

The Integrated Management System for *Salmonella* Control Plan in Italy

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Abstract

Salmonella infections are the main cause of food-borne outbreaks in Italy as well as in other industrialized countries: food of poultry origin is the main source of infection. The European Union legislation identifies in the control of the food chain the more effective approach to ensure food safety, indicating in the primary production a pivotal point for surveillance and control of *Salmonella* infections. In 2003, the European Union set for Member States the objective of reducing the prevalence of *Salmonella* serovars relevant to public health on the basis of specific control programs in breeding flocks of *Gallus gallus* and turkeys, laying hens, broilers and fattening turkeys. In this framework, an information system, named SISalm, was implemented in Italy to collect and manage information derived from the application of the national *Salmonella* control Plan, to standardize data collection and information flows, thus satisfying the needs of all the involved stakeholders, avoiding redundancy and errors. The integration of SISalm with the National Animal identification, registration and traceability System (BDN) and with the Italian Information System for the notification of animal diseases outbreaks (SIMAN) provides a comprehensive data management and reporting tool, which allows monitoring the epidemiological situation at national and local level and the fulfilment of the information debts towards the European Commission and the World Organisation for Animal Health.

Keywords: Control program; Interoperability system; Data collection; European commission; Information system; *Salmonella*

Introduction

Salmonellosis has been for a number of years the most frequent zoonosis within European Union (EU), after campylobacteriosis, with more than 90,000 cases reported each year. In 2013, *Salmonella* remains the main agent of food-borne outbreaks, being responsible of the 22.5% of the total number of outbreaks [1].

Food-borne salmonellosis primarily results in a mild to severe diarrheal illness, known as acute gastroenteritis. Most people infected with *Salmonella* develop diarrhoea, fever, and abdominal cramps between 12 and 72 hours after infection. The illness usually lasts 4 to 7 days, and most individuals recover without treatment. In some cases, diarrhoea may be so severe that the patient needs to be hospitalized. In few cases, the infection may spread from the intestines to the blood stream, and then to other body sites thus requiring medical treatment in order to avoid severe consequences. In very few cases *Salmonella* can cause permanent damages or death. The elderly, infants, and those with compromised immunity are more likely to have a severe illness [2]. It is easy to understand how salmonellosis is responsible of significant economic losses: the European Food Safety Authority (EFSA) has estimated that the total economic burden of human salmonellosis could amount to 3 billion euro a year [3]. The consumption of contaminated food is the main source of infection for humans [4]: contaminated poultry products are traditionally considered one of the main infection routes [5], although this situation is changing lately with infections caused by a wide range of other foods of animal and non-animal origin. In particular, the consumption of undercooked meat and cross-contamination with ready to eat foods are considered important risk factors for humans [6].

Since 2003, the EU adopted an integrated approach to food safety involving the entire supply chain, from farm to fork: the EU legislation on food safety identifies in the control of the food chain the more effective approach to ensure food safety for humans, indicating in the primary production a pivotal point for surveillance and control of zoonotic agents [7,8]. EU Member States, European Commission (EC), European Parliament, EFSA and the European Centre for Disease

Prevention and Control (ECDC) are involved each for their expertise in risk management and assessment. In 2003, considering the risk of *Salmonella* a priority, measures for a broad control of *Salmonella* were established: with the entry into force of Commission Regulation (EC) no. 2160/2003, the EU set for Member States the objectives of reducing the prevalence of *Salmonella* on the basis of specific control programs approved by the Commission. Under subsequent Regulations, programs to control *Salmonella* serovars relevant to public health in breeding flocks of *Gallus gallus* and turkeys, laying hens, broilers, and fattening turkeys, were approved. Moreover, the requirement for farmers to implement an industry sampling program was also introduced, thus emphasising the role of food business operators (FBO) in the achievement of the Community objective of reducing the prevalence of infection [9-12].

