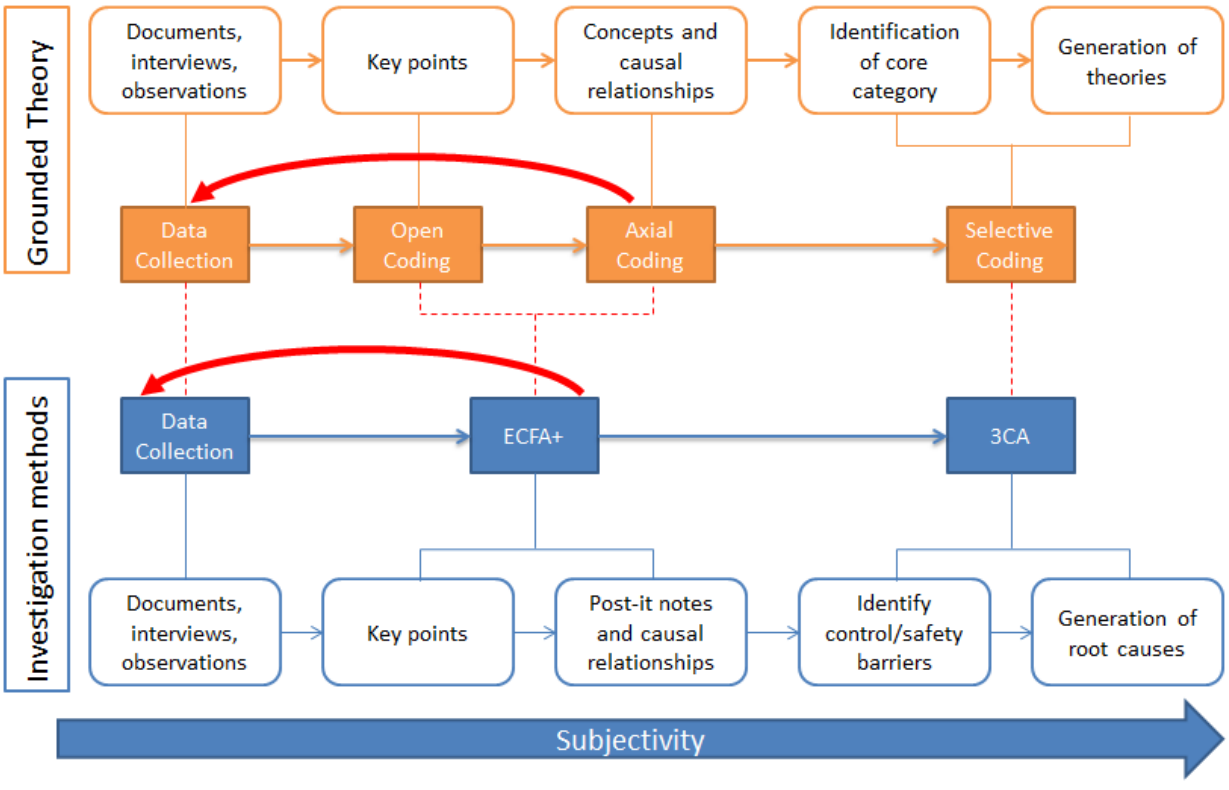


Figure 6.1 Comparison of grounded theory and combination of investigation methods

Grounded theory is a qualitative research method developed by Glaser and Strauss. It is distinguished from traditional research methods by the fact that in grounded theory practices the researcher aims to create theories from data, rather than testing theories with data. During the project we could not help noticing following similarities[2]:

1) Data collection in incidents investigation is analogous to the data collection in grounded theory practices. Data required for ECFA+ are restricted to a more limited scope, mainly from witnesses, logs, photographs, reports, etc., any sources that are related to the incident under investigation; in comparison, the raw data collected for building theories can be from a broader spectrum: interviews, observations, videos, documents, newspapers, etc.
2) The ECFA+ process is analogous to the open and axial coding steps. Open coding identifies the key points of interests, which are roughly conceptualized and labelled. Then the researcher reorganises the concepts and attempts to draw causal relationships between one another, which is called axial coding. The relationships between concepts and categories are drawn according to the researcher's understanding of and explanations to the phenomenon under study. New questions concerning certain concepts and relationships may pop up in the researcher's mind and urge the researcher to collect more data until the researcher is satisfied with the saturation – this repeated cycle is called theoretical sampling. In ECFA+, the researchers also have to summarise key points to have an overall feeling of the data, and then transcribe them on "Post-it" notes describing relevant events and conditions, but the transcription is under prescribed linguistic and logical rules. These events and conditions are then related to each other, forming up storylines in different categories. This process is preferably conducted by a group of researchers, which is not often the case in qualitative research using grounded theory method. However, the way they deal with qualitative data are quite similar, except that ECFA+ has prescribed rules that researchers must abide by while grounded theory method does not.
3) 3CA as a root cause analysis tool resembles the process of selective coding. This step in grounded theory involves selecting the more important concepts and categories, ruling out the ones with little importance to the problem under study, and starting to generate theories. The researcher has the freedom to go back to data collection, continue theoretical sampling if he or she feels the need. During 3CA process, the researchers (still preferably in a group) begin with selecting events that are of the most importance. The events chosen are the ones that have a greater contribution to the unwanted event or situation being investigated. Then under the guidance of prescribed 3CA forms, root causes are generated by the researchers as explanations to the occurrence of unwanted events or situations.

Having compared the combination of ECFA+3CA, the methods we adopted in this project, and grounded theory method in terms of data collection and data analysis practices, we can see that the ECFA+3CA combination bears many resemblances in terms of general research framework with grounded theory method. Such comparison in research frameworks led us to further reflect on the qualities of their conclusions.

[2] We take Strauss and Corbin's approach in grounded theory practice to compare the details.

For qualitative research, objectivity, reliability, internal and external validity are often looked into at the end of the research (Miles & Huberman, 1994). Although it was barely challenged, we think that the objectivity and internal validity of 3CA, as a root cause analysis method that comes after sequencing of facts with ECFA, needs to be carefully thought over during and after the analysis. As for external validity, it is not a concern for ECFA+3CA since investigation is always focused on one particular incident. In Figure 6.1, we marked "subjectivity" on the arrow pointing to the right at the bottom, meaning that in both grounded theory and ECFA+3CA methods the level of objectivity is decreasing. With grounded theory method, the researcher moves gradually away from raw data to the theories he or she has to create, so how much the theories developed by the researcher are grounded to the reality (the original qualitative data) and how reliable the informants or field workers (if in a group) are always in question. This raises similar questions for the ECFA+3CA combination: the level of subjectivity also increases as the researchers move from raw data to root cause analysis, which also gives "theories" explaining possible causes for the incidents. In qualitative research, researchers are encouraged to do the checks on their own or with colleagues, following suggested guidance in form of queries to improve their work. Similarly, in order to achieve more robust and convincing results, we find it helpful to make quality check for both ECFA+3CA more explicit in the project group, especially for a research project like this, in which the conclusions of 3CA are meant to be used as a base for other theories. In particular, if ECFA and 3CA are solely used as tools for post-event evaluation of projects like outbreak control, as a tool for generating lessons, the objectivity and internal validity ought to be given sufficient consideration. The recommendations are shown in Figure 6.2 below.

Objectivity *How are the conclusion of root cause analysis grounded to original evidence?*
- Are there assumptions not listed as hypothetical conditions in the ECFA chart? - Are there relationships between events across different source of evidence? If yes, is the logic of the relationships sound and are they reviewed by an external expert? - Does any critical events used in 3CA caused by hypothetical or unconfirmed conditions? - Can the root causes generated in 3CA be explicitly linked to certain chains of events in the original evidence? - Are there multiple causal factors generated in 3CA contributing to the same significant events? Are there contradictions between them or with other causal factors?
Internal validity *How much sense does the conclusion of root cause analysis make?*
- Are the conclusions of 3CA reviewed by external experts on the incidents under investigation, in a multi-disciplinary group if necessary? - Are there objections to the concluded root causes, especially from the informants or people involved in the incidents? - Do the root causes and the abduction reasoning sound sensible to a person not at all involved in the investigation?

Figure 6.2 Recommended queries on objectivity and validity check for the combined use of ECFA+3CA

During the 3CA practices in this project, we found asking ourselves these questions and taking the results of analyses to people specialised in different knowledge background very helpful for us to revise our work and to gain insights in reworking on the previous sequencing step with ECFA+. We would recommend the same considerations for future use of the ECFA+3CA combination, especially

when applied on the evaluation of incidents, the witness of which is not readily available to contact, and with less-than-abundant written evidence.

