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SAFETY BOARD

Summary

Salmonella in smoked salmon



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Dutch Safety Board

The aim in the Netherlands is to limit the risk of accidents and incidents as much as possible. If accidents or near accidents nevertheless occur, a thorough investigation into the causes, irrespective of who are to blame, may help to prevent similar problems from occurring in the future. It is important to ensure that the investigation is carried out independently from the parties involved. This is why the Dutch Safety Board itself selects the issues it wishes to investigate, mindful of citizens' position of independence with respect to authorities and businesses. In some cases the Dutch Safety Board is required by law to conduct an investigation.

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NB: The full report is published in Dutch. The English summary is the translation of the summary, the consideration and the recommendation of the report. In the event of any discrepancy between these versions, the Dutch text shall prevail.

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SUMMARY AND CONSIDERATION

In the late summer of 2012, the Netherlands experienced an epidemic outbreak of salmonellosis, an infectious intestinal disease caused by eating food contaminated with salmonella bacteria. Thousands of people were affected by diarrhoea, abdominal cramps and fever. In the case of several elderly patients, the disease proved to have contributed to their death. Most of those affected, however, fully recovered after a spell of illness lasting several days to a week.

As the epidemic continued to spread, experts succeeded in pinpointing the source the infection in humans. As it turned out, the source proved to be smoked salmon manufactured at a Greek branch of Dutch smoked salmon manufacturer Foppen Paling & Zalm. The company has a large share of the Dutch market for smoked salmon products, which are widely consumed in the Netherlands. This explains how the disease could spread across the country in such a short period of time.

By the end of the year, the National Institute for Public Health and the Environment (RIVM) had identified a total of 1200 registered cases (that is confirmed by laboratory results) Many of those affected by the symptoms of salmonellosis do find it necessary to see a doctor. Such cases are thus not registered or counted. Based on studies of comparable epidemics in the past, the RIVM estimates the actual number of cases at 23,000. The actual number of deaths is also assumed to be greater than the four cases in which salmonellosis was identified as a factor contributing to the patient's death. These cases all concerned elderly individuals with fragile health, making it difficult to determine the exact cause of death.

In themselves, these figures point to a serious adverse effect on public health. Thousands of people were afflicted by unpleasant symptoms – the epidemic caused distress and discomfort to many, loss of labour productivity and economic damage. In terms of the number of registered victims, the epidemic constitutes the largest food-related bacterial infection in Dutch history. However, intestinal infections due to salmonella are far from exceptional. This common condition affects an estimated 50,000 people a year. The RIVM was only able to distinguish the epidemic from other salmonellosis cases due to the relatively rare strain of bacteria involved (*Salmonella* Thompson). This factor also played a key role in the RIVM's successful effort to pinpoint the source of the infection in humans. If the salmon in the Greek processing plant had been contaminated by a more common type of salmonella, the incident might have been identified at a far later date or gone entirely unnoticed.

When viewed in this context, it seems excessive to regard the 2012 salmonellosis epidemic as a serious threat to public health, much less as a national crisis. Nevertheless, this type of epidemic – caused by a pathogenic micro-organism transmitted through food – can be regarded as potentially dangerous.

After all, many other – and possibly more dangerous – pathogenic bacteria can cause serious health damage and death, such as the *Escherichia coli* O104:H4 bacteria in Germany one year prior to this incident. This is why the Dutch Safety Board decided to conduct an investigation of the 2012 salmonellosis epidemic. The Safety Board sought to establish what measures food manufacturers take to prevent marketing pathogenically contaminated products, governmental supervision on food safety and how the various parties take action in the event of a food safety breach.

