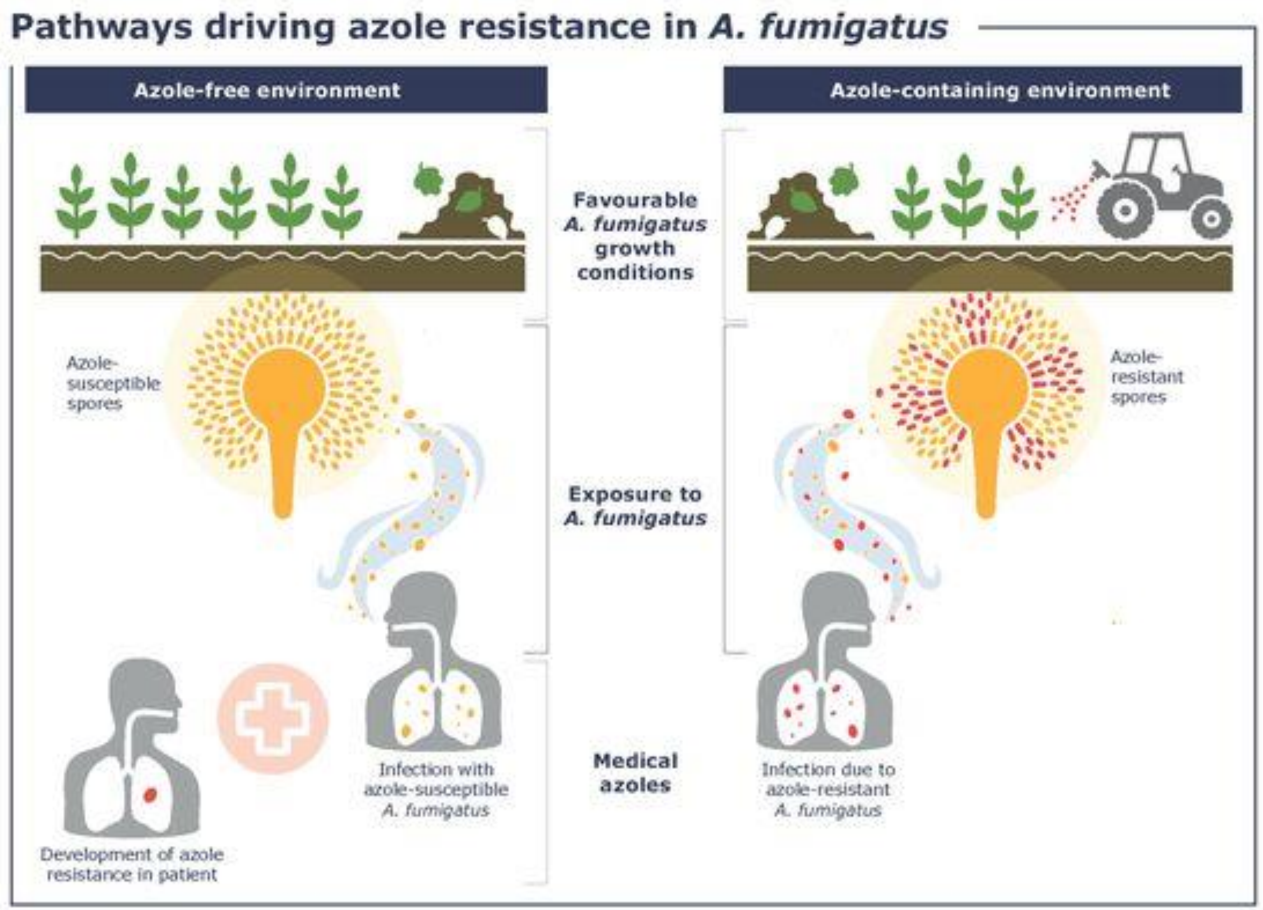
ONE HEALTH INTERAGENCY REPORT ON AZOLE RESISTANCE IN *ASPERGILLUS* SPP.

BACKGROUND

Azoles are broad-spectrum antifungals:

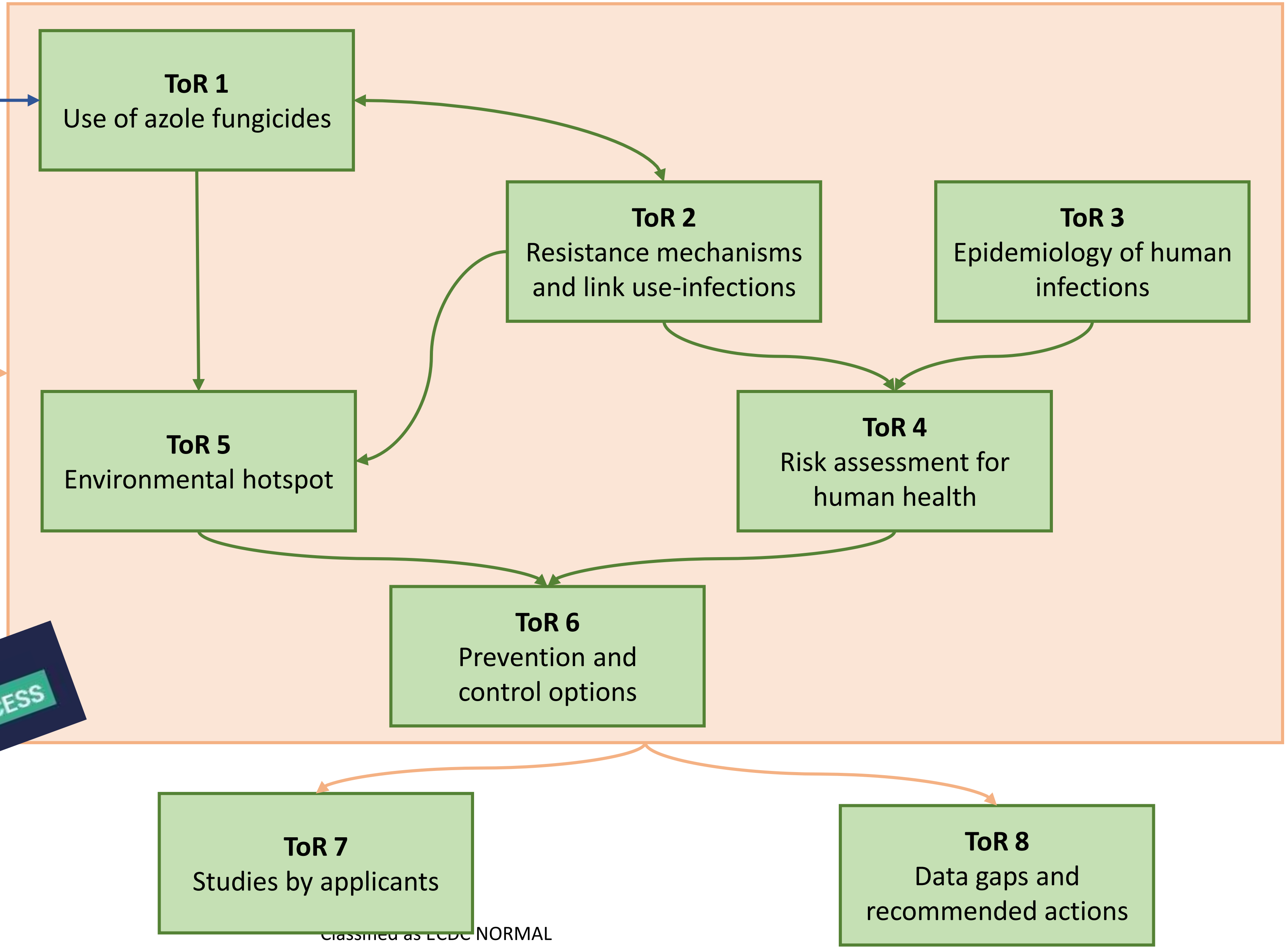
- Human medicinal products
- Veterinary medicinal products (VMPs)
- Plant protection products (PPPs) — EFSA
- Biocidal products (BPs) — ECHA
- Industrial chemicals — ECHA



https://www.youtube.com/watch?v=-mlGuNbN_ss

Classified as ECDC NORMAL

TERMS OF REFERENCE



RESISTANCE AND PUBLIC HEALTH

- Azole resistance in *A. fumigatus* high in Europe:

	Invasive aspergillosis	Chronic pulmonary aspergillosis	Allergic bronchopulmonary aspergillosis
Prevalence (ARAF/Af)	0.7 – 63.6%	5.9 – 59.2 %	0.7 – 63.6 %
Mortality	36-100%	less documented	

- Substantial evidence supports a **link between azole fungicide exposure in the environment and cross resistance selection to medical azoles** in *Aspergillus* species

- Evidence supports hypothesis that transmission of ARAf occurs **from the environment to humans**

- **Azole usage outside the human domain is likely or very likely to contribute** to the selection of ARAf isolates that could cause severe disease such as IA, but the extent of this contribution needs to be better understood

