

Interactions between risk assessors and risk managers during three major food incidents in Europe

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Abstract: Risk analysis consists of risk assessment (RA), risk management (RM), and risk communication (RC). In most countries, RA and RM of food safety are separated to achieve a high scientific integrity, and typically occur in sequential order. However, in case of a food safety incident, even though being separate processes, RA and RM are performed simultaneously due to great time pressure and expected high impacts. The aim of this study was to analyze and evaluate the observed interactions between RA and RM processes, during three major food incidents in Europe, and to provide suggestions for possible improvement. Based on the differences observed between the three cases, strengths and weaknesses of each system have been identified. The enterohemorrhagic *Escherichia coli* (EHEC) crisis in 2011 in Germany, the horsemeat scandal in 2013 in Ireland, and the fipronil incident in 2017 in the Netherlands were used as case studies. Timelines of these incidents and crisis management procedures in place in each of the three countries provided the basis for further analysis. First, results showed that details of the communication processes between RA and RM bodies were frequently lacking in crisis management protocols. Second, RA, RM, and RC processes differed for each incident, due to differences in estimated risk for public health, but also due to differences in the organization within a country. Based on our results, we recommend that crisis management protocols should contain a section on communication between RA, RM, and on communication between member states in the EU.

KEYWORDS

chemical food safety, food safety, mycotoxins, public health, toxicology

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1 | INTRODUCTION

Risk analysis consists of risk assessment (RA), risk management (RM), and risk communication (RC) (CODEX, 2007). Food safety RM starts with identifying the human health risk related to the intake of the food safety hazards via food, and deciding if a scientific RA is needed. RA—consisting of hazard identification, hazard characterization, exposure assessment, and risk characterization—aims to assess the public health risk of food safety hazards (FAO/WHO, 2006). The RA procedure is a systematic procedure combining all scientific and technical information available, as well as all uncertainties and variabilities of the data (van der Fels-Klerx et al., 2018). The scientific RA is the starting point for further RM. The RA conclusions, including its uncertainties, should be well communicated to the risk managers in order to take effective and science-based decisions (FAO/WHO, 2006). Risk managers identify and select the best management options based on RA results as well as other dimensional aspects such as socioeconomic aspects (e.g. economic issues, consumer acceptability, anxiety and expectations, political sensitivity, media pressure, international consistency). RM aims to achieve an as low as reasonably risk and needs to convey the decisions made to the public who often expects complete risk elimination. Communication is thus essential for effective RA and RM at all stages. Furthermore, RC is needed to provide accurate and transparent information to external stakeholders and the public in order to promote the RM decisions taken for increasing its acceptance (FAO/WHO, 2006). When communicating RM decisions to the public, the fact that uncertainties lead to speculation and doubts about the RM decisions needs to be considered.

A separation between RA and RM is recommended to achieve a high scientific integrity. An adequate communication and interaction between the two risk analysis components during each stage is crucial (NRC, 1983; Gabbi, 2007). In the European Union (EU), RA and RM were separated in February 2002 with the establishment of the European Food Safety Authority (EFSA) (Gabbi, 2007). Also in 2002, the WHO stated that an “Effective dialogue among risk assessors, risk managers, and other stakeholders is essential to maximize the utility of the assessment findings and to ensure that both scientific and societal goals are met” (FAO/WHO, 2002). During an incident or a crisis, under great time pressure, RA and RM often take place simultaneously. Risk managers should continuously be informed of the latest RA developments, with open and transparent discussions about data gaps and uncertainties, in order to act appropriately and to adapt the measures taken when new discoveries are made and modified conclusions are drawn. The WHO published

guidelines (2002; 2010; 2011; 2006) for developing national crisis protocols as well as for applying the risk analysis principles and procedures during a food safety crisis. An effective interaction between risk assessors and risk managers during a food safety crisis is made possible by adequate preparation: networks should be established and an adequate infrastructure (e.g., a closed system for communication and data sharing) should be in place (CODEX, 2016; FAO/WHO, 2002, 2010, 2011). These guidelines touch upon general aspects of communication between RA, RM, and RC bodies. However, today, with the widespread use of social media, RA and RM are operating under even more time pressure and communication between RA and RM is becoming even more challenging. The challenge for the risk managers is to find a balance between early communication to prevent further health risks such as intoxications or infections and exactly knowing the origin of the contaminations. Optimal interaction between RA, RM, and RC is essential to prevent large direct and indirect financial and health consequences of food safety incidents. Therefore, the aim of this study was to analyze, compare, and evaluate the observed interactions between RA and RM processes during three major food incidents in Europe and, in relation to existing crisis management procedures, to provide suggestions for possible improvement. The enterohemorrhagic *Escherichia coli* (EHEC) crisis in 2011, the horsemeat scandal in 2013, and the fipronil incident in 2017 were used as case studies. These three incidents have been chosen due to the high public attention they received, due to the many different stakeholders involved, and because each incident had very different conditions regarding (i) the agent (chemical, microbiological, etc.); (ii) the time scale; (iii) the public health impact; and (iv) the structure of the responsible authorities (centralized vs. federal).

2 | MATERIALS AND METHODS

The risk analysis process was investigated for the three food safety incidents considered in this study. Although all three incidents affected many European countries, the focus of this study was on the country where the incident emerged or the country experiencing the largest impact for each incident, which was Germany for the EHEC crisis in 2011, Ireland for the horsemeat scandal in 2013, and the Netherlands for the fipronil incident in 2017. First, the publicly available WHO “framework for developing national food safety emergency response plans” (FAO/WHO, 2010) and the crisis management protocols or procedures in Germany, Ireland, and the Netherlands were retrieved and investigated for the following points: food safety responsibility, public health responsibility, RM and RA

TABLE 1 Food safety risk assessment (RA) and risk management (RM) organization in Germany, Ireland, and the Netherlands

| | Germany | Ireland | The Netherlands |
|--------------------------------|--|---------------------------------------|--|
| Food safety responsibility | BVL and BfR under the Ministry of Food and Agriculture | The FSAI under the Ministry of Health | The NVWA under the Ministries Agriculture, Nature and Food Quality (LNV) and Health, Welfare and Sport (VWS) |
| Public health responsibility | RKI and minister of Health | | |
| RM | BVL and regional authorities | FSAI | NVWA |
| RA | BfR | FSAI (separate group) | BuRo (independent RA and research division of the NVWA) |
| Separation RA and RM | Yes | No | Yes (legally independent within NVWA) |
| Authorities involved in RC | | | |
| Local | Yes | No | No |
| Regional | Yes | No | No |
| National | Yes | Yes | Yes |
| Number of involved authorities | 3 federal and 16 regional | 1 | 5 |

Abbreviations: BVL, German Federal Office for Consumer Protection and Food Safety; BfR, German Institute for Risk Assessment; RKI, Robert Koch Institute; FSAI, Food Safety Authority of Ireland; NVWA, Netherlands Food and Consumer Product Safety Authority.

responsibility, the separation of RA and RM, and the number of authorities involved (Table 1).