Between 2005 and 2012 the EU Summary Reports on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks of the EFSA and the ECDC indicated a clear downward trend of cases of salmonellosis in humans, of food borne outbreaks due to *Salmonella* and of its prevalence in poultry. During these years, human cases of salmonellosis in the EU declined by almost half [13]. The reduction of cases of salmonellosis in humans in the EU continued in 2013, with 82,694 confirmed cases reported in 2013, representing a 7.9% decrease in the EU notification rate compared with 2012. During this year, most Member States achieved the goal of reduction of the prevalence; even in food, particularly fresh meat of poultry, the number of positive samples decreased.

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The continuing decrease of cases of salmonellosis in humans in EU countries is likely to be related to the successful *Salmonella* control programmes in poultry flocks in place in EU Member States, although other control measures along the food chain might also have contributed to this reduction [1].

In Italy, *Salmonella* infections are the main cause of food-borne outbreaks, as well as in other industrialized countries, with 1453 confirmed cases in 2012 [1]. A National *Salmonella* control Plan aimed at controlling relevant *Salmonella* serovars in *Gallus gallus* breeding flocks, laying hens and broilers as well as in fattening and breeding turkey flocks is issued every year in accordance with EU provisions [14,15]. The Plan is prepared by the Italian Ministry of Health in collaboration with the National Reference Laboratory for *Salmonella* and the National Reference Centre for veterinary epidemiology and risk analysis (COVEPI).

The systematic collection of data and epidemiological information produced by the implementation of the National *Salmonella* control Plan is necessary in order to evaluate the effect of the program on *Salmonella* prevalence at primary production level and, thus, it was requested and strongly supported by the central public health authorities. Therefore, the COVEPI was appointed by the Italian Ministry of Health to develop the information system for the management of data resulting from the National *Salmonella* control Plan, named SISalm, in agreement with the community legislation and to satisfy the demand of the veterinary services, the local and central public health authorities and the FBO. SISalm was developed in order to standardize data collection and information flows, thus avoiding redundancy and errors.

Materials and Methods

The national *Salmonella* control Plan

The annual National *Salmonella* control Plan (the last covers 2015 year), is endorsed by the EC in agreement with Article n. 13 of Regulation (EU) n. 652/2014 [16]. The Plan has to be applied in poultry flocks of the following species and type of production:

- Breeding flocks of *Gallus gallus*
- Laying hens of *Gallus gallus*
- Broiler flocks of *Gallus gallus*
- Breeding turkeys
- Fattening turkeys.

In the current Plan, specifications for controls, as well as sanitary measures to be applied in case of detection of *Salmonella* serovars relevant to public health are foreseen. The following serovars are considered as relevant for public health: *S. enteritidis*, *S. infantis*, *S. hadar*, *S. typhimurium* and *S. virchow* for breeding flocks of *Gallus gallus*; *S. enteritidis* and *S. typhimurium* (including the monophasic variant) for the other categories of poultry foreseen by the Plan.

The Plan is mandatory for poultry farms with commercial purposes (not for own consumption) and for farms with capacity of more than 250 animals of *Gallus gallus* (breeding flocks, laying hens, broilers) and turkeys (breeding and fattening flocks). The epidemiological unit is the flock, defined as "all poultry of the same health status of the same breeding cycle, with the same date of placement kept on the same premises or in the same enclosure and constituting a single epidemiological unit". This aspect is crucial because the flock is the unit of reference for the evaluation of the reduction target of the prevalence of *Salmonella*.

According to the Plan, sampling activities must be performed both by public health authorities and FBO and are aimed at identifying flocks positive for *Salmonella* spp. In case of identification of serovars relevant to public health, sanitary measures are put in place in order to control the infection, thus achieving the Community objective of reducing the prevalence and avoiding the dissemination of salmonellae in food products. The sanitary measures applied whenever a flock tests positive for *Salmonella enteritidis* and *Typhimurium* are:

- Slaughtering or killing of animals
- Heat treatment or destruction of carcasses
- Heat treatment or destruction of eggs
- Cleaning and disinfection of the environment, followed by tests on the efficacy of the treatments
- Epidemiological investigation
- Withdrawal of animals belonging to the group
- Revocation of the sanitary qualification

The same measures are taken whenever a flock tests negative for *Salmonella* spp. but the use of antimicrobials or bacterial growth inhibitors is detected.

