Project: Technical assistance to improve implementation of food safety standards and disease crisis preparedness

Training course: Antimicrobial Resistance EU legal framework and monitoring

Lecturer: Blagojcho Tabakovski

Date: ……

Place: Nicosia, Cyprus

Project funded by the European Union within the scope of the Aid Programme for the Turkish Cypriot community, implemented by the NSF Euro Consultants Consortium

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CONTENT

- EU Legislation
- Monitoring of AMR
- Elements of the AMR programs
- Targets
- Sample design
- Sample size
- Reporting

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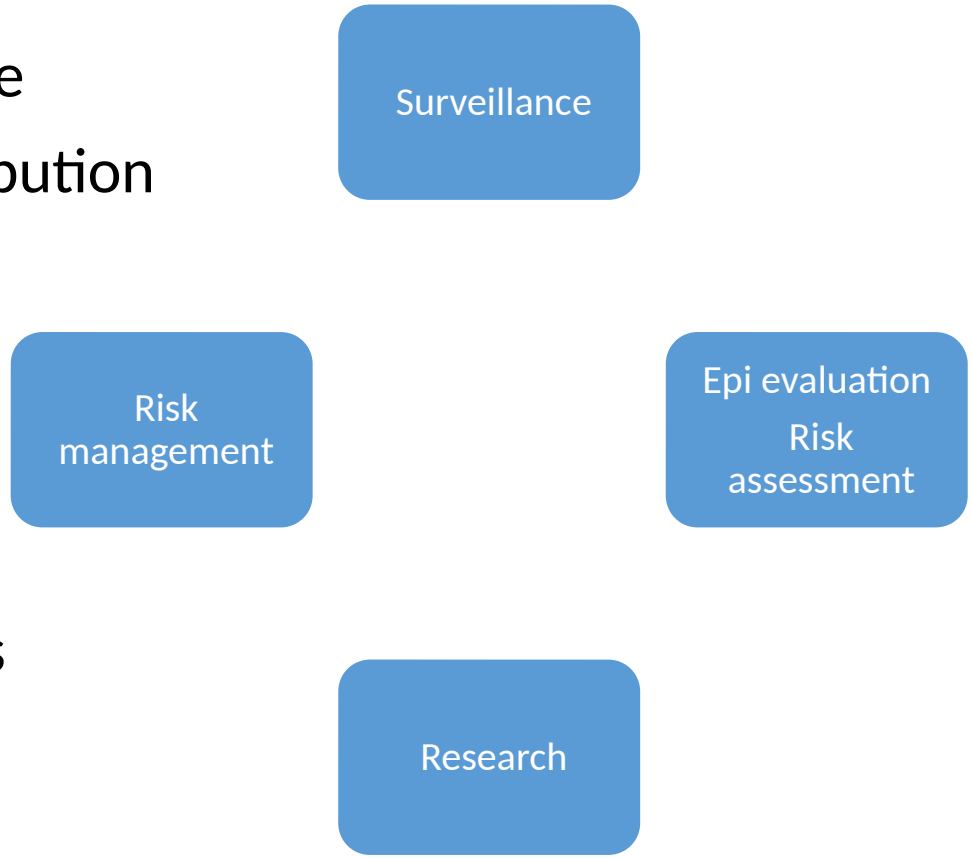
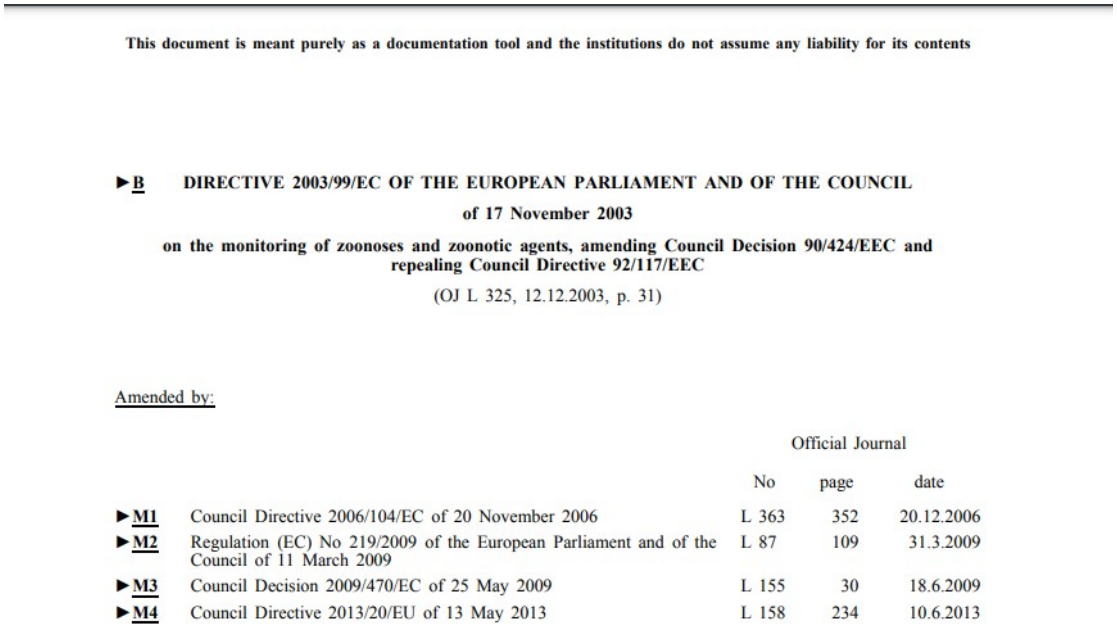
AMR monitoring - why?