6.2.3 Comparisons between recommendations

To conclude the reflection chapter, we would like to compare the recommendations from us and past evaluation reports, and discuss the connection between research methodology and results. The recommendations from Q-fever (by Commissie van Dijk) and Salmonella (by GGD/RIVM) are summarised in Figure 6.3.

Q-fever outbreak *Recommendations by Commissie van Dijk*
- Improve the early signalling (Q-fever added to standard report package); - Clarify task division and communication (Implement response plan of CIb; appoint a contact from CIb to communicate with other stakeholders; CIb should make stepwise plan stating who, when and how a signal should be pursued); - Structure the advisory process (Guidelines for OMT meetings, Communicate guidelines to other actors); - Use implementation indicators (use indicators to evaluate implementations) - Make a protocol for OMT to give advice (knowledge base; SMART principle; deadlines) - Control measures should have priority over research; - VWS and LNV make agreements on a better exchange of humanitarian and veterinarian information; - VWA and GD should form advice on taking measures when potential sources are concerned; - Government should openly communicate what they know and what they do not know; - Experiences of other countries should be taken into account when giving advice; - For non-notifiable disease, OMT should not focus on privacy issues and let these hamper source tracing.
Salmonella outbreak *Recommendations by GGD/RIVM*
- Pay attention to the role of the mayor, and how GGD can provide the mayor with advice; - VWA should implement precautionary principle; - Choose one person or organisation, during an outbreak, to take the leading role; - CIb will make a protocol stating the collaboration between the CIb and parnters (how it should be during outbreak) - There should be structural meetings between involved parites, starting with a face-to-face meeting for acquaintance; - All relevant information should be made available for involved parties in one central place (e.g. blackboard); - At the start of an outbreak state the task division of actors, expectations, responsibilities, and monitor these.

Figure 6.3 Recommendations given in past evaluation reports

From the above table we can see that in the van Dijk/GGD/RIVM reports, recommendations have two shortcomings. First, some recommendations are vague and broad without sufficient details pointing out what tools/processes could be adopted to achieve what is recommended. Second, on the other end, some recommendations are too actor-specific; some systemic elements are not addressed in such a way that when another actor playing a similar role during outbreak control is

placed at a certain position, the preparedness of the outbreak management system is not affected as a result of "accommodating" the new actor and the changes it brings about. In other words, actor-specific recommendations are not generalizable to wide range of scenarios for outbreak control due to the failure to see to systemic factors. In contrast, we present the framework we used in this project to depict how we arrive at our recommendations in Figure 6.4.

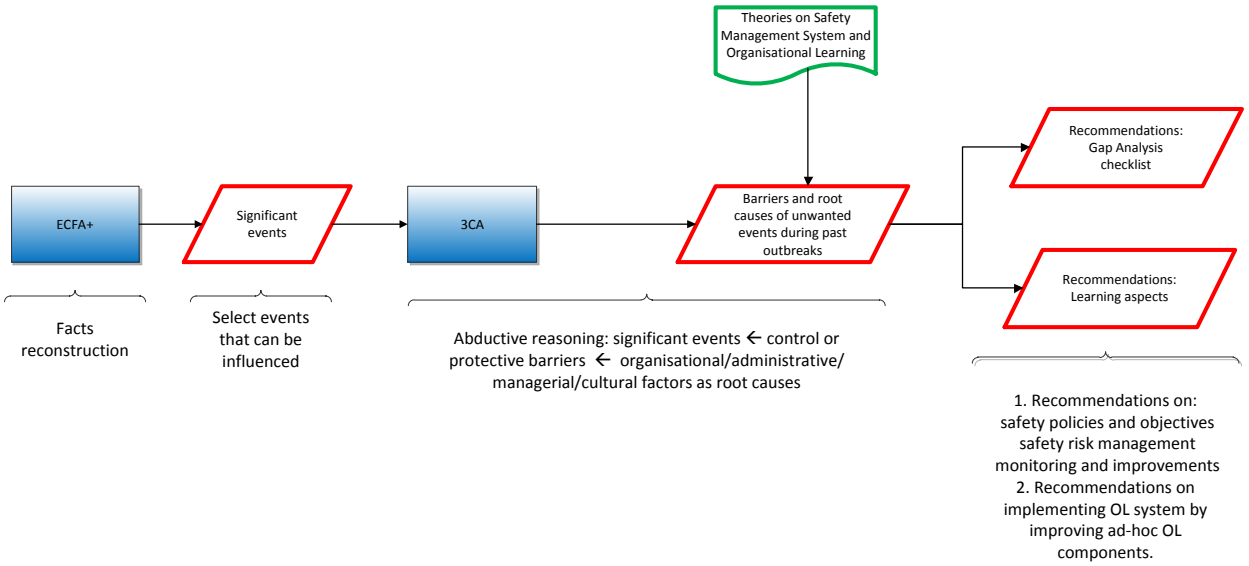


Figure 6.4 Framework of making recommendations in this project

The critical step determining on what aspects recommendations to give is the root cause analysis with 3CA. Moving from ECFA+ to 3CA is analogous to grounded theory approach in qualitative research, which uses neither inductive nor deductive reasoning, but abductive reasoning. Abductive reasoning is about formulating explanations derived from evidence and observations. In our project, we used ECFA+ to reconstruct logical chains of events, picked out significant events which are subject to intervention or control, then followed 3CA principles to formulate explanations which are sufficient but unnecessary for the significant events. We used consulted experts to increase the internal validity of this framework until we had obtained satisfactory 3CA results. After the business process model was built upon 3CA results, a focus group session was organised to evaluate the process model of SMS for outbreak control, based on which we finalised our recommendations from both systemic perspective and learning perspective. Hence we believe that this set of methodologies is able to generate more robust recommendations for improving outbreak control management, and is recommended to be used in similar post-event evaluation projects or explorative studies which seek to build a safety management system.

6.2.4 Limitations of the project and suggestions for future research

The first limitation of this project is the shortage of evidence for facts reconstruction. First of all, we had only four published reports on Q-fever and Samlonella outbreaks. Even if consulting experts at RIVM has been possible throughout the project, there are still gaps in the ECFA charts. Secondly, useful qualitative data is hard to obtain. Both the facts reconstruction and root cause analysis

require logic check because explanations are derived from abductive reasoning, a reasoning scheme shared by grounded theory method in qualitative research. Thus it would require more efforts in confirming the internal validity and to what it extent the explanations can be grounded to what did happen during the two outbreaks. Although we had several project meetings with an expert from RIVM, and a focus group session with more experts engaging in outbreak control management and communication, we still feel a little unsatisfied with the root cause analysis, even taking into account that we have gained satisfactory SMS and BPM model tailored to countering the root causes that could have resulted in the unwanted events.

A second limitation of the project is that the approaches and framework applied to the research is new to the domain of outbreak control. ECFA+ and 3CA have been more frequently used in more "traditional" incidents such as traffic and chemical accidents, while the coupling of safety management system and organisational learning process was successfully applied in aviation industry. However, in this project, ECFA+ was limited to only four past evaluation reports on outbreak management, and the chains of events are over a much longer temporal period than those in traffic or chemical incidents. This "unusual" application still needs validation through reproduction by different researchers or in a similar context.

The application of safety management system theory and organisational learning theory in building the SMS and process model, although the results were approved by the project initiator RIVM, it is still a long way to go to implement every element in the process model within a short time. The implementation of an SMS in aviation industry (EU HILAS project 2005-2009) took much longer research cycle and a series of workshops to lead to a successful application. Therefore we would suggest a stepwise implementation of the process model based on the client's actual needs and financial restrictions. In that case, the blocks and processes to be implemented would require a more thorough investigation in the three systemic elements (human, software, hardware) to achieve operational readiness in every functional block in the demanded part(s) of process model. The research framework should be drastically changed. 3CA in this project aims to produce "theories" to explain the cause of unwanted events during outbreak control. Since the theories are already generated, in order to validate and modify the theories drawn from 3CA, data collection methods, such as participant observation, workshops, and interviews within the unit of observation (one or more organisations in the outbreak management system), are essential to developing concrete policies for the implementation of (part of) the Safety Management System proposed in this project.

References

Buys, J. R., & Clark, J. L. (1995). *Events and Causal Factors Analysis.* SCIENTECH, Inc.

Canada, D. o. (2001). *Railway Safety Management System Regulations.* Retrieved July 2012, from http://laws-lois.justice.gc.ca/eng/regulations/SOR-2001-37/page-1.html#h-2

Canada, H. (2003). *Learning from SARS: Renewal of Public Health in Canada.* Health Canada.

