Exploration of the fipronil in egg contamination incident in the Netherlands using the Functional Resonance Analysis Method

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8	Exploration of the fipronil in egg contamination incident in the Netherlands using the Functional Resonance Analysis Method
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34 Abstract

Following the 2017 fipronil egg contamination incident in the European Union, improvements in safety management continue to be necessary, particularly for regulatory, preventive, and control activities. Drawing from the Dutch and European legislation, and the use of the Functional Resonance Analysis Method (FRAM), the aim of the study was to explore the regulatory framing of the elimination of red mites on poultry farms, the compliance of actual events in 2017 with these hygiene standards and regulations in order to reconcile actual practices with policy directives. The study considers the difference between policy implementation for work-as-imagined and the tasks undertaken in practice i.e., 'work-as-done'. This allows for assessment and analysis of the gap between pre-defined hygiene policy and actual practice and allows for a systemic approach rather than a causal approach to examine the public health incident. The study concludes that it is important for high level policy makers to comprehend the challenges and barriers faced by those implementing policy, and how this could potentially mean that policy in practice is not aligned with what was originally intended. The presented analysis outlines the potential of the FRAM in assessing complex food systems to support a public health investigation of incidents, and to design practical and realistic food safety policies leading to higher levels of stakeholder compliance and improved safety management.

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- Key words: fipronil egg contamination; work-as-imagined; work-as-done; policy;
- 54 FRAM; Netherlands

1. Introduction

Public policies are the outcomes of government efforts to stimulate behaviour changes at institutional and societal levels (Howlett & Mukherjee, 2014; Tummers, 2019). They are adopted by governments to structure relationships and manage behaviour among key stakeholders in order to achieve collective objectives and purposes (Howlett & Mukherjee, 2014). Additionally, public policies often aim to exert power and motivate individuals to do things they are reluctant to do on their own (Stone, 1997). At the same time the successful implementation of public policies requires the availability of resources and a strong commitment by all stakeholders (Ernie & Collier, 2003; Watt et al., 2005). By itself, the implementation of new policies and practices consists of introduction and adoption stages, which are critical in determining the fate and further impact of a given policy directive (Galstyan & Harutyunyan, 2016). Inadequate translation of knowledge into practice and a failure to adapt interventions into a local context can lead to erroneous interpretation of policy directives, and to the presence of a gap between what is planned ('prescribed policy') and what is implemented in practice ('enacted policy') (Grimshaw et al., 2012).

Policy implementation in the food industry is a complex regulatory process that involves a range of actors at different levels of the system (Babu, 2015). When evidence-based food policies ('work-as-imagined') are designed and implemented, it means they are better aligned with the needs of actual practice ('work-as-done'), and therefore are realistic and appropriate to apply to deliver the desired outcomes (Clay-Williams et al., 2015). In complex adaptive systems, such as food systems, work-as-done is often more complex and different to work-as-imagined (Hollnagel, 2012). Multiple barriers influence the implementation of effective policy in the food industry, and three barriers are of particular interest in this study due to their applicability in examining non-compliance with policy (Gunn, 1978; Hunter, 2003; Phulkerd et al., 2017). They are firstly, poor understanding of, and disagreement on the objectives of the

intended policy among policy makers, senior managers, and front-line employees; secondly, inadequately and incorrectly prescribed tasks in cleaning schedules or audit requirements as prescribed by senior and line managers; and the third barrier is the inability to obtain perfect compliance with policies due to changes in policy priorities and poor governance systems (Phulkerd et al., 2017). Consequently, these factors need to be considered in the design of food policies within existing governance structures.

The fipronil in eggs contamination incident in the Netherlands was an example of the outcome of implementing flawed national and private policies on red mite elimination, designed by government and senior management personnel, with a poor understanding of the challenges of real-world pre-audit preparation and audit processes. On the 2nd June 2017, a notification was received by the Belgian Federal Agency for the Safety of the Food Chain (AFSCA) from an egg-breaking plant of a non-compliant result for fipronil (Manning, 2018a). An investigation on the suspect egg laying farm led to further investigations and four days later two potential sources of fipronil were suggested: poultry feed and on farm red mite treatment with Dega-16, undertaken by a Dutch poultry service company (AFSCA, 2017). Two weeks later it was suspected that fipronil had been used in the red mite treatment. Four months later, the economic cost of the incident was estimated as 65-75 million euros. 1.9 million birds were slaughtered, and 77.4 million eggs were affected (Manning, 2018a; Poultry World, 2018).

the compliance of actual events with the hygiene standards and regulations, drawing from the Dutch and European legislation, and the use of the Functional Resonance Analysis Method (FRAM) in the reconciliation of the actual practices and policy directives. Three research questions were developed:

RQ1. How red mites were eliminated in poultry farms (work-as-done)?

104 RQ2. How much 'work-as-done' was aligned with the requirements of the Dutch and European legislation ('work-as-imagined')?

RQ3. How can the FRAM be used for policy development to reconcile the gap between 'work-as imagined' and 'work-as-done'?

2. Poultry hygiene standards and regulations based on Dutch and European legislation

Article 9 of Regulation (EC) 852/2004 of the European Parliament and the Council on the Hygiene of Foodstuff contain requirements and guidance related to good hygiene practices in pullet rearing and egg laying flocks. According to this Regulation, it is important ensure that poultry of the same health status are kept on the same premises and constitute a single epidemiological unit (Regulation (EC) No 852/2004 of the European Parliament and of the Council, 2004). Article 2 of Reg. 2160/2003 sets a similar mandate for housed poultry sharing the same airspace (Regulation (EC) No 2160/2003 of the European Parliament and of the Council, 2003).

In 2002, the European Commission Regulation (EC) No 1490/2002 required the European Food Safety Authority (EFSA) to review the potential for harm by fipronil in food products. In 2006, the then EU Member States concluded that fipronil content below 0.72 mg/kg in eggs would not pose any food safety concerns (EFSA, 2006). Although fipronil is permitted to be

used as a pest control product, the European Commission set a maximum residue level for

fipronil in eggs and poultry meat at 0.005 mg.kg, while completely banning its use on animals

and animal products meant for consumption (European Commission, 2017).

3. Materials and methods

3.1. Study Design

To address the first and second research questions literature analysis was performed to establish supranational and national guidance on treating red mites in poultry farms within the European Union (EU) current in 2017-18, and to gain insight into the events leading to the contamination of eggs (EUWEP, 2012; Defra, 2018; Ministry of Health Welfare and Sport, 2018a). A framework with three categories, adapted from Powell et al. (2009), was considered for exploring factors associated with the fipronil egg contamination incident, including content of the incident, context of the incident, and the process of the incident (see Table 1). The focus of this study was limited to the process of eliminating red mites on poultry farms. Since compliance failures in the incident discussed in this paper occurred at the point where poultry farms were being cleaned by cleaning contractors, only one of the themes of the policy, cleaning and disinfection, was analysed in detail in to achieve the research aim defined in this study.

Take in Table 1

To address the third research question of the study the FRAM was utilised for mapping and modelling 'work-as-done,' a qualitative approach endorsed by safety experts (Stanton et al., 2013). For detailed information on the FRAM, the authors referred to practical instruction guides (Hollnagel et al., 2012; Stanton et al., 2013), and prior publications (Clay-Williams et al., 2015; Damen et al., 2018; Raben et al., 2018). The corresponding author also attended a workshop on the methodology conducted by Professor Erik Hollnagel and Professor David Slater, hosted by the University of Oxford in March 2019.

3.2. Research Instrument

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An initial model of red mite elimination 'as-imagined' was constructed based on an analysis of the European Union of Wholesale with Eggs, Egg Products and Poultry and Game's (EUWEP) European public policy for national agencies within the EU to design their own national public policies (EUWEP, 2012). The authors developed a framework (Appendix 1) which guided the document analysis process and subsequent FRAM analyses. The interrogation of the framework is based on the FRAM method, with minor adaptations made for the analysed incident (Hollnagel et al., 2014).

