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Original article

Proposing new procedures for the management and prevention of foodborne diseases: An Italian experience

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Abstract. *Background and aim:* Foodborne diseases are a public health issue with more than 4,000 outbreaks in 2021 in European Union countries and United Kingdom and their management is important for prevention and controls of outbreaks. Recently, new technological tools and strategies, including whole genome sequencing (WGS), have become available to allow the highest level of discrimination in the investigation of foodborne outbreak. In this study, we presented the updated procedure for assessment of foodborne disease in a community of a Northern-Italy region, Emilia-Romagna. *Methods:* In the Reggio Emilia National Health Service Local Unit (AUSL-RE), foodborne disease monitoring and control are managed by the following health services: public health and hygiene (SIP); hygiene of foodstuffs and nutrition (SIAN) and veterinary public health (SSPV) composing the developed MTA group ('Gruppo Malattie Trasmesse da Alimenti'). Among the new tools being implemented, there is a shared computerized folder and new related managements procedures available to MTA members only, allocating information regarding any material useful to the MTA group. *Results:* The main new features of the new procedure are: information sharing in all phases of the management of the infectious episode, integration of the three services through the creation of the MTA group and updated criteria for procedure activation, and finally a dedicated training programme. *Conclusions:* Timely investigation, management and control of MTA outbreaks is essential for both health and economic reasons. The new features and procedures implemented in this Italian community may allow to identify rapidly the causes of a case or outbreak and better counteract their spread. (www.actabiomedica.it)

Key words: foodborne disease, foodborne outbreak, epidemiology, prevention, procedure

Background

Foodborne diseases are a public health problem. In 2021, 27 European Union (EU) member states and the United Kingdom reported 4,005 foodborne disease outbreaks that involved 32,543 cases, including 2,495 hospitalizations and 31 deaths (1). Foodborne disease is considered any illness that results from the consumption of contaminated food with lived pathogenic microorganisms or their toxins occurring at any

stage of food chain, and can result from ingestion of food contaminated with microorganisms that colonize intestinal mucosa, while foodborne poisoning (or "foodborne toxin outbreak") is an illness caused by the ingestion of food contaminated with preformed toxins. The highest number of cases in EU were related to *Campylobacter* and *Salmonella*. In addition, foodborne diseases can be also caused by toxins such as of *Clostridium botulinum* and *Staphylococcus aureus* (2). In addition to toxins of biological origin, chemical substances can also contaminate food and affect human health, e.g. histamine contamination and the related scombroid syndrome (3,4).

Typically, a foodborne outbreak is defined as an incident in which two or more people develop the same foodborne disease after eating or drinking the same food (5). In this case, it is called a "focal" outbreak because it evolves rapidly over few days or weeks and it is characterized by local food handling, high dose of contamination, self-report or laboratory follow-up, and investigation remains limited to the local level. Several tools are used to investigate this type of outbreak (6): firstly the 'epidemiological survey' that assessed cases, contacts, time and place of the outbreak (such as public establishments, food industry companies, communities, private homes, etc.); secondly the 'food chain traceability' with the analysis of clinical, food and environmental samples. Thus, through epidemiological investigation and traceability, public health professionals are able to identify an outbreak in unrelated subjects sharing a common food or place.

Another type of outbreak is the so-called 'multifocal' or 'diffuse' outbreak, which is characterized by a source of contamination from the production or processing of food, generally with a low dose of contamination. In this case, the investigation is carried out using backward and forward tracing (7,8): backward tracing evaluates the production line of the food chain in order to identify the sources of a contaminated product; instead forward tracing evaluates the distribution line of a suspected food product from the source to the consumer in order to identify the affected individuals and the critical points of the process that failed to prevent food contamination.

A new tool for such surveillance of widespread foodborne disease outbreaks is Whole Genome Sequencing (WGS), which offers the highest level of discrimination in the investigation of foodborne toxins and in a general a more accurate typing of pathogens (9-11). This new tool precisely allows the identification of so-called 'low and slow' outbreaks, i.e., those that are protracted over time with several clinical cases occurring over a long period, even months or years, and spread over national and international territory. As a matter of that, cases may be geographically scattered in different locations without an obvious epidemiological link complicated by the long time frame (12).

