



SALMONELLA NATIONAL CONTROL PROGRAMME MALTA

06 September 2022¹

1. Geographical Background

Malta is an archipelago. There are two main islands which are Malta and the smaller island of Gozo. Malta is approximately 360 Km² being the larger of the two Islands. Gozo lies north of Malta and is much smaller, at less than half Malta's surface area.

Most of the poultry holdings are on the main island of Malta. There are four slaughterhouses which are all situated in Malta. Malta and the smaller sister Island of Gozo are considered as one region

2. Legislative Requirements

Commission Legislation:

Commission Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the Control of Salmonella and other Specified Food-borne Zoonotic Agents. Commission Regulation (EC) No. 1177/2006 Commission Regulation (EC) No 1237/2007 of 23 October 2007 amending Regulation (EC) No 2160/2003 of the European Parliament and of the Council and Decision 2006/696/EC as regards the placing on the market of eggs from Salmonella infected flocks of laying hens. Commission Regulation (EU) No 200/2010 of 10 March 2010 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of Salmonella serotypes in adult breeding flocks of Gallus gallus Commission Regulation (EU) No 517/2011 of 25 May 2011 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of certain Salmonella serotypes in laying hens of Gallus gallus and amending Regulation (EC) No 2160/2003 and Commission Regulation (EU) No 200/2010; Commission Regulation (EU) No 852/04, on the hygiene of foodstuffs; Commission Regulation (EU) No 2073/05 of 15 November 2005 on microbiological criteria for foodstuffs Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonosi

¹ Substitutes the previous SNCP dated 25th June 2019

and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC. Commission Regulation (EU) 2019/268 amending Regulation (EU) NO 200/2010, (EU) No 517/2011, (EU) No 200/2012 and (EU) 1190/2018 as regard certain methods for Salmonella testing and sampling in poultry.

National Legislation:

Veterinary Service Act Chapter 437.

The Animal Welfare Act. 439 LN 119 of 2005 -“Rearing of Broilers Regulation” Products Safety Act L.N. 345 of 2003 on Egg Marketing Standards Regulation. The Standard Hatchery Requirements - SL 36.41 Legal notice 441/2010 under Chapter 36 of the national legislation enforces registration of all farms having more than 20 broilers with the CA. LN 255 of 2012 titled "Measures for the Eradication of Salmonella Regulations, 2012", issued under the Veterinary Services Act Chapter 437.

3. **Aim**

The aim of the programme is to monitor and control Zoonotic Salmonella infection in flocks of Gallus gallus according to provisions laid out in CR 2130/2003 in Malta and Gozo.

3.1 Criteria for Broiler flocks:

To carry out a monitoring and control programme for Zoonotic Salmonella in Broiler flocks of Gallus gallus in accordance to Council Regulation (EC) 2160/2003 and Commission Regulation (EC) No 200/2012; to achieve a reduction of the prevalence of Salmonella Enteritidis and Salmonella Typhimurium, including Monophasic Salmonella Typhimurium serotypes with the antigenic formula 1,4, [5],12:i, as indicated in article 1 of CR 200/2012:- " a reduction of maximum annual percentage of flocks of broilers remaining positive for Salmonella Enteritidis and Salmonella Typhimurium equal to 1% or less".

Flocks covered by the Salmonella National Control Programme (SNCP): The Maltese legislation, Animal Welfare Act. 439 LN 119 of 2005, states that any person or establishment rearing or keeping more than 20 broilers, should be licensed by the competent authority (CA). Those flocks registered with the CA are covered by the SNCP. The SNCP covers all registered and functioning broiler flocks of Gallus gallus reared for meat production on both the Islands of Malta and Gozo, irrespective of their capacity.

3.2 Criteria for Laying Hen flocks:

To carry out a monitoring and control programme for Zoonotic Salmonella in laying flocks of Gallus gallus in accordance to Council Regulation 2160/2003 and Commission Regulation (EU) 517/2011; to achieve a reduction of the prevalence of Salmonella Enteritidis and Salmonella Typhimurium, including Monophasic Salmonella Typhimurium serotypes with the antigenic formula 1,4, [5],12:i). “A reduction of the maximum percentage equal to 2% or less of positive flocks of adult laying hens”. The Union target shall be achieved every year based on the monitoring of the previous year.

Flocks covered by the Salmonella National Control Programme (SNCP):

Layer farms are registered in terms of the Egg Marketing Standard Regulations LN 345 of 2003 under Chapter 427 - The Product Safety Act. In accordance to this law, each individual egg-laying farm is given a unique identity number that has to be printed on all the eggs produced intended for commercial purpose. The programme covers all commercial registered flocks of laying hens of Gallus gallus on Malta and Gozo but does not apply to flocks for private domestic use or leading to the direct supply, by the producer of small quantities of table eggs to the final consumer or to local retail establishments. These latter Food Business Operators (FBO`s) are under the official control of the CA but would not be reported under the SNCP. The programme covers also all rearing flocks of future laying hens. The total number of operational layer holdings is around thirty. This includes holdings having less than 1000 birds. Number of flocks: The number of flocks are around eighty (80). The number of houses in use can fluctuate.