3.3. Data Collection and Analysis

Due to the absence of red mite-specific guidance within the EUWEP (2012) policy document, the authors analysed two additional national red-mite management policy documents. These were the Code of practice for the welfare of laying hens and pullets, published by the Department for Environment, Food & Rural Affairs (DEFRA) in 2018 (Defra, 2018); and Advice on the risks in the poultry meat supply chain, published by the Netherlands Food and Consumer Product Safety Authority (NVWA) in 2018 (Ministry of Health Welfare and Sport, 2018a). It should be noted that both of these documents were produced after the 2017 fipronil incident. The authors deemed it relevant to analyse the United Kingdom's (UK) national policy despite the incident originating in the Netherlands for two reasons. Firstly, the UK was an EU-member country at the time of the incident and hence, its policy would be largely similar to the policy adopted by the Netherlands regarding treating red mites in freerange egg-laying hens. Secondly, the European Commissioner for Health and Food Safety reported that 26 of the 28 EU Member Countries (as of 2017-18) were affected by the incident; of which the UK had imported approximately 700,000 contaminated eggs, but a problem was not identified on UK farms (Boffey & Connolly, 2017; European Commission, 2017). An iterative modelling process was applied (Damen et al., 2018) with preliminary models

developed after analysing each document, and updated versions developed from subsequent document analyses.

The FRAM model reflecting red mite elimination work-as-done was developed by the authors based on an analysis of the 2018 Dutch national investigation report (Ministry of Health Welfare and Sport, 2018b). An iterative modelling process was applied (Damen et al., 2018) with preliminary models developed after analysing each section of the investigation report, and updated versions developed from subsequent analyses. The 'FRAM Model Visualiser version 2.1.0' was used to construct the FRAM models (Hill & Hollnagel, 2018). Document analysis was carried out until data saturation (defined as a criterion for discontinuing data collection once redundancy is identified in the data) was reached for the model (Saunders *et al.*, 2018).

Each hexagon within the FRAM was colour coded based on the nature of the function. Yellow hexagons represent non-cleaning related tasks that should be performed before the cleaning contractor visited the site. Blue hexagons represent tasks specific to dry cleaning that poultry farmers needed to perform before the visit by cleaning contractors; and green hexagons represent tasks that were scheduled to occur during the visit by inspectors and auditors. The FRAM analyses were performed by the corresponding author. Other authors then reviewed the analyses as a means of validation. While the corresponding author is a human factors researcher with experience in analysing food safety incident analysis, the second author has experience in applying socioeconomic and cultural theory in agri-food supply chains, and the third author has experience in applying human factors and accident analysis methods in various domains including food safety culture.

4. Functional Resonance Analysis Method (FRAM)

The FRAM is an analytical framework to analyse and describe the implementation of work-as-done in complex socio-technical systems (Hollnagel, 2012; Stanton et al., 2013). It allows

exploring of the elements behind the performance variability at individual, technical, and organisational levels that may result in an adverse outcome, and to discover their interrelationship (Hollnagel et al., 2008; Hollnagel & Goteman, 2004). While the FRAM is a new approach in the food industry, it has been applied in different areas such as healthcare (Hollnagel, 2012), aviation (Hollnagel et al., 2008), railway traffic supervision (Belmonte et al., 2011), air traffic management (De Carvalho, 2011; Ferreira & Canas, 2019), sustainable construction (Rosa et al., 2015) and manufacturing (Albery et al., 2016). Based on functions or tasks, the FRAM is used for the analysis and modelling of complex systems, allowing analysts to identify and describe functions, characterise the variability of functions, aggregate the variability of functions, and provide suggestions to manage the variability (Hollnagel, 2012). A function represents an activity or a range of activities and is characterised with six aspects (Figure 1) (Damen et al., 2018). In Figure 1, 'Function 1' represents an activity (e.g., power washing of surfaces) contributing to the safety management (e.g., red mite elimination). Each function six aspects: (1) input; (2) output; (3) time; (4) control; (5) resource; and (6) precondition.

Take in Figure 1

5. Results

Table 2 provides a description of the functions modelled in Figures 2 and 3, and highlights

functions unique to the work-as-done scenario.

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5.1. Work-as-imagined: Policy design and dissemination

The red mite elimination 'work-as-imagined' model reflected recommendations from the policy and guidance documents developed by the EU (EUWEP, 2012), the Dutch Food Safety Authority (NVWA, 2018), the Ministry of Health Welfare and Sports (2018a) and the

UK government (DEFRA, 2018) for the use of disinfectants to eliminate red mites in poultry farms by cleaning contractors (Figure 2). The requirements included: (1) having a detailed understanding of relevant Regulation (EC) 2160/2003 of the European Parliament; (2) physically auditing relevant and required documentation; (3) verification of disinfectants for red mite treatment; (4) enforcing a detailed plan (e.g., cancelling a contract with the cleaning contractor and discarding of disinfectants), if disinfectants were disapproved; (5) defining the farms' red mite treatment policy; and (6) achieving disinfection competency and ensuring that documentation has been signed off by private, farm and government auditors. To assess the variability of FRAM functions, the authors defined criteria to extract data from the three policy and guidance documents on red mite elimination (European Union of Wholesale with Eggs Egg Products Poultry and Game, 2012). The EUWEP's 2012 policy on terminal cleaning is a guidance document designed in accordance with Article 9 of the Regulation (EC) 852/2004 of the European Parliament, the Council (of 29 April 2004) on the Hygiene of Foodstuff, Committee of Professional Agricultural Organisations-General Confederation of Agricultural Cooperatives (COPA-CEGECA), which is a union of two big agricultural umbrella organisations representing European farmers (European Union of Wholesale with Eggs Egg Products Poultry and Game, 2012). Regulation (EC) No. 852/2004 and all relevant EC hygiene legislation on the hygiene of foodstuffs applies to all primary products, including eggs. The aim of the EUWEP policy document is to provide a framework for the effective application of Regulation (EC) 2160/2003 of the European Parliament and of the Council on the control of Salmonella and other specified food-borne zoonotic agents (European Union of Wholesale with Eggs Egg Products Poultry and Game, 2012; Union of International Associations, 2003). Information was collated from public policies on treatment for red poultry mites (based on a work-as-imagined philosophy) (DEFRA, 2018; European Union of Wholesale with Eggs

Egg Products Poultry and Game, 2012; Opperhuizen, 2018). On discovery of red poultry mites,

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the poultry farmer needs to book an appropriate (and approved) cleaning contractor well in advance of the depopulation date. The farmer must discuss cleaning and disinfection protocols with the contractor so that there is a clear understanding by the contractor of the farmers' requirements, and to ensure compliance with national guidelines and policy on the use of approved chemicals. Once a consensus has been reached, it is then the farmer's responsibility to depopulate the poultry house by ensuring any dead birds, waste and/or surplus feed are removed and appropriately disposed-off. Prior to commencing (wet) cleaning and disinfection, cleaning contractors are required to dry clean the poultry house and remove any poultry manure. Following the dry-cleaning step, cleaning contractors are allowed to commence cleaning with water and disinfectants. It is mandatory for all moveable equipment and floors to be cleaned and disinfected. Contractors need to treat the poultry house in line with national pest control protocols and in accordance with national guidelines on approved disinfectants for red mite, and as per the instructions on the label i.e., correct dilution rates. If there is a large population of mites in the poultry house, contractors are allowed to use a higher concentration of the mite disinfectant. In essence, contractors are provided the autonomy and responsibility to ensure safe and legal use of mite disinfectants. The steps to apply mite disinfectants are as follows:

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Step 1: Use a high-pressure hose to hose down the poultry house and parts of the poultry house. While using a "high-pressure" hose is not mandatory, it is recommended as the pressure helps to clean the parts of the house that are difficult to reach or hidden from plain sight, i.e., parts of the house where red mites reside. Post cleaning with a hose, the house needs to be left to dry for 10-15 minutes.

Step 2: Once the house has dried, it is advised to repeat Step 1 as it is common for red mites to crawl out of hiding once disturbed during Step 1. Step 1 needs to be repeated until there are

very few red mites left in the house. A decision on the number of repetitions of this step is left up to the discretion of the contractor.

The process of red mite elimination is complete once no more red mites can be detected on physical inspection of the environment. It is also key to note that red mites can be persistent and hence, regular pest management is essential to manage the issue. Farmers must apply a red mite powder at regular intervals in the house (including to perches) as a proactive measure to prevent hens from getting infested with red mites. Table 3 briefly summarises the topics covered by the policy document. Figure 2 illustrates through a FRAM analysis the steps needed to be undertaken by the farm and the cleaning contractor to disinfect the environment against red mites.