Second, the timelines were summarized for all three food incidents to have an overview of the events and dates. The timelines are divided into RA, RM, and RC events. RA consisted of events related to research performed by the authorities and RA bodies whereas RM and RC were actions taken and/or events communicated to the public and were considered together. Communication of RA results to risk managers and to the public differs in the target audience and in the channels used. Communication between RA and RM, through professional channels, aims to provide information to take science-based risk management decisions, whereas RC towards the public aims to improve the general understanding and acceptance of the decisions taken. RM decisions often become visible as RC to the public. Therefore, RM decisions presented in this paper were based on RC.

This separation shows if RM and RC logically follow the findings of the RA. Information regarding the timeline, RA, RM, and RC of the three incidents were retrieved from scientific literature, using the database Scopus, from news articles using the search engines Google NL and Google DE, and from the websites of the food safety authorities in the respective countries as well as the European Commission (EC).

Third, the risk analysis process during the three incidents was assessed. The handling of the three incidents were compared regarding the response time, the application of the precautionary principle, the balance between economics and public health, the quality of communication between RA and RM, and the communication

between Member states of the EU. The process was assessed against the protocols and/or procedures. Some of these protocols were updated after these incidents. In the case the protocol in place during the course of the crisis was not available, it has been checked whether the deviations in the recent protocol have been a topic of the subsequent lessons learned from the crisis.

3 | RESULTS AND DISCUSSION

3.1 | Crisis management procedures

3.1.1 | World Health Organization (WHO)

In its “Guide for application of risk analysis principles and procedures during food safety emergencies” (FAO/WHO, 2011), the WHO describes a system for the categorization of food safety incidents and states that RM options should be based on this categorization. If there is no high risk for public health but, nonetheless, a high level of concern from the public, there might be a need to scale up the RM options. Furthermore, if uncertainty about the nature of the food safety risk exists, risk managers can decide either to delay making a decision or to take action to protect consumers to meet public expectations and perceptions. RC is particularly important in case the selected RM option may appear to be less or more stringent than expected by the public. When communicating the choices of management measures, enough information should be provided to the public and transparency should be maintained without causing unnecessary concerns. Regarding the RC, a

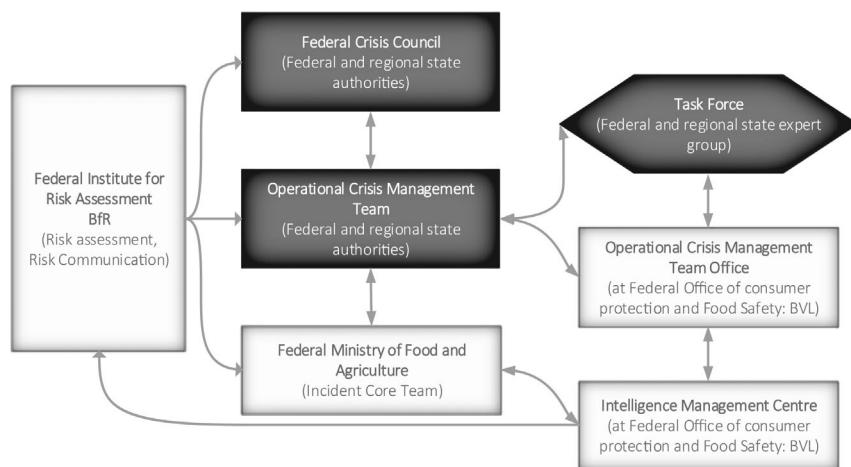


FIGURE 1 Organization of the structures involved in the crisis management in Germany. The risk assessment (RA) is provided from the German Federal Institute for RA (BfR) to the bodies responsible for risk management (RM) with centralized feedback from the Intelligence Management Center. The federal structures are represented by the white boxes; the joint structures of federal and regional authorities are represented by the gray boxes. Based on BVL (2015)

single nominated spokesperson should be appointed and the communication strategies for partners like international organizations and stakeholders like media, general public, industry, and health care professionals have to be prepared (FAO/WHO, 2011).

3.1.2 | Germany

In Germany, a strict organizational separation of RA and RM has been established. RM is the responsibility of each of the 16 Federal States, resulting in a complex situation with regional crisis management protocols. The Federal Ministry of Food and Agriculture and the Federal Office of Consumer Protection and Food Safety (BVL) are responsible for RM at national level. The BVL coordinates regional activities (BfR, 2011 g; van Asselt et al., 2017). RM is performed at national level in a crisis situation, as defined in Regulation No 178/2002 (EC, 2002). The German Federal Institute for Risk Assessment (BfR), established in 2002, is responsible for RA at the national level by preparing expert reports and opinions on food and feed. The Robert Koch Institute (RKI) is the federal authority for the identification, surveillance, and prevention of human diseases.

If implications of the crisis are beyond the concerned federal state, the Federal Ministry of Food and Agriculture can set up a Federal Crisis Council. Members of the Federal Crisis Council are the directors of the federal and regional agencies for food safety and officials of the federal ministry. The Federal Crisis Council provides status reports, recommendations for RM options and takes responsibility for RC. The Federal Crisis Council activates the Operational Crisis Management Team (OCMT) to handle the daily business of the crisis. The members of the OCMT are the heads of the departments of the federal ministry and of the regional agencies. Concerned federal and European agencies may be invited as guests. The tasks of the OCMT are providing state reports, developing strategies for RM,

coordinating measures between regional states and federal agencies, and coordinating RC.

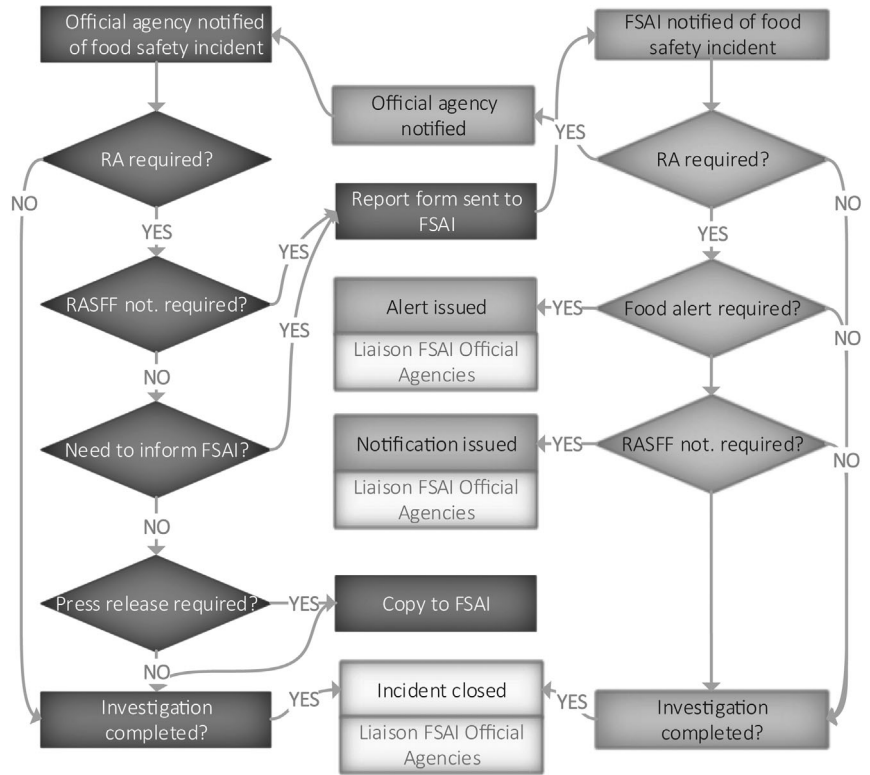
Beside the OCMT, a task force for food and feed safety can be activated by the Federal Crisis Council. The members of this task force are experts from federal and regional agencies on the specific topic and the head of the OCMT. The task force has to compile recommendations for the route cause analysis and measures to control the crisis, provide scientific background information, organize scientific resources and gather data necessary to handle the crisis. The task force communicates continuously through reports to the OCMT. An important hub for the information exchange between regional state authorities, federal authorities, and involved agencies is the intelligence management center activated by the BVL (Figure 1).