4. Structure of the local commercial poultry industry

At present, there are no local breeding flocks of broilers or layers in Malta. There are also no commercial registered turkey farms. The turkeys imported are not sold to commercial farms. The Competent authority retains data relevant to the purchasing of such turkeys and the capacities sold.

Each registered farm is given a license number by the CA. This number is unique and cannot be reissued, even if the farm ceases to operate. The number is made up of letters and numbers. The letters indicate if the farm has an exclusive license for broiler rearing or also for rearing layers. The rearing of both categories is not permitted simultaneously. PB stands for poultry broiler, while PBL stands for poultry broiler and layer unit. PL stands for poultry layer unit. The last letter is either M or G indicating the territory of Malta or Gozo. The licence is renewed annually. If no broilers are reared in a 12-month period the licence is not renewed. The CA (VRD) keeps all relevant information of the registered holding on the national livestock database system which is managed by the Animal Health Section. The database holds information relative to the different flocks reared on the holding eg. Number of birds, date of hatch, batch number of birds, slaughter date/dates. The same batch of birds bought by a farm from the hatchery may be split up in different houses and therefore will be considered as different flocks; however these flocks would have the same batch code.

4.1 Record-keeping on Farm and traceability of birds.

Herd books are issued by the Competent Authority and distributed to all food business operators (FBO`s) with the necessary details to be filled in relevant to poultry batches reared. This herd book has to be filled in by the operator and also records of any medication and any vaccinations are to be included by the private veterinarian. When broiler flocks are slaughtered, the herd book is presented to the official veterinarian. This herd book will be replaced every three years or when the herd book is completed.

Hatching eggs and live birds are traded from EU countries. All trade into Malta are accompanied by documentation/certification in accordance to Directive 2009/158. The identification of batches of birds and the movement document accompanies the birds until they are slaughtered or culled. The

batches of birds at the slaughter house continue to carry the identification code number conferred to them as day-olds by the CA. This number is reproduced on the label of the generated products. The history of the commercial batches of birds reared is held on the National Livestock database (Inter-trace).

4.2 Broiler Flocks:

Structure of Broiler holdings:

Currently there are around 58 operational holdings amounting to an average of 400-450 flocks. The amount of broilers reared in a year is approximately 1,500,000. Holdings are family-run and are generally part-time businesses. There are no free-range farms in Malta / Gozo. All broilers are bred in closed houses, kept on bedding. The houses are generally situated very close to each other. A holding with a capacity of 5000 - 6000 can be divided up into three houses (therefore flocks). The slaughter age of the broilers can vary slightly depending on the market demand such as a seasonal request for capons in December, however, on average the animals are slaughtered between 5 – 6 weeks. The general rule is an all-in-all-out system with a three week resting period between flocks.

The operators have individual agreements with the slaughterhouses they sell their birds to. There are three slaughterhouses all located on the Island of Malta. Generally, each slaughterhouse maintains working relationships with the same number of operators. The slaughterhouses would then sell the produce to retail outlets (butcher shops, supermarkets).

Registration of Farms: Broiler farms are registered with the CA. The operators book the number of birds or day-olds for the next rearing from the hatcheries who import hatching eggs and day-olds. The farmers do not import any day-olds for themselves but all book through the hatcheries. There is no association of poultry breeders and the industry is made up of a quite a number of small farms, all operating individually.

4.3 Layer Flocks

There are no breeding flocks in Malta or Gozo. There are approximately 28 holdings with around 80 flocks, depending on the number of houses used. The number of layers reared annually are around 120,000 birds. Rearing farms generally stock with pullets but operators may stock with day-olds traded from EU countries or hatched locally. To date, there is only 1 free-range farm and most birds are kept in cages on more than one tier, usually up to a maximum of five tiers. All cage houses have manure belts. There are just a few barn-type layer houses. The Maltese archipelago has a limited surface area, so it is uncommon to find large houses. The vast majority of holdings are made up of a number of houses having small capacities. The houses are usually in close proximity of one another. The majority of farms operate on a first-in, first-out basis. The largest holding capacity would be around 30,000. Approximately between 9-12 holdings have less than 350 birds. The birds kept in one house are considered as an individual epidemiological unit in accordance with the Regulation.