Take in Table 3 and Figure 2

The FRAM diagram in Figure 2 highlights all the steps required to take place immediately before, during and after the elimination of red mites from poultry farms. The FRAM functions labelled 1.1 to 1.10 (in yellow) highlight tasks supposed to take place on poultry farms before cleaning contractors visited the site. These tasks revolve around depopulating poultry houses to get the site ready for cleaning. The FRAM functions labelled 2.1 to 2.4 and 2.8 (in blue) highlight dry cleaning activities that poultry farms needed to carry out before being visited by the cleaning contractor. These were largely primary cleaning functions which did not require specialist cleaners. Functions 2.5 to 2.7 (in blue) highlight cleaning activities that were meant to be carried out by the cleaning contractor.

The FRAM functions labelled 3.1 to 3.27 (in green) are activities designed to take place during the inspections and audits by private and independent third-party auditors. An independent third-party auditor was supposed to visit the poultry farm to ensure that required inspection documents were in place, and to verify the quality of private inspections. Inspections

of the cleaning contractor (performed by the private auditor/auditing team) were designed to include mandatory assessments of the safety and regulatory compliance of chemicals used to eliminate red mites. Additional checks on the adequacy of manpower equipment were also designed to be carried out before cleaning contractors could commence their work. In total, 24 checks were explicitly stated in policy documents to ensure that all essential inspections were carried out before cleaning contractors applied chemicals. Aspects relevant to each function have been listed in Appendix 2.

5.2. Work-as-done: The 2017 fipronil in eggs incident

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Fipronil in concentrations above permitted levels was detected in Belgian table eggs in 2017 (Ministry of Health Welfare and Sport, 2018b). The use of fipronil to control pests in agriculture and food producing animals is banned by the EU as fipronil is classified as moderately hazardous for human consumption (Commission Implementing Regulation (EU) No. 781/2013 of 14 August 2013, 2013). Reg. (EU) 2016/2035, Reg. (EU) No. 540/2011 and Reg. (EU) No. 781/2013 state that eggs containing fipronil concentration >0.005 mg/kg should be identified and noted. The regulations further state that eggs and egg-products containing fipronil concentrations >0.72 mg/kg could pose as potential health risks for humans. Investigations by the Ministry of Health Welfare and Sport (2018) established that a Dutch poultry farm cleaning company had knowingly and without notification used Dega-16, a chemical containing fipronil, on poultry farms to eliminate red mites. As a result of noncompliance by the cleaning company, the NVWA blocked approximately 258 farms from trading more eggs, instructed them to recall all their eggs from the market, and prevented farmers in specific geographies from allowing hens and manure to leave the premises (Ministry of Health Welfare and Sport, 2018b). Instructions provided by the NVWA led to disruption in the agri-food supply chain and uncertainty among consumers. This consequently had an impact on the financial stability of poultry farms and other stakeholders within the egg supply chain,

as in addition to the recalls and product destructions ordered by the NVWA, there was also a decline in the sales of Dutch eggs across the EU (Ministry of Health Welfare and Sport, 2018c). In the 2018 Ministry of Health Welfare and Sport's report, large portions of the investigation lean towards finding organisations to blame. The following subsections of this paper are based on the findings from the FRAM analysis (Figure 3) and the 2018 report evaluating events leading up to and immediately after the egg contamination incident.

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Take in Figure 3

Figure 3 highlights tasks that were supposed to be performed as per organisational and national policy, but were not. The FRAM diagram in Figure 3 highlights all the activities that took place immediately before, during and after the visit by cleaning contractors. The colour coding used is the same as used in Figure 2. An additional colour coding has been used in Figure 3. The FRAM functions in red are those activities where there was non-compliance. Discrepancies in cleaning procedures largely occurred within the blue (cleaning contractor) and green (audits and inspections) functions leading to the fipronil contamination. Auditors (government and third-party) did not perform the activities prescribed to them in a robust manner. For instance, multiple government auditors arrived at the site at the same time leading to confusion on the farm. This, in addition to factors such as a poor understanding of regulations led to inadequate audits of farm inspection methods and records. A lack of robustness in audits led to instances of non-compliances such as incomplete paperwork at the farm level going undetected. These points of failure can be seen in the functions with a red circle around the Control and Input aspects in the FRAM diagram in Figure 3. Unlike Figure 2, Figure 3 has two functions without an input activity (i.e., these are points where critical non-compliances occurred leading to incorrectly performed functions) and three functions with inadequate control measures. Although 24 audit and inspection mandatory checks were stated in policy documents and regulations (and highlighted in Figure 2), only sixteen of these checks were

carried out in practice. These non-compliances along the entire process enabled the cleaning contractors to use an illegal chemical during the process of red mite elimination.

This section has considered and addressed RQ1. How red mites were eliminated in poultry farms (work-as-done)?

On conducting a thorough investigation and establishing the extent of the damage caused, the NVWA classified the case as an *incident* and formed an incident investigation team on the 18th of July 2017. The NVWA further blocked 258 farms from trading eggs, chicken, and manure to protect public health (Ministry of Health Welfare and Sport, 2018a). Despite all these actions taken by the NVWA, the investigation commission concluded that the NVWA was ill-prepared for a food safety incident due to: (1) the poor communication of its standards with poultry farmers; and (2) poor enforcement action leading to doubts over its credibility to take decisive action in a proactive manner (Ministry of Health Welfare and Sport, 2018a). Aspects relevant to each function have been listed in Appendix 3.

6. Discussion

The responsibility for food safety lies primarily with food businesses, i.e., companies producing, distributing, processing, and marketing food must actively ensure that they do not introduce products into the market that do not comply with statutory regulations. Inadequate knowledge of relevant policies and regulations meant that the safeguards implemented by egg supply stakeholders were insufficient (Ministry of Health Welfare and Sport, 2018a). Findings also highlighted limited food safety-related risk assessments being implemented by farmers. The Commission concluded that despite stakeholders being aware of the impact (on public health and finances) of using banned chemicals to treat red mites, the risks were either ignored or inadequately assessed by all stakeholders (Ministry of Health Welfare and Sport, 2018a). The aim of this study has been to assess the differences between the criteria defined by

European and Dutch national standards for poultry farmers on the elimination of red mites on poultry farms through policies and the actual events that took place that led to the 2017 fipronil egg contamination incident. The differences between what was envisaged by policy makes and actual practices extended beyond activities at farm level to poultry service companies and the degree to which system standards and regulatory requirements were upheld, the agility of responding to intelligence regarding non-compliance within the sector, and the inability to enact a policy framework that was too complex to work in practice.

This next section addresses RQ2. How much 'work-as-done' was aligned with the requirements of the Dutch and European legislation ('work-as-imagined')?

The system standard adopted by Dutch poultry service companies, IKB Ei (Integrated Chain Management Egg), failed to ensure adherence to points mentioned in its policy. Being a voluntary measure, the system was used to assess the quality of eggs and egg-containing products rather than as a verification system to ensure business compliance with national policy standards and regulatory requirements (Ministry of Health Welfare and Sport, 2018a). The scheme was also found to be lacking in terms of its ability and desire to ensure food safety as IKB PSB, the quality system for poultry service companies, did not impose food safety requirements on participating farms. Additionally, neither IKB Ei nor IKB PSB made improvements to their system standards even after the publication of a report containing critical assessments of these existing systems. The investigation also highlighted that in addition to farm service companies, poultry farms were poorly equipped to deal with food safety incidents (Ministry of Health Welfare and Sport, 2018a). Farms struggled to recall their contaminated eggs from the market as the stakeholders' primary goal was to limit financial impact.