USE OF AZOLE FUNGICIDES

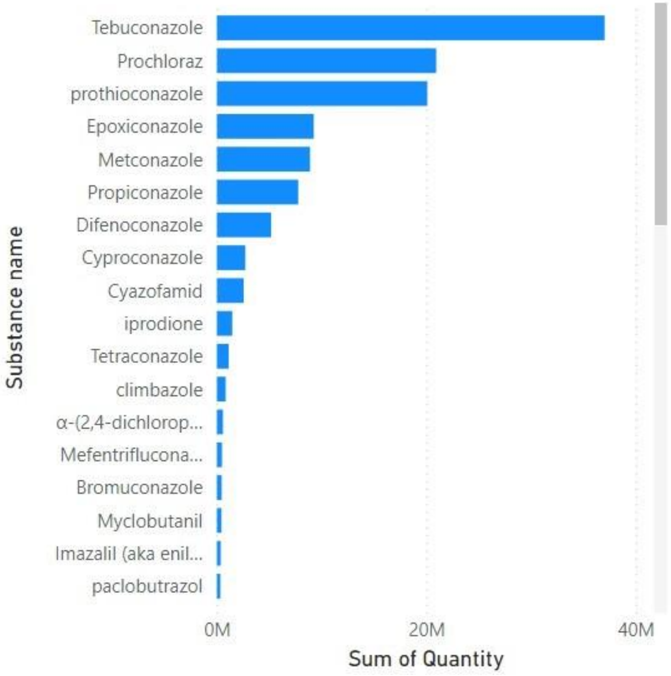
- Overall 2010-2021

- Total 120,000 tonnes
- PPPs 119,000 tonnes

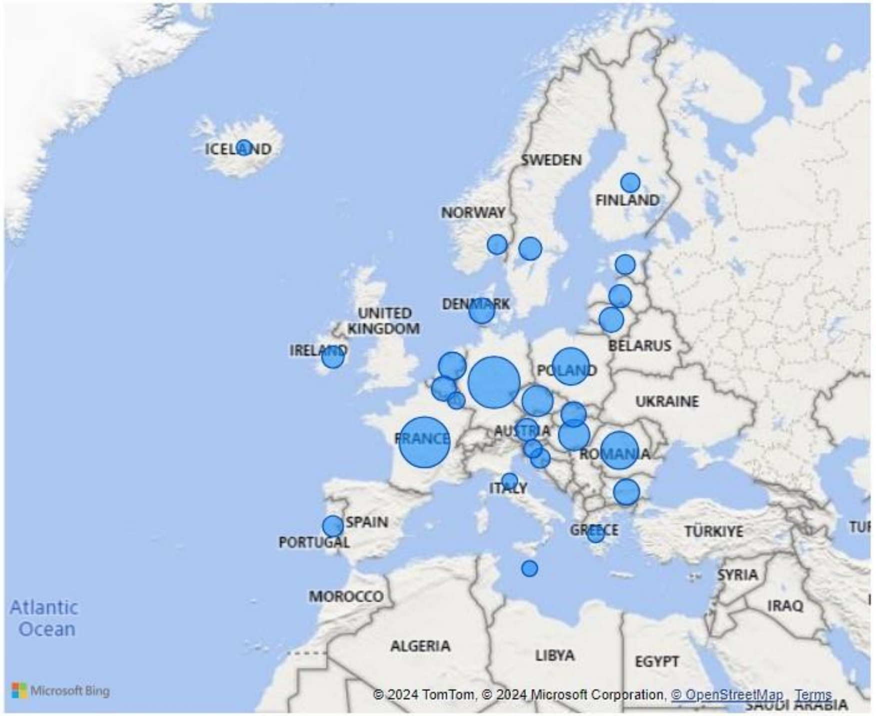
- Only indicative, please note data limitations

Sum of Quantity by Legislation

Sum of Quantity by Substance name

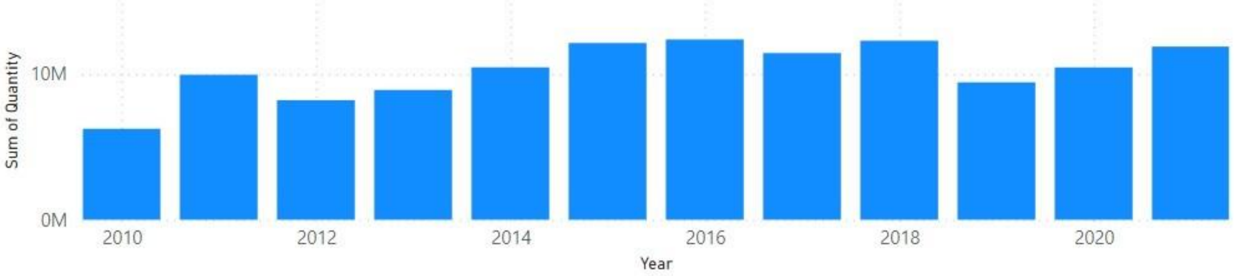


Sum of Quantity by Country



Sum of Quantity by Country

Sum of Quantity by Year



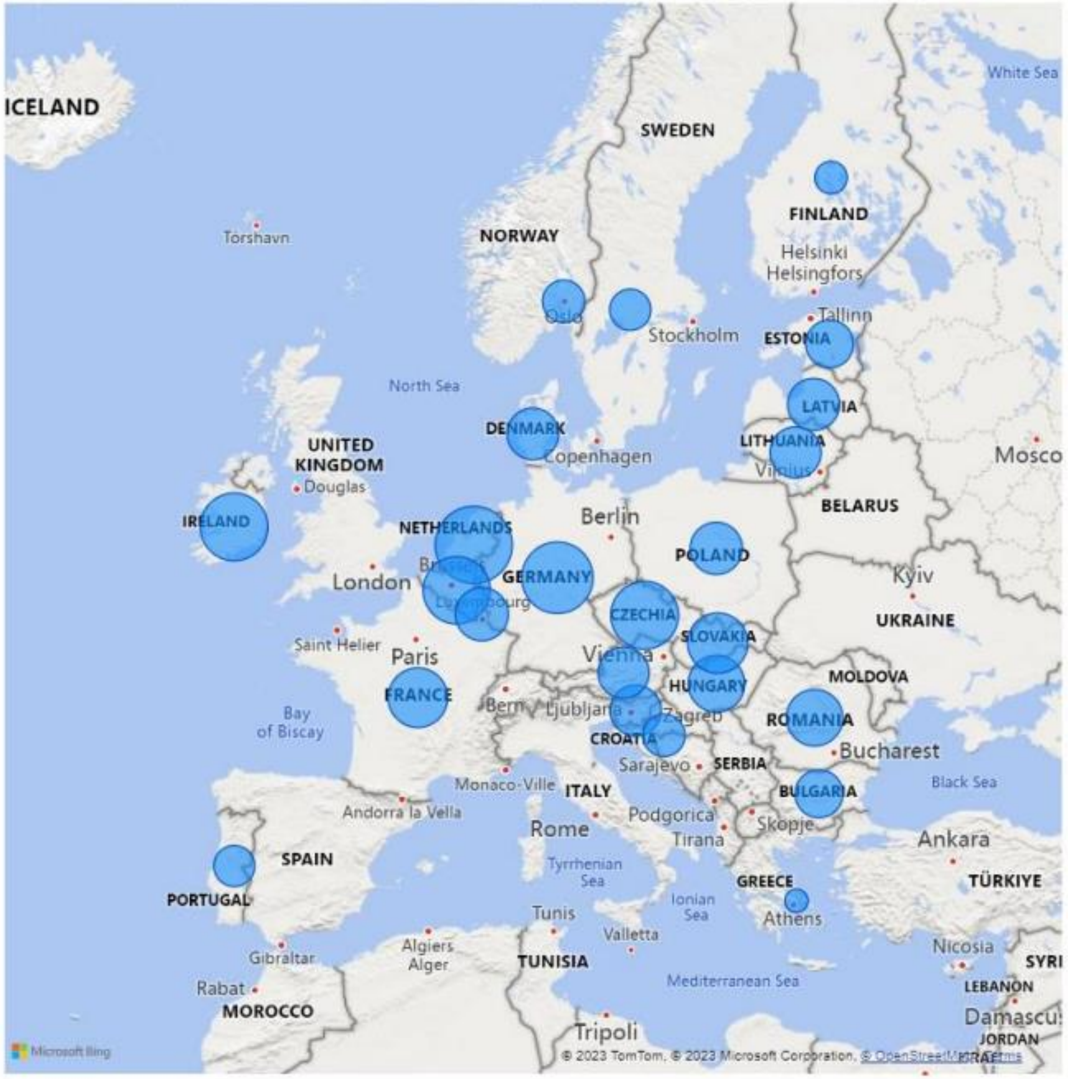
Classified as ECDC NORMAL

USE OF AZOLE FUNGICIDES

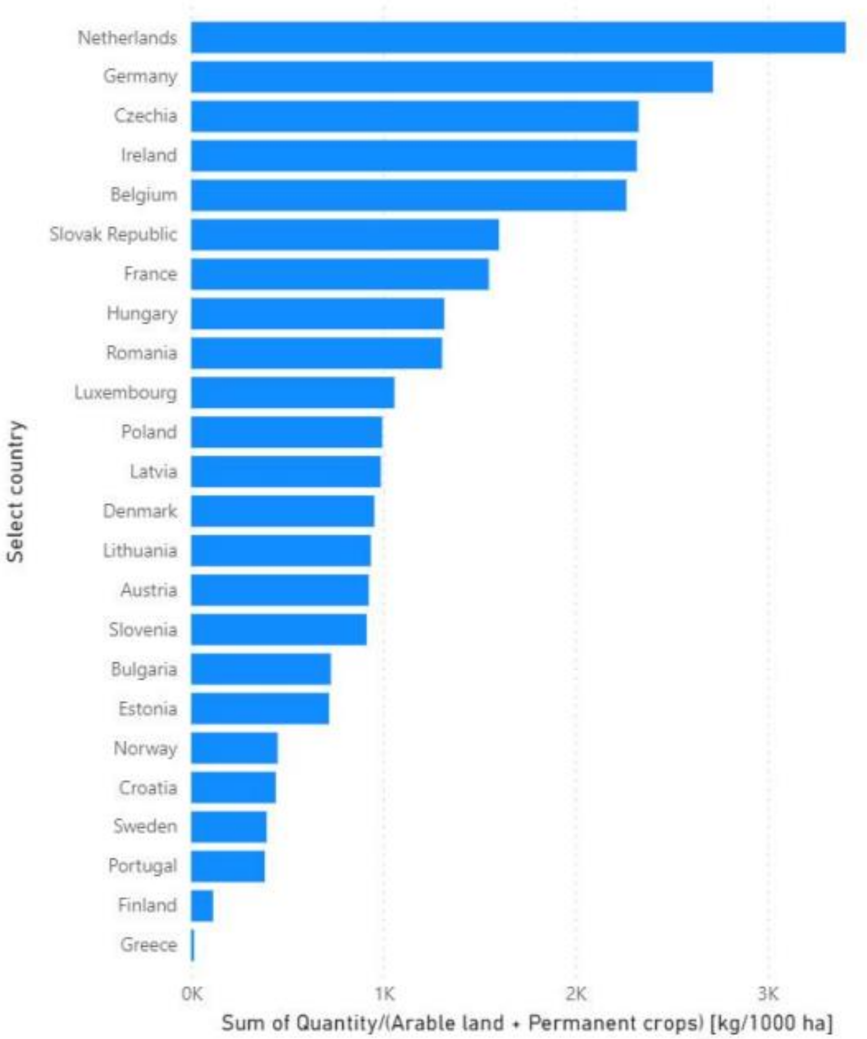
Plant Protection Products

- PPP normalised by arable land and permanent crops
- Not possible for other regulatory frameworks