3.1.3 | Ireland

In Ireland, the main body responsible to protect public health is the Food Safety Authority of Ireland (FSAI). The FSAI comes under the aegis of the Ministry of Health. The FSAI is an independent body with a Scientific Committee and a Food Safety Consultative Council that assists and advises the board of the FSAI. The board directly advises the Chief Executive Officer responsible for, amongst others, RM (FSAI, 2017). In Ireland, RA and RM are performed by separate groups within the same organization, facilitating RC. The FSAI has contracts regarding division of tasks with several official agencies such as the Department of Agriculture, Food and the Marine, the State Laboratory, Consumer Affairs, a health board or a local authority (FSAI, 1998).

The official agency responsible for RM of the incident will depend on the estimated risk to public health, based on hazard characterization (high, medium, or low) as well as the distribution of the food products (limited or wide). If the risk for public health is low, RM is done by the

FIGURE 2 Flowchart of the role of the Irish Food Safety Authority (FSAI) in food safety incidents. The gray boxes represent the role of FSAI (light gray) and official agencies acting on behalf of the FSAI (dark gray) after notification of a food safety incident. The white boxes represent steps where the FSAI and official agencies work together. Abbreviations: RA, risk assessment, RASFF, Rapid Alert System for Food and Feed. Based on FSAI (2004)



investigating agency—an official agency on the list of the FSAI, which has identified a hazard or is taking the lead in the investigation—itsself. If the risk is medium, RM is done by the investigating agency in collaboration with FSAI as necessary. However, if the risk for public health is high, but the distribution of the products is limited, RM is done by the investigating agency in collaboration with the FSAI. Finally, if the risk is high and the products are widely distributed, RM is led by the FSAI in collaboration with the investigating agency. The communication between the agency identifying the incident and the FSAI should first be through the “FSAI incident report form – Notification of food incident” (FSAI, 2004). A filled form should also be sent after the investigation if the investigating agency judges there is still a need to inform the FSAI. After the investigation, if a press release is required, a copy should be sent to the FSAI (2004).

During a food safety incident, the FSAI acts as a central contact point in Ireland for gathering and issuing information, including scientific expertise, notifies, and updates official agencies, and provides briefings to other professionals, government departments, officials, and the media (FSAI, 2004). Figure 2 shows the flowchart of actions taken when an official agency and/or the FSAI are notified of a food safety incident.

3.1.4 | The Netherlands

The Netherlands Food and Consumer Product Safety Authority (NVWA) acts on behalf of the Ministry of Agriculture, Nature and Food Quality (LNV) and the Ministry of Health, Wellbeing and Sports (VWS); both ministries are responsible for food safety in the Netherlands. The NVWA is responsible for RM in the event of a crisis. When a notification from the Rapid Alert System for Food and Feed Safety (RASFF), companies, professionals, hospitals, or sample results is reported in the NVWA’s notification system, the manager of the system classifies the notification. High priority notifications are assessed by an expert from the NVWA. Based on—among others—risk for public health, international character, political sensitivity, and media sensitivity, this expert judges if the crisis coordinator of the NVWA has to be informed or if the notification can be handled as routine. In case the notification cannot be handled as routine, the crisis coordinator of the NVWA will be informed, and an “alert ring team” judges the notification based on the same criteria used by the individual expert. The outcome is that the notification is classified as either routine or incident. If the notification is classified as an incident, an incident team is set up (Figure 3). One collaborator from the NVWA’s

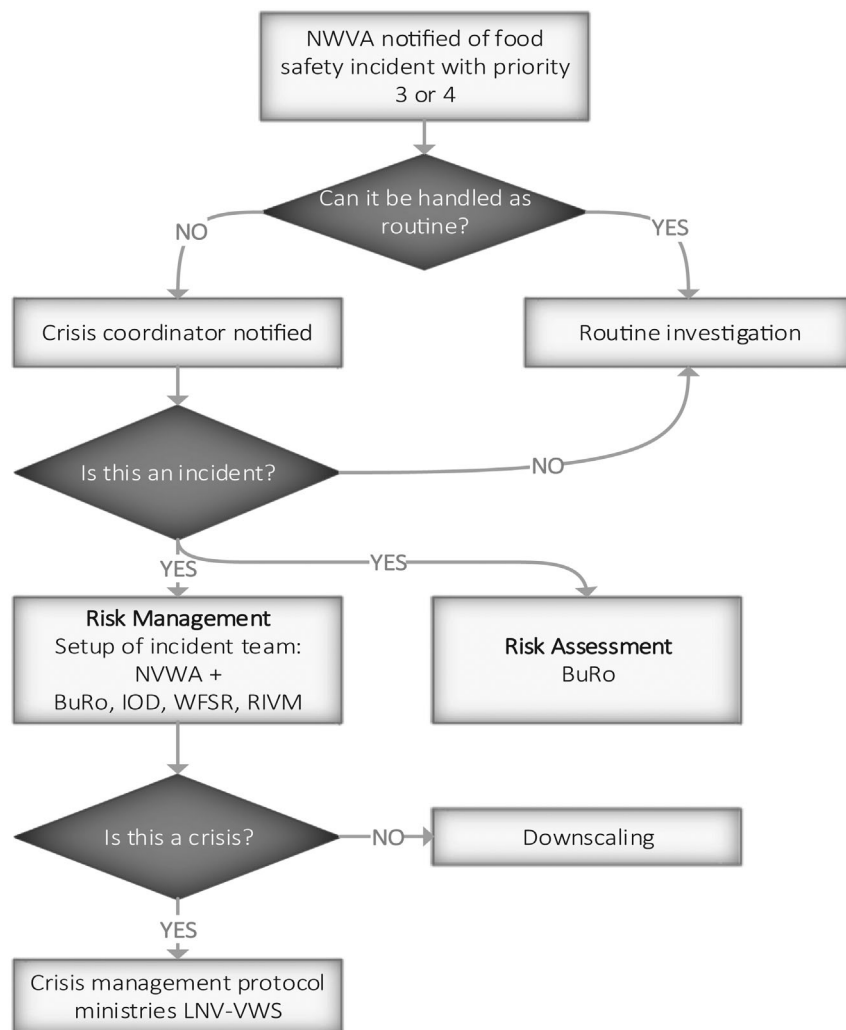


FIGURE 3 Flowchart of risk management procedures of the Netherlands Food and Consumer Product Safety Authority (NVWA). The gray diamonds and white boxes represent the decisions and processes, respectively. Abbreviations: BuRo, the NVWA's division of RA & research; IOD, the NVWA's division of Intelligence and Investigation Service; WFSR, Wageningen Food Safety Research; RIVM, National Institute for Public Health and the Environment; LNV, the Dutch Ministry of Agriculture, Nature and Food Quality; VWS, the Dutch Ministry of Health, Wellbeing and Sports