- To identify the appearance and understanding of distribution AMR
- Provide data, related to risk assessment
- To plan interventions and measures their effect



EU legal framework

- Basic legislation **Directive 2003/99/EC** of the European Parliament and of the council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC



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►B DIRECTIVE 2003/99/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 17 November 2003

on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC

(OJ L 325, 12.12.2003, p. 31)

Amended by:

		Official Journal		
		No	page	date
►M1	Council Directive 2006/104/EC of 20 November 2006	L 363	352	20.12.2006
►M2	Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009	L 87	109	31.3.2009
►M3	Council Decision 2009/470/EC of 25 May 2009	L 155	30	18.6.2009
►M4	Council Directive 2013/20/EU of 13 May 2013	L 158	234	10.6.2013

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Directive 2003/99

- The purpose of this Directive is to ensure that zoonoses, zoonotic agents and related antimicrobial resistance are properly monitored, and that food-borne outbreaks receive proper epidemiological investigation, to enable the collection in the Community of the information necessary to evaluate relevant trends and sources.
- 2. This Directive covers:
- (a) the monitoring of zoonoses and zoonotic agents;
- (b) the monitoring of related antimicrobial resistance;
- (c) the epidemiological investigation of food-borne outbreaks; and
- (d) the exchange of information related to zoonoses and zoonotic agents

Directive 2003/99

- Member States shall ensure that data on the occurrence of zoonoses and zoonotic agents and **antimicrobial resistance** related thereto are collected, analysed and published without delay in accordance with the requirements of this Directive and of any provisions adopted pursuant to it.
- Designated Competent authority and cooperate with CA for:
  - on animal health;
  - on feed;
  - on food hygiene;
  - the structures and/or authorities referred to in Article 1 of Decision No 2119/98/EC;
  - other authorities and organisations concerned.

Directive 2003/99

- Member States shall ensure, in accordance with the requirements set out in Annex II, that monitoring provides comparable data on the occurrence of antimicrobial resistance in zoonotic agents and, in so far as they present a threat to public health, other agents.
- Such monitoring shall supplement the monitoring of human isolates conducted in accordance with Decision No 2119/98/EC.
- The Member States shall assess trends and sources of zoonoses, zoonotic agents and antimicrobial resistance in their territory
- Each Member State shall transmit to the Commission every year by the end of May, a report on trends and sources of zoonoses, zoonotic agents and antimicrobial resistance, covering the data collected and any summaries of them, shall be made publicly available.

Directive 2003/99

- General requirements
- Member States must ensure that the monitoring system for antimicrobial resistance provided for in Article 7 provides at least the following information:
- animal species included in monitoring;
- bacterial species and/or strains included in monitoring;
- sampling strategy used in monitoring;
- antimicrobials included in monitoring;
- laboratory methodology used for the detection of resistance;
- laboratory methodology used for the identification of microbial isolates;
- methods used for the collection of the data.