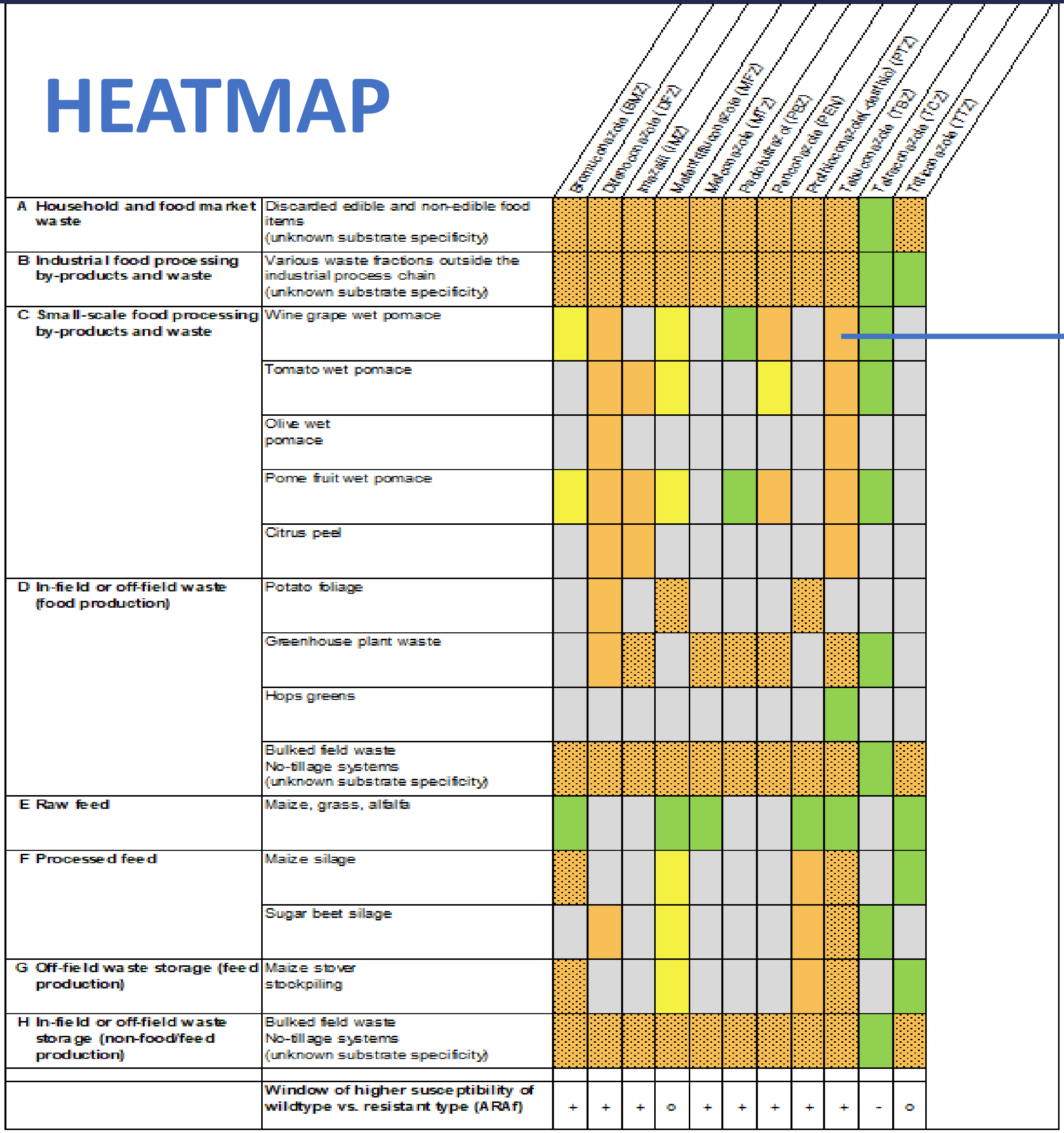
Sum of Quantity/(Arable land + Permanent crops) [kg/1000 ha] by Select country



Sum of Quantity/(Arable land + Permanent crops) [kg/1000 ha] by Select country



ENVIRONMENTAL HOTSPOTS



No risk	No authorisation
Low risk potential	Authorisation AND residues not exceeding PNEC_AF100 OR non-relevant by default
Moderate risk potential	Authorisation AND residues exceeding PNEC_AF100, but not exceeding PNEC_AF10
High risk potential	Authorisation AND residues exceeding PNEC_AF10
Non-negligible risk potential	Authorisation and no data on residues

Environmental hotspots identified:

PPPs

stockpiling of agricultural waste and their possible use as soil amendment or fertiliser for several agricultural crops

BPs

freshly cut wood

PREVENTION AND CONTROL (OF RESISTANCE)

Agriculture

- thoughtful use of azole fungicides
- promoting best practices for waste management and soil fertilization as well as further research

Biocides use

- optimise concentrations of azole fungicides when treating wood
- ensure proper wood waste management

Human medicine

- enhanced disease diagnostics
- surveillance
- increased awareness of this topic

Research and development

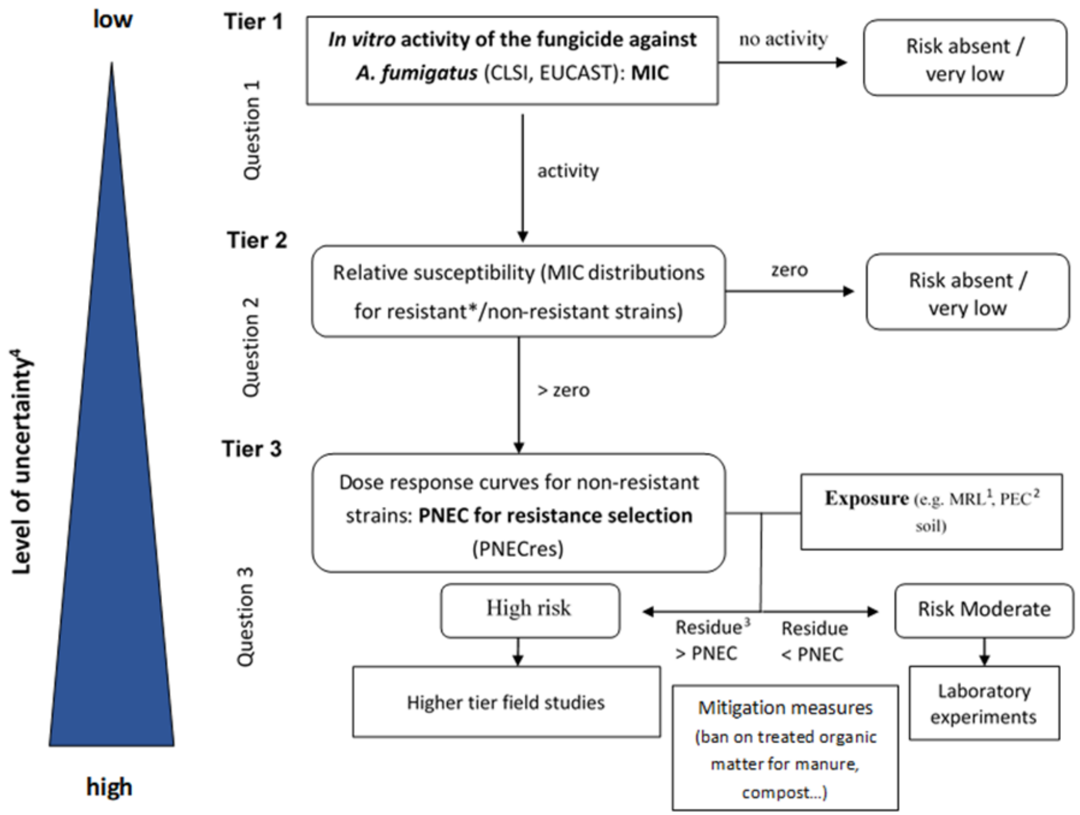
- Encouraging the development of new antifungals with novel mechanisms of action

Approval process

- assess potential for cross-resistance with antifungals used in human medicine before approving new fungicides

RISK ASSESSMENT

Proposal for a preliminary framework for risk assessment during approval procedure



Proposal of a tiered risk assessment approach:

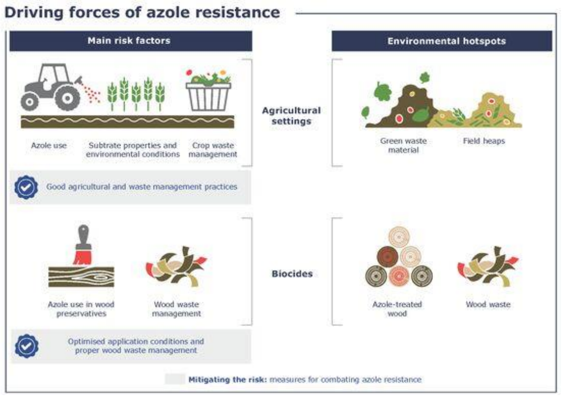
- Tier 1: Basic MIC testing to evaluate resistance risk.
- Tier 2: Examination of susceptibility between wild-type and resistant strains.
- Tier 3: Correlation of PNECres data with exposure data to evaluate higher-risk scenarios.

Emphasis on the need for continued refinement and validation of methods to enhance reliability

DATA GAPS

Areas	Possible actions to address gaps
Use of azole fungicides	Establishment of a **mandatory reporting system** at national level with the appropriate level of detail related to the substance/product used and its specific application (e.g. crop of application) **Overcoming confidentiality issues** that limit dissemination and analysis of the data collected and double reporting
Epidemiology of ARAf	Standardised prevalence studies, strengthen **genomic testing**, screening of different environments
Spread of ARAf	Investigations on **pathways for spread** including cross-border
Hazard-related data	Investigations of resistance mechanisms, effect of other substances, **combined exposure**, other ***Aspergillus*** species
Residues in the environment	Investigate **fate and persistence** in environment, levels in crops/wood waste, waters/soil, human exposure
Environmental hotspots	Investigate growth conditions in specific substrates, waste management practices, **field studies**
Risk assessment methodology	To provide technical specifications for specific studies to be submitted within approval procedures, **refine** preliminary framework for risk assessment

JOINT COMMUNICATIONS



Publication
https://www.efsa.europa.eu/en/efsajournal/pub/9200

Plain Language Summary (PLS)
https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2025.p230103

Annex A: https://zenodo.org/records/14221845
Annex E: https://zenodo.org/records/14223436
Annex F: https://zenodo.org/records/14223460

Scientific Opinion Occurrence of Carbapenemase-producing Enterobacterales in the food chain in the EU/EFTA

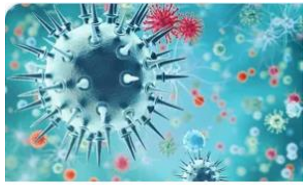
EUROPEAN FOOD SAFETY AUTHORITY

CPE IN THE FOOD CHAIN IN THE EU/EFTA. PART 1: 2025 (TOR1/3)