Organization of the information flow

Data in SISalm is provided by the regional veterinary services, the veterinary service of the local health units, FBO and the official and private laboratories that can access the system with different roles and competences.

As regards data on official sampling, SISalm is fed by the regional veterinary services and by the veterinary service of the local health units (also through the official laboratories), who can access the system also for consulting detailed data of their territorial competence on both FBO and their activities.

Data on industry sampling derives directly from the FBO: once logged in through appropriate credentials, the FBO can feed the system, view and download data only of their own farms according to the registration saved in the National Animal identification, registration & traceability system (BDN) [17]. Industry sampling is an integral part of the controls: where the FBO are required to apply the relevant legislation, the competent authorities have the obligation to ensure its conformity [18]. This principle is valid for all FBO and for all the stages of production, from the farm to the sale of food to the consumer, in line with European policy "from farm to fork" [19]. Moreover, all the results of the sampling activities carried out by the veterinary services and by the FBO are used by the EC to evaluate whether the reduction target is met.

As regards the laboratory analysis of the samples collected by the veterinary services, they are performed by laboratories of public health institutes (Istituti Zooprofilattici Sperimentali). Both public and private laboratories (the latter are allowed to analyse samples taken by FBO) are accredited by a national accreditation body (Accredia) according to the most recent version of EN/ ISO 17025: 2005, as required by Regulation (EC) n. 2160/2003. As regards the analytical methods, *Salmonella* spp. detection is performed according to EN/ISO 6579:2002/Amd1:2007 (for samples taken on behalf of the FBO, alternative methods may be used if validated in accordance with the most recent version of EN/ISO 16140) and serotyping is performed following the Kaufmann-White-Le Minor scheme.

The National Reference Laboratory for *Salmonella* performs the analysis on official confirmatory samples that are collected by veterinary services in exceptional circumstances. Moreover, it organises inter-laboratory comparison studies for the laboratories performing analysis in the framework of the Plan.

Development of the system

SISalm has been designed to fulfil the need to collect and manage data on official and FBO sampling in the framework of the National *Salmonella* control Plan, with the aim to provide a very simple tool to satisfy the monitoring and reporting requests of the relevant competent authorities and of the poultry trade associations.

SISalm is a web application developed using the Java Enterprise Edition (Java EE) platform. Data is managed by the Relational Database Management System (RDBMS) Oracle 10 g version. The software architecture is based on Model-View-Controller (MVC) pattern. Using this pattern the software development is separated in 3 different modules: the MODEL, object representing data; the VIEW, form of visualization of the state of the model; the CONTROLLER that offers facilities to change the state of the model. The development framework is Apache Struts 1.3.8, a solution open source easy to use, common and stable that offers excellent performance. Using the development tools described above, SISalm implementation has been split among the different developers due to the separation between the user interface and the business logic (data model). Moreover, it has been possible to share big portions of code to develop the different interfaces of data management (on-line form, XML files upload, web services). The persistence framework is iBATIS which automates the mapping between RDBMS and Java application. SISalm development phase uses many software libraries open source to realize specific functionalities: Quartz library for automating data process and email's dispatching to the system users, Jasper Reports to develop and build reports with GUI interface, IzsReport to integrate reports inside Java web applications. SISalm uses the web server Apache in Unix OS integrated with Tomcat servlet container. Development tools are: Eclipse IDE (integrated development environment), Toad for oracle to manage database and Qdesigner for data analysing and modelling.