Dijk, C. v. (2010). *Van verwerping tot verherffing: Q-koortsbeleid in Nederland 2005-2010.* Commissie van Dijk.

Duynhoven, Y. T., Isken, L. D., Borgen, K., Besselse, M., Soethoudt, K., haitsma, O., et al. (2009). A prolonged outbreak of Salmonella typhimurium infection related to an uncommon vehicle: hard cheese made from raw milk. *Epidemiol. infect. 137*, 1548-1557.

Hoek, W. v., Dijkstra, F., Schimmer, B., Schneeberger, P. M., Vellema, P., Wijkmans, C., et al. (2010). Q fever in the Netherlands: an update on the epidemiology and control measures. *Eurosurveillance 15(12)*, 1-4.

ICAO. (2009). *Safety Management Manual.* Montréal: International Civil Aviation Organisation.

IMO. (2002). *International Safety Management (ISM) Code.* Retrieved July 2012, from http://www.imo.org/blast/mainframe.asp?topic_id=287

Isken, L. D., Roorda, J., Kok, L. d., Kaur, P., Ouwerkerk, I. M., & Stenvers, O. F. (2008). *Eindrapport "Evaluatie Salmonella typhimurium ft 560 uitbraak in Twente".* RIVM.

Jeeninga, W., Vos, E. H., Bon-Martens, M. J., & Sande, J. C. (2008). *Evaluatie Q-koortsuitbraak 2007 in de GGD-regio Hart voor Brabant.* GGD Hart voor Brabant.

Karagiannis, I., Morroy, G., Rietveld, A., Horrevorts, A. M., Hamans, M., Francken, P., et al. (2007). Q fever outbreak in the Netherlands: a preliminary report. *Eurosurveillance 12(32)*, 1-4.

Kingston, J. (2002). *Control Change Cause Analysis.* Delft: The Noordwijk Risk Initiative Foundation.

Kingston, J., Frei, R., Koornneef, F., & Schallier, P. (2007). *Defining Operational Readiness to Investigate.* Delft: The Noordwijk Risk Initiative Foundation.

Kingston, J., Jager, J., Koornneef, F., Frei, R., & Schallier, P. (2007). *Events and Conditional Factors Analysis Manual.* Delft: The Noordwijk Risk Initiative Foundation.

Koornneef, F. (2000). *Organised Learning from Small-scale Incidents. PhD Thesis.* Delft: Delft University Press.

Koornneef, F., & Hale, A. R. (2004). *Organisational Learning and Theories of Action In: J. H. Andriessen & B. Fahlbruch, (eds.) How to manage experience sharing - from organisational surprises to organisational knowledge.* Amsterdam: Elsevier Science.

Koornneef, F., Hale, A. R., & Dijk, a. W. (2005). Critical assessment of the organisational learning system of the fire service in response to fatal accidents to firemen. *In ESREL 2005 - Advances in Safety and Reliablility. Tri City, Poland.* Taylor & Francis Group, 2005, London.

Koornneef, F., Stewart, S., & Akselsson, R. (2010). Bringing SMS in aviation to life by human integration: buidling on the ICAO SMS and transitioning away from a static regulatory approach. *10th International Probalistic Safety Assessment and Management Conference.*

Koornneef, F., Stewart, S., Akselsson, R., & Ward, M. (2009). *Organisational Learning & Organisational Memory Framework. Book chapter (draft) and report submitted to the European Commission. HILAS.* Dublin.

Miles, M. B., & Huberman, A. M. (1994). *An Expanded Sourcebook: Qualiatative Data Analysis (second edition).* Sage.

RIVM. (2007). *Eindrapport evaluatie Q-koortuitbraak in Noord-Brabant 2007.* RIVM.

Scimmer, B., Morroy, G., Dijkstra, F., Schneeberger, P. M., Weers-Pothoff, G., Timen, A., et al. (2008). Large ongoing Q fever outbreak in the south of the Netherlands. *Eurosurveillance 13(7-9)*, 1-3.

Smith, T. A. (2010). *Continual Renewal and Improvement of System/Safety Performance (CRISP) to Safety Management.* Mocal Inc.

Verschuren, P., & Doorewaard, H. (2010). *Designing a Research Project (Second Edition).* The Hague: Eleven International Publishing.

Weick, K. E. (1995). *Occasions for Sensemaking In "Sensemaking in Organisations".* Sage.

Weick, K. E. (1995). *The Nature of Sensemaking In "Sensemaking in Organisations".* Sage.

Weick, K. E. (1995). *The Substance of Sensemaking In "Sensemaking in Organisation".* Sage.

Weick, K. E. (2002). Puzzles in Organisational Learning: An Exercise in Disciplined Imagination. *British Journal of Management, Vol. 13*, S7-S15.

Whelan, J., Noel, H., Friesema, I., Hofhuis, A., Jager, C. M., Heck, M., et al. (2010). National outbreak of Salmonella typhimurium Dutch phage type 132 in the Netherlands. *Eurosurveillance 15(44)*, 1-4.

Appendix I

Ministry of LNV

LNV was responsible for agricultural food and animal safety issue, as well as the execution of preventive measures concerning livestock diseases. It was the leader in the Q-fever outbreak in the Netherlands during 2007-2010. It is now (or part of?) the Ministry of Economic Affairs, Agriculture and Innovation (Ministerie van Economische Zaken, Landbouw en Innovatie, EL&I). As a ministry of the Dutch government, LNV had legislative power in the time of the outbreak.

Ministry of VWS

(Ministerie van Volkgezondheid, Welzijn en Sport, VWS)

Except for sports, the Ministry of VWS operate in the public health domain. Together with health insurers, and other healthcare service providers, the Ministry of VWS is tasked with ensuring enough supplies and facilities so that people have sufficient choices. During the outbreak of Q-fever, VWS was responsible for formulating policy goals and ensuring the tasks were performed in a well-targeted, effective, and efficient way.

nVWA

(Nederlandse Voedsel- en Warenautoriteit)

nVWA is an independent agency in the Ministry of EL&I, and a delivery agency for VWS. The three main task of nVWA are supervision, risk assessment and risk communication in the field of food and consumer products. Other important activities are incident and crisis management, giving policy advice to the Minister of LNV. It also liaises with other ministries when needed.

The ultimate task of nVWA is to protect human and animal health. It monitors food and consumer products to safeguard public health, animal health and welfare. The Authority controls the whole production chain, from raw materials and processing aids to end products and consumption.

The General Inspection Service (De Algemene Inspectiedienst, AID), Plant Protection Service (Plantenziektenkundige Dienst, PD), and Food and Wellbeing Authority (Voedsel en Waren Autoriteit) merged on Jan 1, 2012 as nVWA. Before that, VWA did not provide service in inspection and plant protection. It was the old VWA that intervened in the Salmonella outbreak during 2006-2007.

RIVM

RIVM makes useful and independent knowledge available to the central government and local governments to formulate policies and take measures. Also, RIVM schedule and implement nationwide tasks in the field of public health and the environment.

- Policy support to government(s)
- National coordination

- Prevention and intervention programmes
- Provision of information to professionals and citizens
- Knowledge and research
- Support for inspections
- Emergency functions

RIVM give information and consultations to VWS and EL&I, in terms of both policy directions and inspections. However, the research methods of RIVM are independent of the clients, having its own Supervisory Committee to oversee the scientific quality of the research. RIVM support the policy-making, coordinate the implementation of policies, and provide guidelines and strategies, all of which are important source of information for professionals in the field of infectious disease control and healthy living. In terms of prevention and intervention programmes, RIVM ensures that diseases are prevented or detected early so that the patients can receive timely treatment.

RIVM position itself as a learning organisation. All knowledge RIVM acquires are through its own research and investigation, or through integrating public knowledge. The knowledge is maintained by self-examination and in alliance with other research institutes to ensure the knowledge is sufficient in quality.

The inspection function of RIVM is two-fold: inspection of the quality of healthcare, disease prevention, and medical products, and inspection of the quality of the environment. The enforcement of inspection and related policies are joint efforts: independent bodies verify the rules and laws. There is also a signalling function for situations when existing rules are vague and unworkable.

In case of potential disasters, RIVM must give quick analysis on the situation and give recommendation on measures to be taken by the government, especially in cases of infectious diseases, food safety issue, and the environment.