independent division of Risk Assessment and Research (BuRo), the NVWA's division of Intelligence and Investigation Service (IOD), Wageningen Food Safety Research (WFSR), the National Institute for Public Health, and the Environment (RIVM) are present during the NVWA's incident consultations to enhance interaction between RA and RM. An additional umbrella body representing the industry involved might be present when a specific food product is involved, for example: the Central Organ for Quality Affairs in the Dairy chain (COKZ) when dairy products are involved or the Dutch Egg Control Authority (NCAE) when eggs are involved. BuRo is responsible for the RA process and provides independent advice to the inspector-general of the NVWA and the ministries of LNV and VWS. BuRo is not part of the RM team for the sake of independence. The incident manager requests BuRo to conduct a RA via a member of the NVWA's management team. The request is made, both by phone and in writing. BuRo assesses the request and sends an answer to the NVWA via a member of the NVWA's management team. The application should contain the following information: initial

question, some background information, the relevant laws, which elements the answers should contain, the deadline, and the degree of confidentiality. If there is not enough information available, BuRo assesses the risk with a quick scan or a worst-case scenario, stating the assumption and uncertainties (NVWA, personal communication).

3.2 | Differences in RA, RM, and RC approaches

The timelines of the EHEC outbreak in Germany, the horsemeat scandal in Ireland, and the fipronil incident in the Netherlands are shortly described and summarized in Figures 4, 5, and 6, respectively. Events are divided into RA, RM, and RC events. These timelines served as basis to further analyze and evaluate the observed interactions between RA, RM, and RC processes during these three incidents.

Interactions between RA, RM, and RC differed during each incident. All three cases are food-related incidents

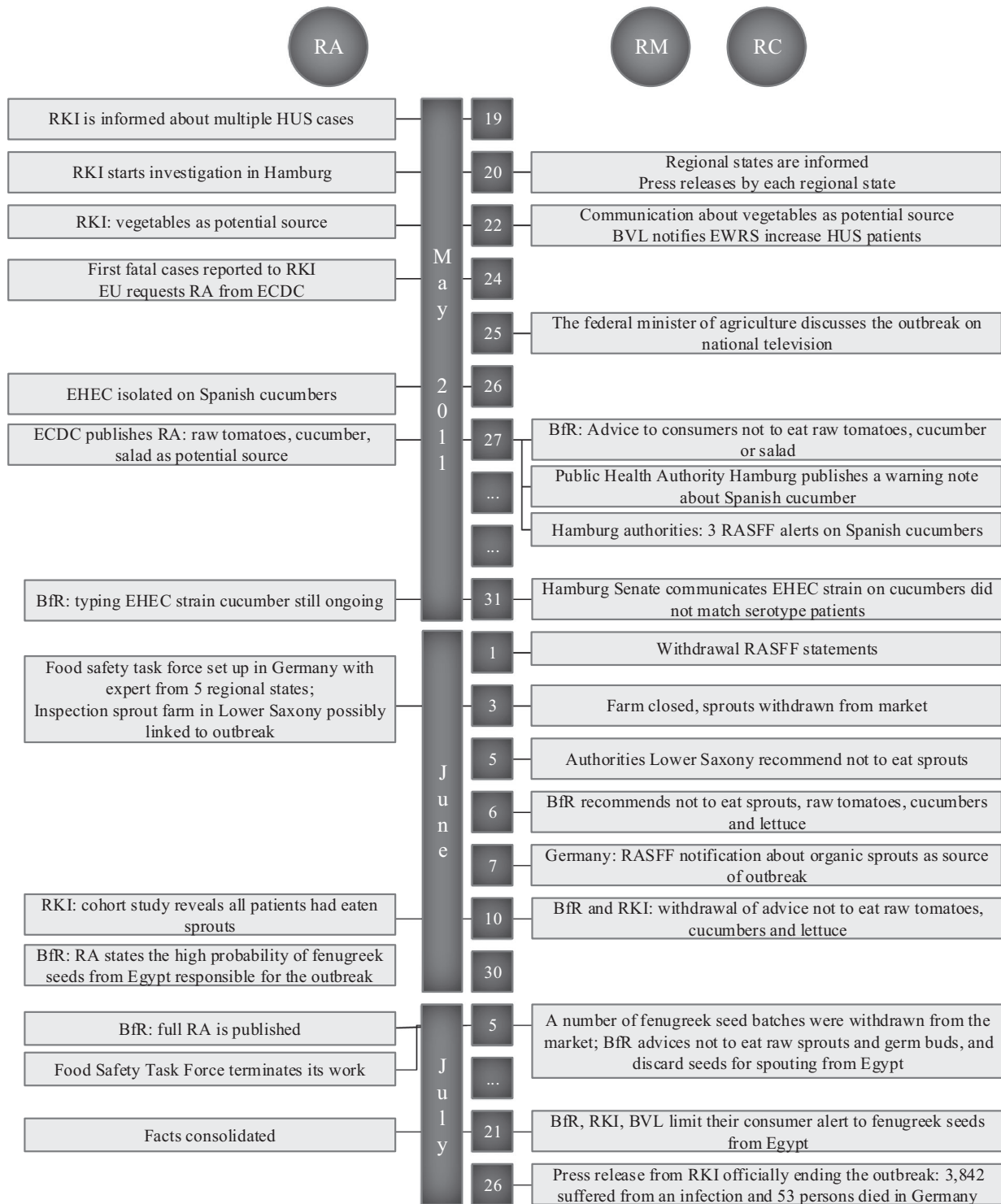


FIGURE 4 Timeline of the enterohemorrhagic *Escherichia coli* (EHEC) crisis in Germany in 2011. Abbreviations: RA, risk assessment; RM, risk management; RC, risk communication; RKI, Robert Koch Institute; BfR, German Federal Institute for Risk Assessment; ECDC, European Centre for Disease Prevention and Control; BVL, German Federal Office for Consumer Protection and Food Safety; EWRS, European Early Warning and Response System; HUS, Haemolytic Uremic Syndrome; RASFF, Rapid Alert System for Food and Feed Safety (Bernhard et al., 2011; BfR 2011a, 2011b, 2011c, 2011d, 2011e, 2011f, 2011h; Brenner & Zacharis, 2011; ECDC, 2011a; EFSA, 2011; Frank et al., 2011; Hamburg de, 2011 May 26, 2011 May 31; Hamburger Morgenpost, 2011 May 20, 2011 May 22; LAVES & NLGA, 2011; RKI, 2011; RASFF, 2011a, 2011b, 2011c, 2011d; WHO, 2011; Zeit Online, 2011 May 26)