Results

SISalm collects detailed data on the sampling activities considered in the National *Salmonella* Control Plan and is available on the website of the veterinary information systems of the Italian Ministry of health (www.vetinfo.sanita.it) together with BDN and other national information systems. The use of SISalm became mandatory in 2009 for the collection of data on official sampling in all the poultry categories considered by the Plan and of data on sampling activities carried out by FBO only in broiler flocks; in 2010 the use of the system became mandatory also for turkey flocks (data both on official and FBO sampling). Since 2012, data on FBO sampling are being collected for all the poultry categories considered by the Plan.

In SISalm data can be entered using forms on line or uploading XML files and can be queried by form on line summarizing and grouping data by sampling period, farms, flocks sampled, samples and results. Each report can be downloaded by the users in relation to their own territorial competence. It is also possible to download in Microsoft Excel format all details of the data entered according to the specific role of the users. Moreover, the system produces reports with statistics on the trend of the sampling plan, showing for example how many samples are collected in a given region and time period compared to those expected, how many positive results and which *Salmonella*

serovars have been isolated. All reports are available in Excel format (Table1).

Recently, SISalm has been implemented with the functionality of managing the list of the private laboratories authorized for the analysis of the FBO samples (Figure 1). Private laboratories must sign up by filling out the form available in SISalm, if meeting the requirements foreseen by the legislation. SISalm interfaces both with the database of Accredia to confirm the requirements satisfaction during time, and with the National Reference Laboratory for *Salmonella*, which organizes periodically proficiency tests, in order to verify the ability of the laboratories to isolate *Salmonella* spp.

The integration of SISalm with the BDN and other national information systems is line with the strategies of interoperability aiming at data sharing, avoiding double reporting and inefficiencies due to the need to maintain aligned different archives. The interoperability between SISalm and the BDN is complete: data and information on poultry farms and flocks are read directly from the BDN. The integration with the BDN allows printing sampling models with the information on the farm already pre-filled in the registry section. In this way, handwritten models with information often illegible can be avoided.

SISalm cooperates also with the Italian Information System for the notification of outbreaks of animal diseases (SIMAN), allowing the automatic notification of the suspected outbreak [20]: in case of a positive result to one or more of *Salmonella* serotypes relevant to the Plan (either in case of official and FBO sampling), SISalm automatically load the suspected outbreak using a web service technology. In this case, SIMAN sends an email alert to the local and regional veterinary services and to the Ministry of Health. Each week the email alert is renewed in case of the absence of confirmation/deletion of the suspected outbreak.

Data on official sampling collected by SISalm is also automatically reported to the Italian Community Co-financed Eradication Programmes system, named "Rendicontazioni", which is the official web application in Italy in charge to send these data to the EC, thus fulfilling the information debt in accordance to Decision (EC) n. 2008/940 and Decision (EC) n. 2003/886.

Data collected by SISalm also feed the Italian information system on zoonoses data collection (SINZoo), which gathers data on the monitoring of zoonoses and zoonotic agents in animal health, food and feed, in order to fulfil the information debt towards the EC through the information system of the EFSA, as required by Directive (EC) n.2003/99 [21]. In particular, data collected by SISalm is aggregated and processed according to the EFSA's specifications for the evaluation of the reduction target set by the EU legislation [22,23].