The salmonella infection

As soon as the infection with *Salmonella* Thompson had been confirmed by the RIVM, a team of experts (headed by the RIVM) joined forces with the Netherlands Food and Consumer Product Safety Authority (NVWA) to identify the source of the bacteria. After a six-week investigation, traces of evidence led to smoked salmon produced by the fish processing company Foppen Paling & Zalm in Harderwijk. Shortly after this notification from the NVWA, the company confirmed that the contamination of its smoked salmon indeed originated from one of its three locations, a processing plant in Preveza, Greece. The food industry regards safety as integral to the quality of its products. The company also devotes a great deal of attention to this aspect. This is reflected in its application of the Hazard Analysis and Critical Control Points (HACCP) system, a safety management method widely used in the food industry. As a part of the hazard analysis underlying this safety strategy, the company assessed hundreds of threats to its production system and implemented preventive measures.

This prompts the question how a food processing company with such a focus on safety could become the source of the largest food-related bacterial epidemic in Dutch history. As it turns out, the company was unaware of the risk of salmonella bacteria contaminating and subsequently reproducing on fish. This can be explained by the fact that the sector had not witnessed such an event prior to this particular incident. The company had not included this risk in its hazard analysis or implemented any precautionary measures. Nor did it conduct regular inspections to check for salmonella. As a result, the contaminated salmon was shipped from the Greek processing plant without being noticed.

One could question if the company failed to live up to its responsibilities by restricting the scope of its hazard analysis to known industry hazards? Should perhaps measures have been taken against potential hazards, no matter how remote the chance of their occurrence? According to the safety management method, *all* potential hazards must be included in the analysis. However, there is a broadly held consensus amongst parties implementing this strategy: restrictions must be applied if the hazard analysis is to remain feasible in practice. Many companies do so by limiting the analysis to hazards that could realistically be expected to occur in practice. However, risk classification based solely on experience-based knowledge yields a rather limited picture of reality. In a sense, this is actually a desirable outcome – in our efforts to make the complex world around us more manageable, we tend to simplify things.

Here too, it would be all too easy to conclude that the company could and should have identified and managed the – then unfamiliar – risk of salmonella contamination. However, the Safety Board does not feel such a conclusion would be justified. At the time of preparing its safety strategy, the smoked salmon manufacturer could not have anticipated that its products would become contaminated with salmonella in the summer of 2012. This view is supported by all individuals and parties interviewed within the framework of this investigation, including customers, suppliers, supervisory authorities, certification bodies and knowledge institutes. However, the company's failure to anticipate the salmonella contamination of its products does not preclude from drawing lessons from its overall approach to controlling the overall hygiene of the production process.

There is no way to determine how the salmonella bacteria found their way into the Greek processing plant. However, the investigation did identify two changes in the production process that eventually caused the production lines to become contaminated.

The problems started after the introduction of new trays used to transport the fish fillets along the production lines. As the investigation showed, the porous mid-layer in these trays proved to be an ideal environment for salmonella bacteria. The bacteria were not fully removed during the cleaning process in the tunnel washer and could so reproduce freely. Several sub-optimal conditions at the Greek plant seem to have converged: the new trays were not effectively cleaned, and the location used to store them in between use was not temperature-controlled. As a result of the warm summer weather, temperatures in the non-temperature-controlled storage room rose to a point where the salmonella bacteria could reproduce optimally.

Ever since the Greek processing plant first became operational, the quality control department in Harderwijk had occasionally been concerned about hygiene standards. Sample tests regularly showed small peaks in the amount of intestinal bacteria. Every time such a peak occurred, the quality control department took hygiene measures in order to improve conditions at the plant. When a new series of peaks occurred after May 2012, the quality control department interpreted this as a sign that a stricter cleaning regime at the Greek plant was required. Although this stricter cleaning regime did yield improvements, they were of a temporary nature. Although the peaks shown in the trend analyses remained within the company's thresholds, the food manufacturer should have conducted or commissioned further studies in order to determine the underlying cause of the recurring enteric bacteria surges.