Egg-packing stations. There is no central egg-packing plant. The farmers can either sell the eggs produced directly to shops, supermarkets or egg-collectors, who in turn would deliver to shops / supermarkets. All farmers pack their own egg produce, some are already approved as a packing centre and the rest are in progress of approval. The majority pack the eggs manually, only a few producers have automation for grading, stamping and packing.

Registration of Farms: Layer farms are registered in terms of the Egg Marketing Standard Regulations LN 345 of 2003 under Chapter 427 -The Product Safety Act. In accordance to this law each individual egg-laying farm is given a unique identity number that has to be printed on all the eggs produced on that farm and sold to shops, supermarkets or egg-collectors. This legislation excludes eggs sold directly to the consumer. The CA is responsible for issuing the unique identity number. Egg laying farms are therefore registered with the CA, whereby a unique registration number is given to the farm, following registration then the unique marking number for the eggs is issued. Control at retail level falls under a different Ministry.

4.4 Hatcheries

There is only one registered hatchery on the Island of Malta. Hatching Regulations LN48 of 1997 lays down the provisions that regulate the national hatchery establishments. Hatching eggs are traded from EU member states. All consignments are moved with the official Intra Trade Certificate issued according to the new Animal Health Law. The hatcheries are legally obliged to report to the VRD, as competent authority, the number of hatching eggs imported; they input the data in the National Livestock Database sending an email in which it is declared the TRACES number, the total quantity of eggs and the number of hatched eggs. At this stage the system will assign a unique and progressive batch number. A second email will be sent indicating the holding of destination of the chickens split in unique and progressive sub-batches. The system will automatically assign the amount of animals to each holding depending on the limit given to it by the CA. The slaughterhouse or the operator himself, in the case of spent layers, which generally do not enter the food chain, will then send another email to the system indicating the number of slaughtered/culled animals and the farm of origin so that the system can remove these animals from the single farm. A new movement for a new batch of birds is only allowed by the system after a three-weeks resting period between rearing of different batches of broilers.

4.5 Feed Mills and Official Controls at Feed Level.

There are four large feed mills (two small feed mills had ceased production and are distributing package feeds from EU. These source and produce feed material and additives to produce the majority of feed supplied to local farms. Feed materials are sourced from UE and non-EU countries. These are mixed with premixes and other additives from the EU (predominantly UK). Some also source, and place on the market, packed compound feeds. Legal notice 374/2005, regarding the "Circulation and Use of Feed Materials regulates the responsibility of feed mills. This is the MT transposition of Directive (EU) 96/25 which was repealed by Regulation (EU) 767/2009. A small number of farms carry out home mixing. To date all the feed mills carry out their own sampling and have samples tested at accredited labs in EU

Official visits are carried out on all feed mills and also the on-farm mixers. All six commercial feed mills have an HACCP programme in place and are visited at least once annually by CA officials. Documentation regarding auto-control checks is verified during official controls and an annual sampling programme whereby official samples are collected from all the major feed mills, where at least one sample from each type of poultry feed produced is collected. Annually, random sampling is also carried out on some of the home mixers. Samples of feed are also collected from the layer holdings at least once annually as part of the SNCP. The finished feed is sampled direct from farm. In cases when there is a positive isolation of Salmonella, depending on the circumstances, CA officers may return to the farm to investigate and re-sample. In cases of home mixing, the different

components would be sampled. If Salmonella spp. is isolated, investigation at the feed mill is carried out and necessary corrective actions are issued and followed-up.

5 Organization and responsibilities of the Competent Authority

The Veterinary Regulation Directorate (VRD), is the competent authority (CA) responsible for the SNCP. The VRD falls under the Ministry for Agriculture, Fisheries, and Animal Rights (MAFA), within the Animal Health and Welfare Department (AHWD).

Background information:

The Island of Malta is approximately 350sqm and therefore there is only one central authority; all offices are situated on the same premises, with the exception of the Border Inspection Post and the Veterinary Office in Gozo. The Veterinary office in Gozo is responsible for the organization of the sampling of poultry flocks, on-farm inspections and supervision of culling or other regulatory provisions that may be issued by the CA.

5.1 The Veterinary Regulation Directorate (VRD)

The VRD falls under the Animal Health and Welfare Department (AHWD). The VRD (CA), together with the National Veterinary Laboratory is responsible for the organisation, supervision, implementation and enforcement of the Salmonella National Control Programme

5.1.1 The National Veterinary Laboratory (NVL)

The NVL is ISO 17025 accredited and Salmonella isolation as per ISO method 6579 is part of the accreditation scope: The responsibilities of the NVL under the SNCP are:

- The collaboration with the Animal Health Unit – Poultry Section in the supervision of the sampling and implementation of the SNCP.
- The analysis of official and part of unofficial samples under the SNCP, ensuring that samples are analysed in accordance with time frame and methodology as laid down in the programme in accordance with Commission Regulations
- Collaborate and co-ordinate with the Public Health Laboratory for the typing of positive Salmonella spp. isolated at the NVL.
- Issuing of laboratory reports to be sent by post/ e-mail to operators.
- Communicate confirmed isolation of Salmonella targeted serovars within 24 hours positive results (excluding weekends) to the OV of the Poultry Section, the official veterinarians at the white meat slaughterhouses (for broiler flocks) and the Director of the VRD, via e-mail and/or phone.
- Assist in the training of VRD personnel responsible for sampling on-farm in accordance with the Commission Regulations.

