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

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## 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.



**Key words: fipronil egg contamination; work-as-imagined; work-as-done; policy; 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 aim of this study was to explore the elimination process of red mites on poultry farms, and 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)?

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

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 free-range 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

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

211 **Take in Figure 1**

212 ## 5. Results

213 Table 2 provides a description of the functions modelled in Figures 2 and 3, and highlights
214 functions unique to the work-as-done scenario.

215 **Take in Table 2**

216 ### 5.1. Work-as-imagined: Policy design and dissemination

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

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

242 Information was collated from public policies on treatment for red poultry mites (based
243 on a work-as-imagined philosophy) (DEFRA, 2018; European Union of Wholesale with Eggs
244 Egg Products Poultry and Game, 2012; Opperhuizen, 2018). On discovery of red poultry mites,

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:

*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

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 non-compliance 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,

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

324 **Take in Figure 3**

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

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

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

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

511 RQ3 asked "How can the FRAM be used for policy development to reconcile the gap between
512 'work-as imagined' and 'work-as-done'?" The FRAM can be used proactively as a tool for
513 incident analysis as it helps to establish *emergent themes* based on work-as-done rather than
514 solely comparing negative events with expectations of a process (Hounsgaard, 2016). Thus,
515 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.

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718

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

Adapted from Powell *et al.*, 2009.

| Theme | Issue |
|---|---|
| Content of the incident: what are safety improvement measures and why have them in place? | Lack of agreement that safety improvement was necessary<br>Lack of clarity about the nature of the incident and how the proposed new improvements fitted with existing and related practice |
| Context of the incident: what are the features of the local environment? | Poor fit with local organisational priorities.<br>Poor fit with local organizational structures (e.g. departments).<br>Adverse effects of previous organizational improvements (e.g. reorganizations)<br>Lack of direct and indirect resources to support the improvement |
| Process of the incident: how safety improvements challenge professional roles and identities? | Divergent views among food professionals about responsibility for various aspects of safety improvement<br>Conflict with longstanding professional boundaries and 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. | |
| 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. | |
| To dry surfaces | Surfaces should be allowed to dry before disinfection. | Fig 2 and 3 |
| To book cleaning contractor | On completion of the *prewash* stage, trained and certified external cleaning contractors must be booked for treating the red mite infestation problem. | Fig 2 and 3 |
| | | 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. | |
| To carry out primary cleaning | First stage of cleaning of the environment after | Fig 2 and 3 |
| | | Fig 2 and 3 |
| | | Fig 2 and 3 |
| | the depopulation stage. | |

| 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 |

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

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 Measures | | Location |
| | | | 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 disinfection | | Forward planning |
| | | | 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 transport of hens | Catching and loading of 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?<br>What does the function change? |
| **Output** | What is the outcome of the function?<br>Does the EUWEP, DEFRA or the NVWA policy document need to be used?<br>Does anything need auditing or checking?<br>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?<br>What happens if the preconditions are not available? |
| **Resource** | What resources are needed to perform the function?<br>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)<br>What is the purpose of this function? Why is it done? Are there formal procedures controlling the function?<br>Are there assigned people who control the function (e.g., private auditors)? Do unofficial work practices or culture control the function?<br>Are there constraints (e.g., resources)? |
| **Time** | Is there a time element **related** to the function?<br>Is there a delay in performing the function? What are the consequences of delays?<br>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 |
|---|---|

| 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 | 2.8. To book cleaning contractor |
| Aspect | Description of Aspect |
| Input | Cleaning contractor supplies rigorously |
| Output | Verified cleaning contractor hired |
| Control | Approved disinfectants |
| | 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 |
| | 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 |

| | |
|---|---|
| Input | Auditor in disinfectant storage room |
| Output | Disinfectant audited |
| Precondition | Disinfectant checklist is developed |
| Control | Understanding of Regulation (EC) 2160/2003 of the European Parliament |
| Name of function | 3.19. To understand relevant regulations |
| Aspect | Description of Aspect |
| Output | Understanding of Regulation (EC) 2160/2003 of the European Parliament |