CIb (Centrum Infectieziektebestrijding) of RIVM

The Centre for Infectious Disease Control (CIb) is part of the National Institute for Health and Environment (RIVM). Generally speaking, it is tasked with signalling, controlling and preventing infectious disease for the benefit of public health in the Netherlands. CIb is also assumed to take the leading role in the Outbreak Management Team (OMT) in case of a threatening epidemic is on the way and calls for a multidisciplinary group of experts. The task of the OMT is to give professional advice to the VWS on the infectious disease control. CIb consists of six functional units in terms of scientific research, management and control, all of which are described as below.

Unit of Policy, Management and Advice

- Encourage new developments relating to the infrastructure and organisation of infectious disease control.
- Supporting the management of line management and project leaders in the field of finance, contract, and information on quality, health, safety and environment protection policies.
- Research and account management: ensure a strategic research policy and good programming and accountability for clients.

- Implementation and advice on subsidiary schemes.
- International cooperation.

Unit of Epidemiology and Surveillance
(Epidemiologie en Surveillance, EPI)

- Initiate and encourage research into the occurrence and spread of infectious diseases.
- Support and advice in investigating outbreaks of infectious diseases.
- Develop surveillance systems
- Sharing and distributing gained knowledge, including through publication of scientific papers and RIVM reports in the field of epidemiological research on infectious diseases.
- Liaise with other EU countries on surveillance and control of infectious diseases.
- Work closely with GGD, universities and professionals in order to become as productive as possible in terms of the interaction between science and infectious disease control.

National Coordinator for Infectious Disease Control
(Landelijke Coödinatie Infectieziektebestrijding, LCI)

- Daily advice to professionals in the field, particularly for GGD doctors and nurses.
- Crisis management during an epidemic or one that is impending.
- Preparation guidelines for those who involved in an epidemic.
- Establish communication and information for CIb.

Unit of Vaccinology
Former Nederlands Vaccin Instituut, founded January 1, 2011 as part of CIb.

- Research, development and improvement of existing and new vaccines.
- Immunological and clinical immunological research for vaccines.

Laboratory of Infectious Diseases and Screening
(Laboratorium voor Infectieziekten en Screening, LIS)

- Patient-oriented epidemiologic diagnosis in the field of bacteriology, virology, parasitology and mycology.
- Surveillance and molecular epidemiology of antibiotic resistance.
- Testing the effectiveness of the National Immunisation Programme (Rijksvaccinatieprogramma)
- Monitoring pathogen populations
- (Other responsibilities concerning newborns, not related to pathogens)

Laboratory for Zoonoses and Environmental Microbiology
(Laboratorium voor Zoönosen en Omgevingsmicrobiologie, LZO)

- Detection of microbial threats from animals, food and the environment.
- Advice on intervention on and response to outbreaks and emergencies.
- Surveillance research and transmission source research through both laboratory and mathematical modeling.

- Assess risks, identify risk factors, and determine the effectiveness of managerial actions.
- Compiling comprehensive reports.
- Bring expertise in national and international scientific panels and workgroups.

GGD

GGD Nederland is the Association of GGDs (Community Health Services) in the country. Local GGDs are responsible for preventive healthcare. They monitor health risks to all residents in the country. The tasks of local GGDs are not always identical for they could be given special assignments based on context. Some common functions and responsibilities are socio-medical advice, child healthcare, medical screening, epidemiology, and health education. Also, GGD function as the information source and contact person for stakeholders in the regions, such as GPs, company doctors, the media, and the general public.

In the time of Q-fever outbreak in 2007-2010, GGD HvB, Helmond, Brabant-zuidoost, and Brabant-west were involved in the outbreak control. The GGDs were tasked to detect the source of infection, stop the source and trace contacts from the infected population. They are informed by physicians and laboratories in local hospitals of the infected human patients. These notifications are processed in an automated system (OSIRIS), which are then analysed by EPI/IVM. GGDs can be requested information within the range of its responsibilities by RIVM and related ministries.

COKZ

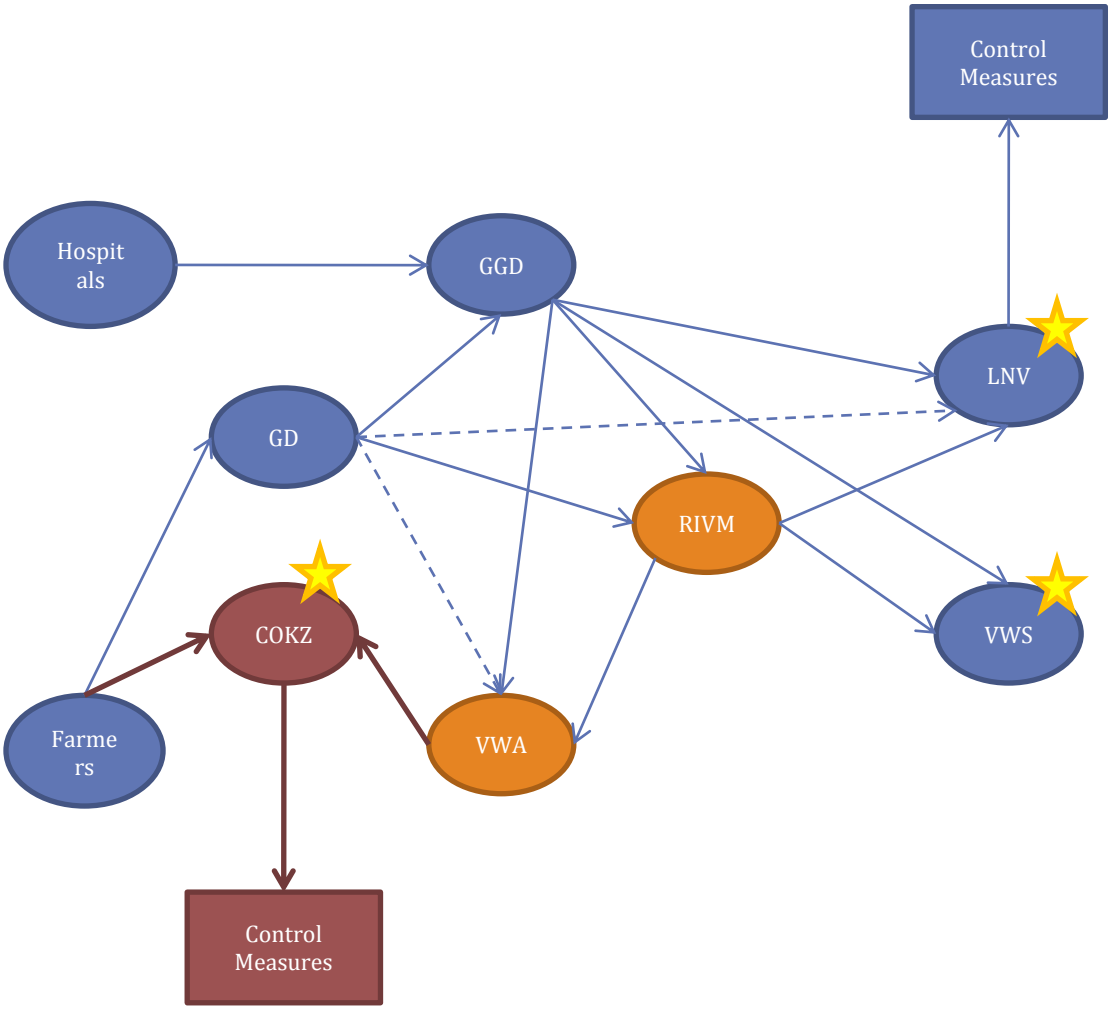
(Centraal Orgaan voor Kwaliteitsaanelegenheden in de Zuivel, COKZ)

COKZ is the Netherlands Controlling Authority for milk and milk products. COKZ perform controls, inspection, and communicate with its knowledge on dairy legislation over process and product quality criteria on behalf of the government. They do not have legislative power, but are the authority that can enforce the laws and regulations in dairy industry by creating quality criteria and makes sure the production activities are in compliance with laws and regulations. COKZ perform its activities in the framework of national or EU regulations. COKZ is commissioned by the Ministry of VWA to supervise the milk and dairy sector.

GD

GD is a private organisation that combines the expertise in animal health and laboratory diagnosis. Beside monitoring and eradication of diseases, GD also engage in research projects to identify emerging diseases and to develop new laboratory tests. GD claims on its website that it collects information related to monitoring programmes from laboratory and farm visits, and then report to the government.