- Assist VRD in organizing the training session for operators and private laboratories, as necessary, in sampling protocol of the SNCP.
- Assist VRD in supervision authorised private labs to carry out analysis of unofficial samples under the SNCP.
- Collecting and maintaining SNCP analytic data.
- Co-ordinate with the Public Health Department regarding epidemiological trend of Salmonellosis in humans.

5.1.2 The Animal Health Unit:

The Poultry Section is headed by an official veterinarian. The Section is responsible for the organization, implementation and reporting of the SNCP, as listed below:

- The registration of local poultry farms and hatcheries and issuing of operating licenses.
- The registration and issuing of unique batch identification numbers of poultry flocks purchased by the operators.
- The issuing of the movement document
- Management of related data on poultry holdings uploaded on the National Livestock Database (Inter-trace).
- The sampling on poultry holdings, including that fall under the SNCP.
- On-farm inspections (Bio-security and Welfare checks, census checks).
- Supervision and/or implementation of regulatory provisions required under the SNCP on poultry holdings.
- Collaborate with the National Veterinary Laboratory and the official veterinarians on white meat slaughterhouses in the implementation of the SNCP.
- The issuing of notices and letters to operators and communication of positive results to operators (through meetings or phone communication).
- The Safety of the Food Chain Unit: is responsible for slaughterhouses and processing plants. The Section is responsible for certain provisions under the SNCP, as listed below:
 - Responsible for the checking of food chain information at the white meat slaughterhouses.
 - Sampling at the slaughterhouses, whenever necessary.
 - Issuing and enforcement of any corrective actions at slaughterhouse level.

5.1.2.1 The Unit ensures that provisions under the SNCP are implemented by the Food Business Operator (FBO).

5.1.3 The Trade Unit implements checks on intra-community trade and third country imports.

- Control of Intra-trade certification
- Co-ordination with the Animal Health Unit with regards to supervision of trade of day-olds and pullets.

6. Sampling requirements of the Salmonella National Programme

The minimum requirements are those currently dictated in Commission Regulations: (EC) 200/2012 for broiler flocks and (EC) 517/2011 for layer flocks. FBOs have to communicate results of analysis to the CA. The food business operators that carry out own-checks are asked to send in the laboratory results not later than two weeks from due date of sampling. An official veterinarian is responsible of the Poultry Section within the Animal Health Unit of the CA. Amongst other responsibilities; the Unit is responsible for the registration and issuing of the unique batch identification number of a poultry flock purchased by the operators. The Unit is also responsible for the management of all data related to poultry holdings uploaded on the National Livestock Database (Inter-trace). The Unit is responsible for poultry on-farm sampling, including that of the SNCP. The support staff has the tools to keep track of the sampling frequency. If the FBO fails to provide the results, after attempts to remind him/her, the CA issues a warning letter and may carry out the sampling. The CA may also consider recommending the Ministry of Health, responsible for retail shops, to withdraw the approval of the sale of commercial eggs of a particular establishment, in accordance with Regulation (EC) 2160/2003.

6.1 The Minimum Sampling Requirements for Food Business Operators

6.1.1 Broiler flocks

Two pairs of boot swabs are taken per house, two to three weeks prior to slaughter. Each pair of boot swabs is used to cover 50% of the house. The sampler has to walk around the house possibly sampling all parts of the house. The boot swabs are then taken off gently not to shake off faecal matter, turned inside out and placed in a sterile bag. The two boot swabs are then pooled together. All separate houses on the same premises are considered as a separate flock and sampled separately. FBO may be authorized to sample only one flock per round on those holdings with more than one flock where:

- an all in / all out system is used in all flocks of the holding;
- the same management applies to all flocks;
- feed and water supply is common to all flocks;
- during at least the last six rounds, tests for Salmonella spp. according to the sampling scheme set out by the implementing Regulation was carried out in all flocks on the holding and samples of all flocks of at least one round were carried out by the competent authority; (v) all results from the testing for SE or ST were negative;

- The boot swabs have to be collected according to provisions of point 2.2 of Annex to Regulation (EU) No 200/2012. A culled chicken is also collected for the screening of antimicrobial residue analysis. This sample is always tested by the NVL for screening of antimicrobial residues even for own checks.