Directive 2003/99

- Reporting
- Initially, the following must be described for each zoonosis and zoonotic agent (later only changes have to be reported):
  - monitoring systems (sampling strategies, frequency of sampling, kind of specimen, case definition, diagnostic methods used);
  - vaccination policy and other preventive actions;
  - control mechanism and, where relevant, programs;
  - measures in case of positive findings or single cases;
  - notification systems in place;
  - history of the disease and/or infection in the country.

Directive 2003/99

- Reporting
- Each year the following must be described:
  - relevant susceptible animal population (together with the date the figures relate to):
    - number of herds or flocks,
    - total number of animals, and
    - where relevant, methods of production involved;
  - number and general description of the laboratories and institutions involved in monitoring.

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Directive 2003/99

- Reporting
- Each year the following details on each zoonotic agent and data category concerned must be described with their consequences:
  - changes in the systems already described;
  - changes in previously described methods;
  - results of the investigations and of further typing or other method of characterisation in laboratories (for each category reported on separately);
  - national evaluation of the recent situation, the trend and the sources of infection;
  - relevance as zoonotic disease;
  - relevance to human cases, as a source of human infection, of findings in animals and food;
  - control strategies recognised that could be used to prevent or minimise transmission of the zoonotic agent to humans;
  - if necessary, any specific action decided in the Member State or suggested for the Community as a whole on the basis of the recent situation.

Directive 2003/99

- Reporting
- Reporting of results of examinations

Results shall be given by stating the number of epidemiological units investigated (flocks, herds, samples, batches) and the number of positive samples according to the case definition. The results shall, when necessary, be presented in a way which shows the geographical distribution of the zoonosis or the zoonotic agent.

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Directive 2003/99

- Specific requirements
- Member States must ensure that the monitoring system provides relevant information at least with regard to a representative number of isolates of *Salmonella spp*., *Campylobacter jejuni* and *Campylobacter coli* from cattle, pigs and poultry and food of animal origin derived from those species

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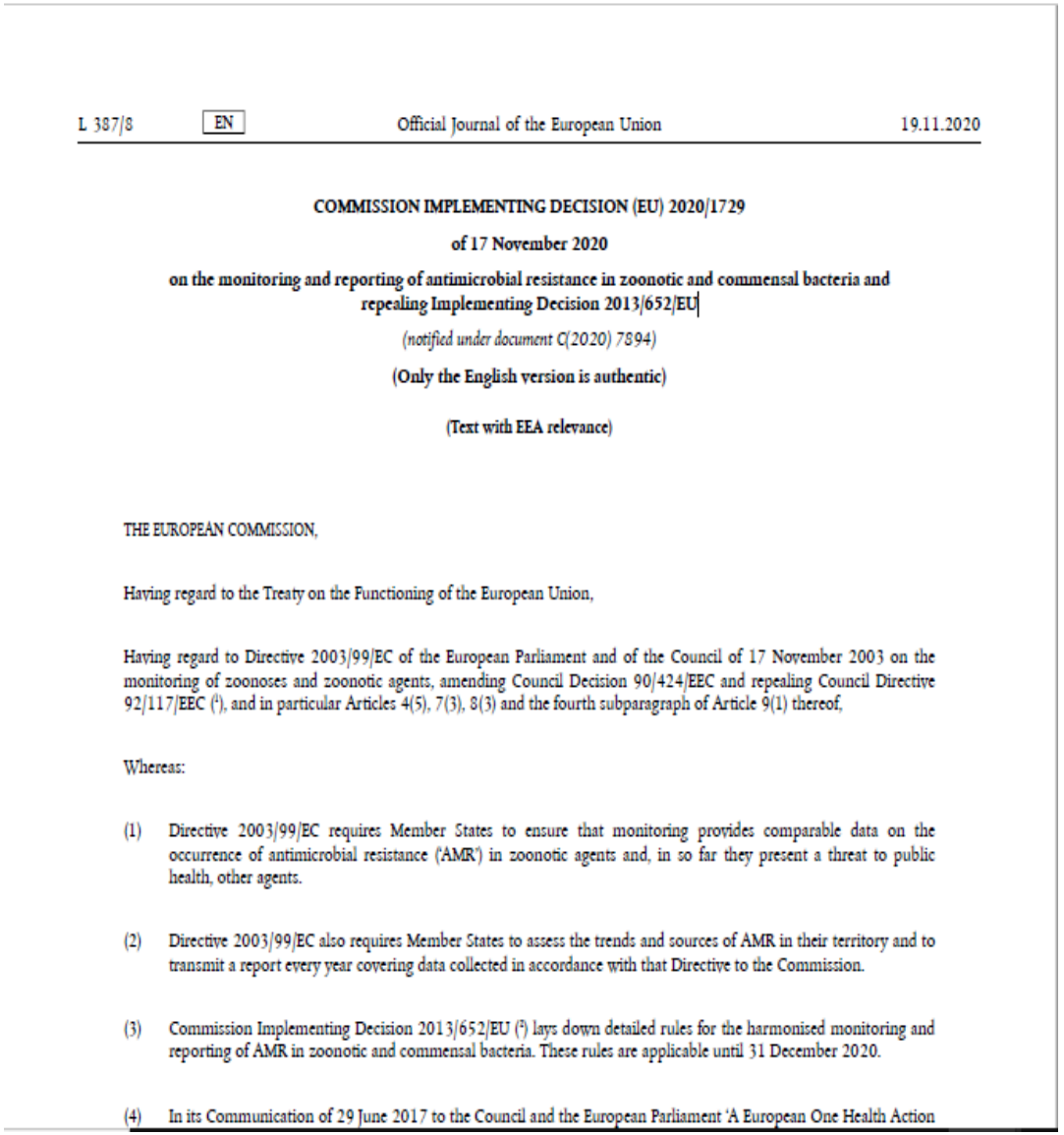
Other legislation