Overview of Stakeholders in the Q-fever and Salmonella Outbreak Cases



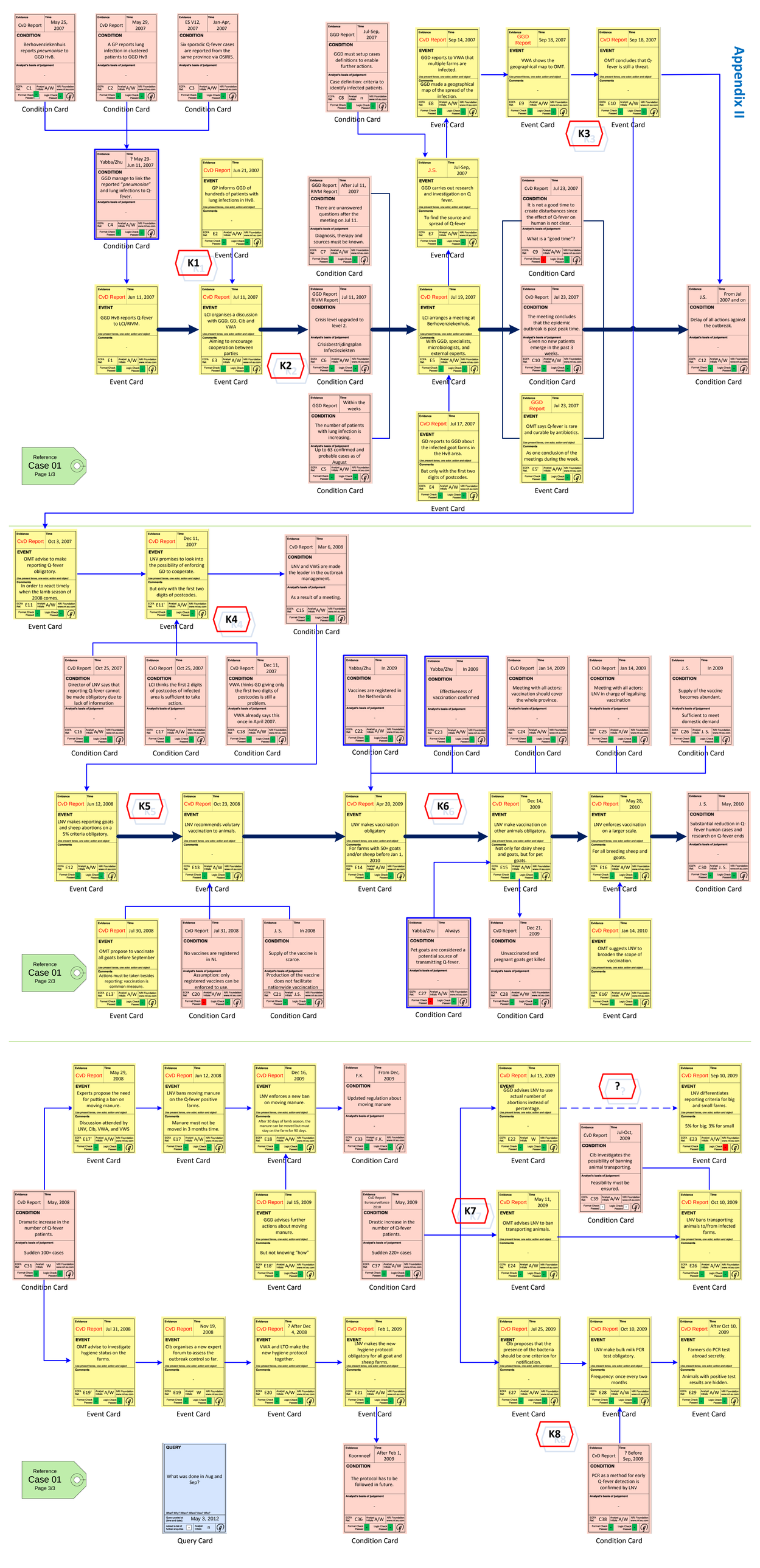
Red shapes and firm arrows - Stakeholders and information flows in case of dairy products

The rest - in case of general infectious disease outbreak which originates from animals or products

Dashed arrows - information flows that did not happen but were supposed to

Green shapes - learning organisation

Starred shapes - Stakeholders with legislative or regulatory power


Appendix II
Reference
Case 01
Page 1/3
Reference
Case 01
Page 2/3
Reference
Case 01
Page 3/3
K1
K2
K3
K4
K5
K6
K7
K8
?
Condition Card
Event Card
Query Card
CvD Report May 25, 2007
CONDITION
Berhovenziekenhuis reports pneumoniae to GGD HvB.
CvD Report May 29, 2007
CONDITION
A GP reports lung infection in clustered patients to GGD HvB
CvD Report ES V12, 2007 Jan-Apr, 2007
CONDITION
Six sporadic Q-fever cases are reported from the same province via OSIRIS.
GGD Report Jul-Sep, 2007
CONDITION
GGD must setup cases definitions to enable further actions.
Case definition: criteria to identify infected patients.
CvD Report Sep 14, 2007
EVENT
GGD reports to VWA that multiple farms are infected.
GGD Report Sep 18, 2007
EVENT
VWA shows the geographical map to OMT.
CvD Report Sep 18, 2007
EVENT
OMT concludes that Q-fever is still a threat.
Yabba/Zhu 7 May 29-Jun 11, 2007
CONDITION
GGD manage to link the reported "pneumoniae" and lung infections to Q-fever.
CvD Report Jun 21, 2007
EVENT
GP informs GGD of hundreds of patients with lung infections in HvB.
J.S. Jul-Sep, 2007
EVENT
GGD carries out research and investigation on Q fever.
To find the source and spread of Q-fever
GGD Report RIVM Report After Jul 11, 2007
CONDITION
There are unanswered questions after the meeting on Jul 11.
Diagnosis, therapy and sources must be known.
CvD Report Jul 23, 2007
CONDITION
It is not a good time to create disturbances since the effect of Q-fever on human is not clear.
What is a "good time"?
CvD Report Jun 11, 2007
EVENT
GGD HvB reports Q-fever to LCI/RIVM.
CvD Report Jul 11, 2007
EVENT
LCI organises a discussion with GGD, GD, Cib and VWA
Aiming to encourage cooperation between parties
GGD Report RIVM Report Jul 11, 2007
CONDITION
Crisis level upgraded to level 2.
Crisisbestrijdingsplan Infectieziekten
CvD Report Jul 19, 2007
EVENT
LCI arranges a meeting at Berhovenziekenhuis.
With GGD, specialists, microbiologists, and external experts.
CvD Report Jul 23, 2007
CONDITION
The meeting concludes that the epidemic outbreak is past peak time.
Given no new patients emerge in the past 3 weeks.
J.S. From Jul 2007 and on
CONDITION
Delay of all actions against the outbreak.
GGD Report Within the weeks
CONDITION
The number of patients with lung infection is increasing.
Up to 63 confirmed and probable cases as of August
CvD Report Jul 17, 2007
EVENT
GD reports to GGD about the infected goat farms in the HvB area.
But only with the first two digits of postcodes.
GGD Report Jul 23, 2007
EVENT
OMT says Q-fever is rare and curable by antibiotics.
As one conclusion of the meetings during the week.
CvD Report Oct 3, 2007
EVENT
OMT advise to make reporting Q-fever obligatory.
In order to react timely when the lamb season of 2008 comes.
CvD Report Dec 11, 2007
EVENT
LNV promises to look into the possibility of enforcing GD to cooperate.
But only with the first two digits of postcodes.
CvD Report Mar 6, 2008
CONDITION
LNV and VWS are made the leader in the outbreak management.
As a result of a meeting.
CvD Report Oct 25, 2007
CONDITION
Director of LNV says that reporting Q-fever cannot be made obligatory due to lack of information
CvD Report Oct 25, 2007
CONDITION
LCI thinks the first 2 digits of postcodes of infected area is sufficient to take action.
CvD Report Dec 11, 2007
CONDITION
VWA thinks GD giving only the first two digits of postcodes is still a problem.
VWA already says this once in April 2007.
Yabba/Zhu In 2009
CONDITION
Vaccines are registered in the Netherlands
Yabba/Zhu In 2009
CONDITION
Effectiveness of vaccination confirmed
CvD Report Jan 14, 2009
CONDITION
Meeting with all actors: vaccination should cover the whole province.
CvD Report Jan 14, 2009
CONDITION
Meeting with all actors: LNV in charge of legalising vaccination
J. S. In 2009
CONDITION
Supply of the vaccine becomes abundant.
Sufficient to meet domestic demand
CvD Report Jun 12, 2008
EVENT
LNV makes reporting goats and sheep abortions on a 5% criteria obligatory.
CvD Report Oct 23, 2008
EVENT
LNV recommends voluntary vaccination to animals.
CvD Report Apr 20, 2009
EVENT
LNV makes vaccination obligatory
For farms with 50+ goats and/or sheep before Jan 1, 2010
CvD Report Dec 14, 2009
EVENT
LNV make vaccination on other animals obligatory.
Not only for dairy sheep and goats, but for pet goats.
CvD Report May 28, 2010
EVENT
LNV enforces vaccination on a larger scale.
For all breeding sheep and goats.
J. S. May, 2010
CONDITION
Substantial reduction in Q-fever human cases and research on Q-fever ends
CvD Report Jul 30, 2008
EVENT
OMT propose to vaccinate all goats before September
Actions must be taken besides reporting: vaccination is common measure.
CvD Report Jul 31, 2008
CONDITION
No vaccines are registered in NL
Assumption: only registered vaccines can be enforced to use.
J. S. In 2008
CONDITION
Supply of the vaccine is scarce.
Production of the vaccine does not facilitate nationwide vaccination
Yabba/Zhu Always
CONDITION
Pet goats are considered a potential source of transmitting Q-fever.
CvD Report Dec 21, 2009
CONDITION
Unvaccinated and pregnant goats get killed
CvD Report Jan 14, 2010
EVENT
OMT suggests LNV to broaden the scope of vaccination.
CvD Report May 29, 2008
EVENT
Experts propose the need for putting a ban on moving manure.
Discussion attended by LNV, Cib, VWA, and VWS
CvD Report Jun 12, 2008
EVENT
LNV bans moving manure on the Q-fever positive farms.
Manure must not be moved in 3 months time.
CvD Report Dec 16, 2009
EVENT
LNV enforces a new ban on moving manure.
After 30 days of lamb season, the manure can be moved but must stay on the farm for 90 days.
F.K. From Dec, 2009
CONDITION
Updated regulation about moving manure
CvD Report Jul 15, 2009
EVENT
GGD advises LNV to use actual number of abortions instead of percentage.
CvD Report Sep 10, 2009
EVENT
LNV differentiates reporting criteria for big and small farms.
5% for big; 3% for small
CvD Report May, 2008
CONDITION
Dramatic increase in the number of Q-fever patients.
Sudden 100+ cases
CvD Report Jul 15, 2009
EVENT
GGD advises further actions about moving manure.
But not knowing "how"
CvD Report Eurosurveillance 2010 May, 2009
CONDITION
Drastic increase in the number of Q-fever patients.
Sudden 220+ cases
CvD Report May 11, 2009
EVENT
OMT advises LNV to ban transporting animals.
Jul-Oct, 2009
CONDITION
Cib investigates the possibility of banning animal transporting.
Feasibility must be ensured.
CvD Report Oct 10, 2009
EVENT
LNV bans transporting animals to/from infected farms.
CvD Report Jul 31, 2008
EVENT
OMT advise to investigate hygiene status on the farms.
CvD Report Nov 19, 2008
EVENT
Cib organises a new expert forum to assess the outbreak control so far.
? After Dec 4, 2008
EVENT
VWA and LTO make the new hygiene protocol together.
CvD Report Feb 1, 2009
EVENT
LNV makes the new hygiene protocol obligatory for all goat and sheep farms.
CvD Report Jul 25, 2009
EVENT
Cib proposes that the presence of the bacteria should be one criterion for notification.
CvD Report Oct 10, 2009
EVENT
LNV make bulk milk PCR test obligatory.
Frequency: once every two months
CvD Report After Oct 10, 2009
EVENT
Farmers do PCR test abroad secretly.
Animals with positive test results are hidden.
QUERY
What was done in Aug and Sep?
May 3, 2012
Koornneef After Feb 1, 2009
CONDITION
The protocol has to be followed in future.
CvD Report ? Before Sep, 2009
CONDITION
PCR as a method for early Q-fever detection is confirmed by LNV