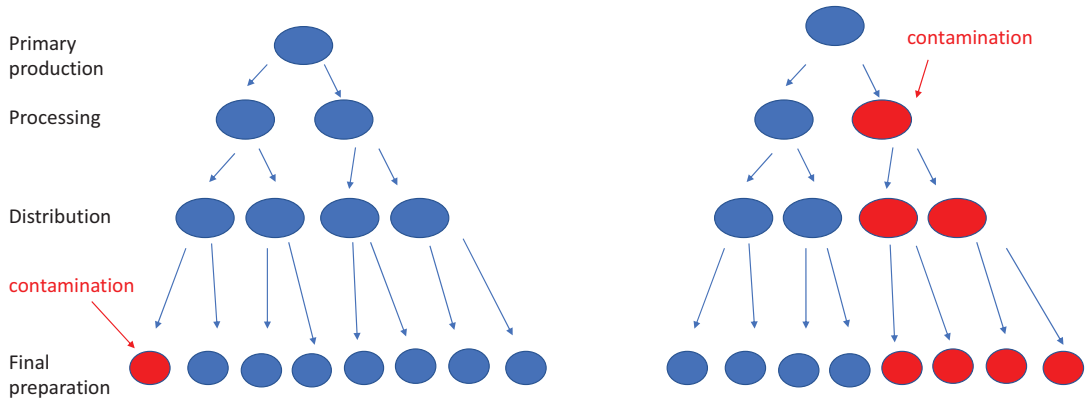
Figure 1 shows the difference between "focal" outbreak and "multifocal or diffuse" foodborne outbreak (8,13).

The WGS is fundamental in outbreaks caused by strains that have had time to change in the environment or in their natural hosts and are characterized by higher variation than those observed in focal outbreaks (9,14).

In Europe, WGS is currently used to investigate foodborne disease caused by *Salmonella enterica*, *Listeria monocytogenes* and toxin-producing *Escherichia Coli* (STEC) which can cause Hemolytic Uremic Syndrome (HUS) (15). For this reason, an apparent single case, through implementation of WGS techniques could be recognized as part of a widespread outbreak that needs to be investigated. This was the case of a recent outbreak of listeriosis Serotype (ST) 155 that involved 12 Italian Regions over a period of several months (16).

The Emilia-Romagna Regional Prevention Plan has been recently approved, setting goals, strategies, and actions for health promotion to improve the management of foodborne diseases in a timely and efficient manner (17). The Emilia-Romagna Region's strategies are: 1) Establishment of Regional technical coordinating group that has to coordinate the Local Health Authorities (AUSL) in the integrated management of foodborne diseases; 2) Appoint one contact person of every AUSL who plays the role of "case manager", coordinating survey activities within every AUSL and also participates in the regional technical coordination group; 3) Creating the corporate interdisciplinary team; 4) Timely and also accurate management of individual cases (18).

Moreover, Emilia-Romagna Region's MTA Platform is a useful tool to quickly share documents such



	FOCAL	MULTIFOCAL O DIFFUSE
Source	Local food handling	At production or processing
Contamination dose	High	Low
Detection	Self-reporting, lab-follow-up	Lab based, subtype surveillance
Investigation	Local, tracing back	Complex, multistate investigation Back and foward tracing

Figure 1. Difference between focal and multifocal/diffuse outbreak, extract from "tracing back and forward-source identification in foodborne outbreak".

as epidemiological survey, clinical information about cases and food chain materials such as food and environmental sample reports. According to the Regional Prevention Plan, objectives in relation to foodborne outbreaks need to be implemented by each Local Health Authority (AUSL) (17) and the two objectives are: 1) Implementation and availability of informative and awareness-raising interventions tailored for food business operators and consumers as well as for health professionals; 2) Increase in outbreak management rates on Regional MTA Platform from 25% in 2022 to 95% in 2025.

In particular within every AUSL, foodborne diseases are managed by the Public Health Department that is the structure entrusted with healthcare at community level, dealing with promotion and improvement of health, welfare and quality of life, prevention of accidents and diseases linked with risks in the living and working environments, food safety and animal welfare (19). In the RE-AUSL, the foodborne disease was managed by the following services: public health and hygiene (SIP); hygiene of foodstuffs and nutrition (SIAN) and veterinary public health (SSPV). The Flow Chart of the management is shown in Figure 2: the foodborne disease was notified to the public health and hygiene service (SIP) that carries out the epidemiological survey. The case was managed by the hygiene of foodstuffs and nutrition service (SIAN) when the putative cause of the disease was food from a public business or food business, or by the veterinary public health service (SSPV) in case of raw material of animal origin.