Self-task Mandate BIOHAZ, SO adopted 12 March 2025

Current status: Occurrence, genes, bacteria, clones, mobile genetic elements, Sources, geographical and temporal distribution

Methods in use: Detection, cgharacterization



Biological Hazards

WG Carbapenemases

Transmission dynamics: Documented transmission routes, risk factors

Contingency, mitigation plans:

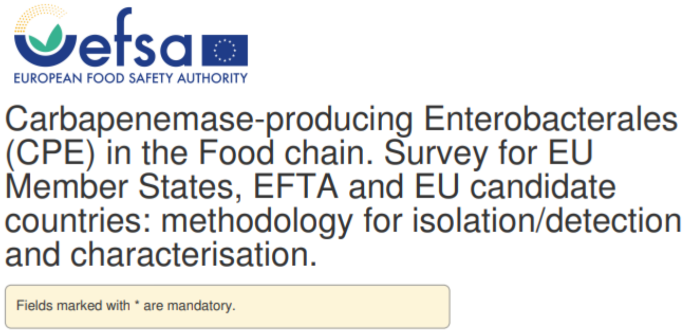
Observers:

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

European Commission

DATA AND METHODOLOGY

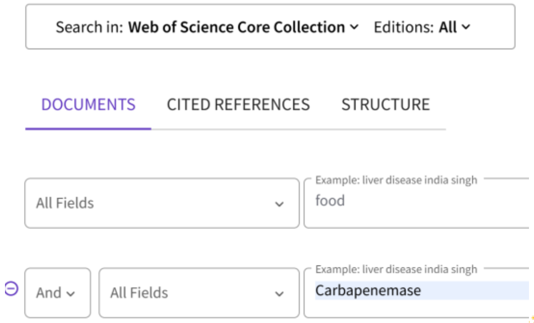
EUSurvey:



EUSR-AMR data

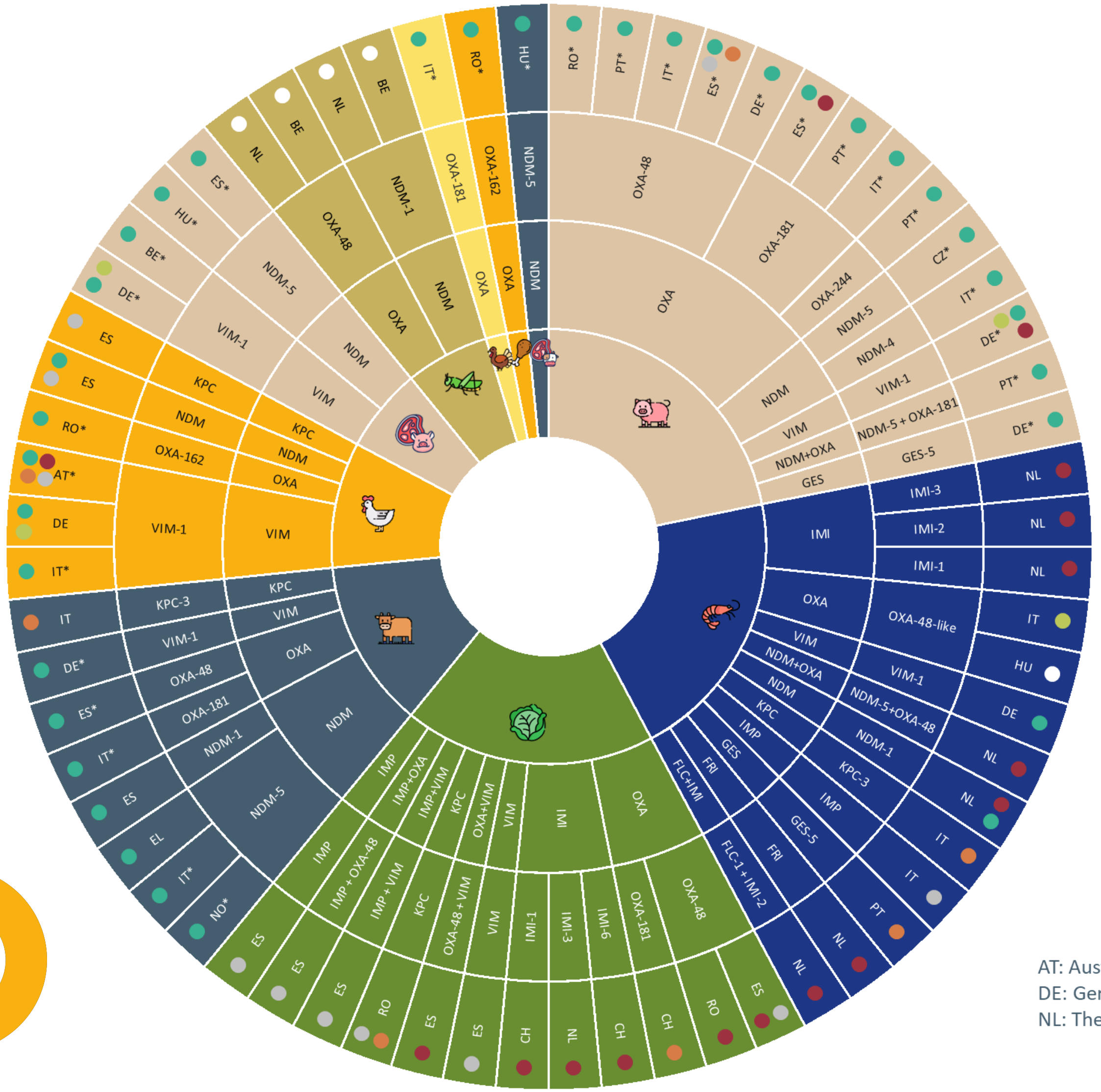
→

Lit. searches 2011-Febr. 2025



GENES, BACTERIA, CLONES, PLASMIDS

Carbapenemase-encoding genes in the food-chain in the EU/EFTA countries (2011 – 2024)



- Aquaculture, sea/freshwater food
- Bovine meat
- Bovines and/or their environment
- Broilers and/or their environment
- Chicken meat
- Ready-to-eat insects
- Pigs and/or their environment
- Pig meat
- Turkeys and/or their environment
- Foods of non-animal origin

* : Contains isolates from the EU monitoring

- *E. coli*
- *Klebsiella sp.*
- *Salmonella enterica*
- *Enterobacter sp.*
- *Other*
- *Unknown*

AT: Austria, BE: Belgium, CH: Switzerland, CZ: Czechia, DE: Germany, EL: Greece, ES: Spain, HU: Hungary, IT: Italy, NL: The Netherlands, NO: Norway, PT: Portugal, RO: Romania

Icons taken from https://www.flaticon.com

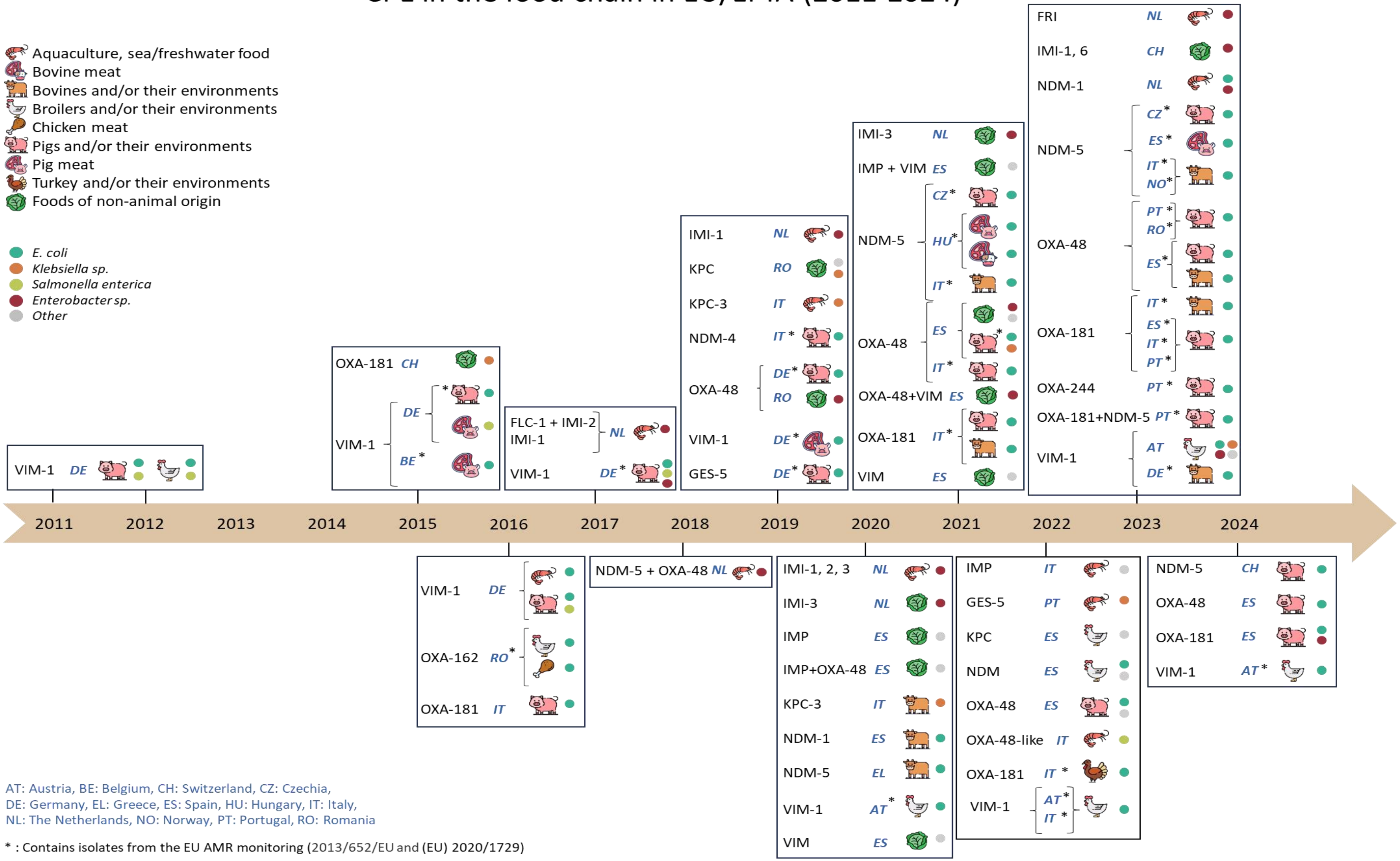
22 gene variants from 9 carbapenemase families. The most common VIM-1, OXA-48 and OXA-181, followed by NDM-5, and IMI-1.