The development and maintenance of an effective food safety strategy requires expertise, and the ability to distance oneself in order to assess situations objectively. As the investigation showed, the company could have applied its internal expertise and experience more effectively to increase alertness to potential hazards. Furthermore, the efforts made to bring in external expertise were limited. In its efforts to find suitable reusable transport trays, for example, the company could have applied the expertise and experience of its cleaning product supplier and discussed potential risks with them. Food manufacturers must apply the knowledge and qualities of other parties in order to develop an effective safety strategy that takes into account a broad range of hazards. This requires both continuous focus and a resourceful approach.

As the investigation showed, the sharing of quality and safety information is not common practice in the fish processing industry. Experience-based knowledge of new and innovative materials is also limited, making it even more difficult to effectively think over all potential consequences related to their application.

The smoked salmon manufacturer set up food safety and monitoring agreements with its various suppliers and customers. The company also met the various applicable certification requirements. Until the time of the outbreak, the company had not received any external signals or complaints about food safety from its customers suggesting that something was wrong. Dutch supervisory authority NVWA regarded the company as a modern operation. Its inspectors considered the smoked salmon manufacturer Foppen Paling & Zalm as one of the more responsible companies in the industry in terms of food safety. This conclusion was based on the inspection activities, consisting of a three-yearly audit and multiple announced and unannounced inspection visits per year. More intensive supervision would not have identified the salmonella outbreak, as the risk of salmonella was not associated with smoked salmon. The outbreak is widely regarded as an unfortunate chain of events.

The RIVM surveillance system

In mid-August 2012, the RIVM's Centre for Infectious Disease Control (CIb) found the rare salmonella strain *Salmonella* Thompson in the stool samples of ten patients. This type of salmonella is extremely rare – only few cases are registered in the Netherlands each year – and it had already been identified four times in the previous two weeks. The CIb thus concluded that this relatively high occurrence rate might be caused by an infection originating from a single source.

The relatively unique strain of bacteria involved – a purely coincidental factor – made it easier to identify the epidemic. If the patients had been infected with a more common type of bacteria, the outbreak might have gone unnoticed amongst the thousands of annual salmonellosis cases in the Netherlands. Nevertheless, the RIVM performed its surveillance tasks admirably. The institute demonstrated its ability to identify minor variations in the bacterial associations of the various patient samples. This competency will be crucial to the early identification of future epidemics, some of which may involve pathogenic agents of a more virulent nature than salmonella.

Source investigation by RIVM, NVWA and municipal health services

The RIVM decided to trace the source of the infection, and duly informed the Netherlands Food and Consumer Product Safety Authority (NVWA) of its intentions. The source investigation took the NVWA, RIVM and relevant municipal health services a total of six weeks to complete. The RIVM's Centre for Infectious Disease Control (CIb) played a leading role in the investigation process. However, the CIb could not have conducted the investigation without the cooperation of the municipal health services, whose task it was to interview the various patients and ask them what they had eaten on the days before they fell ill and where they had bought the food products concerned. The RIVM then subjected the resulting data to a statistical analysis. Over the course of the investigation, the RIVM remained in close contact with the NVWA, which served in an advisory capacity at weekly meetings.

The NVWA took action every time an RIVM analysis identified a product as suspicious – the NVWA was then responsible for intercepting this product and determining whether it had been contaminated with the relevant type of salmonella bacteria. Following this approach, on 27 September 2012 the collaborating parties identified smoked salmon from fish processing company Foppen Paling & Zalm as the source of the epidemic.

A lead time of six weeks appears long for an investigation of such urgency. Therefore the Dutch Safety Board analysed the progress of the investigation process. The investigation by the RIVM was a labour-intensive process: a large amount of patient data had to be statistically compared with control group data before the nature and source of the contaminated food product could be determined with sufficient certainty. The RIVM, NVWA and municipal health services all carried out their duties in a professional and expedient manner. The intensive cooperation between the parties certainly contributed to the positive outcome. The Dutch Safety Board is of the opinion that the methods applied in this investigation could prove extremely useful in controlling future epidemics.