Public monitoring of food safety is the NVWA's responsibility in the Netherlands (Ministry of Health Welfare and Sport, 2018a). The authority, an agency in the Ministry of

Agriculture, Nature and Food Quality (LNV) has its own Intelligence and Investigation Services (IOD). The IOD is responsible for conducting criminal investigations with support from the Public Prosecution Services, in the Netherlands (Ministry of Health Welfare and Sport, 2018a). The NVWA comprises of an independent scientific advisor, and the Bureau for Risk Analysis and Research (BuRO). The BuRO is tasked with assessing food safety hazards, product safety, and animal welfare. Despite a detailed structure with delegated powers, multiple limitations were identified by the Commission at this regulatory level (Ministry of Health Welfare and Sport, 2018a). A key investigation finding was that although the contamination of eggs was officially declared in 2017, the NVWA had received three tip-offs from whistleblowers, and through IOD investigations as early as November 2016, regarding the illegal use of fipronil by a farm cleaning company to combat red mites in poultry farms (Ministry of Health Welfare and Sport, 2018a). However, through to 2018, inspectors and standard owners had been unsuccessful in preventing fipronil contaminated eggs repeatedly penetrating the market. Since preliminary investigations and media trials scrutinised farm practices, farmers often questioned existing regulatory structures, standards and national NVWA policies. Pressure increased on consumer trust of national standards and the credibility of NVWA actions was questioned (Ministry of Health Welfare and Sport, 2018a). Although the NVWA is commissioned to ensure food safety in the Netherlands by the Public Health Wellbeing and Sports (VWS) and the Agriculture, Nature and Food Quality (LNV) departments of the government, public supervision of egg safety is commissioned in practice to a private organization. This organization, the Dutch Control Authority for Eggs (NCAE), is a part of a privately managed, independent administrative body, the Central Body for Quality Issues in Dairy (COKZ) (Food and Veterinary Office, 2013). It is also important to note that the production, distribution and sale of organic eggs and their compliance with EU Regulations is monitored by another supervisory authority, Foundation Skal Biocontrole, under the guidance

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of the LNV department (Ministry of Health Welfare and Sport, 2018b). A finding in the 2018 report highlighted that the system (food safety legislation, policies, and guidance documents) designed to guarantee the safety of eggs was complex and unclear (Ministry of Health Welfare and Sport, 2018a). The complex structure of Dutch regulatory agencies, as illustrated in Figure 3 and in the 2018 report, provides an insight into why farmers and the investigation commission felt that the Dutch egg safety system was poorly design and too complex to navigate.

Once the fipronil incident was declared, it was the NVWA's responsibility to ensure consumer safety (Opperhuizen, 2018). Despite receiving tip-offs in 2017, the BuRO within the NVWA failed to follow protocol and perform a risk assessment. If a risk assessment had been carried out, the NVWA would have been able to pursue enforcement action based on the Plant Protection Products and Biocides Act (Wgb). However, it would be crucial in this scenario for the NVWA to identify which stakeholder to prosecute, the farm(s) or the poultry cleaning company. Failure to clearly identify the non-compliant stakeholders led to financial losses for multiple stakeholders across the egg supply chain as farmers were largely portrayed in a negative light by media publications (e.g., BBC News, 2017; Cook, 2017). A poorly defined regulatory system led to delays in egg safety investigations and communication of this information to importing countries (Reuters Staff, 2017).

Post the incident, there was widespread confusion among consumers about the extent of exposure to fipronil through contaminated eggs (Ministry of Health Welfare and Sport, 2018b). The confusion stemmed from the government agency level. In January 2017, the BuRO provided an oral assessment of the extent of consumer exposure to fipronil based on inadequate information (Ministry of Health Welfare and Sport, 2018b). A similar incomplete investigation was carried out in April 2017 by the IOD and the Public Prosecution Services (Ministry of Health Welfare and Sport, 2018b). Further, inadequate resources and a lack of collaboration between the IOD and the supervisory divisions within the NVWA lead to investigations not

commencing until June 2017 (Ministry of Health Welfare and Sport, 2018b). The lack of collaboration was a consequence of a lack of clarity regarding the restrictions on sharing information (such as investigation proceedings) between divisions and departments. This led to decisions being inadequately documented and responsibilities being poorly defined (Cook, 2017; Ministry of Health Welfare and Sport, 2018b; Reuters Staff, 2017). All these failures at the enforcement agency level contributed to the widespread distribution of contaminated eggs across global egg supply chains.

Variability and interdependence between the two FRAM models are apparent in the functions around regulatory controls, as auditors (both private and government) were required to have a detailed understanding of relevant regulations and policies prior to auditing documents and verifying regulatory compliance regarding the disinfectants used. In an ideal scenario (i.e., Figure 2) regulations and policies provided outputs that served as important control measures for several downstream functions. However, as illustrated in Figure 3, most of the functions were left incomplete (i.e., red) due to an inadequate understanding of the regulatory and policy requirements by key stakeholders. This subsequently led to failure in discarding illegal/unapproved disinfectants from storage units and inadequate control over other functions such as carrying out surface spraying, approving mite disinfectants, auditing cleaning contractor supplies and engaging a compliant cleaning contractor.

Interdependence was particularly apparent for the function "to audit documents" since as many as six downstream functions were associated with it and were severely impacted leading to several other non-compliances across the system. It can also be argued that there was an over-reliance on documentation checks as seen in Figure 2. Multiple stakeholders were tasked with verifying completion of documents, while there were minimal checks physically inspecting disinfectants, and no checks to ensure stakeholders had robust understanding of what were approved or unapproved disinfectants. Indeed, the poultry cleaning contractor was able

to commit fraud, renaming the fipronil-based disinfectant, without identification by other stakeholders. Functions that represent farmers cancelling cleaning contracts seemed to have no robust control structure in place leading to an over-reliance on farmers' autonomy and an insecure assumption of the degree of their understanding of regulations regarding cleaning and disinfection of poultry farms.

Although farmers received multiple inspection reports (through private and government inspections) they relied on cleaning contractors to adhere to the national regulations and policies on eliminating red mites from poultry houses (Ministry of Health Welfare and Sport, 2018b). However, regulations and policies did not account for downstream functions that controlled upstream functions. For example, existing policies failed to ensure that a final check of disinfectants was carried out by farmers before being used by cleaning (Cook, 2017; Ministry of Health Welfare and Sport, 2018b). Additionally, although auditors were trained to carry out inspections, their understanding of regulations and policies was not evaluated (Ministry of Health Welfare and Sport, 2018b). There was also no mechanism in place to educate auditors and cleaning contractors about the importance of various regulations and policies.

There was an over-reliance on regulations and checks based on policies designed by policymakers higher up the hierarchical chain to ensure that banned disinfectants and chemicals were not used to clean poultry houses (Ministry of Health Welfare and Sport, 2018b). Future policies and governance structures must focus on improving the *underpinning and core cultures* (Manning, 2018b) within farms and associated organisation (e.g., specialist farm cleaning companies). The intention of policies which aim to improve *underpinning cultures* would be to improve organisations' espoused and unspoken values which often guide employee behaviour and attitudes towards legislation and standard operating procedures. These policies also play a critical role in defining the depth of an audit/inspection of service providers to the

food organisation (poultry farms in this case study). Improving *core cultures* requires an initial understanding of assumptions made by employees about their role within in the agri-food system. These assumptions are often misunderstood or misrepresented (Manning, 2018b). Going forward, policy makers need to allow for more of an *active input* from all relevant stakeholders. Modern information technology systems may allow for greater ease of provision of such input. National food safety governance bodies might also consider limiting the number of information sources that they currently use as this would also reduce the amount of and possibility for conflicting information. Farmers could rely on simple written instructions/reminders instead of lengthy checklists and policies to follow on a day-to-day basis. Negative incidents are often the outcome of a chain reaction of technical and social barriers such as lengthy and complex policies and protocols, confusion among staff and time-related stressors (Brown et al., 2000). This phenomenon can be observed in Figures 2 and 3 where despite detailed policies (Figure 2), the actions performed in the real-world (Figure 3) did not comply with the required protocol.

Investigating *work-as-done* offers a new dimension to food safety, regulatory design, compliance and policy design rather than focusing policy design and redesign primarily on avoiding previous food safety incidents which although important, are very specific in their nature (Soon et al., 2020). When designing robust food safety policies it is important to consider potential outcomes arising from everyday routine performance; exceptionally good performance; as well as near-misses and food safety incidents (Eurocontrol, 2013, p. 25).

RQ3 asked "How can the FRAM be used for policy development to reconcile the gap between 'work-as imagined' and 'work-as-done'?" The FRAM can be used proactively as a tool for incident analysis as it helps to establish *emergent themes* based on work-as-done rather than solely comparing negative events with expectations of a process (Hounsgaard, 2016). Thus, adopting such an approach helps to improve supply chain resilience (de Sá et al., 2019; Faour-

Klingbeil et al., 2015; Lord et al., 2017; Nayak & Waterson, 2017, 2019; Thatcher et al., 2019). The 2017 fipronil incident clearly shows the dangers at multiple levels of a practice gap in the implementation of public health policies between work-as-imagined and work-as-done.

7. Conclusion

This study has considered the activities before and during the 2017 fipronil incident showing a clear difference between how red mites were eliminated on poultry farms in practice 'work as done' and 'work as imagined' in predefined public hygiene policies. There were failures in 'work as done' at all hierarchical levels of food safety governance from farmers through to supply chain stakeholders and the regulators themselves. Within the imagined scenario, there were assumptions of what would happen and what would be achieved, and this failed to be enacted in practice.