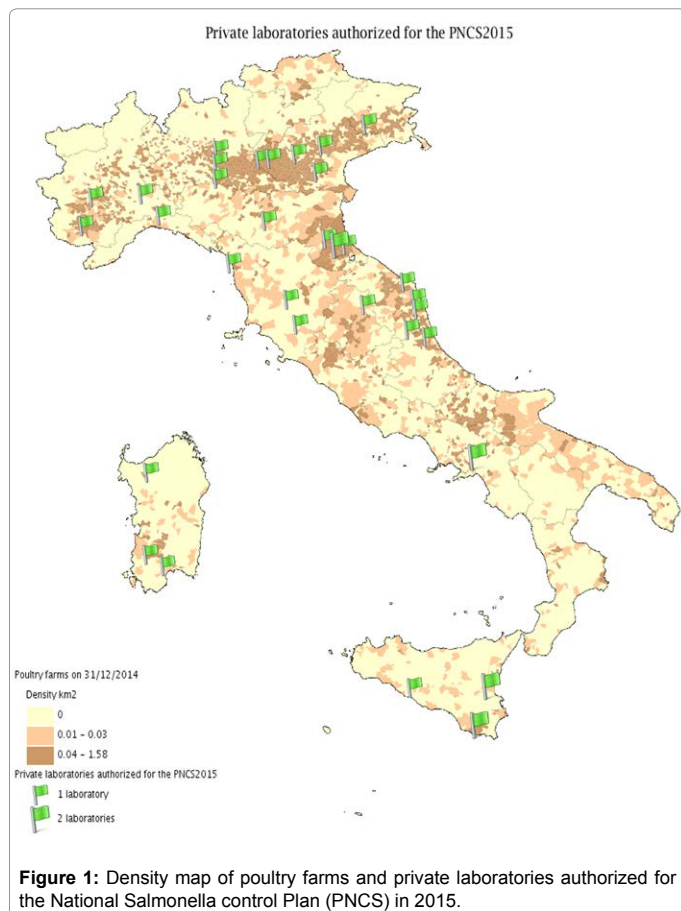
A Help-Desk and a service telephone call centre (800 08 22 80) are available to support users and to solve, whenever possible, certain tasks, such as the activation of a new access. Figure 2 shows the number of accounts issued and the total number of requests for assistance from 2010 to 2014. Both have increased steadily over the years, due to the implementation of the compulsory registration of the FBO sampling. Another support is provided by e-mail (sizoo.support@izs.it) to help in technical, functional and epidemiological issues.

Discussion

The new approach to the protection of human health against food-borne zoonoses, starting from the control at primary production stage, has been a real revolution in the context of the food chain. The National *Salmonella* control Plan is part of this framework, since the FBO play an

Region	Flocks to be tested	Flocks tested at holding	Flocks positive for Salmonella	Flocks positive by serovars						
				S.Enteritidis	S.Typhimurium	S.Hadar	S.Virchow	S.Infantis	S.Infantis	Others
Abruzzo	159	56								
Basilicata	15	34								
Calabria	0	0								
Campania	7	6	1					1		
Emilia Romagna	202	202	1							1
Friuli Venezia Giulia	24	48								
Lazio	4	8	1							1
Liguria	0	0								
Lombardia	243	317	5					2		3
Marche	9	4								
Molise	59	57	2							2
Piemonte	139	201								
Puglia	7	7								
Sardegna	3	5								
Sicilia	0	0								
Toscana	0	0								
Trentino - Alto Adige (Bz)	0	0								
Trentino - Alto Adige (Tn)	9	19								
Umbria	58	79	1							1
Valle D'Aosta	0	0								
Veneto	261	210	2							2
TOTAL ITALY	1199	1253	13					3		10

Table 1: Reports with statistics on official control activities carried out by the Local Competent Authorities on breeding flocks of *Gallus gallus* in 2014



active and pivotal role: while the number of official controls is limited to a percentage of the farms, the 100% of the monitoring is ensured by the sampling carried out by the FBO, since the FBO of farms included in the program are obliged to report to SISalm all controls for each breeding cycle and each flocks.

The integration of SISalm with other national information systems has improved the quality of data collection (for instance, it's not possible to entry data on the sampling activities if the flock is not recorded or if it has been closed in the BDN) and has allowed a comprehensive reporting with statistics on the sampling activities planned and carried out, on the laboratory results and on the outbreaks.

Moreover, this integration allows to fulfil the information debts towards the EC and the World Organisation for Animal Health (OIE) (Figure 3), thus avoiding reporting the same information with different timelines and different levels of aggregation. In this way, data is always uniform and unique because it originates from a single source. Through the use of SISalm, the information flow is unique and traces the entire process, from the sampling to the analytical results, both for official and industry sampling. Competent authorities have always at their disposal the updated information on farms and flocks, on FBO sampling, on the tested samples, on the analytical results, on the laboratories involved, etc. Data collected also allows the programming of activities, their periodic verification and risk analysis.