Recall of the contaminated smoked salmon products

The NVWA's announcement that the salmonella outbreak was presumably linked to Foppen Paling & Zalm's smoked salmon came as a complete surprise to the company and its customers. Initial reactions were characterised by disbelief: none of the parties involved had ever considered the possibility of such an outbreak. The company then attempted to limit the scale of the inevitable recall.

Following an analysis of the sample results, the fish producing company informed the NVWA that the contaminated smoked salmon had originated from the Greek processing plant and stated that the recall could thus be limited to Greek products. Shortly after this announcement, however, it became clear that various products from the Greek plant featured the oval-shaped Dutch identification symbol. It was thus impossible for consumers to determine the origin of the company's smoked salmon products, which could also no longer be easily verified by the NVWA. In the subsequent days, the NVWA critically followed the company's attempts to limit the scope of its recall. The uncertainty was further exacerbated several days later, as it became clear that one of the company's earlier statements – to the effect that all products for the US market had been manufactured in Harderwijk – was incorrect. The NVWA then decided to push for a broad recall of all of Foppen Paling & Zalm's smoked salmon products regardless of their origins, including any shipments abroad. The company's managers spent the next few days attempting to exercise damage control.

In the early afternoon of 28 September 2012, the NVWA and Foppen Paling & Zalm called the company's major customers to issue a strong recommendation: recall all the company's smoked salmon products from consumers. Like the company itself, the retailers were caught unaware by the news. Various retailers immediately issued instructions to remove the products from their stores and duly inform their customers. Others tried to obtain further details from the fish producing company and the NVWA before deciding to recall smoked salmon products from consumers. That moment came at the end of the afternoon, when the NVWA issued a press release that left little room for interpretation: consumers were warned and advised to return or throw away all smoked salmon products manufactured by Foppen Paling & Zalm.

The retailers had no choice but to withdraw all the company's – Greek and Dutch – smoked salmon products from sale.

Some retailers failed to quickly and effectively inform their customers about the dangers involved in consuming contaminated salmon. For example, notices apologising for the inconvenience were posted above the empty supermarket shelves, but the stores failed to include any warnings for customers who had already purchased smoked salmon or instruct them to return the contaminated products or throw them away. The Dutch Safety Board also determined that almost none of the parties involved immediately deployed all available means of communication.

According to the RIVM's observations, the epidemic continued to spread after all products had been removed from the stores. The number of registered cases continued to rise for weeks after the last contaminated salmon products had been recalled. Apparently, some people were unaware that all smoked salmon products stored in their refrigerator or freezer would have to be thrown away or returned to the store.

Role NVWA

Like the parties involved, the NVWA was surprised by the scale of the recall. As the number of affected companies grew, the NVWA was forced to expand the scale of its response organisation. It informed the companies involved to the best of its abilities, and monitored the product recall process. As most information was orally communicated to the affected companies, not everything was entirely clear to them and they later confirmed to have been inconvenienced as a result. The NVWA – also during the acute phase – focused on monitoring the affected companies and enforcing their compliance rather than developing an optimal joint crisis strategy. The various government bodies and companies involved took positions without any further consultation. However, the situation required a shared vision on strategy from all the involved parties in order to ensure rapid and effective action.

This lack of coordination between government bodies and companies also caused confusion amongst consumers as to the progress and effectiveness of the incident management efforts. Social media reflected the foremost question on consumers' minds: had the problem been resolved, and could shoppers now rest assured that the food on offer was safe?

Conclusions of the investigation

The general conclusion of the investigation is that in the food processing industry contaminations may occur that cannot be predicted, are difficult to prevent and can thus not always be prevented by conventional safety strategies. The industry must continually be alert and study risk factors, especially in cases where production methods change.