This article describes the change of foodborne disease procedure of RE-AUSL to improve the management of foodborne disease in the light of new regional and national regulations.

Methods

The Province of Reggio Emilia has 530,000 inhabitants and the Reggio Emilia Health Care Authority (RE-AUSL) is divided into six districts.

To be in line with the latest regional and national strategies on the management of foodborne diseases, the RE-AUSL quickly adopted interventions involving three relevant services: SIP, SIAN and SSPV. In RE-AUSL, a multidisciplinary team called MTA

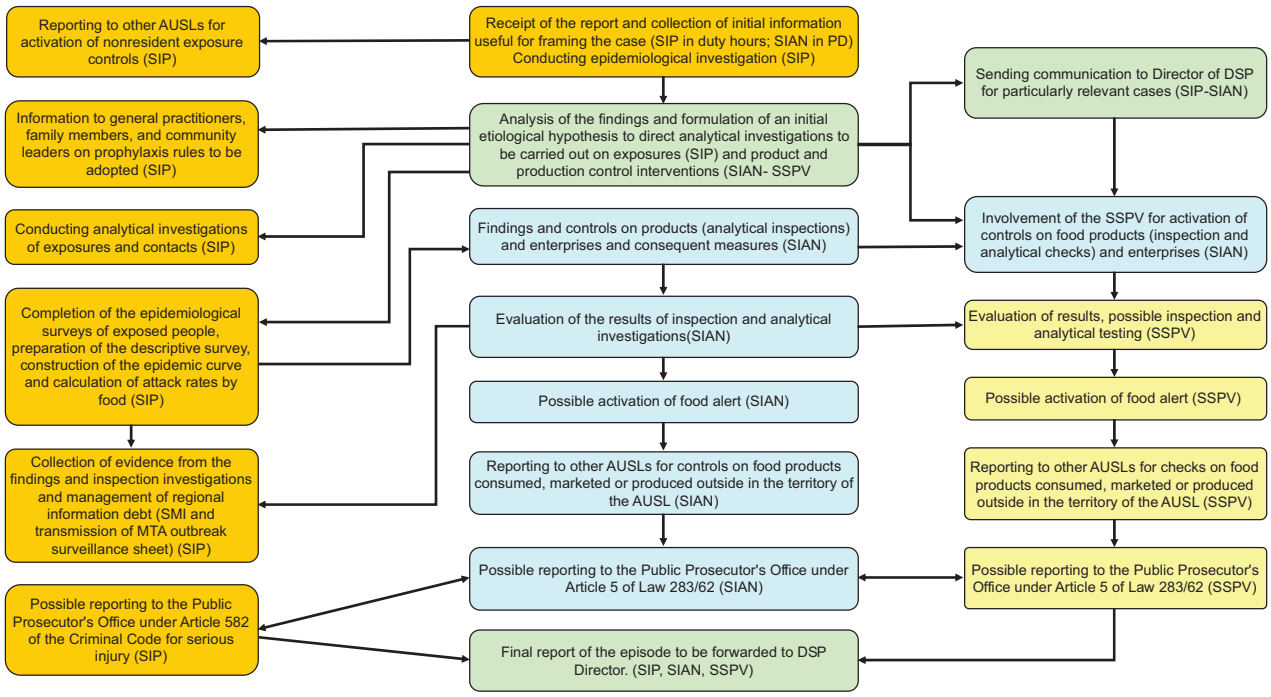


Figure 2. Flow chart of foodborne disease case management in the Public Health Department in the previous procedure.

group ('Gruppo Malattie Trasmesse da Alimenti') was implemented with participation of professionals from the three services: in particular, one physician and three health assistants/nurses from the SIP, one physician and one prevention technician from the SIAN, and one veterinarian and one prevention technician from SSPV. The RE-AUSL states that MTA regional contact persons are physicians from SIP and SIAN, and the veterinarian from SSPV.