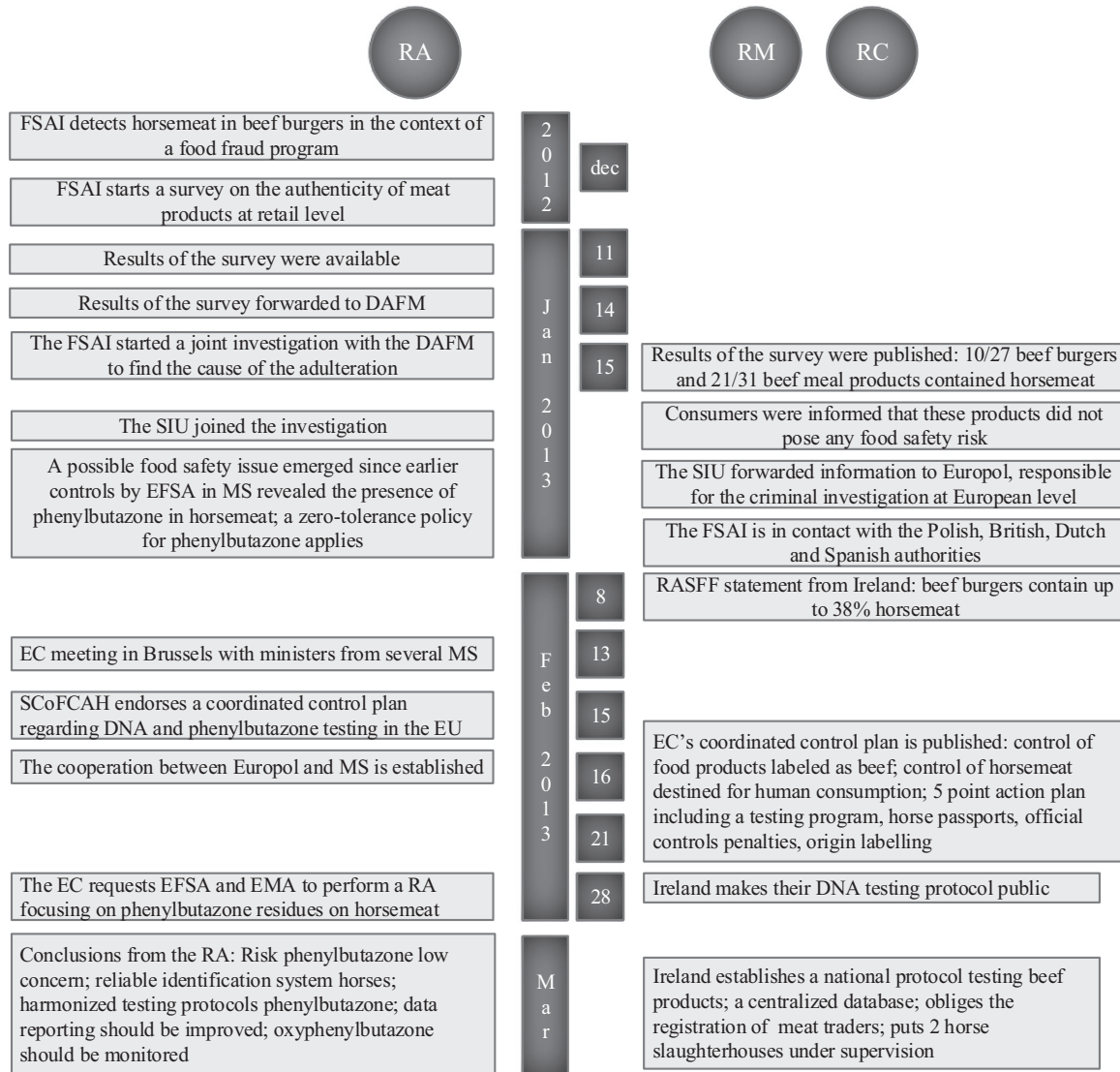


FIGURE 5 Timeline of the horsemeat scandal in Ireland in 2012–2013. Abbreviations: RA, risk assessment; RM, risk management; RC, risk communication; FSAI, Food Safety Authority of Ireland; DAFM, Department of Food, Agriculture and the Marine; SIU, Special Investigative Unit; EFSA, European Food Safety Authority; MS, EU Member State; ScoFCAH, Standing Committee of the Food Chain and Animal Health; EC, European Commission; EMA, European Medicines Agency; RASFF, Rapid Alert System for Food and Feed Safety (DAFM, 2013; FSAI, 2013; EFSA, 2013a, 2013b; RASFF, 2013a, 2013b; EC, 2013 February 13, 2013 February 14, 2013 February 15)

but due to the type of hazard, the starting point of the incident and the organization of handling a food safety crisis in the respective country, RA, RM, and RC were approached differently in each case. Delays in response time occurred during all three incidents but due to different reasons. Crisis management protocols and procedures were in place in all three countries but were often incomplete and not tailor-made for the particular case. Mainly due to the application of the precautionary principle, the balance between public health and economic losses was in favor of public health during all three incidents. The independency of RA and RM had to be kept but the more close the responsible bodies worked together, the less independent RA and RM were in practice. Ger-

many's federal system led to a much more complex RC than the centralized or national organizations such as in Ireland and in the Netherlands. Several RC and RM errors led to unnecessary concerns at the consumer level and led to extra economic losses. The main differences observed during all three incidents are summarized in Table 2 and are further contemplated in the remainder of this article.

3.2.1 | Response time

The three food incidents presented in this study each had an onset at a different stage of the food supply chain. The