6.1.2 Layer flocks

Samples are collected according to provisions of point 2.2 of Annex to Regulation (EU) No 517/2011. Rearing flocks are sampled as day-old chicks and two weeks prior to onset of the laying phase. The day-olds are generally sampled and checked by the CA, when these are imported as day-olds from other member states. The day -olds are sampled at the trade post. In this case chick liners and any dead chicks (a minimum of 10/consignment) are sampled by the CA support staff. This is however not a common occurrence. The FBO prefers to import point-of-lay pullets which would be then sampled on farm in the same manner as the adult laying flocks. Adult laying flocks are to be sampled every 15 weeks during the laying period. The authorised FBO collects two faecal samples from each of the houses holding caged flocks. The faecal samples are collected from the manure belt. Each faecal sample should amount to at least 150gramms. The two samples are then pooled into one sample at the laboratory. There are very few barn houses and from these type of houses, two pairs of boot swabs are collected. As with broiler houses, the boot swabs are to be moistened in a sterile diluent prior to being worn on the boots. The sampler has to walk around the house possibly sampling all parts of the house. Two pairs of boot swabs are collected per house. The boot swabs are taken off gently not to shake off faecal matter, turned inside out and placed in a sterile bag. Some samplers find it difficult to walk on the slats and try to collect faecal material from under the slats.

6.1.3. Training of FBOs in sampling under SNCP.

Food business Operators have to undergo training by the CA to be authorized to carry out sampling under the SNCP. After such a training course, a certificate of attendance is issued by the CA. The last session was carried out in 2020. The aim is to have a training session every two years. Only the FBO trained by the CA are permitted to sample, otherwise the sampling is carried out by the CA. When carrying out own checks, the operator has to fill in the official sampling sheet provided by the CA with all details relevant to the samples. This has to be signed and submitted to the CA on the sampling day together with a culled layer hen or broiler chicken taken from one of the houses sampled. Antimicrobial residue screening analysis is carried out by the NVL on muscle tissue samples using commercial ELISA screening tests for certain residues. The CA can cross-check the information supplied on the sampling sheet with the Intra-trace. An SOP detailing the procedure of sampling based on the Regulation is available. The support staff under the CA responsible for the on-farm sampling, also undergo training on sampling techniques and biosecurity measures on a regular basis.

6.2 Sampling requirements under official sampling.

6.2.1 Broiler Flocks

The CA has to carry out official analysis on:

- at least 10% of broiler flocks having 5000 and over capacity per year.
- if deemed necessary, on other flocks in a holding where a positive flock (Salmonella Enteritidis, Monophasic Salmonella Typhimurium and Salmonella Typhimurium) was identified, up to six-months prior.
- In case of suspicion of Salmonella infection when investigating foodborne outbreaks.

Two pairs of boot swabs are collected from each house sampled. Each pair of boot swabs should cover 50% of the house. The two pairs are then pooled together.

6.2.2. Layer Flocks

- One layer flock per holding having a capacity of at least 1000 birds.
- On other layer flocks in a holding where a positive Salmonella Enteritidis, Monophasic Salmonella Typhimurium and Salmonella Typhimurium was identified, up to six-months prior.
- At the age of 24 +/- 2 weeks in laying flocks housed in buildings where the relevant Salmonella was detected in the preceding flock.
- In case of suspicion of Salmonella infection when investigating foodborne outbreaks.

In the case of official samples taken by authorized and trained personnel of the CA, two faecal samples of approximately 150gramms each and two dust samples of approximately 100gramms each are collected per house sampled. If dust samples cannot be collected, additional faecal samples are collected instead. The provisions of sampling are always according to provisions of point 2.2 of Annex to Regulation (EU) No 517/2011. The two faecal samples are pooled into one sample and the two dust samples are pooled into one sample. In barn-type houses, apart from two boot swabs collected from each house sampled, a dust sample is also collected as described above.

7. **Biosecurity measures on farm.**

In the beginning of the implementation on the SNCP, a meeting was held in 2010 and repeated every two years for poultry breeders. The last one by one training was provided in 2021. During this meeting, a leaflet and training detailing proper cleaning and disinfection practices was shown. Two documents were also distributed; one was related to biosecurity and the other to AMR. In 2016, biosecurity guidelines were placed on the website of the Department. These guidelines deal with hygiene and biosecurity measures (e.g. disinfection facilities at the entrance of the farm, clean area

around the holdings, usage of separate clothes, separate area for the storage of tools, proper feed storage, disinfection of the holdings before the introduction of new animals).