First, an online repository was created with restricted access to MTA group members only. This tool allows the implementation of epidemiological surveys, sampling reports, retail and catering business inspections, and the storage of any material useful to the MTA group. Secondly, the role of the MTA group, its components and the tools used were explained in the procedure. For example the tools used by the group were: synoptic table (to identify the possible causative agent), the information system used by SIAN and SSPV services that is useful to up-to-date management of the registry of Food Sector Operators, to registration of the official control activities carried out; the water supply networks as water can also carry pathogenic microorganisms (20) responsible for MTA and the Rapid Alert System for Food and Feed (RASFF) portal enabling the rapid and effective exchange of information between Member States and the European Commission in cases of risk to human health from food or feed is detected (21). These tools, which were previously used only by the single services, were shared with the whole MTA group to evaluate the case together. Finally, the MTA group decided the new criteria of the procedure activation and the elements considered were epidemiology, pathogenicity, clinical features and prognostic factors, clinical severity related to possible diffusion in sensitive patient settings such as nursing home.

The MTA group organized weekly meetings from December 2022 to April 2023 attended by all group members in order to change the procedure and organize a foodborne disease management training course. The target of the goal were the operators of these three services of the Department of Public Health. While organizing the training course, the course program was primarily defined and there was the division of topics among the speakers. Second, presentations were

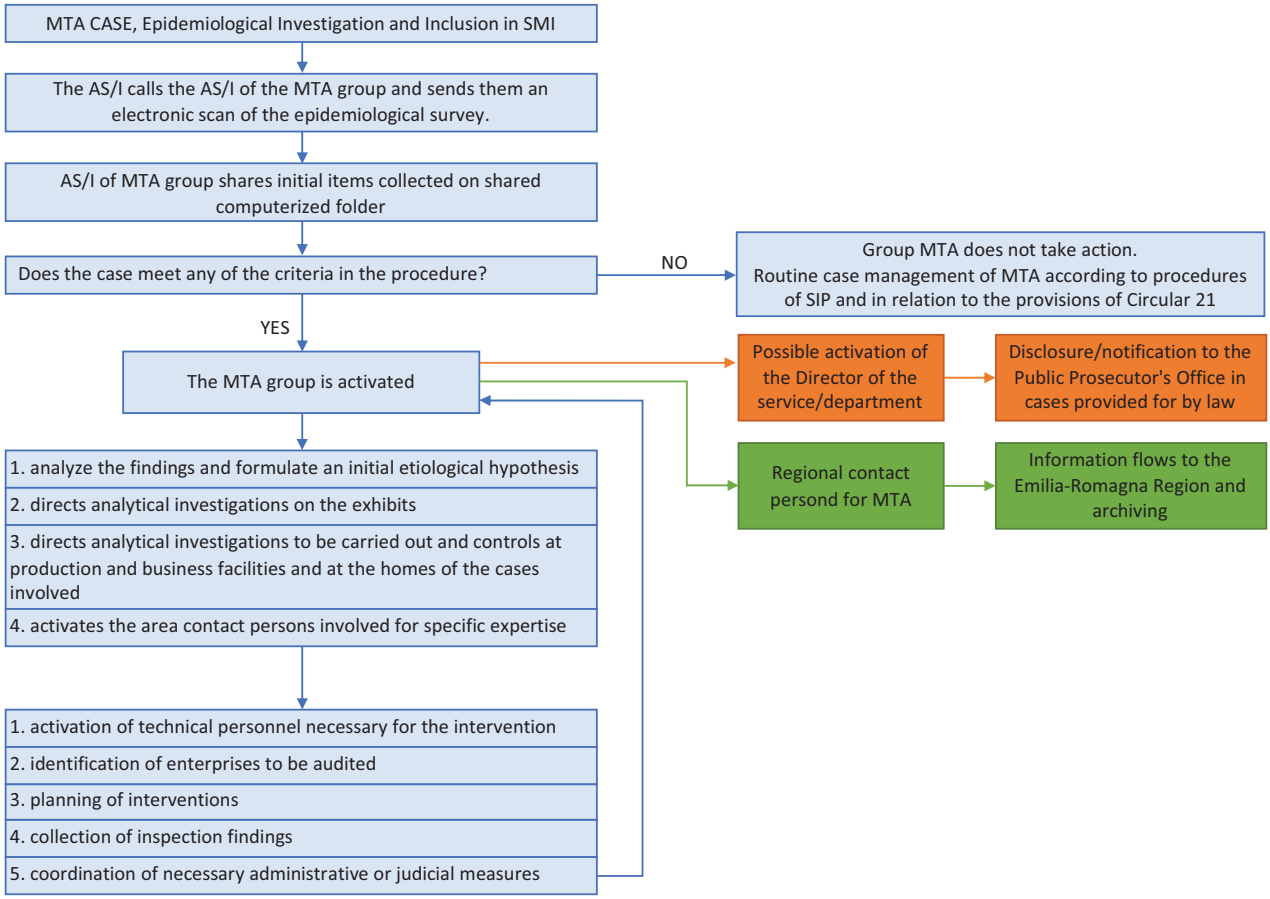


Figure 3. Flow chart of foodborne disease case management in public health department in the new procedure.

prepared and shared with the group members. The training course was conducted in two editions to allow for as much participation as possible.