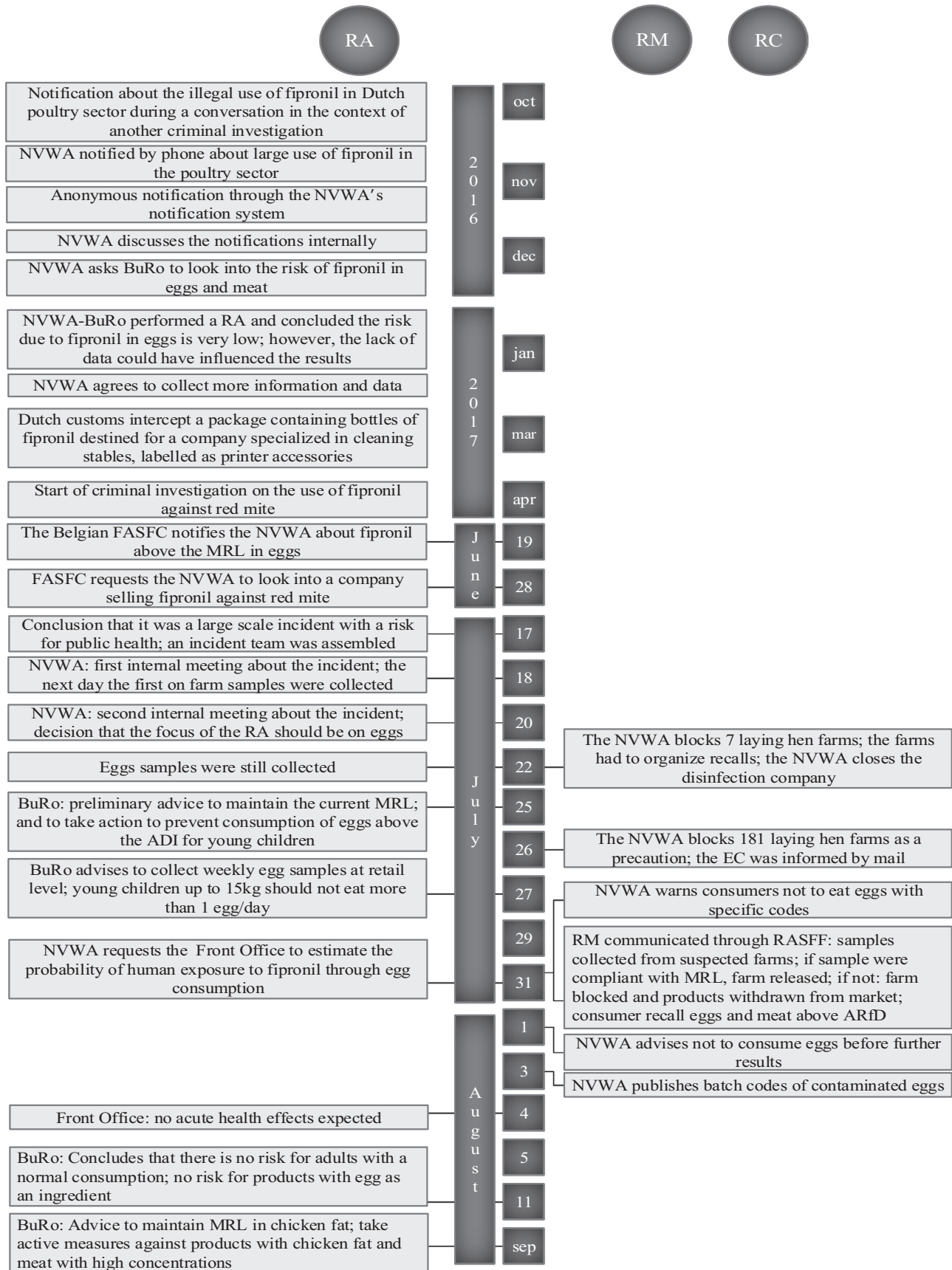


FIGURE 6 Timeline of the fipronil incident in the Netherlands in 2016–2017. Abbreviations: RA, risk assessment; RM, risk management; RC, risk communication; NVWA, Netherlands Food and Consumer Product Safety Authority; BuRo, the NVWA's division of RA & research; FASFC, Belgian Federal Agency for the Safety of the Food Chain; MRL, maximum residue limit; ADI, acceptable daily intake; ARfD, acute reference dose; RASFF, Rapid Alert System for Food and Feed Safety (EC, 2017; Sorgdrager, 2018; NOS, 2017 August 1, 2017 August 2; NVWA, 2017; NVWA/BuRo, 2017a, 2017b, 2017c; 2017; RIVM & RIKILT, 2017)

TABLE 2 Risk assessment (RA), risk management (RM), and risk communication (RC) during three food incident or fraud cases

| | EHEC crisis | Horsemeat scandal | Fipronil incident |
|--|---|--|---|
| Response time | Delay in recognition of the outbreak | Delay in RA and communication to member states | Long delay between notification and RM (6 months) |
| Crisis management protocol or procedures | Yes | Yes but did not include food fraud | Yes but incomplete |
| Independence RA | Independent approach | Not applied | Independent approach |
| Precautionary principle | Fully applied | Fully applied | First 6 months: not applied After 6 months: applied |
| Economy versus public health | Biased towards public health | Biased towards consumer rights (food fraud) | Economy regarded in the first months, then biased towards public health |
| Clear responsibilities | Overlapping between federal and regional authorities, unclear who provides RC | Yes | Yes |
| Clear RC | Premature warnings, which had to be corrected | Yes | Unclear, not transparent, contradicting |

EHEC crisis started at the end of the food chain with the observation of an increased level of human EHEC cases in certain regions in Germany. The direction of the investigation was upstream starting from the affected consumers to the food products and/or producers responsible for the contamination. In this case, the questions of severity of the disease and the impact of the infections were answered from the beginning. On the other hand, the food products responsible, the contamination route, and details on the distribution were unknown and required detailed investigation. During the EHEC crisis, the first communication line was the internal communication between public health authorities at county level, regional level, and federal level (RKI). The notification delay between the regional public health authorities was the reason that the RKI stepped in when many infections had already happened (Figure 4), and only then it became apparent that a larger outbreak was ongoing. Shorter notification times have been implemented as a response to the lessons learned of the EHEC crisis (Osterloh, 2013; Rissland et al., 2013). The food safety authorities became involved when the infections appeared to be foodborne. At this time, the information on a high number of HUS and severe enteritis cases among consumers had already reached the public (LAVES & NLGA, 2011). The divided responsibility for health and food safety as well as the division between regional and federal authorities seemed to have influenced the response time and contributed to delays during this incident.

The second incident considered, the horsemeat scandal, started with the discovery of horse DNA in food products labeled as beef at retail level. The investigation was performed both upstream the supply chain to iden-

tify the source of the contamination, and then downstream to identify and localize the affected companies and products. This investigation was complex and took several weeks due to the involvement of many European countries. After having been identified, the products were immediately withdrawn from the market. A possible health hazard, that is, the presence of phenylbutazone residues, was identified with a slight delay due to the fact that the focus of this investigation was food fraud. A RA from 1997 performed by the European Medicines Agency (EMA) advised a zero-tolerance policy for phenylbutazone in food products (EFSA, 2013a). The European Commission requested EFSA to perform a novel RA on 28th February. Results of the European RA were published in March 2013. The fact that the origin of the horsemeat was not completely traceable opened potential for other possible risks.

The third incident started when the NVWA was notified about the illegal use of the pesticide fipronil at primary production level. No RM actions were taken after initial notifications. Notifications were made via different routes and were not entered in the central notification system of the NVWA. Therefore, it took many months before a connection was made between the separate notifications (Sorgdrager, 2018). It took more than 6 months before any RM action was decided upon, after the discovery of high levels of fipronil in eggs at retail level, in Belgium. Unlike the other incidents, the contamination route was known or found rather quickly. The investigation was performed downstream the supply chain to identify all food products containing contaminated eggs.