In Malta, national legislation is in force for providing general rules for the eradication of salmonella in broiler and laying hen flocks (Veterinary Services Act SL 104). The regulation refers to the control measures stated in the EU legislation and provides rules for the producer eligibility for compensation, including biosecurity measures. The mentioned national legislation states that “the producer shall follow all advices and recommendations regarding biosecurity measures to prevent salmonella infection“. The compensation of infected flocks is connected to the presence of proper biosecurity measures. A biosecurity programme is regularly checked using specific checklists. No farm has separate entrances. It is recommended that as much as possible vehicles should not go into a farm. The use of a pressure-washer for the wheels is highly recommended.

7.1 Personnel on farm:

A high percentage of farms are small in capacity and are family-run, therefore few people would be responsible for the daily management of the animals. There is no legal obligation for people handling live animals to carry out medical checks. The larger holdings have employees.

7.2 Pest control

Pest control (mice, rats and birds) is generally addressed through the use of nets on the windows, correct maintenance of building structures and the use of venom.

7.3 Use of clean protective clothing, disinfection pans:

The use of clean protective clothing and disinfection of boots when moving between houses is continuously being reminded to FBO by sampling staff.

7.4 Water supply:

The water supply can be direct from the main government supply or from private bore holes. As from 2016, corrective actions were issued requesting water analysis in accordance with (EC) 852/2004. The competent authority has a plan for on-farm inspections depending whether the holdings are considered low-risk, medium-risk or high -risk depending on the history of Zoonotic Salmonellosis infection. During these visits, the biosecurity measures are evaluated and corrective actions would be issued depending on the outcome and followed-up accordingly. Every check-list is a control document. Any noncompliance follows the internal SOP for enforcement. The enforcement measures consist of: verbal and written improvement notice, corrective action request with deadline, warning letter, fines and finally suspension and or revocation of license.

8. **Laboratories and analytic methods**

Laboratories involved in analysis of official and non-official samples collected under the SNCP are accredited to ISO 17025: 2017 and the analytic methods for salmonella detection are in accordance to EN/ISO 6579-1:2017/AMD 1:2020 excluding clause 9.5.4, as laid down in provisions of the Annex point 3.2 of Regulation (EU) 200/2012 and point 3.1 of Regulation (EU) No. 517/2011. The analytic method is within the accreditation scope of the approved laboratories. There is only one state

laboratory involved in the SNCP. The National Veterinary laboratory (NVL) within the same Ministry as the competent authority. The NVL is responsible for all analysis of official samples and also for a certain percent of analysis of unofficial samples, which are carried out on behalf of the FBO. The NVL falls under the AHWD. Officers from the VRD are responsible for official sampling but also for some of the sampling falling under the non-official analysis. Samples are transported and submitted to the laboratory in accordance with the provision laid down in point 2.2.4 and 3.1 of Regulation (EU) 200/2012 and point 3.1 of Regulation (EU) No. 517/2011. Samples are tested within 48 hours from submission to the lab and within four days from sampling. Samples are generally submitted within a few hours with the exception of samples collected in Gozo, which are submitted within 24-30 hours. The National Veterinary Laboratory carries out analysis until biochemical identification of the isolates. Stereotyping is carried out by the *Istituto Zooprofilattico delle Venezie*, Italy, being also the NRL for Italy and an OIE reference laboratory for Salmonella. Results are then sent to the NVL through e-mail for immediate action.

Private laboratories involved in unofficial analysis carried out under the SNCP have to be approved by the CA. A memorandum of understanding will be established between the private lab and the CA. Currently there is a local laboratory, some FBO send their samples also to a lab in Italy (Sicily). Both laboratories are accredited and have also submitted proficiency testing documentation to the NVL. The CA is in process of reevaluating the approval of the private laboratories designated to participate in SNCP. The CA will ensure that these laboratories involved will participate in collaborative testing coordinated by the NRL or delegated to the NVL in Malta or under the supervision of the competent authority where the laboratory is placed. A list of approved laboratories will be made public on the website of the Ministry.

9. Control measures and specific requirements carried out on positive flocks and their products.

A Positive Flock is one found to be infected with Salmonella Enteritidis (SE) and Salmonella Typhimurium (ST), including monophasic ST I,4,[5],12:i:-.

There are different control measures implemented depending if it is a broiler flock or a layer flock.

9.1 Control Measures on Positive Broiler Flocks.

9.1.1 Control Measures implemented by the FBO.

- The owner has to respect the restrictive measures issued by the CA. The entry of vehicles and personnel on the infected holding is to be restricted and strict biosecurity measures (protective clothing, boots, the use of foot baths and disinfection pits for vehicles) have to be respected to avoid spreading of infection out of the holding and between different houses.
- The operator is to inform the CA on the date or dates of slaughter. Information of the Salmonella status has to appear on the food chain information form, which the operator submits to the slaughterhouse.