Results and discussion

At the end of the weekly meetings, the group implemented the new procedure which is outlined in Figure 3. After the reporting of a suspected foodborne disease, the health assistant/nurse of the district carries out the epidemiological survey and has to report it to the health assistants/nurses of the MTA group. The MTA health assistant enters the epidemiological data on the regional infectious disease portal (22). The health assistants of MTA group update the MTA repository with the preliminary epidemiological elements and inform the entire MTA group if the suspected case is in accordance with the eligible criteria described in Table 1. Cases not included in the procedure criteria above indicated are managed according to "Circolare n. 21 del 24.11.1999" based on "Circolare n° 4 del 13 marzo 1998" (23) that explains measures to be taken against the sick, their cohabitants and community contacts.

Considering the preliminary information, the MTA group formulates possible etiological hypotheses to guide the clinical investigations on the index case(s) and the analytical investigations at the production and commercial facilities as well as residence of the subject(s). In the home inspections, if the source of the infection is unknown, the inspections are performed by SIAN and SSPV technicians jointly. On the contrary, if the source of the infection is raw material of animal origin, the inspections are performed by SSPV and in case of not-animal origin raw material

and surface sample, the inspections are performed by SIAN.

Following this preliminary assessment, the MTA group members pertaining to individual services activate the supervisor of the specific territory of SIAN and/or SSPV service area to take the necessary actions such as intervention of the technical personnel, identification of factory to be audited, planning of interventions, collection of the findings of inspections, and coordination of necessary administrative or judicial measures. Public business or food business pertain to SIAN, instead SSPV inspects in case of raw material of animal origin (for example butcher and fish shop). The inspections are performed by SIAN and SSPV jointly in case of business registered in the lists of both SIAN and SSPV.

The results of the various assessments must be referred to the MTA group who eventually informs the Department director in case of need to undertake measures of special importance such as information to the Public Prosecutor's Office.

In case of clinical sample positive for *Salmonella*, *Listeria monocytogenes* and STEC, the hospital laboratory sends the clinical sample to the reference MTA laboratory, namely the Istituto Zooprofilattico Sperimentale (IZS) "Bruno Ubertini" of Lombardy an Emilia-Romagna Regions. The IZS analyzes the sample with WGS method, and it communicates the microorganism strains to the hospital laboratory and to Emilia-Romagna Region, in particular Community Prevention and Public Health Service. If a case belongs to an outbreak, the regional reference notifies the reference of the AUSLs affected by the outbreak. The MTA Department representative is responsible to insert the MTA document of regional MTA platform.

The main features of the new procedure are information sharing in all phases of the management of the infectious episode, integration of the three services through the creation of the MTA interdepartmental group and updated criteria for activating the procedure.

Information sharing

The first new element is the sharing of information among all group members starting with the epidemiological investigation that is from the very early stages of management a foodborne disease. A common digital database was implemented to share information such as anonymous epidemiological survey, inspection reports, analytical reports of food sampling and environmental swabs, clinical reports and auxiliary documents and all group members are up to date in a timely manner to plan next steps.

Integration of the three services

Before the procedure update, the case of foodborne disease was handled sequentially by the three services with limited to null integration: the notification was sent to SIP that carries out the epidemiological survey. The case was secondly managed by SIAN in case of suspected origin of the food related to a retail and catering businesses or food business. The SSPV was activated by SIAN in case of animal origin of the food matrix or animal origin industry. The three Services had limited integration in all phases of the management of the episode.

In the new procedure the MTA group members are activated after the epidemiological investigation and group members analyze together the initial evidence and decide in a multidisciplinary way on the next steps to be taken (inspections, analytical assessments, etc.). The MTA group aims to improve the integration of the skills and expertise of the three services from the case report. Its task is to analyze the elements that have emerged and it formulates an initial etiological hypothesis to direct controls at production and commercial facilities and the clinical investigations on cases.