- **Regulation (EU) 2019/6** of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC
- **Regulation (EU) 2019/4** of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of **medicated feed**, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC
- **Regulation** (EU) 2021/578 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council with regard to requirements for the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals
- **Regulation** (EU) 2022/209 establishes the format of the data to be collected and reported in order to determine the volume of sales and the use of antimicrobial medicinal products in animals in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council
- **Regulation** (EU) 2021/16 laying down the necessary measures and practical arrangements for the Union database on veterinary medicinal products (Union product database)

Legislation for surveillance

- COMMISSION IMPLEMENTING DECISION (EU) 2020/1729 of 17 November 2020 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria and repealing Implementing Decision 2013/652/EU



L 387/8 EN Official Journal of the European Union 19.11.2020

COMMISSION IMPLEMENTING DECISION (EU) 2020/1729

of 17 November 2020

on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria and repealing Implementing Decision 2013/652/EU

(notified under document C(2020) 7894)

(Only the English version is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (1), and in particular Articles 4(5), 7(3), 8(3) and the fourth subparagraph of Article 9(1) thereof,

Whereas:

(1) Directive 2003/99/EC requires Member States to ensure that monitoring provides comparable data on the occurrence of antimicrobial resistance ('AMR') in zoonotic agents and, in so far they present a threat to public health, other agents.

(2) Directive 2003/99/EC also requires Member States to assess the trends and sources of AMR in their territory and to transmit a report every year covering data collected in accordance with that Directive to the Commission.

(3) Commission Implementing Decision 2013/652/EU (2) lays down detailed rules for the harmonised monitoring and reporting of AMR in zoonotic and commensal bacteria. These rules are applicable until 31 December 2020.

(4) In its Communication of 29 June 2017 to the Council and the European Parliament 'A European One Health Action

Article 1 - Subject matter and scope

- This Decision lays down harmonized rules for the period **2021-2027** for the monitoring and reporting of antimicrobial resistance ('AMR') to be carried out by Member States in accordance with Article 7(3) and 9(1) of **Directive 2003/99/EC** and Annex II (B) and Annex IV thereto.
- The monitoring and reporting of AMR shall cover the following bacteria:
  - (a) *Salmonella spp*.;
  - (b) *Campylobacter coli* (*C. coli*);
  - (c) *Campylobacter jejuni* (*C. jejuni*);
  - (d) Indicator commensal *Escherichia coli* (*E. coli*);
  - (e) *Salmonella spp*. and *E. coli* producing the following enzymes:
    - (i) Extended Spectrum β-Lactamases (ESBL);
    - (ii) AmpC β-Lactamases (AmpC);
    - (iii) Carbapenemases (CP).
- The monitoring and reporting of AMR may cover indicator commensal *Enterococcus faecalis* (*E. faecalis*) and *Enterococcus faecium* (*E. faecium*).