- Once the infected flock arrives at the slaughterhouse, the crates have to be washed and disinfected properly.
- The slaughterhouse has to include in its HACCP plan, the procedure and precautions to take when slaughtering Salmonella infected flock or flocks of unknown Salmonella status.
- The slaughter batch of infected flock have to be slaughtered or at the end of a slaughter day or on their own, without other birds from other flocks being slaughtered afterwards.
- Cleaning and disinfection after slaughter has to be carried out with utmost care (disinfectant authorized refer to point 13).
- The slaughterhouse will take samples in accordance to the Annex of Commission Regulation (EU) No. 1086/2011. A copy of the result of the analysis has to be submitted immediately to the CA once received.
- The animal by- products produced are collected in bins. These bins are supplied by the Thermal Facility. The feathers and green offals are collected in separate bins. The by-products are Category 2 and their collection is controlled and verified by the OV in charge at the slaughterhouse.
- If the poultry carcasses are to be processed, then the processing plant is to ensure and verify that the batch number of the processed products can be traced back to the origin. The processing plant has to comply with CR (EU) No. 1086/2011 and carry out analysis in accordance with this Regulation.
- If Salmonella spp. is isolated from the neck skins, the serovar has to be typed. If serotyping results in identification of the targeted serovars, Salmonella Enteritidis, Monophasic Salmonella Typhimurium or Salmonella Typhimurium, the slaughterhouse has to implement the measures requested by the CA.

9.1.2 Control Measures implemented by the CA.

- The CA issues a restrictive notice. There is to be no movement of infected animals between houses and out of the holding, only for the purpose of culling or until slaughter. The movement document prior to slaughter is issued by the Animal Health Unit of the CA.
- The Official Veterinarian i/c of the white meat slaughterhouse (OV) has to make sure that the Food Chain Information (FCI) is duly filled. The CA has an SOP to outline slaughter procedures and management of such carcasses and of results from analysis of slaughtered infected flocks, to guarantee reduction of spread of the zoonoses. The OV has to record on a checklist that a number of precautions and conditions are in accordance to the SOP. An example of the precautions is that the infected flock is to be slaughtered at the end of slaughter or the flock is slaughtered on its own during the slaughter day.

- The OV has to ensure that the slaughterhouse operator samples neck skins in accordance with the Regulation on microbiological criteria, (EU) No. 1086/2011.
- If serotyping of neck skins results in identification of targeted serovars, the CA carries out a traceability exercise and appropriate action is taken.
- Cleaning of the house where the flock originated from has to be verified by the CA to have been effective, through sampling of official environmental samples and microbiological analysis to be carried out by the NVL. The Animal Health & Welfare Unit of the CA will only issue the permit for re-stocking if no *Salmonella* spp. is isolated from official samples taken after disinfection of the infected house / houses.

9.2 Control Measures on Positive Layer Flocks.

There are specific requirements on the consumption of eggs from layer flocks due to the presence of or suspected of the presence of SE or ST (including monophasic ST I,4,[5],12:i:-) as laid down in Annex II.D of Regulation (EC) No 2160/2003. Eggs from such flocks cannot be used for human consumption unless heat treated. Eggs from these flocks shall be marked and considered as class B eggs.

9.2.1 Control Measures implemented by the CA.

Flocks suspected of being infected with the targeted serovars after initial serotyping or found to be positively infected with the targeted serovars are placed under official restrictions and no eggs, poultry or poultry meat will be permitted to be moved from the infected house without authorisation from the CA. A Test Report is issued with a declaration of official restriction. A census is carried out within a few days from official restriction on the holding by officials from the CA, to verify the size of the infected flock/s.

Destination of products: Eggs originating from positive flocks are not sold as fresh eggs but have to be either destroyed or heat-treated. Officials from the Competent Authority (CA) are to carry out regular (generally daily) on-site checks to verify the number of Class B eggs produced and that biosecurity measures are respected. All records of this census are kept at the CA. If the operator chooses to go for heat-treatment. The eggs are generally sent to Italy to a heat-treating facility since there is no heat-treating facility on the Island. The eggs are stored over a few days at the holding and not permitted to be moved from the premises. When the eggs are dispatched, an Intra-trade document is issued by the CA and signed by the Official Veterinarian. This option is rarely chosen as it is not to be cost-effective once the cost of packaging and transport is deducted. If, the operator decides to destroy the eggs, these are placed in approved leak-proof bins and transported in approved vehicles to the only Thermal facility Unit present on the Island for incineration. At the Thermal facility records of the weight of material incinerated are produced and passed on to the Poultry Unit at the CA. The CA can thus cross-checked with the records obtained from the daily checks carried out on-farm on the eggs being stored.