***E. coli*: *66 different STs:* ST23-Complex, ST101-Complex ST10-Complex, ST542; Enterobacter spp. (10 STs), Klebsiella spp. (4 STs) and Salmonella enterica (2 STs).**

Frequent plasmids: IncHI2, IncC, IncX3, IncI, IncL

TEMPORAL DISTRIBUTION AND SOURCES

CPE in the food chain in EU/EFTA (2011-2024)



Icons taken from https://www.flaticon.com

Most reports from terrestrial animals, mainly from pigs, followed by bovines and poultry.

Compared to meat, more frequently detected in food derived from aquatic animals and food of non-animal origin (including imported products) exhibiting greater diversity in bacterial species and carbapenemase genes

Increase in number of reports, mainly from pigs, with a surge in

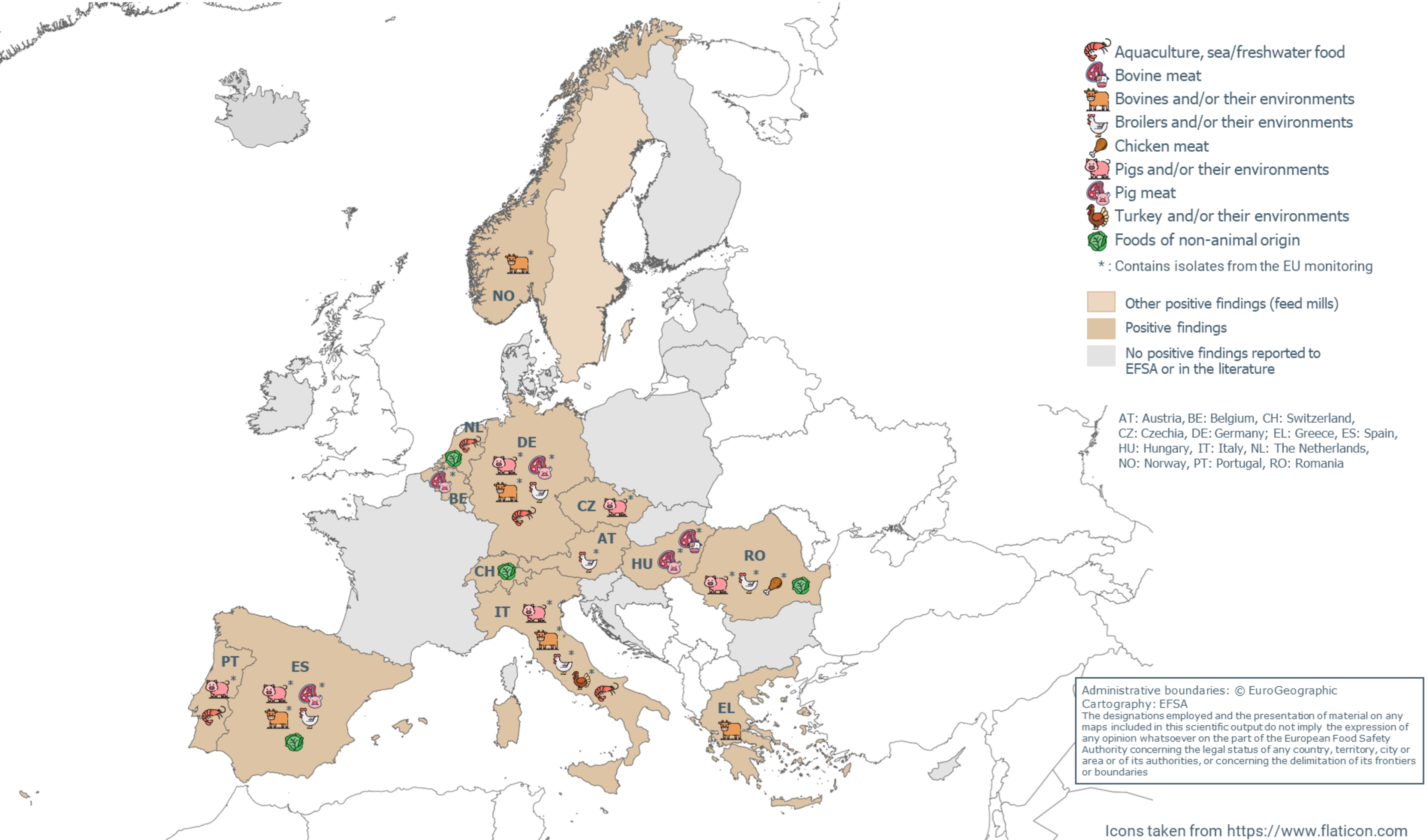
2021:
OXA-18: Italy

2023:
OXA-48: Spain

OXA-181, OXA-48, OXA-244 & *bla*NDM-5: Portugal

GEOGRAPHICAL DISTRIBUTION

CPE in the food chain in the EU/EFTA (2011-2024)

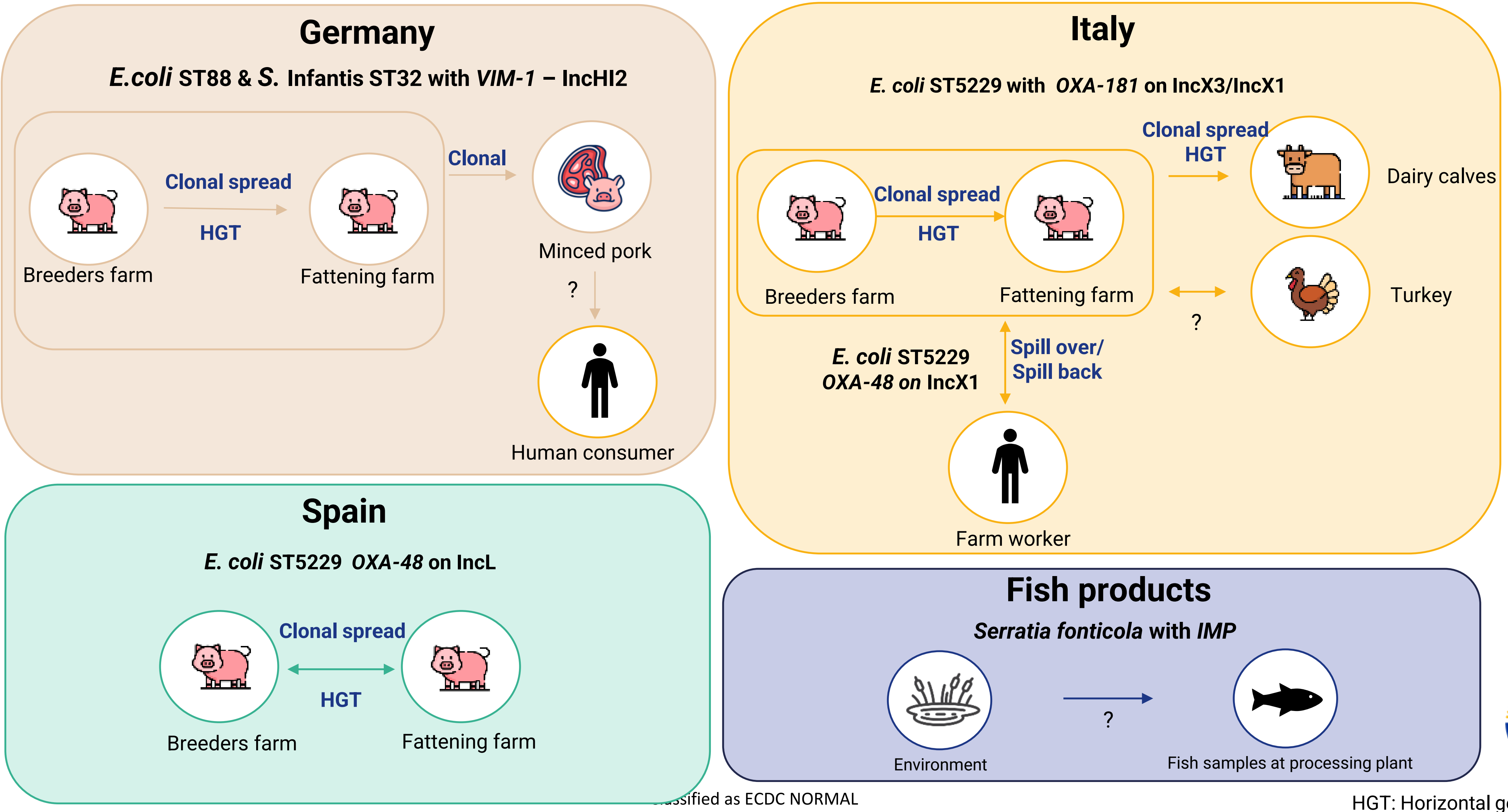


Icons taken from https://www.flaticon.com

Reported in 14 EU/EFTA countries (11 of them though the official EU monitoring)

Pig production a source across multiple countries (e.g. Germany, Italy, Czechia, Spain & Portugal)

TRANSMISSION DYNAMICS IN THE FOOD CHAIN



HGT: Horizontal gene transfer

TRANSMISSION FOOD CHAIN AND HUMANS: CIRCUMSTANTIAL EVIDENCE, FINDING OF SAME STRAINS/GENES IN BOTH THE FOOD CHAIN & IN HUMANS

Spill-over →
← Spill-back

		Food chain	Human settings
E. coli	ST5229	Pigs	Human workers
	ST10	Pig, bovine, chicken meat, seafood	Global significant NDM-5 producer in humans
	ST38	Pig, broiler, turkey	European clinical setting
	ST48	Pig	Frequent in humans
	ST101	Pig, broilers	Detected in humans
	ST410	Pig, bovine	Common carrier reservoir for NDM-5
K. pneumoniae	ST307	Milk filters	Human clinical isolate
S. Infantis	ST32	Pig farm, minced pork	? → Human consumers
Plasmids	IncL	Pigs (bovines)	Typical humans
	IncX1	Pigs	Classified as Farm workers