Condition Card

Evidence: J.S. | Time: In 2006
CONDITION
RIVM conducts Salmonella surveillance in human patients.
Analyst's basis of judgement: -
ECFA Ref: C2 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: J.S. | Time: Before Feb 6, 2006
EVENT
LMTA sends testing samples from a surveillance project to RIVM.
Use present tense, one actor, action and object
Comments: LMTA Twente participants the surveillance.
ECFA Ref: E3 | Analyst Initials: J.S. | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Feb w2, 2006
EVENT
RIVM confirms the same Salmonella phage type in 18 patients from Enschede.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E4 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: J.S. | Time: Feb 9, 2006
CONDITION
RIVM meets with VWA and GGD.
Analyst's basis of judgement: Internal meeting about who should do what.
ECFA Ref: C4 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Reference
Case 02
Page 1/4

Evidence: RIVM Report | Time: Feb 23, 2006
EVENT
GD finds Salmonella-positive manure samples on Farm A.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E18 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: After Feb 23, 2006
CONDITION
GD does not report to anybody.
Analyst's basis of judgement: GD is not obliged to share the information.
ECFA Ref: c14 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

S1
S1

Evidence: RIVM Report | Time: Mar 13-17, 2006
CONDITION
LIS/RIVM confirms ft 561 in the beef samples.
Analyst's basis of judgement: -
ECFA Ref: E15' | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Mar 20-24, 2006
CONDITION
LCI/RIVM concludes that the beef samples and the patients are infected by the same phage type.
Analyst's basis of judgement: -
ECFA Ref: C15 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Mar 6-10, 2006
EVENT
GD finds Salmonella in a clinical sick cow on Farm A.
Use present tense, one actor, action and object
Comments: Phage type unknown
ECFA Ref: E19 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Mar w2, 2006
EVENT
GD delivers beef sample to LIS/RIVM for testing
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E20 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Mar 13-17, 2006
EVENT
LIS/RIVM tests the samples.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E21 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Mar 13-17, 2006
EVENT
VWA starts source tracing with beef.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E22 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Mar w3, 2006
EVENT
VWA confirms Farm A as a suspected source.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E23 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Apr w1, 2006
EVENT
VWA starts research on cheese production process on Farm A.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E24 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Apr 14, 2006
EVENT
VWA tests milk, cheese, butter samples
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E25 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Apr 14, 2006
CONDITION
Negative results in all tests allows VWA only to continue watch Farm A.
Analyst's basis of judgement: -
ECFA Ref: C16 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Mar 27-31, 2006
EVENT
GD finds 47 cows with anti-Salmonella antibody during a blood test on Farm A.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E26 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Apr 10-28, 2006
EVENT
GD conducts research on the manure from the 47 sick cows on Farm A.
Use present tense, one actor, action and object
Comments: Two rounds of tests are conducted: 10-14, 24-28
ECFA Ref: E27 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Apr 10-28, 2006
EVENT
GD finds 4 S. typhimurium positive cows
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E28 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Apr 10-28, 2006
EVENT
GD sends positive samples to LIS/RIVM for typing
Use present tense, one actor, action and object
Comments: GD sends the samples in both rounds of research.
ECFA Ref: E29 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Before Feb 6-10, 2006
CONDITION
Both samples show S. typhimurium ft 561 postive.
Analyst's basis of judgement: -
ECFA Ref: C3' | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Before 1-5, 2006
EVENT
LIS/RIVM tests the samples.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E21 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: May 1-5, 2006
EVENT
GD killed the 4 infected cows secretly.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E30 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Jul 17-21, 2006
CONDITION
Whether the slaughtered cows ends up in the food chain is unknown to VWA
Analyst's basis of judgement: -
ECFA Ref: C17 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Feb 6-10, 2006
CONDITION
EPI/RIVM notices a rise in the number of S. typhimurium ft. 561 cases.
Analyst's basis of judgement: 24 isolates are found
ECFA Ref: C3 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: May 1-5, 2006
CONDITION
LIS/RIVM confirms the manure samples positive of S. typhimurium ft 561.
Analyst's basis of judgement: -
ECFA Ref: C17' | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Feb w2, 2006
EVENT
VWA starts source tracing with pork samples.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E5 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Feb w2, 2006
CONDITION
VWA concludes that pork samples are not traceable.
Analyst's basis of judgement: -
ECFA Ref: C5 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Feb 13-17, 2006
EVENT
EPI/RIVM reports the VWA tracing results to GGD
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E7 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Feb 13-17, 2006
EVENT
GGD starts 1st round survey in Enschede.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E6 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Mar 13-17, 2006
CONDITION
The survey indicates that the patients shop at certain supermarkets.
Analyst's basis of judgement: -
ECFA Ref: C6 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Mar 20-24, 2006
EVENT
GGD meets with VWA about the survey and possible new sources.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E8 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: Zhu | Time: Aug 12-13, 2006
CONDITION
Someone advises Farm A alternatives to keep running business.
Analyst's basis of judgement: -
ECFA Ref: C22 | Analyst Initials: W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Aug 16, 2006
CONDITION
The samples are negative.
Analyst's basis of judgement: -
ECFA Ref: C23 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Aug 15, 2006
EVENT
LZO takes cheese samples from Farm A again.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E39 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Mar 20-24, 2006
CONDITION
VWA cannot take action based on survey and without directions.
Analyst's basis of judgement: -
ECFA Ref: C7 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Mar 20-24, 2006
CONDITION
RIVM decides to help GGD with source tracing
Analyst's basis of judgement: RIVM's expertise could lead VWA somewhere.
ECFA Ref: C8 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Reference
Case 02
Page 2/4