Article 1 - Subject matter and scope

- The monitoring and reporting of AMR shall cover the following food-producing animal populations and food:
  - (a) broilers;
  - (b) laying hens;
  - (c) fattening turkeys;
  - (d) bovine animals under one year of age;
  - (e) fattening pigs;
  - (f) fresh meat from broilers;
  - (g) fresh meat from turkeys;
  - (h) fresh meat from pigs;
  - (i) fresh meat from bovine animals.
- Member States shall monitor and report AMR in specific combinations of bacteria/antimicrobial substances/food-producing animal populations and fresh meat derived thereof in accordance with Articles 3 and 4.

Annex to Decision (EU) 2020/1729

- Part A
  - Sampling framework and analysis
  - Sampling frequency
  - Sampling design and sample size
  - Antimicrobial testing

- Part B
  - Reporting

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Annex to Decision (EU) 2020/1729

- Part A
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- Part B
  - Reporting

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Decision 2020/1729/EC

Who conducts the testing?

National Reference Laboratory (NRL) and other designated laboratories

- "Slaughter batch" means a group of animals originating from the same herd, raised together in the same conditions and sent to the slaughterhouse on the same day
- "Batch" means a group or set of identifiable products obtained under practically identical conditions using a given process and produced in a specific location during a specific production period

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Decision 2020/1729/EC

Salmonella spp. isolates obtained from:

- samples of each population of laying hens, broilers and fattening turkeys taken in the framework of the national control for control of salmonella;
- samples of caecal content taken at slaughter from fattening pigs, except for Member States implementing a national program for the control of salmonella which has been approved at EU level;
- samples of caecal content taken at slaughter from bovine animals under one year of age where the national production of meat of those bovine animals is more than 10 000 tons per year;
- samples of fresh meat of broilers and turkeys taken at the border control posts.

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Decision 2020/1729/EC

C. coli and *C. jejuni* isolates obtained from

- samples of caecal content taken at slaughter from broilers;
- samples of caecal content taken at slaughter from fattening turkeys where the national production of turkey meat is more than 10 000 tons per year;
- samples of caecal content taken at slaughter from bovine animals under one year of age where the national production of meat of those bovine animals is more than 10 000 tons per year;
- samples of caecal content taken at slaughter from fattening pigs.

Decision 2020/1729/EC

Indicator commensal *E. coli* isolates obtained from:

- samples of caecal content taken at slaughter from broilers;
- samples of caecal content taken at slaughter from fattening turkeys where the national production of turkey meat is more than 10 000 tons per year;
- samples of caecal content taken at slaughter from fattening pigs;
- samples of caecal content taken at slaughter from bovine animals under one year of age where the national production of meat of those bovine animals is more than 10 000 tons per year;
- samples of fresh meat of broilers, turkeys, pigs and bovine animals taken at the border control posts.

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Decision 2020/1729/EC

(d) ESBL- or AmpC- or CP-producing E. coli isolates obtained from:

- samples of caecal content taken at slaughter from broilers;
- samples of caecal content taken at slaughter from fattening turkeys where the national production of turkey meat is more than 10 000 tons per year;
- samples of caecal content taken at slaughter from fattening pigs;
- samples of caecal content taken at slaughter from bovine animals under one year of age where the national production of meat of those bovine animals is more than 10 000 tons per year;
- samples of fresh meat of broilers, turkeys, pigs and bovine animals taken at retail;
- samples of fresh meat of broilers, turkeys, pigs and bovine animals taken at the border control posts.