The use of FRAM allowed an exploration of the conditions and interactions between various functions and their outputs in the case study example, and helped to assess the limitations of current food safety policies and regulations designed solely by policy and lawmakers. This approach to policy design does not reflect the lived experience of those who take part in day-to-day activities especially if high-level policy makers do not fully comprehend the challenges and barriers faced by individuals implementing policy and the methods they might use to overcome these challenges. This study has shown how the FRAM can be used for policy design and redesign to reconcile the gap between work-as imagined and work-as-done. The ability to establish interdependence and variability between functions informs the identification of opportunities for improvement in current practices and policies especially in the event of a food safety incident where multiple factors are of influence. One of the limitations of this study was that the authors were unable to carry out ethnographic observations and incorporate observed behaviours and actions within the models. Consequently, the authors were also unable to determine high-priority functions in the process of elimination of red mites

from poultry farms. In future studies, the FRAM approach could be used to develop mechanisms to improve existing practices within agri-food supply chains. Whilst the FRAM has been used to perform a reflective desk-review in this study, it also has a role in supporting multi-stakeholder activity to design evidence-based food policies that are less complex and with a greater likelihood of being complied with in practice.

Funding

- This research did not receive any specific grant from funding agencies in the public,
- 548 commercial, or not-for-profit sectors.

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5.

1 Table 1: Factors that undermined policy implementation in the egg trading industry

Adapted from Powell et al., 2009.

Theme	Issue
Content of the incident:	Lack of agreement that safety improvement was necessary
what are safety	Lack of clarity about the nature of the incident and how the
improvement measures and	proposed new improvements fitted with existing and related
why have them in place?	practice
Context of the incident:	Poor fit with local organisational priorities.
what are the features of the	Poor fit with local organizational structures (e.g.
local environment?	departments).
	Adverse effects of previous organizational improvements
	(e.g. reorganizations)
	Lack of direct and indirect resources to support the
	improvement
Process of the incident: how	Divergent views among food professionals about
safety improvements	responsibility for various aspects of safety improvement
challenge professional roles	Conflict with longstanding professional boundaries and
and identities?	norms.

Table 2: Description of the FRAM functions

Functions	Descriptions	Location of Functions
To complete cleaning and disinfection of coop	Successful disinfection and cleaning of chicken farms (storage plants).	Fig 2
Power Washing of coop	Thorough cleaning of chicken coop at least once every 12 months using water-jets and approves soap.	Fig 2 and 3
To carry out surface spraying	Spraying surfaces with low-pressure disinfectants to remove fine dust and soften stuck-on manure.	Fig 2 and 3
Prewash of surfaces	Cleaning of surfaces prior to the visit by a professional (third-party) cleaning company.	Fig 2 and 3
Steam cleaning of the site	Process used to clean difficult equipment such as cages.	Fig 2 and 3
To wipe surfaces with cloth	Process used to clean difficult equipment such as cages.	Fig 2 and 3
To dry surfaces	Surfaces should be allowed to dry before disinfection.	Fig 2 and 3
To book cleaning contractor	On completion of the <i>prewash</i> stage, trained and certified external cleaning contractors must be booked for treating the red mite infestation problem.	Fig 2 and 3
To define farm's mite disinfection standards	Identify and establish legally compliant farm's disinfection standards.	Fig 2 and 3
To depopulate poultry house	Catching, carrying, and crating of laying hens at the end-of-lay period.	Fig 2 and 3
To carry out primary cleaning	First stage of cleaning of the environment after the depopulation stage.	Fig 2 and 3

Functions	Descriptions	Location of Functions
To dry clean site	Blowing down or vacuuming dust from high fittings and buildings and sweeping floors to remove litter.	Fig 2 and 3
To carry out repairs by the cleaning company	Repairs likely to dislodge hidden litter/dust should be carried out after disinfection and before washing.	Fig 2 and 3
Detection of red mites in coop	Physical inspection at the end or during of an egg-laying cycle.	Fig 2 and 3
To carry out audits & inspections	Routine inspection of all areas by government and private auditors to ensure compliance with cleaning, disinfection and hygiene policies and legislation.	Fig 2 and 3
Multiple government auditors arrive at cleaning company	Arrival of multiple auditors due to poor communication.	Fig 3
Government auditor arrives at cleaning company	Arrival of the auditor to assess degree of compliance.	Fig 2
To take auditor to documentation room	Auditor is taken to the documentation room where they can assess records.	Fig 2 and 3
To audit documents	Physical audit of disinfection, cleaning and hygiene documents.	Fig 2 and 3
To take auditor to disinfectant storage room	Government auditor is taken to the storage room to assess the disinfectants (including name and compliance with EU Regulations).	Fig 2 and 3
Audit of disinfectants	Physical audit of disinfectants.	Fig 2 and 3
To understand relevant regulations	Developing a detailed understanding of regulations related to disinfection, cleaning and hygiene of poultry houses.	Fig 2
To develop audit documentation checklist	Design of checklist to ensure necessary checks are performed.	Fig 2 and 3
To develop permitted disinfectant checklist	Design of a detailed checklist listing permitted disinfectants.	Fig 2 and 3

Functions	Descriptions	Location of Functions
To discard disinfectant from storage	Discarding disapproved disinfectants from storage units to prevent their wrongful use.	Fig 2 and 3
To warn or take legal action against cleaning company	Take enforcement action in the event of misuse of chemicals by cleaning company.	Fig 2 and 3
To catch hens	Catching hens to depopulate the environment.	Fig 2 and 3
To ensure training to catch hens	Providing adequate training to ensure animal welfare during the catching process.	Fig 2
To ensure clean PPE is available	Provision of clean protective personal equipment as per EU Regulations to ensure biosecurity.	Fig 2 and 3
To ready transport equipment	Ensuring licensed or authorised vehicles have been organised prior to loading hens and equipment.	Fig 2 and 3
To load hens onto trucks	Loading hens without causing them harm and in a manner which ensures biosecurity.	Fig 2 and 3
To take hens to loading area	Hens taken to loading area to complete depopulation phase.	Fig 2 and 3
To take farm auditor to documentation room	Farm auditor is taken to the storage room to assess the disinfectants (including name and compliance with EU Regulations).	Fig 2 and 3
To define farm's mite monitoring standards	Definition of private standards using the EU Regulations as a baseline.	Fig 2 and 3
To develop farm audit checklist	Design of a checklist to ensure compliance during internal audit.	Fig 2 and 3
To book re-audit date	To carry out a repeat audit in the event of serious non-compliance	Fig 2 and 3
Farm auditor arrives at disinfection company	Arrival of farm auditor to inspect the contracted cleaning company.	Fig 2
Farm cleaning contract cancellation	Contract cancellation with cleaning company in the event of non-compliance.	Fig 2

Functions	Descriptions	Location of Functions
To audit adequacy of manpower	Auditors evaluating availability of skilled/trained labour to perform the disinfection processes.	Fig 2 and 3
To audit adequacy of disinfecting equipment	Auditors evaluating availability and readiness of disinfecting equipment.	Fig 2 and 3
To approve or disapprove adequacy of manpower	Decision on availability and readiness of personnel to deliver the disinfection service.	Fig 2 and 3
To approve or disapprove adequacy of equipment	Decision on availability and readiness of equipment to perform the disinfection service.	Fig 2 and 3
To develop equipment removal and drycleaning checklist	Checklist to ensure all equipment is removed and all areas are dry cleaned prior to the disinfection stage.	Fig 2
To take auditor to mite disinfectant storage room	Government auditor is taken to the storage room where mite disinfectants are stored for an audit of chemicals used.	Fig 2 and 3
Audit of mite disinfectants	Government auditor performs an inspection of the chemicals used and their compliance with EU Regulations.	Fig 2 and 3
To approve or disapprove mite disinfectant	Decision based on compliance of chemicals with EU Regulations.	Fig 2
To audit cleaning contractor supplies	Internal audit of chemicals by the farm auditor.	Fig 2 and 3
To ensure least financial losses	Potential egoistic approach to ensure financial sustainability at the expense of public health and environmental sustainability.	Fig 3
To approve mite disinfectant	Approval regardless of compliance with EU Regulations	Fig 3

6 Table 3: EUWEP policy on good hygiene practices in pullet rearing and egg laying

7 flocks

8 Adapted from European Union of Wholesale with Eggs Egg Products Poultry and Game, 2012, pp. III–IV.

Process	Theme	Topic
On the farm	Risk Management	Location
	Measures	Site
		Buildings
		Equipment
		Vermin, feral animals and insect control
		Domestic animals on site
		Feed
		Water
		Litter supply (for non-caged birds)
		Veterinary products
		Record keeping
		Routing hygiene and husbandry
	Management	Personnel and visitors
		Livestock management
		Egg management
	Cleaning and	Forward planning
	disinfection	Removal of equipment and dry cleaning
		Used litter/manure
		Water system
		Washing
		Disinfection
		Assemble and checking of equipment
		Microbiological monitoring of cleaning and
		disinfection
		Specific measures after detection of
		Salmonella
Depopulation and	Catching and loading of	
transport of hens	hens	
	Transport of hens	Hygiene during transport
		Vehicles

Appendix 1: Topic list used during document analyses to identify aspects and coupling of FRAM functions

Adapted from Damen et al., 2018.