Escherichia coli

NDM-5, OXA-48, OXA-181, VIM-1

Klebsiella pneumoniae

KPC-3

Salmonella Infantis

VIM-1, NDM-1, OXA-48

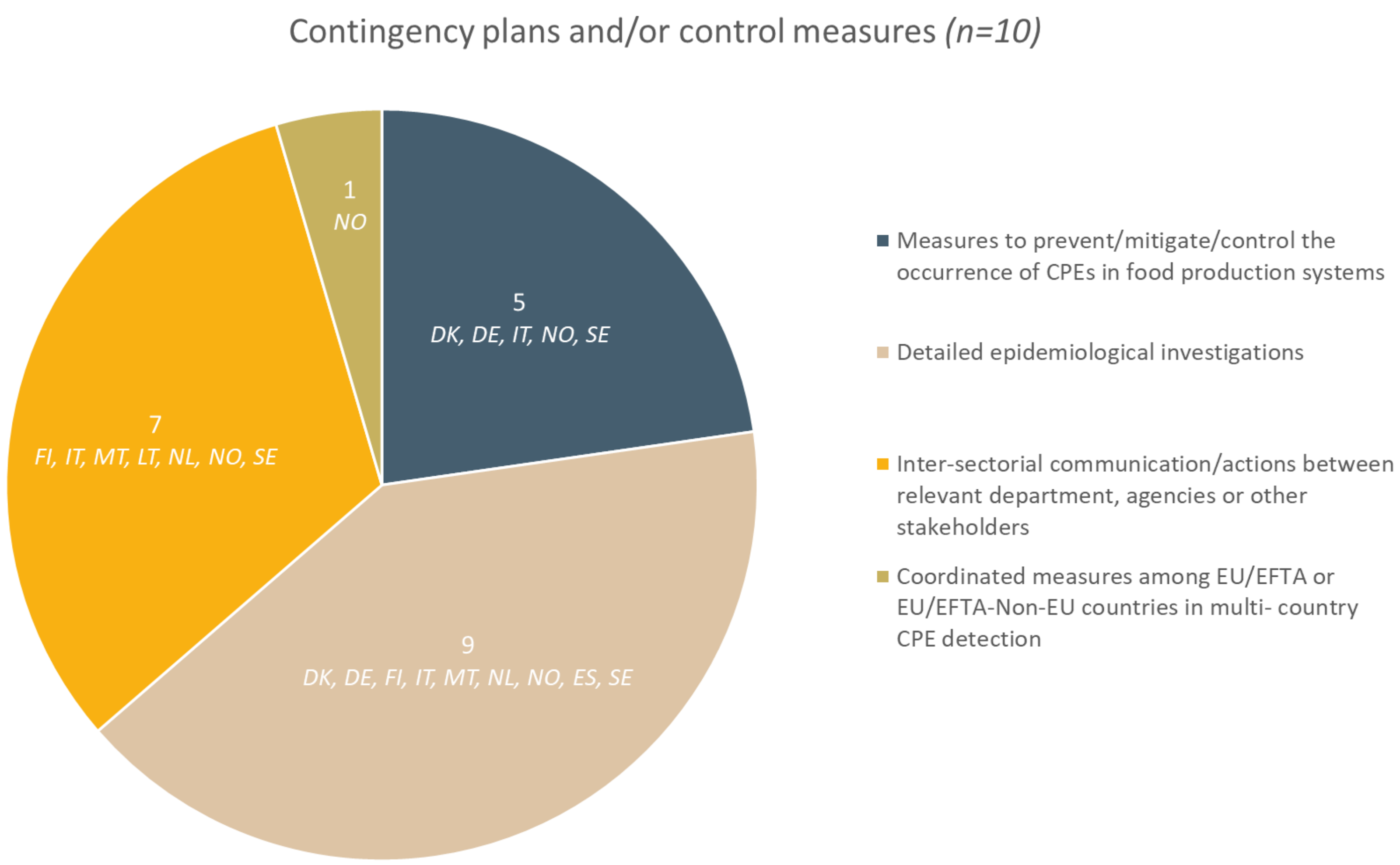
Plasmids

IncL-OXA-48 IncX1-OXA-181

DETECTION AND CHARACTERIZATION METHODS

- **No single culture-based method** allows detection of all CPE in a sample, **no culture-independent method** has been thoroughly evaluated.
- Methods used by the official labs for the EU monitoring consist of a (non-selective) pre-enrichment culture, followed by isolation on selective media. This represents a **compromise between sensitivity, specificity and costs**. These methods only target *E. coli*, and miss other clinically relevant Enterobacterales.
- Protocols to **improve the sensitivity** by using **selective enrichment and/or PCR and metagenomic approaches** to detect carbapenemase genes in enrichment cultures, followed by culture of PCR-positive enrichments, are used in some EU/EFTA countries, but have only been validated for specific situations
- At least 24 EU/EFTA countries, the official laboratories have **capacity for WGS**.

CONTINGENCY PLANS, CONTROL MEASURES

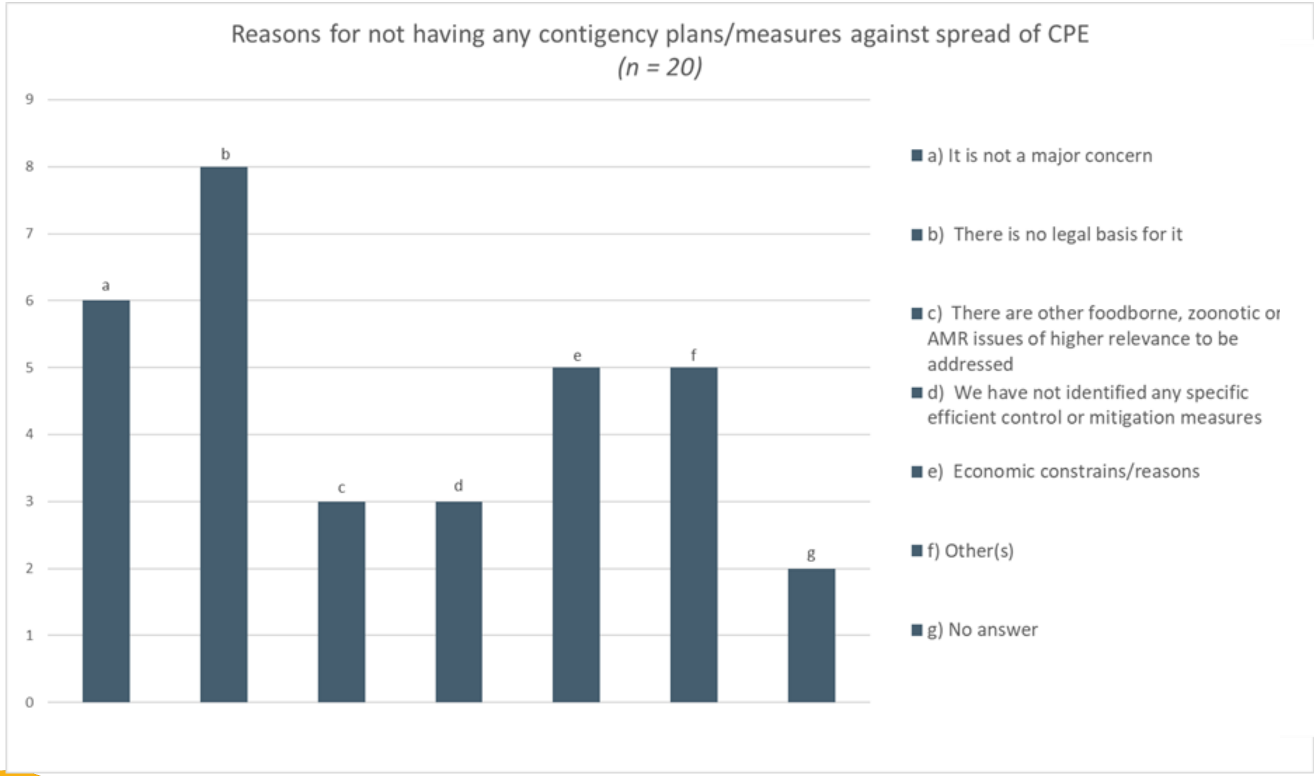


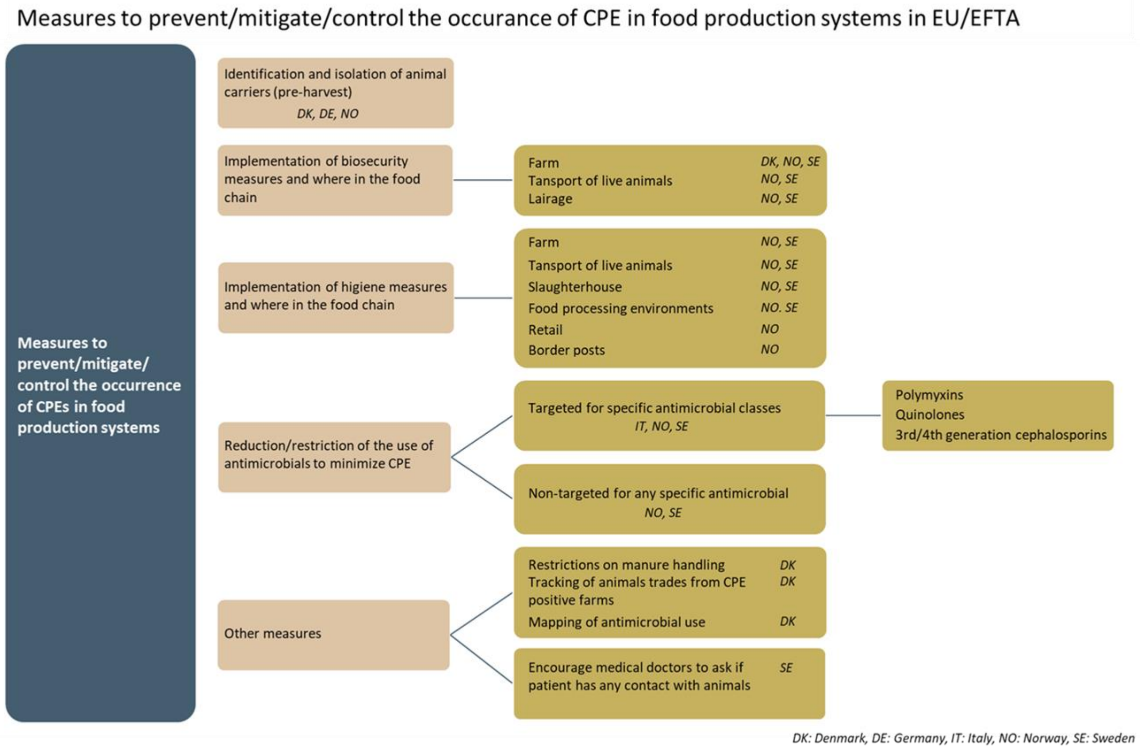
DK: Denmark, DE: Germany, ES: Spain, FI: Finland, IT: Italy, LT: Lithuania, MT: Malta, NL: The Netherlands, NO: Norway, SE: Sweden

10/30 EU/EFTA countries have specific contingency plans for CPE control:

- **Germany, Italy, The Netherlands, Norway, Sweden & Spain** already reported CPE
- **Denmark, Finland, Lithuania & Malta** have not yet reported any CPE

CONTINGENCY PLANS, CONTROL MEASURES





CPE- RECOMMENDATIONS TO FILL IDENTIFIED GAPS

MONITOR additional sources:

- seafood (aquaculture),
- foods of non-animal origin,
- Imports into EU
- others

Perform further studies to clarify transmission:

- trace-back-forward investigations,
- drivers for spread, risk factor analysis

MONITORING additional bacteria:

Klebsiella spp., *Enterobacter* spp., *Salmonella* spp., others

Detection methods:

- Increase sensitivity
- perform/harmonize characterization of MGE

Different types of studies/research that could be conducted were proposed:

Molecular epidemiology, temporal and spatial correlation, experimental validations, advanced computational modelling, metagenomics/microbiome analysis

WHAT COMES NEXT

ToR2: New data generation, partnership MSs

To **collaborate** with **countries and with the EURL-AR** with the purpose of **generating new data** through a specific project (**EFSA outsourcing, 2024 to 2026**).