The new criteria of activation

Previously, the procedure was applied in the following cases: Epidemic Outbreak or Epidemic Event i.e. situation in which there were occurrence of cases of illness higher than expected at a given time and place, or in the single case of botulism and scombroid syndrome. The new criteria are described in Table 1.

Listeriosis and HUS have been included in the new criteria because they are dangerous infections that can respectively cause meningitis/sepsis (24) and kidney failure/hemolysis (25) in child. We emphasize that

Table 1. The procedure new criteria for identification of epidemic outbreak or epidemic event of a foodborne disease.

Epidemic Outbreak or Epidemic Event
single case of botulism
single case of scombroid syndrome
single case of Listeria
single case of Hemolytic–uremic syndrome (HUS)
case "potentially related" to epidemic clusters of relevance or emerged within social welfare or social-health facilities (i.e. nursing homes or hospitals)
single case whose epidemiological investigation reveals situations worthy of further investigation (i.e. hepatitis A in a patient who has not traveled outside Italy)

16 cases of listeriosis (+700% over the previous year) and 3 cases of HUS (+50%) were reported in the province of Reggio Emilia in 2022.

The training course

The training course explained both the foodborne disease transmission and the new procedure. We focused on *Salmonella*, *Listeria Monocytogenes* and *Escherichia Coli* in the context of HUS because these pathogens are sequenced with WGS and we explained the main new procedure features and the tools used by the MTA group.

The training course was divided into a theoretical part held in the morning and a practical exercise held in the afternoon. Attendance was 100% of those registered, and at the end of the event participants were asked to fill out a satisfaction questionnaire.

Epidemiological investigation of MTA outbreaks is essential for Italy and also for the Emilia-Romagna Region for both health and economic reasons. MTA may cause death or several clinical complications such as meningitis in the elderly (26), in childhood (27,28) and miscarriage or fetal death in pregnant woman (29,30).

Food production and food exports both in the EU and worldwide are important economic sectors especially for Emilia-Romagna Region which is one of the most important regions of Italy by export volume (31). The international reliability of agri-food control systems depends on the safety of production and many non-EU countries have established specific sanitary additional requirements to guarantee animal health and food safety. Such requirements are in some instances included already in agreements and protocols signed by these countries with Italy and/or other EU countries in order to import food products of animal origin (32). MTA outbreak assessment is therefore important to prevent further cases of infection by taking preventive measures such as exploring environmental factors that may contribute to contamination in various locations; identifying potential mitigation measures or knowledge gaps; and reviewing regulations to identify provisions that can be strengthened (33). Early recognition of outbreaks is an essential element of food safety.

The WGS method allows the identification of an outbreak made by apparent individual and unrelated cases identified in other provinces or regions (34,35). For this reason, one of the tools used by the MTA Group is the RASFF Alert System (21).

The change of procedure and the three new elements are the first steps to identify the etiology of the outbreak and prevent further cases. The following elements are necessary to achieve this result: 1) timely and accurate epidemiological investigation in order to identify food consumed by cases and their family and possible leftovers, 2) the integration of MTA group members to assess all elements 3) environmental and food sampling as far as possible.

Additional operational tools are the Regional MTA Platform by AUSL, Regional and Enternet Center MTA referents in the management of disseminated MTA cases in order to share information quickly for outbreak investigations. The percentage of outbreak management on the MTA platform is one of the indicators described in regional prevention plan. In 2025, 95% will be the goal of each AUSL in the Emilia-Romagna Region. The training of healthcare workers is one of the most important element to reach the two local objective, and it is necessary to improve the management of foodborne cases (36).

Abbreviations: AUSL-RE: Azienda Unità-Sanitaria Locale di Reggio Emilia (Reggio Emilia Local Health Unit); HUS: hemolytic–uremic syndrome; IZS: Istituto Zooprofilattico Sperimentale; MTA: Malattie Trasmesse da Alimenti (Foodborne Deseases);

SIAN: Servizio di Igiene degli Alimenti e della Nutrizione (Food Hygiene and Nutrition Service); SIP: Servizio Igiene e Sanità Pubblica (Public Health Unit); SSPV: Servizio Sanità Pubblica Veterinaria (Official Veterinary Service); WGS: whole genome sequencing.

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Conflict of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

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