As to how smoked salmon contaminated with salmonella could reach consumers in this specific case, despite the many precautions taken, the Dutch Safety Board concludes that Foppen Paling & Zalm's quality system was not capable of preventing the risk of salmonella contamination despite meeting the relevant legal requirements. Furthermore, the actual salmonella contamination was not identified before the salmon products could reach the consumer market, but only came to light after consumers suffering from

persistent stomach cramps had visited their doctors and been subjected to further examination. The contaminated salmon was shipped out of the processing plant unnoticed as a result of two factors: no one regarded salmonella as a realistic hazard to salmon products, and the salmonella contamination was not identified in laboratory analyses.

The investigation shows that manufacturers will have to monitor the various signs more intensively in order to identify and acknowledge new and unexpected hazards and risks. The company should have made more targeted use of its HACCP team and internal and external expertise in purchasing the new trays and interpreting the results of the trend analyses. Furthermore, agreements between the various food chain partners, certification procedures and governmental oversight are not geared to the identification and acknowledgement of new and unexpected hazards and risks in the food industry.

As to the efforts to identify the outbreak of salmonellosis, the Dutch Safety Board concludes that the various official bodies worked effectively to identify the outbreak and pinpoint its source. The responsible government bodies carried out these duties in an effective, well-coordinated manner. However, when it came to controlling the outbreak, effectiveness decreased as companies started to recall the contaminated food products. During this phase of the operation, private sector parties such as the manufacturer and the various retailers were also assigned roles and responsibilities.

The manufacturer opted for a limited recall effort, despite the fact that this was not feasible due to the absence of clear product markings indicating the source of the products to consumers, and the absence of a tracing system geared to a fast recall effort on this scale.

Some of the smoked salmon manufacturer's customers (including several major supermarket chains) took a reticent attitude despite the acute urgency of the situation. Furthermore, in their communication with consumers the supermarket chains failed to consistently advise them about the risks involved and specify a course of action. They also failed to warn their customers in the most direct manner that would have been possible considering the range of communication means at their disposal.

The NVWA failed to clearly communicate its role and the various mutual expectations to the companies involved. Furthermore, the NVWA's response organisation proved underprepared and ill-equipped to deal with a food safety problem on this scale. The organisation's interpretation of its role as a national authority proved to be confined.

During the incident management phase, the NVWA focused on its role as a supervisory authority. In the view of the Dutch Safety Board, however, it should also monitor the progress of joint incident management efforts and intervene where necessary.

The NVWA failed to harmonise efforts with the companies involved and develop a joint vision on the most effective approach. The NVWA's limited interpretation of its role and approach during the incident resulted in confusion amongst the various companies, who were expected to take decisive action.

These factors also had undesirable effects on the communication process during the crisis. The government's incident communication strategy is centred around the government bodies' actual role, rather than consumer perceptions. Furthermore, communications by government bodies during the crisis – the NVWA in this case – fail to allow for consultation with the companies involved. This resulted in concern amongst consumers, and was detrimental to consumer confidence in food safety and the response actions of both companies and government bodies.

PRACTICAL LESSONS AND RECOMMENDATION

Over the course of the investigation, the various parties demonstrated their ability to learn from the incident and initiated various improvements. The lessons learned from this investigation will serve to confirm the necessity of these measures. All other companies and organisations involved in the food industry should apply these lessons and examples as a guideline for reassessing their own safety strategy, in order to help identify previously unknown risks. Like the responsibility to provide safe food, the duty to learn from incidents is not optional.

In general terms, this investigation concludes that in the food processing industry unforeseeable contaminations may occur that are difficult to prevent and thus cannot be ruled out. This means the industry will have to prepare itself for such incidents. Obviously, prevention is better than cure – also in the food industry. In cases where prevention is simply not possible, it is recommendable to familiarise oneself with the cure. The Dutch Safety Board is of the opinion that various parties could make further improvements in this area.¹

The processing of vulnerable, organic materials is always subject to new and unexpected risks, and many companies do not have the knowledge to identify and control every potential contamination. This means *food manufacturers* will have to prepare for such new and unexpected risks in a different manner. One effective strategy might be to invest in close ties with external parties that do have access to this knowledge, and can then be rapidly deployed in the event of an incident.