The response time differed in all three cases. The response time was short in case of the EHEC crisis, mainly

since public health was directly affected. In case of the horsemeat scandal, a potential risk for public health was not immediately identified but contaminated products were rapidly identified and recalled nonetheless. During the fipronil incident, the response time was long. No risk for public health was identified at the start. RM decisions were accelerated when authorities in Belgium detected high levels of fipronil in eggs exceeding the respective maximum residue limit (MRL). RM decisions were made even more promptly when consumers started to get concerned.

3.2.2 | Risk analysis and precautionary principle

Since people were falling ill or died during the EHEC crisis, the public was closely watching every RM and RC step. This incident required a special communication strategy with a strong focus on precautionary measures and a clear communication of uncertainties. A number of RA and RM activities were implemented immediately. RKI experts investigated the outbreak epidemiologically, which brought raw vegetables in the focus of the investigation (RKI, 2011). This enabled BVL and BfR to provide an initial guidance to the public. The real challenge was the communication of these precautionary measures with adequate stringency and to convey the message of a high uncertainty at the same time. Consumers were advised to refrain from eating raw tomatoes, cucumbers and lettuce even though these commodities were not identified as the source of the EHEC contamination. The precautionary principle was applied to protect consumers. This advice was however not based on scientific evidence from a RA. This kind of biased RC cumulated when regional authorities issued a warning note on Spanish cucumbers and even placed a RASFF alert. The link to the outbreak was wrongly suspected as shown later in a molecular analyses of the isolate. This led to high economic losses for businesses associated with those vegetables, who were not linked to the outbreak (Karch et al., 2012).

Two issues were at hand during the horsemeat scandal in Ireland: illegal products being brought onto the market and products that were potentially affecting public health. The risk analysis process generally worked well during the horsemeat scandal in Ireland. Throughout the incident, the precautionary principle was applied. Due to uncertainty, lack of data, not having a rapid diagnostic test available, and the illegal horsemeat not being regulated as food product, the FSAI advised not to consume any suspicious food. The focus was however on food fraud rather than food safety. Products labeled as beef contain horsemeat were recalled and advised not to be consumed to protect consumer rights.

During the fipronil incident, the RA was based on assumptions regarding the dose of fipronil used against red mite. Early 2017, based on the chosen assumptions, BuRo concluded that there was no acute risk for public health related to the consumption of eggs (Sorgdrager, 2018). This could explain why no product recalls were started. However, no RM options were taken at primary production stage either. In the second half of 2017, more than 6 months after the first report of fipronil use, the risk assessors concluded the same as earlier that year: the risk for public health was very low in general. The RA process was, however, difficult due to many uncertainties and assumptions that had to be made. EFSA derived an acceptable daily intake (ADI) and an acute reference dose (ARfD) for fipronil (EFSA, 2006). The ADI assumes a lifetime exposure whereas the ARfD assumes a single exposure, and both measures are invalid for fipronil since the exposure to fipronil was weeks or months. When considering either the ADI or the ARfD, adverse health effects could not be excluded in the worst-case scenario, that is, for the consumption of multiple highly contaminated eggs per week by small children of eggs. For all other scenarios, the adverse health effects were very small or even nonexistent (van der Merwe et al., 2018). EFSA did not set limits between the ADI and the ARfD based on an intermediate duration of exposure and, therefore, the RA for the fipronil incident was uncertain. In the second half of 2017, with the incident becoming more widespread and international, another management option was chosen: the NVWA chose to implement the precautionary principle by prohibiting farms from selling eggs and performing recalls at retail level. During the summer of 2017, the NVWA warned consumers not to eat eggs with specific codes, and the spokesperson of the NVWA advised the public not to eat eggs until further notice (NOS, 2017 August 1; NOS, 2017 August 2). This unclear and nontransparent communication resulted in confusion among consumers. In this respect, RC deviated from the WHO guidelines stating that when communicating the choices of control measures, enough information should be provided and transparency should be maintained without causing unnecessary concern (FAO/WHO, 2011).

It might have been helpful early 2017, to have supplemented the scientific RA, focused on public health, with an assessment of the political, reputational, regulatory and commercial aspects, since the risk for public health was very low and the economic losses for the poultry sector were immense. An economic assessment of the management options was performed only in a later stage of the incident, indicating that the fipronil case had cost the entire Dutch poultry production chain €65–75 million (Horne et al., 2017) or a loss of €369,000 per poultry farm involved (Sok, Horne, & Meuwissen, 2020). Even though

the human health risk was low, measures to manage the risk were still needed since—in the second half of 2017—it turned out that 26% of retail samples contained fipronil residues exceeding the MRL (Rijksoverheid, 2017) while fipronil is prohibited to be used for all food-producing animals in the EU (EC, 2017, August 10). Food business operators have to comply with EU regulations and to block the poultry farms was, therefore, legally justified.

3.2.3 | Communication between RA and RM

RA and RM are institutionally separated in most countries to ensure scientific integrity but communication before, during, and after the RA process is needed to use the full potential of the RA. Risk analysis should be an iterative process, and interaction between RA and RM is needed (FAO/WHO, 2019). Communication between RA and RM needs to be carefully prepared in the emergency plans so that risk managers know how the results from RA should be interpreted (e.g., how uncertainty should be interpreted) and used (Andersson et al., 2020). Science provides hypotheses, probabilities, and uncertainties. However, risk managers, journalists, and consumers often request clear-cut facts while uncertainties in RA are inevitable. The impact of these uncertainties should be well communicated to risk managers in order to apply the precautionary principle if the estimated risk becomes large in case one of the initial assumptions changes. Especially in a crisis or incident situation with great time pressure, it is important that risk assessors and risk managers respect their different roles in the process and at the same time trust each other and acknowledge the importance of continuous two-way communication.

In the case of the EHEC crisis in Germany, the risk was estimated to be high in the RA, whereas the source was uncertain. Consumers were, therefore, advised to refrain from eating different types of foods. Consumers were confused by the different messages, but RM did follow the RA process, which was evolving and updated as new information became available. In Germany, there is a clear separation between RM (BVL) and RA (BfR) at federal level (Figure 1). The fact that the BfR, RKI, and the BVL published shared press releases is an example of good communication between RA and RM, and shows that management options were agreed upon. At federal level, risk assessors and risk managers put forward the same message to the public. The separation of RA and RM in Germany and the shared responsibilities between federal and local authorities led sometimes to seemingly premature RM and RC. However, these actions were the result of an assessment of necessary actions against the uncertainties of the knowledge at the time and the expectations of the public.

RA provided sound and scientifically based assessments with a clear indication of the current uncertainties. RM on the other hand took actions to protect the consumers as fast and as effective as possible with a clear focus on the precautionary principle.