| | |
|---|---|
| Name of function | 3.17. To develop audit documentation checklist |
| Aspect | Description of Aspect |
| Output | Documentation checklist is developed |
| Name of function | 3.22. To develop permitted disinfectant checklist |
| Aspect | Description of Aspect |
| Output | Disinfectant checklist is developed |
| Name of function | 3.24. To discard disinfectant from storage |
| Aspect | Description of Aspect |
| Input | Disapproved disinfectants |
| Output | Disinfectant discarded |

| | |
|---|---|
| Name of function | 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 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 |

| Name of function | 3.13. To develop farm audit checklist |
|---|---|
| Aspect | Description of Aspect |
| Output | Developed farm audit checklist |
| Name of function | 3.23. To book re-audit date |
| Aspect | Description of Aspect |
| Input | Paperwork is either unavailable or incomplete |
| Name of function | 3.12. Farm auditor arrives at 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 | Farm cleaning contract cancellation |
|---|---|
| Aspect | Description of Aspect |
| Input | Paperwork is either unavailable or incomplete |
| | Disapproved disinfectants |
| | Cleaning chemicals disapproved |
| Name of function | 3.10. To audit adequacy of manpower |
| Aspect | Description of Aspect |
| Input | Paperwork is available and completed |
| Output | Manpower adequacy audited |
| Name of function | 3.11. To audit adequacy of disinfecting equipment |
| Aspect | Description of Aspect |
| Input | Paperwork is available and completed |
| Output | Equipment adequacy audited |

| Name of function | 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 |
|---|---|

| 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 | Poor 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 | Poorly audited disinfectants |
| Precondition | Disinfectant checklist is developed |
| Control | Understanding 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 | 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 | Incorrect audit of red mites |
| Output | Wrongly 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 |

Figure

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

Adapted from (Ferreira and Canas, 2019).