Decision 2020/1729/EC

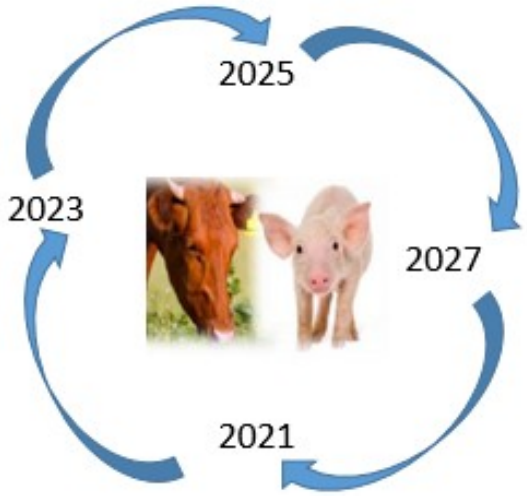
Where a Member State decides to monitor indicator commensal *E. faecalis* and *E. faecium* in accordance with Article 1(3), isolates of these bacteria obtained from:

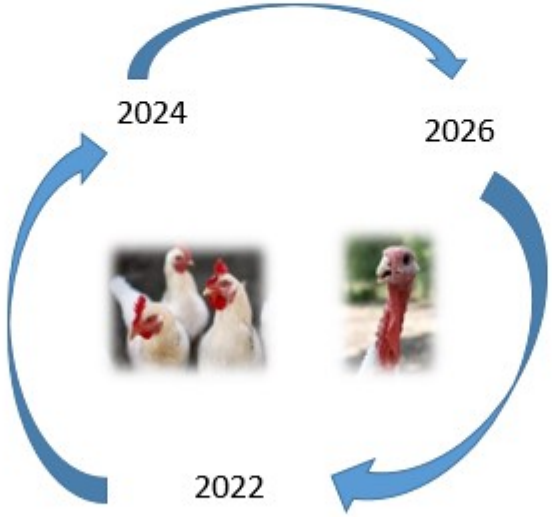
- samples of caecal content taken at slaughter from broilers;
- samples of caecal content taken at slaughter from fattening turkeys where the national production of turkey meat is more than 10 000 tons per year;
- samples of caecal content taken at slaughter from fattening pigs;
- samples of caecal content taken at slaughter from bovine animals under one year of age where the national production of meat of those bovine animals is more than 10 000 tons per year.

Decision 2020/1729/EC

In the years 2021, 2023, 2025 and 2027: AMR monitoring shall be carried out in fattening pigs, bovine animals under one year of age, pig meat and bovine meat.

In the years 2022, 2024 and 2026: AMR monitoring shall be carried out in laying hens, broilers, fattening turkeys and fresh meat derived from broilers and turkeys.





Decision 2020/1729/EC

Sampling design and sample size

- At slaughterhouse level
- Sample design
  - EFSA technical specifications on randomised sampling for harmonised monitoring of antimicrobial resistance in zoonotic and commensal bacteria
  - proportionate stratified sampling of samples of caecal content in slaughterhouses processing at least 60 % of the specific domestic animal population
  - Distribution over the monitoring period
  - Randomisation of sampling days for each month
  - Epidemiological unit for broilers and fattening turkeys is the flock
  - The epidemiological unit for fattening pigs and bovine animals under one year of age is the slaughter batch
  - Only one sample from the same epidemiological unit shall be taken per year
  - sample shall be taken from one carcass (10 carcasses for poultry) randomly selected from the epidemiological unit.

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Decision 2020/1729/EC

Sampling design and sample size

- At slaughterhouse level
- <u>Sampling size:</u>
  - At least 300
  - Reduced to 150 (repenting on the annual production)

Decision 2020/1729/EC

Sampling design and sample size

- At retail level
- Sample design
  - EFSA technical specifications on randomised sampling for harmonised monitoring of antimicrobial resistance in zoonotic and commensal bacteria
  - proportional allocation of the number of samples to the population of the geographical region
  - even distribution over the monitoring year
  - randomization of the sampling days of each month
  - batches to be sampled on a given day shall be randomly selected
- Sample size:
  - 300
  - Reduced to 150 (repenting on the annual production)

Decision 2020/1729/EC

Sampling design and sample size

- At the border control post
- Sample design
  - EFSA technical specifications on randomised sampling for harmonised monitoring of antimicrobial resistance in zoonotic and commensal bacteria
  - country of origin with an even distribution over the monitoring year of the consignments of imported fresh meat
  - all border control posts designated for fresh meat
  - batches to be sampled on a given day shall be randomly selected
  - If a consignment is composed of different batches, the samples shall be taken from different batches
  - samples shall not be pooled.