The close collaboration among the Italian Ministry of Health, the COVEPI, the National Reference Laboratory for *Salmonella*, the local and regional veterinary services, the poultry trade associations and Accredia have helped to improve the quality of the whole information system:

- By making the indispensable changes to the BDN (a New Registry of poultry farms has been released on July 2014);

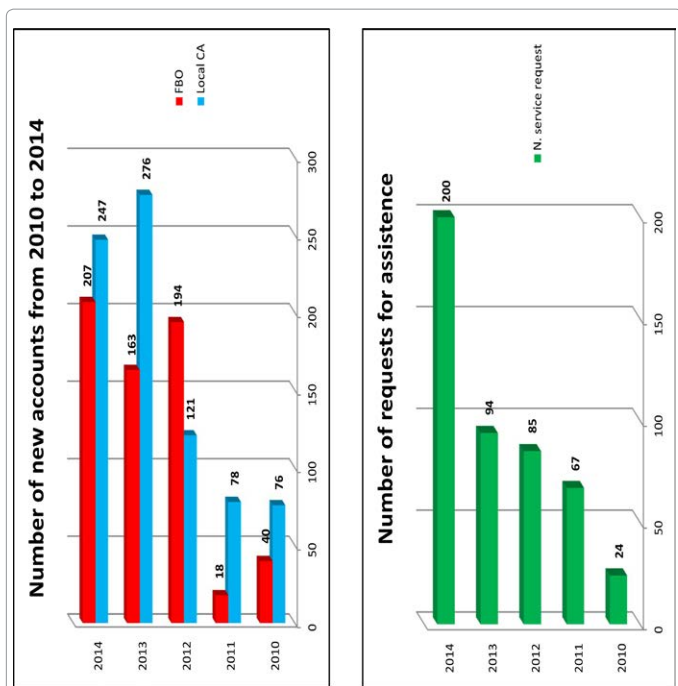


Figure 2: Number of active accounts and requests for assistance from 2010 to 2014.

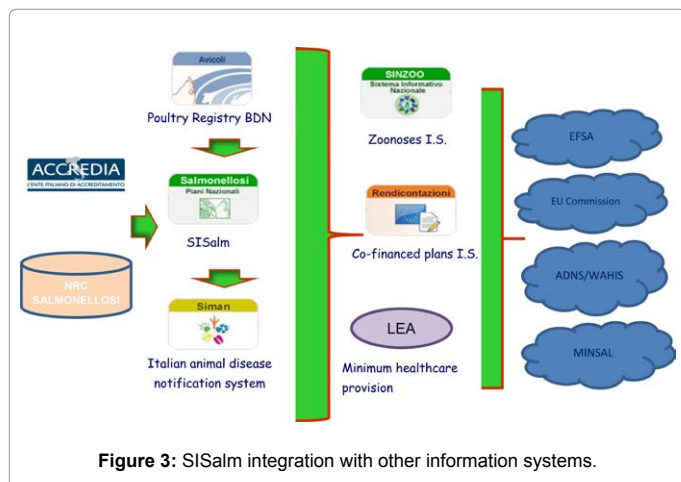


Figure 3: SISalm integration with other information systems.

- By allowing the feeding of SISalm directly by the FBO;
- By creating a centralized list of private authorized laboratories published by SISalm in collaboration with Accredia and the National Reference Laboratory for *Salmonella*.

Finally, using SISalm, the registration of official and FBO sampling has increased, as well as the state of implementation of the New Registry of poultry farms.

Overall, the use of the system has allowed an effective monitoring of the epidemiological situation of salmonellosis in poultry flocks, a prompt management of the outbreaks and has improved the economy of the entire surveillance system. Moreover, the application of the control measures foreseen by the Plan has led to the achievement of the annual reduction target of the prevalence of *Salmonella*.

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