Destination of infected flocks: The infected positive flocks are culled. In Malta spent laying hens do not usually enter the food chain. Even more so, infected laying hen flocks are not slaughtered for human consumption. If the case had to arise than the measures elaborated in point 9.1.2 would be implemented. The infected flock is culled and then incinerated. Once culled, the birds are loaded

in leak-proof bins which are transported to the Thermal facility. The same procedure of disposal is followed, as described above for condemned for the eggs above. Birds from an infected flock, when culled, are sent for incineration. The same procedure, as for the destruction of eggs is observed for the culling of infected flocks.

10. Criteria for official confirmatory sampling in accordance with Annex II D4 (B) of Regulation (EC) 2160/2003.

Such criteria may be implemented only for layer flocks under the following circumstances:- (i) the FBO proves with documentation a vaccination programme according to requirements as requested by the CA in point 10 of the SNCP and that the premises are up to relevant standards of hygiene and biosecurity. (ii) Reasonable suspicion of improper sampling, not according to Regulation (EU) 517/2011. Confirmatory Sampling is not implemented when: (a) a FBO is found repeatedly noncompliant in relation to bio security measures. (b) If there are investigations of Salmonella outbreaks in humans which would be reported to the CA and which would implicate the particular farm or restricted area.

11. Use of specific methods to control Salmonella in poultry.

11.1 Official Controls to verify that antimicrobials are not used in the SNCP.

The use of antimicrobials as a specific method to control Salmonella in poultry is not permitted in accordance with provisions laid down in Article 2 of Regulation (EC) No 1177/2006. The CA verifies the correct implementation of this measure by analysing sample for antimicrobial testing every sampling session, even when the FBO carries out own checks. In the latter case, a broiler chicken or a hen is taken from one of the flocks sampled on the premises, chosen at random. The sample is submitted to the NVL and tested for presence of antimicrobial agents. A screening test is run using the six-plate antimicrobial residue test. In 2014 the method was validated also for poultry muscle and the analysis is included in the accreditation scope. When positivity arises, the FBO is asked to produce a prescription. If the FBO has a valid prescription and the use of antimicrobials is according to Regulation requirements, an appropriate withdrawal time is allowed and re-sampling and analysis is carried out. If no prescription is produced and the FBO denies use of antimicrobials, the sample would be sent for confirmatory analysis abroad since such analysis is not carried out locally. In the meantime, for broiler flocks, if there is no time for re-analysis, the flock may then be slaughtered under "unknown Salmonella status" following the provisions detailed in point 9.1.1. Once the presence of antimicrobial residues is confirmed, then in accordance with the internal enforcement procedure, a warning letter is sent to the FBO and an investigation is carried out. A repeated offense would then give rise to a fine, according to the Veterinary Service Act. If the situation continues to repeat itself, the Veterinary Service Act allows the CVO to withdrawal or suspend the license.

11.2 Salmonella Vaccination

Salmonella vaccination as a specific measure in the control of Salmonella infection is voluntary. FBO implement vaccination in laying flocks. The CA is also responsible of the registration of veterinary drugs and vaccines. Only those live vaccines that can be bacteriologically detected from the wild strain will be permitted to be registered.

12. **Compensation to Food Business Operators**

The Subsidiary Legislation under the Veterinary Services Act Chapter 437: SL 437.104 titled "Measures for the Eradication of Salmonella Regulations" provides for the compensation rates as applicable. The rates are prescribed by a government notice issued in the Government Gazette. The average market prices are provided by the National Statistics Office. New rates are going to be published for the current year. The SL provides a deduction in compensation rates depending on the biosecurity conditions and also if the FBO has already had a positive flock in the past. Timelines are not detailed in the legislation. The farmer applies for the compensation and once the vetting of all the documents is satisfactory and the rates have been published, the compensation is passed for payment.

13. **Official procedure to verify effectiveness of cleaning and disinfection after depopulation of positive flocks of poultry**

The CA will lift official restrictions and authorize re-population after there is verification of the efficiency of disinfection of the infected poultry house. Official environmental samples are collected by the CA and analysed at the NVL. The FBO is advised to clean thoroughly, giving particular attention to areas and equipment difficult to reach. Fans, drains, slats etc. should not be neglected. Steam cleaning is recommended and use of a disinfectant such as Virkon. Fumigation should be carried out after cleaning. Once cleaning and disinfection have been completed, the FBO informs the CA. The CA has an internal SOP detailing sampling procedure under the SNCP. Samples are taken using sterile moistened boot swabs to wipe areas like the doors, walls, feeders, drinkers and fans. A pair of boot swabs is used per area sampled. The floor of the house is sampled by walking with the boot swabs in a zig-zag manner to cover the surface area properly. Restrictions will be lifted if all samples result negative to salmonella isolation. If this is not the case, the area in question is re-sampled and analysed.