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Sampling design and sample size

- At the border control post
- Sample size

Type of fresh meat	Recommended annual sampling frequency rates of consignments arrived at the border control posts
Broiler meat	3 %
Turkey meat	15 %
Pig meat	10 %
Bovine meat	2 %

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Decision 2020/1729/EC

Antimicrobial susceptibility testing

- Number of isolates to be tested
- For *Salmonella spp*:
  - Up to 170 isolates
  - 85 reduction depending on the production
  - when the number of isolates yearly available is lower than the upper limit, all of them shall be tested

Decision 2020/1729/EC

Antimicrobial susceptibility testing

- Number of isolates to be tested
- For *C. coli* and *C. jejuni*:
  - Up to 170 isolates
  - 85 reduction depending on the production
  - geographical representativeness and, where possible, an even distribution of the date of sampling over the year
  - when the number of isolates yearly available is lower than the upper limit, all of them shall be tested

Decision 2020/1729/EC

Antimicrobial susceptibility testing

- Number of isolates to be tested
- For indicator commensal *E. coli*:
  - Up to 170 isolates
  - 85 reduction depending on the production
  - when the number of isolates yearly available is lower than the upper limit, all of them shall be tested
- For ESBL-, AmpC- and CP- producing *E. coli*:
  - all isolates obtained from samples referred to in point

Decision 2020/1729/EC

Antimicrobial susceptibility testing

- Analytical methods for detection and antimicrobial susceptibility testing
  - epidemiological cut-off values and the concentration ranges set out in Decision to determine the antimicrobial susceptibility of *Salmonella spp*., *C. coli*, *C. jejuni*, indicator commensal *E. coli*, *E. faecalis* and *E. faecium*.
  - *E. coli* and *Salmonella* isolate showing resistance to cefotaxime or ceftazidime or meropenem with first panel shall be further tested with a second panel of antimicrobial substances in accordance with Decision
  - Specific monitoring of ESBL- or AmpC- or CP-producing *E. coli*
  - broth micro dilution method according to the reference method ISO 20776-1:2019
  - Alternative method, - Member States may decide to authorise the use of Whole Genome Sequencing (‘WGS’) as an alternative method to broth micro dilution

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Reporting

- information for each individual isolate
- data dictionary and the electronic collection forms provided by EFSA
- sampling designs, stratification and randomisation procedures per animal populations and food categories
- Depending on the test
  - using antimicrobial susceptibility testing
  - using WGS

Decision 2020/1729/EC

Reporting antimicrobial susceptibility testing results

- Unique identifier or code of the isolate
- Bacterial species
- Serovar (for *Salmonella spp*.)
- Food-producing animal population or food category
- Stage of sampling
- Type of sample
- Trade Control and Expert System (TRACES) code of the border control post (for testing of imported meat only)
- Common Health Entry Document (CHED) reference of the consignment (for testing of imported meat only)
- Country of origin of the consignment (for testing of imported meat only)
- Sampler
- The sampling strategy

Decision 2020/1729/EC

Reporting antimicrobial susceptibility testing results

- Date of sampling
- Date of start of analysis (isolation)
- Identifier or code of the isolate given by the laboratory performing the antimicrobial susceptibility testing of the isolate
- Date of susceptibility testing
- Antimicrobial substance
- Minimum Inhibitory Concentration (MIC) value (in mg/L)
- Synergy testing with clavulanic acid for ceftazidime
- Synergy testing with clavulanic acid for cefotaxime

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Decision 2020/1729/EC

Reporting WGS testing results

- Unique identifier or code of the isolate
- Bacterial species
- Food-producing animal population or food category
- Stage of sampling
- Type of sample
- TRACES code of the border control post (for testing of imported meat only)
- CHED reference of the consignment (for testing of imported meat only)
- Country of origin of the consignment (for testing of imported meat only)
- Sampler
- The sampling strategy