FPA "data generation on CPs in food-producing animals"
Contract: 3 years (end 2024- 2027), Budget 1.5 mill Co-funding (20%).

Contractor (coordinator + MSs):
EURL-AR/NRLs-AR Network labs, Art. 36
https://www.eurl-ar.eu/participants.aspx

WP0: coordination
WP1: protocols,
WP2: epidemiological studies
WP3 in depth (WGS) analysis
WP4: genomics comparison analyses.

End of 2027: Update State of the art

Review all new data/evidence generated by the Member States and the EURL-AR,

ECDC Networks, to collaborate in ToR2d

AN UPDATE ON THE 2023 AMR EU SUMMARY REPORT

EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

EUROPEAN FOOD SAFETY AUTHORITY

2023- EUSR on AMR

Commission Implementing Decision 2020/1729/EU

Lays down specific tech. requirements **2021 - 2027**

EU MSs and other Reporting Countries

Collect & Report AMR data

Data on AMR in **food-producing animals** and **derived meat**

- *Salmonella*
- *Campylobacter*
- Indicator *E. coli*
- *MRSA*

Data on AMR in **humans**

- *Salmonella*
- *Campylobacter*

EUROPEAN FOOD SAFETY AUTHORITY

EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

2022-2023 EUSR on AMR

EU Summary Report on Antimicrobial resistance

SCIENTIFIC REPORT

The European Union summary report on antimicrobial resistance in zoonotic and indicator bacteria from humans, animals and food in 2021–2022

European Food Safety Authority (EFSA) | European Centre for Disease Prevention and Control (ECDC)

- Annual report
- Jointly produced by EFSA and ECDC
- Summarises AMR findings for two consecutive years

AMR **monitoring** is performed on a **biennial basis** and the **sampling** in a **rotating basis**

- Even years:
- Odd years:

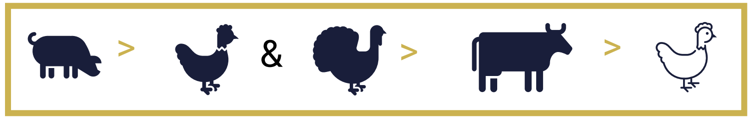
- Food-producing animals **most frequently consumed** in the EU
- **Healthy** animals, domestically produced

https://doi.org/10.2903/j.efsa.2025.9237

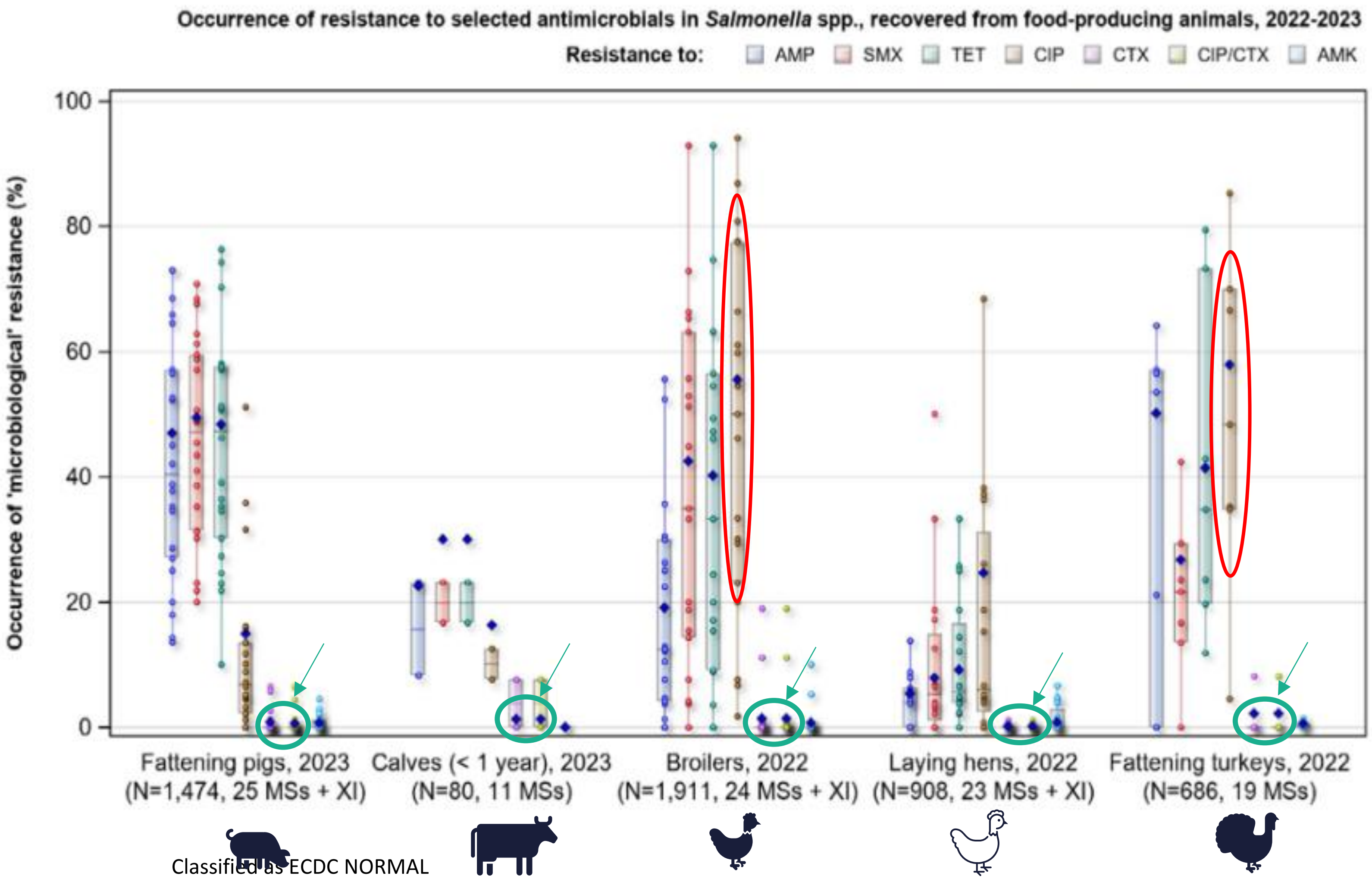
Publication date: 5th of March

Salmonella spp. Animals

- From low (laying hens) to high resistance to AMP, SUL and TET



- From moderate (pigs and calves) to high (laying hens) and very high (broilers & turkeys) resistance to flouroquinolones (CIP)
- Very low/low resistance to third generation cephalosporins (CTX) in animals
- From very low (pigs, turkeys and laying hens) to low (broilers and calves) combined resistance to CIP/CTX
- Very low resistance to AMK in pigs and poultry populations and not detected in calves



Campylobacter spp. Animals

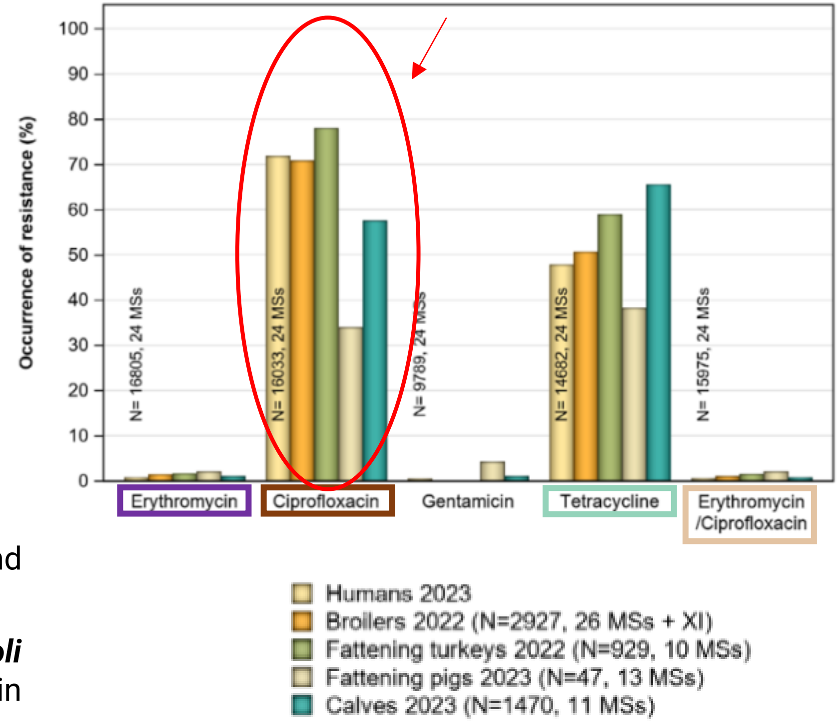
- The level of overall resistance to TET ranged from **high** to **extremely high** in food-producing animals in ***C. jejuni*** *and* ***C. coli***

- **High** to **extremely high** resistance levels to **CIP** in ***C. jejuni*** and ***C. coli*** in food-producing animals