Surprisingly, the complex risk analysis structure in Germany provided advantages, which were not recognized at the first glance. The interactions between different levels and authorities challenged the decisions being made constantly and required fast corrections. This iterative approach made the whole process more efficient. For example, when an EHEC strain was found on cucumbers in Hamburg, the BfR had to act fast and communicate promptly about the results of the typing of the strain. The main disadvantage of the complex administrative structure was though that the regional authorities tended to take actions, even when the assessment of the situation was not completely clear. The impact of the measures in a greater context was often inestimable. For example, the message on cucumbers had been issued regionally but impacted different member states of the EU. The RA at regional level identified potential hazards. However, RA does not consider the economic impact at national or even at European level. RM and RC should carefully consider all factors and should also communicate uncertainties. A coordinated approach at national level could help to communicate clearly without any contradictions.

It seems that in countries with a more centralistic structured approach, such as Ireland, communication was better coordinated (FSAI, 2004). The lack of independency of RA and RM in Ireland led to not recognizing potential risks of the horsemeat scandal for public health, which were revealed only after deeper analysis (e.g., Phenylbutazone). No RA was requested immediately after the detection of horsemeat but RM was initiated in the first place with high priority. The first RM options were therefore not based on RA. However, products were recalled and the precautionary principle was therefore applied. The aim of RM was to defend consumer rights and to protect consumers from food fraud. The potential health hazard had not been recognized at this stage. Communication between RA and RM started after the initiation of the RA.

In the case of the fipronil incident, the RA concluded that the risk was low but elevated for young children. This conclusion was indeed communicated to the consumers but, since massive recalls were being performed nonetheless, it was perceived as confusing. Here, RM did not follow RA. Since the risk was estimated to be low, and the economic impact was high, a rational RM option could have been to take legal actions against the companies involved, to stop the use of fipronil in the poultry sector, informing the consumers about the possible presence of fipronil in eggs, communicating about the low health risk, but

without performing massive recalls. However, although being rational from both an economic and public health perspectives, accepting products exceeding the MRL on the market may result in conflicts with legislation and the maintenance of consumer's confidence in the authorities.

The independency of RA was important in protecting public health in all three incidents presented. RA assessed the potential risks without premature conclusions and free from the considerations of potential economic losses or negative public perception, which were assessed by RM. Communication between RA and RM appeared to have been limited in the horsemeat incident in Ireland, due to the fact that a health risk was not recognized from the start. RA did not play its usual role in this case. The balance of the system was therefore somewhat disturbed. Whereas it will always be challenging to timely intervene when limited information is available, structured, and documented communication between RA and RM would make the whole process more transparent for consumers and stakeholders involved, and would contribute to maintaining the confidence of stakeholders in the risk analysis process.

3.2.4 | Crisis management protocols and procedures

Most countries have crisis management protocols in place describing the actions that have to be taken when a food safety incident has been identified. Very few of these protocols are publicly available though. The Irish protocol is publicly available, whereas the Dutch and German protocols are not publicly available. Due to the structure of the RM bodies, these protocols were scattered over local and regional administrative levels in Germany. Public availability of protocols facilitates the assessment of the actions taken during a crisis. In the Netherlands, the NVWA did have a food safety crisis management in place at the time of the fipronil incident but it did not lead to a successful handling of the incident. Therefore, major updates on the document were performed after the incident. The protocols and/or procedures retrieved were difficult to compare in some aspects: the major part of the protocols described the country's structure, such as which bodies are responsible for each task, as well as the incident team structure, which are country-specific. Comparable aspects were the incident classification (e.g., routine or severe), the need for a scientific RA, and some general aspects such as openness in communication. Some of these aspects were followed during the three major food incidents described above.

Even though protocols are in place, these protocols might not be followed due to different reasons. Each incident had its own dimension and general protocols might

not be tailored enough to suit all different aspects of a food crisis. For example, since food fraud incidents were not included in the crisis management protocol of the FSAI, the flowchart depicted in Figure 2 was not followed. Since it was a food fraud case and it was unclear whether public health was at risk, a RA was not immediately started.

Furthermore, the situation might evolve so fast that agencies involved in the risk analysis process react without consulting the protocols. Most protocols focus on the communication of RA towards RM to influence policy making. For example, as described previously, the Irish protocol states that the FSAI needs to be informed via a form after the investigation. However, during incidents, the insatiable appetite of the public for news relating to risk and even the amplification of risk in different social media channels, puts pressure on the risk analysis process. It is, therefore, important to have generic crisis management protocols in place that include communication procedures during the RA process and address ongoing discussions in social media. Following guidelines systematically might prevent RM jumping to conclusions prematurely. Furthermore, working routines need to be optimized in order to have clearly defined roles of the parties and to avoid contradictory statements in RC. Practicing the risk analysis process by simulating a hypothetical crisis situation might additionally give insight into aspects that were unforeseen a priori.

3.2.5 | Communication between member states

For all three incidents, the first notification of the incident through RASFF was relatively late in the timeline of the incident. The EHEC outbreak started on May 1, 2011, but was recognized as an outbreak only on the 20th May after which the first notification in EWRS was placed on the 22nd May (ECDC, 2011b). The FSAI detected horsemeat in beef burgers in December 2012 and informed RASFF only on 8th February, whereas many European authorities were already involved at that point. Communication within the country was well carried out but communication with other member states could have been sooner. Fipronil was discovered in the Netherlands late 2016 and in Belgium in June 2017, whereas notification through RASFF was in July 2017. After the fipronil incident of 2017, the EC concluded that cooperation, communication, and a harmonized approach are essential for an effective risk analysis process during a food safety incident. It ensures trust and, therefore, in case of a widespread food safety incident, RA, RM, and RC should be harmonized and coordinated within the EU. RC should be

coordinated between member states (EC, 2017, September 26) to avoid confusion at the consumer level. Regarding these three incidents, earlier and better use of the RASFF system could have improved RC and a harmonized approach between member states. Notification systems were in place but were not fully utilized. Earlier exchange of information through RASFF could have speeded-up and improved RA and RM processes. Delayed communication between member states has been observed during all three incidents. However, since only three incidents were studied in this research, this aspect might not be generalizable to all incidents in the EU and could be a topic for future research.

4 | CONCLUSION

Better communication between RA, RM, and RC may decrease unnecessary health consequences and financial losses of a food safety incident. Flaws in RM and RC are frequently the result of uncertainties and of applying the precautionary principle. It is important to make corrections as soon as possible and to communicate the uncertainties from the beginning. Furthermore, communication between member states in the EU could be improved by earlier use of notification systems such as RASFF. Also at the national level, notification systems should be in place and utilized. Entering all notifications in the same system could help making links between cases and could prevent an incident from being missed.

Crisis management protocols should contain a section on communication between RA, RM, and RC, stating the best ways of communication, the frequency of communication and how to deal with uncertainties. Risk analysis is evolving and the pressure of social media is increasing immensely. Therefore, protocols need to be frequently updated. Communication strategies, both between RA, RM, and RC and towards the public should be an important topic in these updated protocols. In order to keep risk assessors, risk managers, and risk communicators up to date, simulated incidents could be organized on a regular basis. Alternatively, workshops could be organized to assess strengths and limitations of responses to past incidents, and not to repeat previous mistakes. Social media adds a new challenge for RA, RM, and RC. Institutions involved need to provide reliable and transparent communication which stands strongly against false information potentially circulating on social media.

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CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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