Evidence: RIVM Report | Time: Mar 20-24, 2006
EVENT
EPI/RIVM sends new questionnaires to GGD.
Use present tense, one actor, action and object
Comments: Questions about beef products added.
ECFA Ref: E9 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Mar 20-24, 2006
EVENT
GGD starts 2nd round survey.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E10 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: After 24, 2006
CONDITION
The survey points to the same supermarkets as indicated in the 1st round survey.
Analyst's basis of judgement: -
ECFA Ref: C9 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: May w1, 2006
EVENT
VWA takes 28 samples from the supermarkets for testing.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E11 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: After May w1, 2006
CONDITION
VWA gains negative results in all samples.
Analyst's basis of judgement: -
ECFA Ref: C12 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Apr 11, 2006
EVENT
RIVM links infection with Farm A through interview outside Twente.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E12 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Apr 17-21, 2006
EVENT
GGD starts 3rd round survey.
Use present tense, one actor, action and object
Comments: Questions about dairy products added.
ECFA Ref: E13 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: Epidemiol. Infect. | Time: W15, 2006
CONDITION
The survey points to Farm A.
Analyst's basis of judgement: -
ECFA Ref: C10 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: Epidemiol. Infect. | Time: W15, 2006
EVENT
VWA takes samples from Farm A for the first time.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E14 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: After May w1, 2006
CONDITION
VWA gains negative results in all samples.
Analyst's basis of judgement: -
ECFA Ref: C13 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Jun 19-23, 2006
EVENT
GGD reports that new patients shopped at specific supermarkets
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E15 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Jun 19-23, 2006
EVENT
VWA finds a specific branch of the chain supermarkets.
Use present tense, one actor, action and object
Comments: Based on the postcode of the new patients.
ECFA Ref: E16 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Jun 26-30, 2006
EVENT
VWA tests beef, meat&fillet American from 2 branches of the chain supermarkets.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E17 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Jun 26-30, 2006
CONDITION
VWA gains negative results in all samples.
Analyst's basis of judgement: -
ECFA Ref: C11 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Mar 27-31, 2006
EVENT
GD finds 47 cows with anti-Salmonella antibody during a blood test on Farm A.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E26 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Apr 10-28, 2006
EVENT
GD conducts research on the manure from the 47 sick cows on Farm A.
Use present tense, one actor, action and object
Comments: Two rounds of tests are conducted: 10-14, 24-28
ECFA Ref: E27 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Apr 10-28, 2006
EVENT
GD finds 4 S. typhimurium positive cows
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E28 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Apr 10-28, 2006
EVENT
GD sends positive samples to LIS/RIVM for typing
Use present tense, one actor, action and object
Comments: GD sends the samples in both rounds of research.
ECFA Ref: E29 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Before 1-5, 2006
EVENT
LIS/RIVM tests the samples.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E21 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: May 1-5, 2006
EVENT
GD killed the 4 infected cows secretly.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E30 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Jul 17-21, 2006
CONDITION
Whether the slaughtered cows ends up in the food chain is unknown to VWA
Analyst's basis of judgement: -
ECFA Ref: C17 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Nov 20-24, 2006
EVENT
GD finds 12 Salmonella-positive cows on Farm A.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E32 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Nov 20-24, 2006
CONDITION
The cows are killed.
Analyst's basis of judgement: Because of? (Go to 3CA)
ECFA Ref: C18 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Aug 7-8, 2006
CONDITION
Samples from the cheese factory are S'typhimurium ft. 561 positive.
Analyst's basis of judgement: -
ECFA Ref: C19 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Reference
Case 02
Page 3/4

Evidence: Epidemiol. Infect. | Time: Aug 2, 2006
EVENT
LZO takes samples for testing on Farm A.
Use present tense, one actor, action and object
Comments: Swabs from water, the shop, and cheese factory.
ECFA Ref: E33 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Before Aug 11, 2006
EVENT
LZO tests these samples.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E34' | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Aug 11, 2006
EVENT
LZO states cheese from Farm A is highly suspected to be the source of infection.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E34 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Aug 11, 2006
EVENT
VWA suggests Farm A to close its shop.
Use present tense, one actor, action and object
Comments: (The shop on the farm sells cheese.)
ECFA Ref: E35 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Aug 11, 2006
EVENT
Farm A refuses to close the shop.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E36 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Aug 12-13, 2006
EVENT
Farm A cleans and disinfects the cheese factory.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E37 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

S3
S3

Evidence: RIVM Report | Time: Aug 9, 2006
EVENT
LZO takes cheese samples from Farm A workplace.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E38 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Aug 14-18, 2006
CONDITION
The samples are negative.
Analyst's basis of judgement: -
ECFA Ref: C20 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: After Aug 18, 2006
CONDITION
Farm A will no longer cooperate in research.
Analyst's basis of judgement: -
ECFA Ref: C21 | Analyst Initials: A | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: Epidemiol. Infect. | Time: Sep 24, 2006
CONDITION
Continued survey by RIVM outside Twente indicates that patients ate cheese from Farm B.
Analyst's basis of judgement: -
ECFA Ref: C24 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Oct 13, 2006
EVENT
VWA collects cheese samples from Farm B for testing.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E40 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Oct 23-27, 2006
CONDITION
All test results are negative.
Analyst's basis of judgement: -
ECFA Ref: C25 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: A/W | Time: Oct 23-27, 2006
CONDITION
LZO doubts the testing method of VWA's
Analyst's basis of judgement: -
ECFA Ref: C27 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

S2
S2

Evidence: Koornneef | Time: After Nov 11, 2006
CONDITION
VWA's testing method is faulty.
Analyst's basis of judgement: -
ECFA Ref: C29 | Analyst Initials: F.K. | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Oct 13, 2006
EVENT
LZO/RIVM collects cheese samples from Farm B for testing.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E41 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Oct 23-27, 2006
CONDITION
LZO gains positive results with cheese samples from Farm B
Analyst's basis of judgement: -
ECFA Ref: C26 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Oct 30-Nov 11, 2006
EVENT
LZO tests the samples again using VWA's testing method.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E42 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Oct 30-Nov 11, 2006
CONDITION
All test results are negative.
Analyst's basis of judgement: -
ECFA Ref: C28 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Reference
Case 02
Page 4/4

Evidence: RIVM Report | Time: Oct 9-13, 2006
EVENT
VWA called COKZ to join the research
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E43 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Nov 3, 2006
EVENT
COKZ collects 10 cheese samples from Farm A for LZO/RIVM to test.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E44 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Nov 6-14, 2006
EVENT
LZO/RIVM confirms 2 out of 10 cheese samples infected by S. typhimurium ft 561.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E45 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Nov 3, 2006
CONDITION
Information from COKZ shows that Farm B buys cheese from Farm A.
Analyst's basis of judgement: -
ECFA Ref: C31 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Nov 14, 2006
EVENT
VWA announces that cheese from Twente is the source of the S. typhimurium outbreak.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E46 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Before Nov 21, 2006
CONDITION
Milk for two batches of cheese produced before Nov 21, 2006 are not heated before production.
Analyst's basis of judgement: -
ECFA Ref: C32 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: After Nov 24, 2006
CONDITION
Cheese production on Farm A is supervised by COKZ, including destruction of infected batches.
Analyst's basis of judgement: -
ECFA Ref: C33 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Oct 30-Nov 3, 2006
CONDITION
COKZ and VWA discussed the possibilities of supervising the cheese production on Farm A.
Analyst's basis of judgement: -
ECFA Ref: C30 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Nov 13, 2006
EVENT
COKZ announces new regulations concerning cheese production.
Use present tense, one actor, action and object
Comments: Before being made into cheese, milk must be heated to 72 centigrade from then on.
ECFA Ref: E47 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Dec 4-18, 2006
EVENT
COKZ destroys the two batches of cheese.
Use present tense, one actor, action and object
Comments: -
ECFA Ref: E48 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Event Card