Aspects	Questions
Input	What starts the function?
	What does the function change?
Output	What is the outcome of the function?
	Does the EUWEP, DEFRA or the NVWA policy document need to be used?
	Does anything need auditing or checking?
	Who is the recipient of the output? Who will use what is produced?
Precondition	What needs to be in place so that the function can be completed as planned?
	What happens if the preconditions are not available?
Resource	What resources are needed to perform the function?
	What happens of the resources are not available?
Control	Specific goals for the function (e.g., to carry out an activity within certain legal frameworks)
	What is the purpose of this function? Why is it done?
	Are there formal procedures controlling the function?
	Are there assigned people who control the function (e.g., private auditors)? Do unofficial work practices or culture control the function?
	Are there constraints (e.g., resources)?
Time	Is there a time element related to the function?
	Is there a delay in performing the function? What are the consequences of
	delays?
	Time has four options: (1) too early; (2) on time; (3) too late; and (4)
	function did not occur.

Appendix 2: Aspect labels for each function in Figure 2.

Name of function	2.7. To complete cleaning and disinfection of coop
Aspect	Description of Aspect
Precondition	As few mites as possible
Control	Physical monitoring of cleaning & disinfection
Name of function	2.6. Power Washing of coop
Aspect	Description of Aspect
Input	Spray surfaces to saturation point
Output	As few mites as possible
Precondition	Spraying hard to reach surfaces
	Use approved mite disinfectant
Resource	Power washer
Control	Repaired equipment
	Approved disinfectants
	Approved manpower adequacy
	Approved equipment adequacy
Name of function	2.5. To carry out surface spraying
Aspect	Description of Aspect
Input	Washed inside and outside of house
	Dried inside and outside of house
Output	Spray surfaces to saturation point
	Spraying hard to reach surfaces
	Use approved mite disinfectant
Control	Repaired equipment
	Approved disinfectants
	Approved manpower adequacy
	Approved equipment adequacy

Name of function	2.1. Prewash of surfaces
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Description of Aspect
Dry cleaned shed
Loosened adherent dirt
Verified cleaning contractor hired
2.2. Steam cleaning of the site
Description of Aspect
Loosened adherent dirt
Clean equipment
Pressure steamer
2.3. To wipe surfaces with cloth
Description of Aspect
Clean equipment
Clean fittings
2.4. To dry surfaces
Description of Aspect
Clean fittings
Washed inside and outside of house
Dried inside and outside of house
2.8. To book cleaning contractor
Description of Aspect
Cleaning contractor supplies rigorously
Verified cleaning contractor hired
Approved disinfectants
Approved manpower adequacy
Approved equipment adequacy
3.1. To define farm's mite disinfection standards
Description of Aspect
Pressure steamer
Disinfection protocols defined

D : .: CA

	Dry cleaning equipment
	Power washer
Control	Understanding of Regulation (EC) 2160/2003 of the European Parliament

Name of function	1.9. To depopulate poultry house
Aspect	Description of Aspect
Input	Hens loaded
Output	Poultry house depopulated
Precondition	Ensure removal of dead birds
	Ensure removal of rubbish
	Ensure removal of surplus feed
	Equipment removal and drycleaning checklist developed
	Clean out the coop - get rid of any bedding
Name of function	To carry out primary cleaning
Aspect	Description of Aspect
Output	Ensure removal of dead birds
	Ensure removal of rubbish
	Ensure removal of surplus feed
	Clean out the coop - get rid of any bedding
Name of function	1.10. To dry clean site
Aspect	Description of Aspect
Input	Poultry house depopulated
Output	Dry cleaned shed
Precondition	Dry cleaning equipment

Name of function	To carry out repairs by the cleaning company
Aspect	Description of Aspect
Output	Repaired equipment
Name of function	1.2. Detection of red mites in coop
Aspect	Description of Aspect

Output	Egg laying cycle ended
Name of function	3.14. To carry out audits & inspections
Aspect	Description of Aspect
Output	Ensure legal compliance
	Ensure compliance with farm standards

Name of function	3.15. Government auditor arrives at cleaning company
Aspect	Description of Aspect
Input	Ensure legal compliance
Output	Government auditor arrives
Name of function	3.16. To take auditor to documentation room
Aspect	Description of Aspect
Input	Government auditor arrives
	Farm auditor arrives
Output	Auditor arrives at documentation room
Name of function	3.18. To audit documents
Aspect	Description of Aspect
Input	Auditor arrives at documentation room
	Farm auditor arrives at documentation room
Output	Paperwork is available and completed
	Paperwork is either unavailable or incomplete
Precondition	Documentation checklist is developed
Control	Understanding of Regulation (EC) 2160/2003 of the European Parliament

Name of function	3.20. To take auditor to disinfectant storage room
Aspect	Description of Aspect
Input	Paperwork is available and completed
Output	Auditor in disinfectant storage room
Name of function	3.21. Audit of disinfectants
Aspect	Description of Aspect

Auditor in disinfectant storage room
Disinfectant audited
Disinfectant checklist is developed
Understanding of Regulation (EC) 2160/2003 of the European Parliament
3.19. To understand relevant regulations
Description of Aspect
Understanding of Regulation (EC) 2160/2003 of the European Parliament
3.17. To develop audit documentation checklist
Description of Aspect
Documentation checklist is developed
3.22. To develop permitted disinfectant checklist
Description of Aspect
Disinfectant checklist is developed
3.24. To discard disinfectant from storage
Description of Aspect
Disapproved disinfectants
Disinfectant discarded
To warn or take legal action against cleaning company
Description of Aspect
Disinfectant discarded
Cleaning chemicals discarded
1.3. To catch hens
Description of Aspect
Hens caught
Cleaned and disinfected transport crates
Clean protective clothing and footwear
Trained farm personnel or contractors
Egg laying cycle ended

Name of function	1.6. To ensure training to catch hens
Aspect	Description of Aspect
Output	Trained farm personnel or contractors

Name of function	1.5. To ensure clean PPE is available
Aspect	Description of Aspect
Output	Clean protective clothing and footwear
Name of function	1.4. To ready transport equipment
Aspect	Description of Aspect
Output	Cleaned and disinfected transport crates
	Cleaned and disinfected transport vehicles
Name of function	1.8. To load hens onto trucks
Aspect	Description of Aspect
Input	Hens in loading area
Output	Hens loaded
Control	Cleaned and disinfected transport vehicles

Name of function	1.7. To take hens to loading area
Aspect	Description of Aspect
Input	Hens caught
Output	Hens in loading area
Name of function	3.5. To take farm auditor to documentation room
Aspect	Description of Aspect
Input	Farm auditor arrives
Output	Farm auditor in documentation room
Name of function	3.7. To define farm's mite monitoring standards
Aspect	Description of Aspect
Input	Farm auditor in documentation room
Output	Physical monitoring of cleaning & disinfection
	Farm auditor arrives at documentation room