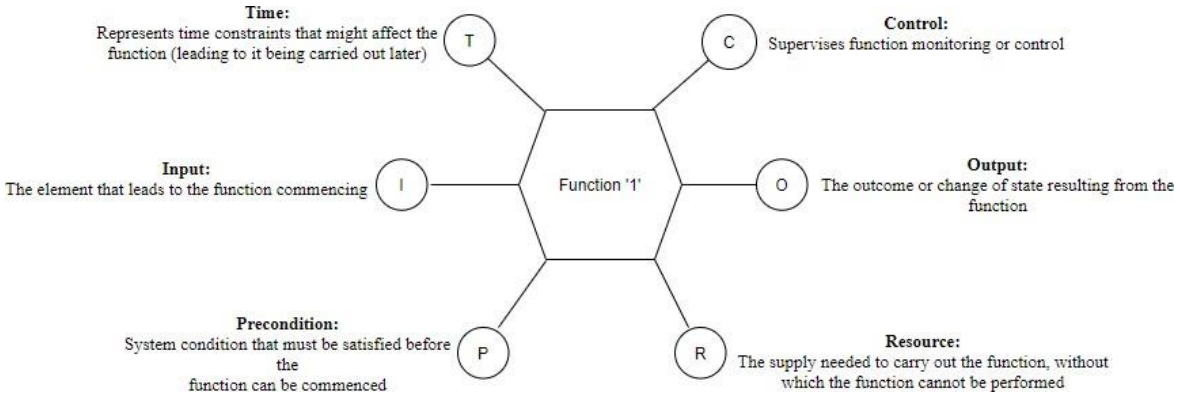
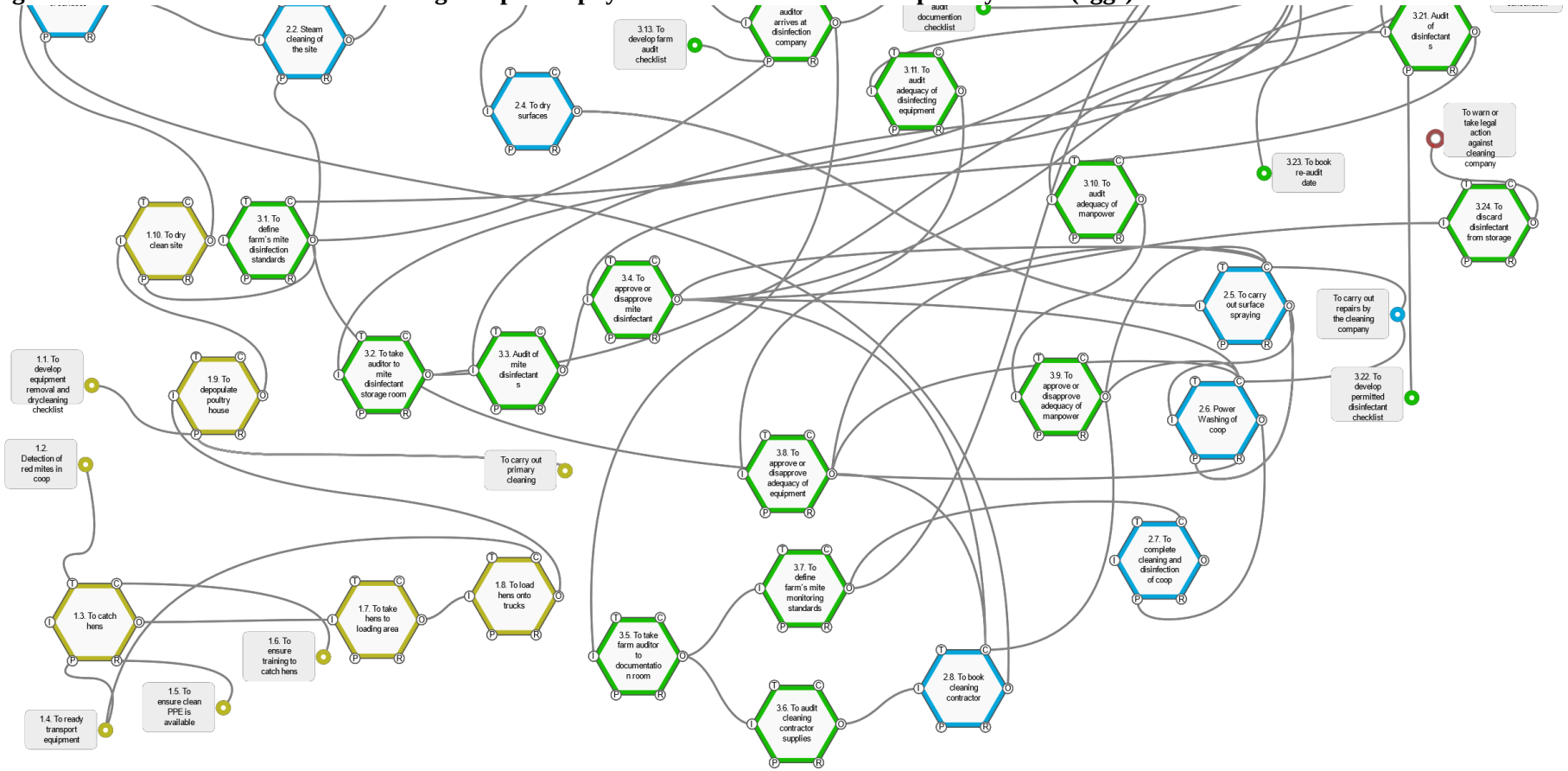