The requirements formulated as part of a safety strategy are a necessary but inadequate precondition for effective food safety monitoring. Knowledge of the product and primary process, a targeted deployment of an HACCP team during change processes, and an alert, critical attitude are crucial to identify potential shortcomings in the production process in time.

Food manufacturers and retailers are usually prepared for incident management processes, such as product recalls. Effective preparation for large-scale incidents will require further reinforcement of the incident management organisation and the introduction of a more effective tracing system. Companies should also conduct regular tests to determine whether their organisation and system are capable of functioning adequately during a large-scale food safety incident. This will require further cooperation with the various industry organisations and the NVWA.

¹ This section offers a general description of the various options. Appendix 9 features concrete examples targeted at the various parties involved identified during the investigation.

In the event that an incident should take place despite these preparations, *retailers* will generally be responsible for taking measures in stores to ensure consumer safety and issuing clear and timely communications to their customers. This will require preparation in order to ensure that all available means of communication can be applied effectively. Retailers, food manufacturers and the NVWA need to cooperate during both the preparation stages and actual incidents. Communications between these parties have to be harmonised in order to ensure a consistent message to consumers.

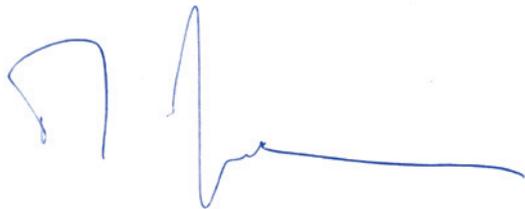
An important lesson from this investigation is that cooperation and the exchange of knowledge between individual food manufacturers and between manufacturers and government bodies is not common practice. *Industry organisations (such as the FNLI and CBL)* can play an important role in this regard, for example as knowledge platforms to help share the lessons learned from such incidents. It would also be recommendable to permanently include these organisations in the NVWA's incident management consultations or, in the event of a crisis, in consultations with the Ministry of Health, Welfare and Sport.

The investigation underlines the crucial role of the *Netherlands Food and Consumer Product Safety Authority* during incident management processes. The NVWA is responsible for overseeing the course of events during an incident and monitoring joint incident management efforts. In view of the individual responsibilities of the various private companies and government bodies involved, the Dutch Safety Board is of the opinion that the NVWA should adopt a central role during incidents. In terms of safeguarding consumer safety, the NVWA is the most suitable party to ensure coordination and cooperation between government bodies and food companies. This applies to both the actual prevention of outbreaks and communication with consumers. To this end, the organisation should also include food companies and retailers or their representatives in its incident management consultations. In order to fulfil this role effectively, the NVWA will have to reinforce its existing incident management organisation. This will require the further strengthening of its knowledge position, especially in the area of food chain risk management. The NVWA must provide food companies with advance information ("during peacetime") on mutual expectations, roles and the necessary procedures in the unfortunate event of an incident. Where possible, the organisation should also hold training exercises to actively practice such cooperation with the food companies.

The Dutch Safety Board concludes that the NVWA should play a prominent role in disseminating and implementing these lessons, and has formulated the following recommendation:

Recommendation to the NVWA

Actively monitor joint incident management efforts by government bodies and companies – including the necessary preparations – in your capacity as a national authority, take action where necessary, and demonstrate how you ensure this.

A handwritten signature in blue ink, consisting of a large, rounded initial 'J' followed by a series of connected loops and a long horizontal stroke at the end.

T.H.J. Joustra
Chairman of the Dutch Safety Board

A handwritten signature in blue ink, featuring a stylized initial 'M' with several vertical strokes, followed by a long, sweeping diagonal stroke.

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