Aspect I Output I Name of function 3 Aspect I Input I	3.13. To develop farm audit checklist Description of Aspect Developed farm audit checklist 3.23. To book re-audit date Description of Aspect Paperwork is either unavailable or incomplete 3.12. Farm auditor arrives at disinfection company Description of Aspect Ensure compliance with farm standards Farm auditor arrives Disinfection protocols defined
Output I Name of function 3 Aspect I Input I	Developed farm audit checklist 3.23. To book re-audit date Description of Aspect Paperwork is either unavailable or incomplete 3.12. Farm auditor arrives at disinfection company Description of Aspect Ensure compliance with farm standards Farm auditor arrives
Name of function 3 Aspect I Input I	3.23. To book re-audit date Description of Aspect Paperwork is either unavailable or incomplete 3.12. Farm auditor arrives at disinfection company Description of Aspect Ensure compliance with farm standards Farm auditor arrives
Aspect I Input I	Description of Aspect Paperwork is either unavailable or incomplete 3.12. Farm auditor arrives at disinfection company Description of Aspect Ensure compliance with farm standards Farm auditor arrives
Input I	Paperwork is either unavailable or incomplete 3.12. Farm auditor arrives at disinfection company Description of Aspect Ensure compliance with farm standards Farm auditor arrives
-	3.12. Farm auditor arrives at disinfection company Description of Aspect Ensure compliance with farm standards Farm auditor arrives
Name of function 3	Description of Aspect Ensure compliance with farm standards Farm auditor arrives
	Ensure compliance with farm standards Farm auditor arrives
Aspect	Farm auditor arrives
Input I	
Output	Disinfection protocols defined
Precondition I	Distinction protocols defined
I	Developed farm audit checklist
Name of function I	Farm cleaning contract cancellation
Aspect	Description of Aspect
Input I	Paperwork is either unavailable or incomplete
I	Disapproved disinfectants
	Cleaning chemicals disapproved
Name of function 3	3.10. To audit adequacy of manpower
Aspect	Description of Aspect
Input I	Paperwork is available and completed
Output	Manpower adequacy audited
Name of function 3	3.11. To audit adequacy of disinfecting equipment
Aspect	Description of Aspect
Input I	Paperwork is available and completed
Output	Equipment adequacy audited
Name of function 3	3.9. To approve or disapprove adequacy of manpower

Aspect

Description of Aspect

Input	Manpower adequacy audited
Output	Approved manpower adequacy
Name of function	3.8. To approve or disapprove adequacy of equipment
Aspect	Description of Aspect
Input	Equipment adequacy audited
Output	Approved equipment adequacy
Name of function	1.1. To develop equipment removal and drycleaning checklist
Aspect	Description of Aspect
Output	Equipment removal and drycleaning checklist developed

Name of function	3.2. To take auditor to mite disinfectant storage room
Aspect	Description of Aspect
Input	Paperwork is available and completed
Output	Auditor in disinfectant storage room
Name of function	3.3. Audit of mite disinfectants
Aspect	Description of Aspect
Input	Auditor in disinfectant storage room
Output	Disinfectant audited
Name of function	3.4. To approve or disapprove mite disinfectant
Aspect	Description of Aspect
Input	Disinfectant audited
Output	Disapproved disinfectants
	Approved disinfectants

Name of function	3.6. To audit cleaning contractor supplies
Aspect	Description of Aspect
Input	Farm auditor in documentation room
Output	Cleaning contractor supplies rigorously

Appendix 3: Aspect labels for each function in Figure 3.

Name of function	2.5. To complete cleaning and disinfection of coop
Aspect	Description of Aspect
Precondition	As few mites as possible
Control	Physical monitoring of cleaning & disinfection
Name of function	4.4. Power Washing of coop
Aspect	Description of Aspect
Input	Spray surfaces to saturation point
Output	As few mites as possible
Precondition	Spraying hard to reach surfaces
	Use approved mite disinfectant
Resource	Power washer
Control	Repaired equipment
	Wrongly approved disinfectants
	Approved manpower adequacy
	Approved equipment adequacy
Name of function	4.3. To carry out surface spraying
Aspect	Description of Aspect
Input	Washed inside and outside of house
	Dried inside and outside of house
Output	Spray surfaces to saturation point
	Spraying hard to reach surfaces
	Use approved mite disinfectant
Control	Repaired equipment
	Wrongly approved disinfectants
	Approved manpower adequacy
	Approved equipment adequacy

Name of function 2.1. Prewash of surfaces	
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Aspect	Description of Aspect
Input	Dry cleaned shed
Output	Loosened adherent dirt
Precondition	Verified cleaning contractor hired
Name of function	2.2. Steam cleaning of the site
Aspect	Description of Aspect
Input	Loosened adherent dirt
Output	Clean equipment
Precondition	Pressure steamer
Name of function	2.3. To wipe surfaces with cloth
Aspect	Description of Aspect
Input	Clean equipment
Output	Clean fittings
Name of function	2.4. To dry surfaces
Aspect	Description of Aspect
Input	Clean fittings
Output	Washed inside and outside of house
	Dried inside and outside of house
Name of function	4.10. To book cleaning contractor
Description	Book appropriate cleaning contractor by auditing contractor's policies and procedures followed to depopulate and clean.
Aspect	Description of Aspect
Input	Incorrectly audited cleaning contractor supplies
Output	Verified cleaning contractor hired
Control	Approved manpower adequacy
	Approved equipment adequacy
Name of function	3.1. To define farm's mite disinfection standards
Aspect	Description of Aspect
Output	Pressure steamer

	Disinfection protocols defined
	Dry cleaning equipment
	Power washer
Control	Understanding of Regulation (EC) 2160/2003 of the European Parliament

Name of function	1.9. To depopulate poultry house
Aspect	Description of Aspect
Input	Hens loaded
Output	Poultry house depopulated
Precondition	Ensure removal of dead birds
	Ensure removal of rubbish
	Ensure removal of surplus feed
	Quick completion of equipment removal and drycleaning checklist
	Clean out the coop - get rid of any bedding
Name of function	1.10. To carry out primary cleaning
Aspect	Description of Aspect
Output	Ensure removal of dead birds
	Ensure removal of rubbish
	Ensure removal of surplus feed
	Clean out the coop - get rid of any bedding
Name of function	1.11. To dry clean site
Aspect	Description of Aspect
Input	Poultry house depopulated
Output	Dry cleaned shed
Precondition	Dry cleaning equipment

Name of function	2.6. To carry out repairs by the cleaning company
Aspect	Description of Aspect
Output	Repaired equipment
Name of function	1.2. Detection of red mites in coop

Aspect	Description of Aspect
Output	Egg laying cycle ended
Name of function	3.12. To carry out audits & inspections
Aspect	Description of Aspect
Output	Ensure legal compliance
	Ensure compliance with farm standards

Name of function	4.8. Multiple government auditors arrive at cleaning company			
Aspect	Description of Aspect			
Input	Ensure legal compliance			
Output	Auditors arrive			
Name of function	3.13. To take auditor to documentation room			
Aspect	Description of Aspect			
Input	Auditors arrive			
Output	Auditor arrives at documentation room			
Name of function	3.14. To audit documents			
Aspect	Description of Aspect			
Input	Auditor arrives at documentation room			
	Farm auditor arrives at documentation room			
Output	Poor quality audits completed			
	Incomplete paperwork detected by chance			
Precondition	Documentation checklist is developed			
Control	Understanding of Regulation (EC) 2160/2003 of the European Parliament			

Name of function	3.15. To take auditor to disinfectant storage room			
Aspect	Description of Aspect			
Input	oor quality audits completed			
Output	Auditor in disinfectant storage room			
Name of function	3.16. To audit disinfectants			
Aspect	Description of Aspect			

Input	Auditor in disinfectant storage room			
Output	porly audited disinfectants			
Precondition	isinfectant checklist is developed			
Control	nderstanding of Regulation (EC) 2160/2003 of the European Parliament			
Name of function	3.9. To develop audit documentation checklist			
Aspect	Description of Aspect			
Output	Documentation checklist is developed			

Name of function	3.17. To develop permitted disinfectant checklist			
Aspect	Description of Aspect			
Output	Disinfectant checklist is developed			
Name of function	4.5. To discard disinfectant from storage			
Aspect	Description of Aspect			
Input	Disapproved disinfectants			
Output	Disinfectant discarded			
Name of function	4.7. To warn or take legal action against cleaning company			
Aspect	Description of Aspect			
Input	Disinfectant discarded			
	Cleaning chemicals discarded			

Name of function	1.3. To catch hens			
Aspect	Description of Aspect			
Output	Hens caught			
Precondition	Cleaned and disinfected transport crates			
Resource	Clean protective clothing and footwear			
Control	Trained farm personnel or contractors			
Time	Egg laying cycle ended			
Name of function	1.6. To ensure adequate training to catch hens			
Aspect	Description of Aspect			
Output	Trained farm personnel or contractors			