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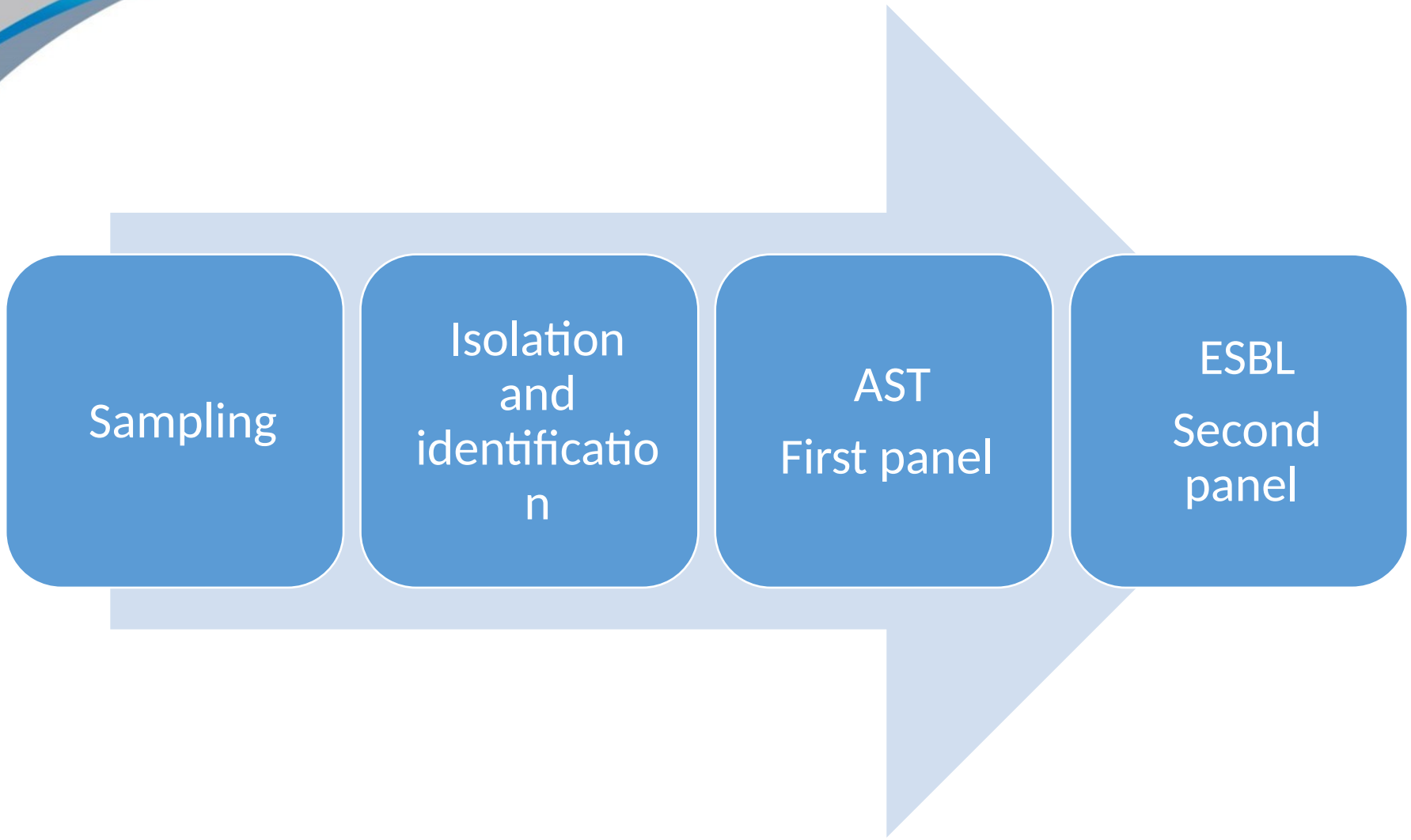
Decision 2020/1729/EC

Reporting WGS testing results

- Date of sampling
- Date of start of analysis (isolation)
- Identifier or code of the isolate given by the laboratory
- Date of sequencing
- Version of the predictive tool
- AMR-conferring genes data
- Sequencing technology used
- Library preparation used

Summarized


Sampling
Isolation and identification
AST
First panel
ESBL
Second panel

CONTACT

Project e-mail: foodsafetyprojectTCc@gmail.com

THANK YOU FOR YOUR ATTENTION

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