**Figure 2: FRAM based on a work-as-imagined philosophy for red mite elimination in poultry farms (eggs)**



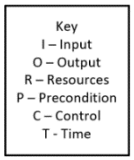
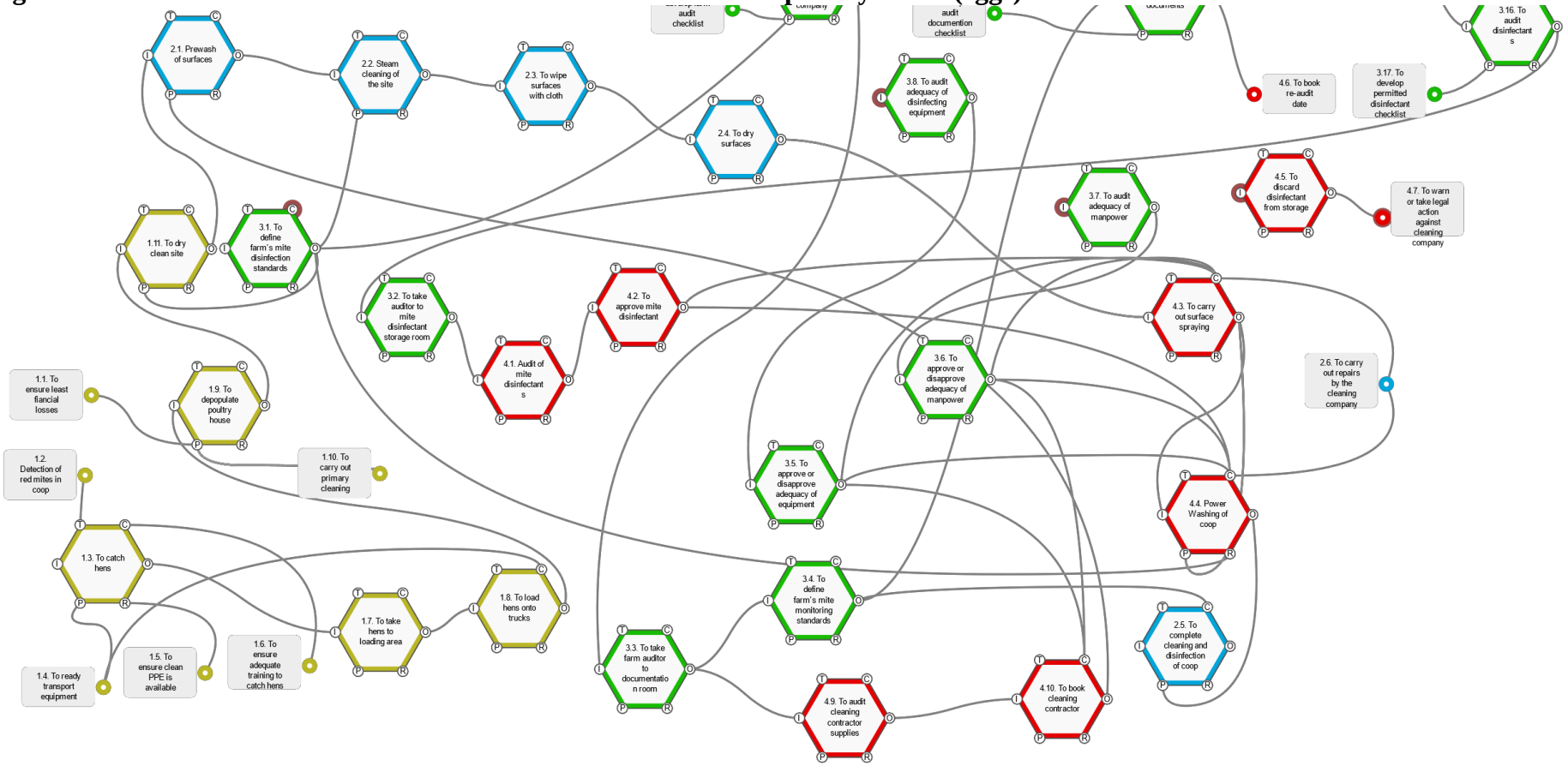
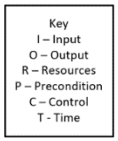

Key
I – Input
O – Output
R – Resources
P – Precondition
C – Control
T - Time

**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

- 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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