Name of function	1.5. To ensure clean PPE is available		
Aspect	Description of Aspect		
Output	Clean protective clothing and footwear		

Name of function	1.4. To ready transport equipment			
Aspect	Description of Aspect			
Output	Cleaned and disinfected transport crates			
_	Cleaned and disinfected transport vehicles			
Name of function	1.8. To load hens onto trucks			
Aspect	Description of Aspect			
Input	Hens in loading area			
Output	Hens loaded			
Control	Cleaned and disinfected transport vehicles			
Name of function	1.7. To take hens to loading area			
Aspect	Description of Aspect			
Input	Hens caught			
Output	Hens in loading area			

Name of function	3.3. To take farm auditor to documentation room			
Aspect	Description of Aspect			
Input	Farm auditor arrives			
Output	Farm auditor in documentation room			
Name of function	3.4. To define farm's mite monitoring standards			
Aspect	Description of Aspect			
Input	Farm auditor in documentation room			
Output	Physical monitoring of cleaning & disinfection			
	Farm auditor arrives at documentation room			
Name of function	3.11. To develop farm audit checklist			
Aspect	Description of Aspect			
Output	Developed farm audit checklist			

Name of function	4.6. To book re-audit date			
Aspect	Description of Aspect			
Input	Incomplete paperwork detected by chance			
Name of function	3.10. Farm auditor arrives at the disinfection company			
Aspect	Description of Aspect			
Input	Ensure compliance with farm standards			
Output	Farm auditor arrives			
Precondition	Disinfection protocols defined			
	Developed farm audit checklist			
Name of function	3.7. To audit adequacy of manpower			
Aspect	Description of Aspect			
Input	Disapproved disinfectants			
	Paperwork is available and completed			
	Cleaning chemicals disapproved			
Output	Manpower adequacy audited			
Name of function	2.9. To audit adaptacy of disinfacting againment			
	3.8. To audit adequacy of disinfecting equipment			
Aspect	Description of Aspect			
Input	Paperwork is available and completed			
Output	Equipment adequacy audited			
Name of function	3.6. To approve or disapprove adequacy of manpower			
Aspect	Description of Aspect			
Input	Manpower adequacy audited			
Output	Approved manpower adequacy			
Name of function	3.5. To approve or disapprove adequacy of equipment			
Aspect	Description of Aspect			
Input	Equipment adequacy audited			
Output	Approved equipment adequacy			

Name of function	1.1. To ensure least financial losses			
Aspect	Description of Aspect			
Output	Quick completion of equipment removal and drycleaning checklist			
Name of function	3.2. To take auditor to mite disinfectant storage room			
Aspect	Description of Aspect			
Input	Poorly audited disinfectants			
Output	Auditor in red mite disinfectant storage room			
Name of function	4.1. Audit of mite disinfectants			
Aspect	Description of Aspect			
Input	Auditor in red mite disinfectant storage room			
Output	Incorrect audit of red mites			

Name of function	4.2. To approve mite disinfectant			
Aspect	Description of Aspect			
Input	ncorrect audit of red mites			
Output	Vrongly approved disinfectants			
Name of function	4.9. To audit cleaning contractor supplies			
Aspect	Description of Aspect			
Input	Farm auditor in documentation room			
Output	Incorrectly audited cleaning contractor supplies			

3

1 Figure 1: An example of a FRAM function hexagon with the six aspects

Adapted from (Ferreira and Canas, 2019).

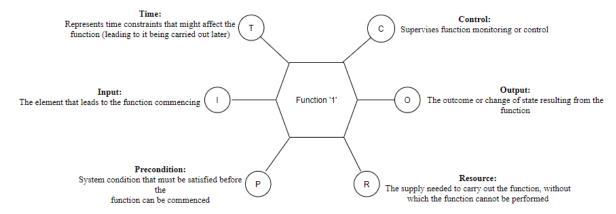
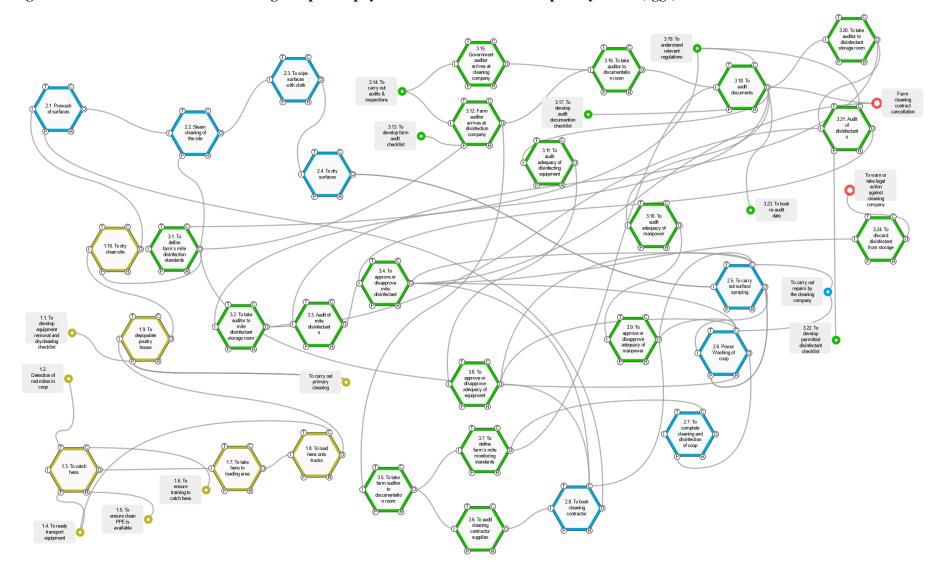


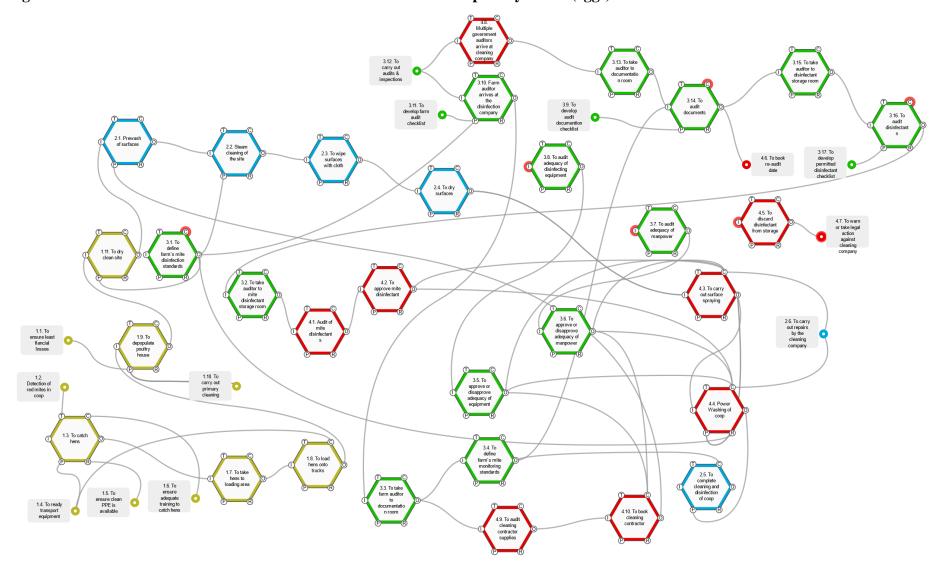
Figure 2: FRAM based on a work-as-imagined philosophy for red mite elimination in poultry farms (eggs)



Key
I – Input
O – Output
R – Resources
P – Precondition
C – Control
T - Time

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Figure 3: FRAM based on work-as-done for red mite elimination in poultry farms (eggs)



Key
I – Input
O – Output
R – Resources
P – Precondition
C – Control
T - Time

Highlights (for review)

Highlights

- 2017 Fipronil in egg contamination incident in the Netherlands was explored.
- Red mites were eliminated through practices that did not comply with regulations.
- Performance variability in public hygiene policies was a key failure in work as done.
- The use of FRAM was of value in assessing complex food systems.

Exploration of the fipronil in egg contamination incident in the Netherlands using the Functional Resonance Analysis Method

The authors whose names are listed immediately below certify that they have NO affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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Louise Manning: Validation, Resources, Writing – Review & Editing

Patrick Waterson: Validation