Evidence: RIVM Report | Time: Mar 12-16, 2007
CONDITION
Remaining batches under watch are destroyed or released based on test results.
Analyst's basis of judgement: -
ECFA Ref: C34 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

Evidence: RIVM Report | Time: Apr 27, 2007
CONDITION
Outbreak control ends
Analyst's basis of judgement: Officially ended?
ECFA Ref: C35 | Analyst Initials: A/W | NRI Foundation www.nrf.au.com
Format Check Passed | Logic Check Passed

Condition Card

3CA: Control Change Cause Analysis

Appendix III

(0) *Significant Events*[(a)] ↓	(1) Change to person or thing *(include attribute altered)*	(2) Agent of change *(include actor and action)*	(3) Adverse effect of change	(4) Work controls or protective barriers implicated in (1)/(2) *(controls or barriers with direct effect at "the coal face")*	(5) Signif-icance Rating *(1 to 3, where 3 = very)*	(6) In what way was each measure at (4) ineffective *(be specific and precise)*	(7) In what way did upstream* processes fail to identify or prevent the problems noted in (6) *(be specific and precise)*	(8) "Why"? *(ask "why" of each entry in column 7)*
Farmers do PCR tests abroad in secrecy. (E29)	Doing PCR tests abroad	Farmers	Failure to identify the exact number of infected animals on the farms	1) Farmer's decision 2) Supervision from LNV 3) Inter-national regulation during crisis	3	1) The farmers should have willingly participated the mandatory PCR tests arranged by LNV. 2) LNV's supervision on bulk milk only was not enough; statistics of the farm should have been part of the supervision. 3) EU laboratories that perform the tests for the farmers should notify the Dutch organisations when a sample turns out to be positive. 4) As the only organisation holding firsthand data on the outbreak, GD should be obligated to report without reservation to facilitate decision-making. 5) There was no compensation scheme for an actor at a disadvantage in the network. GD suffers financial loss if farmers go to other labs. In order to safeguard their finance (by maintaining the farmers trust) GD chose not to tell. 6) OMT is composed of a group of experts (specialists and scientists), they should have given precise advice based on facts or research in order for the investigation to be performed sooner. 7) "Give advice" is too informal to become constructive for outbreak management. 8) Hygiene status of the dairy farms has always been a "risk-bearing area" that lacks supervision. The importance of it is not considered in the first	1) Once the infected animals were detected by the officially enforced new testing method, the animals would be killed and the farmers would suffer from economic losses. 2) Risk management was poorly executed. LNV did not exhaust the list of risks that could compromise the effectiveness of monitoring and control. 3) It requires legislation or a formal agreement between EU countries. 4) It requires legislation, not merely informal agreement between GD and the government. 5) Ignoring loser management (economic loss) in decision-making in a network. 6) Wrong composition of OMT, mostly researchers in the OMT but no policy makers. 7) Outbreak management is not organised in a project management manner to have clear objectives and responsibilities for each stakeholder. 8) Regulations on the "risk-bearing areas" are not well implemented, even though such regulations exist. 9) Risk assessment procedure is not based on systematic methodologies. 10) The working process during outbreak management is incomplete. 11) Evaluation of the advice and coordination of the feasibility study of the advice given by OMT not in place; lack of project management in feasibility study.	1) As private business entity, it is the farmer's natural instinct to avoid financial losses by any means possible. Besides, farmers tend to keep to themselves rather than make noises about "surprises". 2) LNV was not experienced in human-animal infectious disease outbreak management before, and they did not foresee the act of the farmers. 3) European Commission did not enact proposals to regulate such "grey areas" during crisis. 4) Before the outbreak, it was taken for granted that GD would cooperate. 5) The financial issue was not on the agenda of decision-making rounds. 6) LNV or VWS did not want to participate in the OMT; or failed to realise the importance of attendance; or when OMT was formed, having a representative of policy-makers was not considered at all. 7) Lack of experts / leaders experienced in managing risk assessment with in the OMT 8) Supervision issue in the dairy industry. 9) Risk assessment activities, specifically investigation, analysis, and risk reduction plans, are not organised and
GD reveals partial postcode of the infected farms. (E4)	Revealing only partial information about the infection	GD	Delay in control measures being taken	4) Obligation of providing information during crisis 5) Financial compensation for farmers or GD (by LNV)	3			
OMT gives vague advice on hygiene protocols. (E19')	Giving vague advice	OMT	Delay in source tracing and investigation	6) Obligation of providing concrete advice 7) Guidelines to regulate the content of advice given by OMT 8) Supervision of "risk-bearing areas" on the farms	2			
OMT gives late advice on control measures. (E13', E17', E19', E24)	Giving advice on control measures too late.	OMT	Delay in feasibility study in all control measures; Delay in control measures being taken	9) Guidelines to regulate OMT to give exhaustive advices 10) Supervision from the network to coordinate OMT and others	3			
OMT gives inconsistent information. (E10, E5')	Giving inconsistent information	OMT	Delay in feasibility study in all control measures	11) Supervision from the network to check validity and logic of the advice given by OMT and all the others	2			

a) Complete column (0); a significant event is one that *creates an adverse change in the control of work.*
b) Complete columns (1) to (4) ONE ROW AT A TIME
c) Review table and assign significance rating in column (5)
d) Decide which rows are to be considered further
e) If required, complete columns (6) to (8) ONE ROW AT A TIME (be specific, general statements are not helpful and reflect lack of insight into actual problems)

* ***Upstream*** *meaning organisationally, administratively or managerially prior to the matter in question*

3CA: Control Change Cause Analysis

GD reveals information too late. (E18, E20)	Revealing knowledge too late	GD	Delay in source tracing	12) obligation of notifying suspected sources	2	place by OMT 9) Lack of documentation regulating risk assessment and risk reduction 10) There is no supervision or evaluation mechanism to coordinate the communication of "advice" given by OMT to other actors. 11) There should have been a mechanism or a special task team to evaluate the content, logic, validity of the advice given by the OMT. 12) As the only organisation holding firsthand data on the outbreak, GD is obligated to report without reservation to facilitate decision-making. 13) VWA should have full knowledge on all relevant stakeholders in the network. 14) VWA should have professionally trained experimenters that are not rigid in designing testing methods. 15) VWA is the regulatory body with strong rules for testing quality; however they should always update their knowledge on the changes of EU laws in their field. 16) VWA should have acted on precautionary principle as far as food safety is concerned.	12) It requires legislation, not merely informal agreement between GD and the government. 13) Incomplete knowledge management network. 14) VWA has insufficient expertise, wrong people on the research team. 15) 16) VWA will get sued if they do not follow the strict regulations even for not keeping up with updated EU laws.	managed. 10) Lack of legalised documentation or act on the business process during disease outbreak. 11) Lack of management in decision-making when risk reduction options are being selected, where systematic evaluation on all possible options is urgently essential. 12) Before the outbreak, it was taken for granted that GD would report. 13) VWA emphasized internal knowledge sharing, internal communication and internal expert exchange, but ignored the external exchanges and sharing. 14) The expertise of research staff in VWA was never doubted and challenged during crisis. They only practice their research routine by following the regular standards, ignoring the sensitivity issue. 15) VWA forgot to renew their knowledge on updated EU regulations. 16) VWA was not aware of the precautionary principle during time of crisis; using common senses instead.
VWA calls in COKZ too late. (E43)	Calling in critical stakeholder too late	VWA	Delay in control measures being taken	13) Knowledge on stakeholder network available	3			
VWA tests samples with faulty method. (E11. E14, E17, E25)	Using the wrong method in testing samples	VWA	Delay in source tracing	14) Professionalism of investigators 15) Knowledge on relevant technical standards	3			
VWA decides not to take measures on farm A. (E25)	Deciding not to take action while it can	VWA	Delay control measures on farm A being taken	16) Knowledge on relevant EU laws	2			

*Note: Blue texts – from Q-fever case; Red texts – from Salmonella case.

a) Complete column (0); a significant event is one that *creates an adverse change in the control of work.*
b) Complete columns (1) to (4) ONE ROW AT A TIME
c) Review table and assign significance rating in column (5)
d) Decide which rows are to be considered further
e) If required, complete columns (6) to (8) ONE ROW AT A TIME (be specific, general statements are not helpful and reflect lack of insight into actual problems)

* ***Upstream*** *meaning organisationally, administratively or managerially prior to the matter in question*

Appendix IV

Business Process Model of Safety Management System for Infectious Disease Outbreak Management