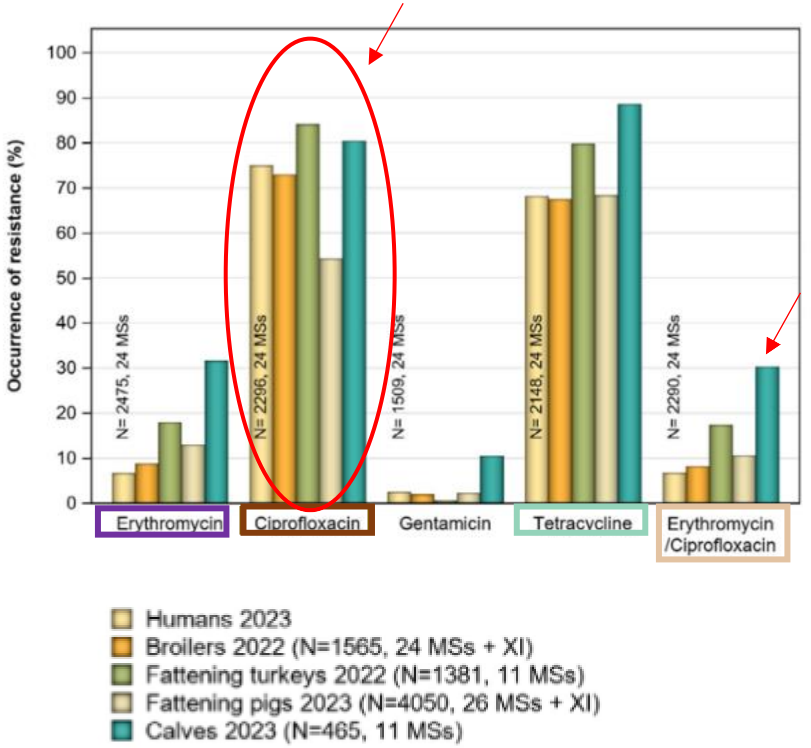
- Resistance to **ERY** at **low** levels in ***C. jejuni*** in animals, while higher levels of resistance detected in ***C. coli***

- Combined resistance to **CIP/ERY:**
  - **Very low** to **low** in ***C. jejuni*** from poultry, pigs and calves
  - **Low** in ***C. coli*** from broilers, **moderate** in ***C. coli*** isolated from pigs and fattening turkeys and **high** in calves

C. jejuni

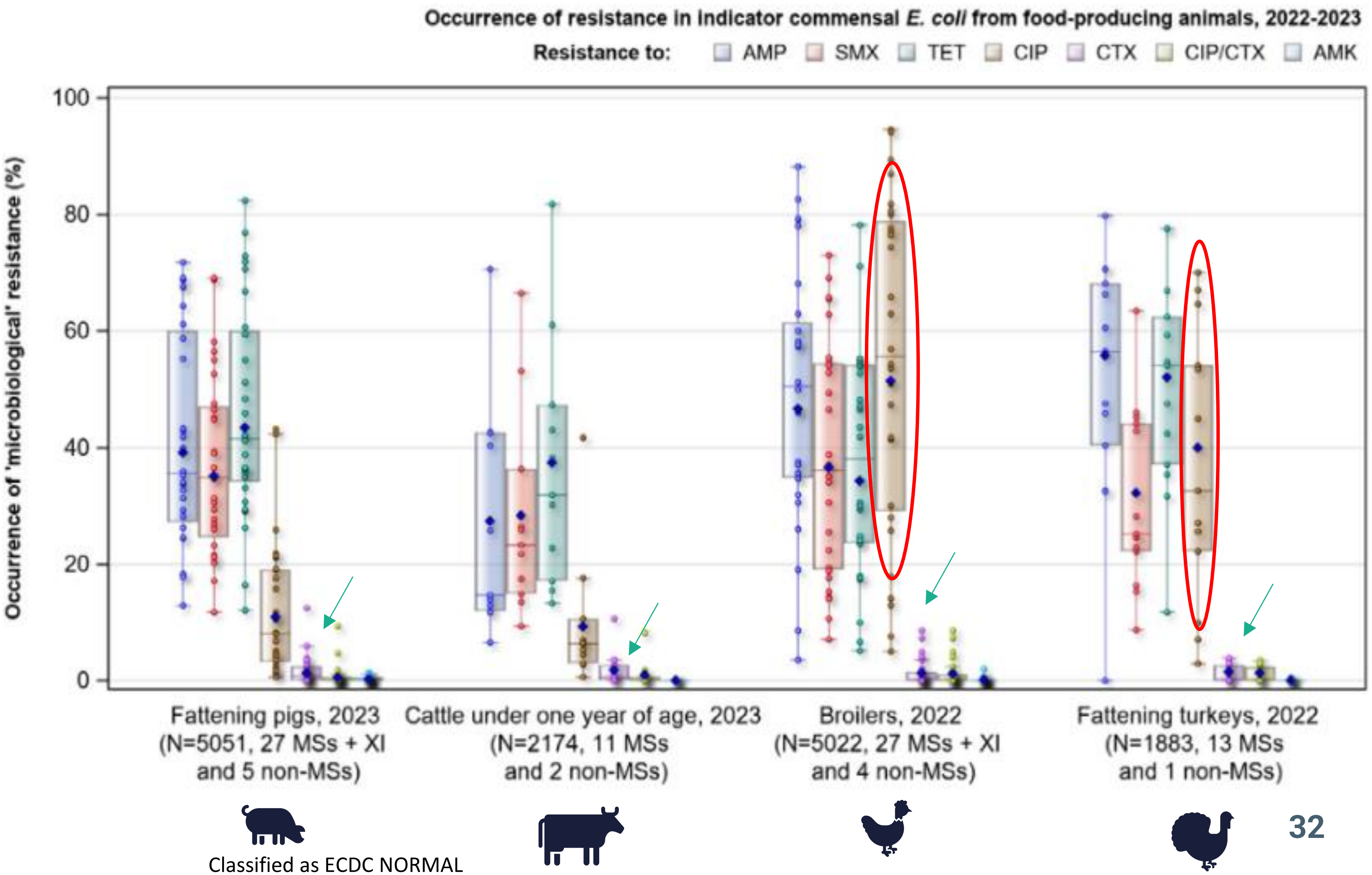


C. coli



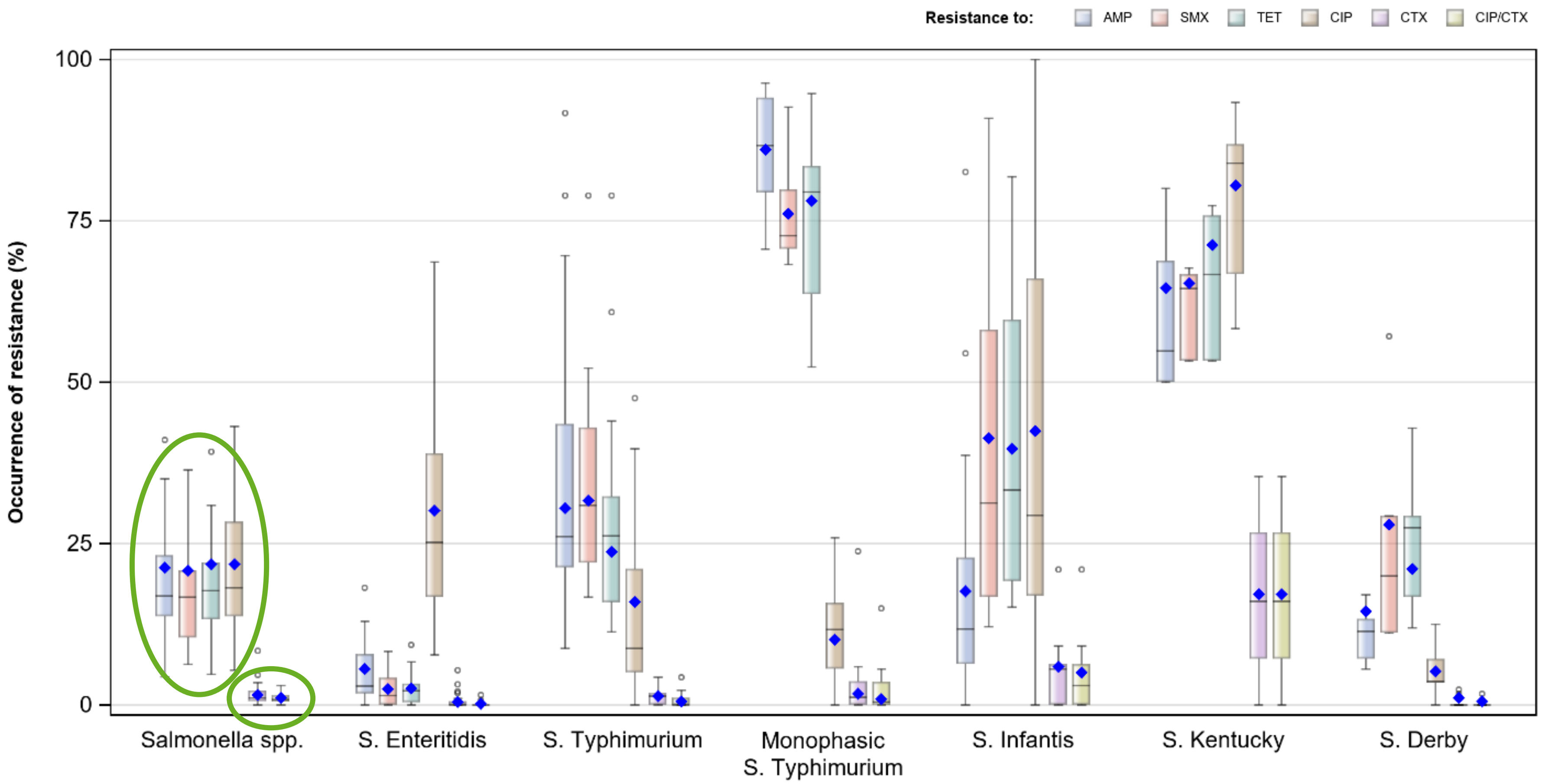
Indicator *E. coli* Animals

- **High** levels of resistance to commonly used antimicrobials (**AMP**, **SMX**, **TET**)
- **Important** resistance to fluoroquinolones (***CIP***) in broilers and turkeys
- **Low** resistance to cefotaxime (**CTX**)
- Combined resistance to **third-generation cephalosporins** and **fluoroquinolones** (***CIP/CTX***) was generally **uncommon** in all animal categories.
- **Very low** levels of resistance to **AMK**
- Resistance to high priority critically important antimicrobials (**HPCIA**) was **uncommon** for **colistin** and **azithromycin**



Resistance in *Salmonella* spp. from humans, EU/EEA, 2023 - major difference by serovar (1)

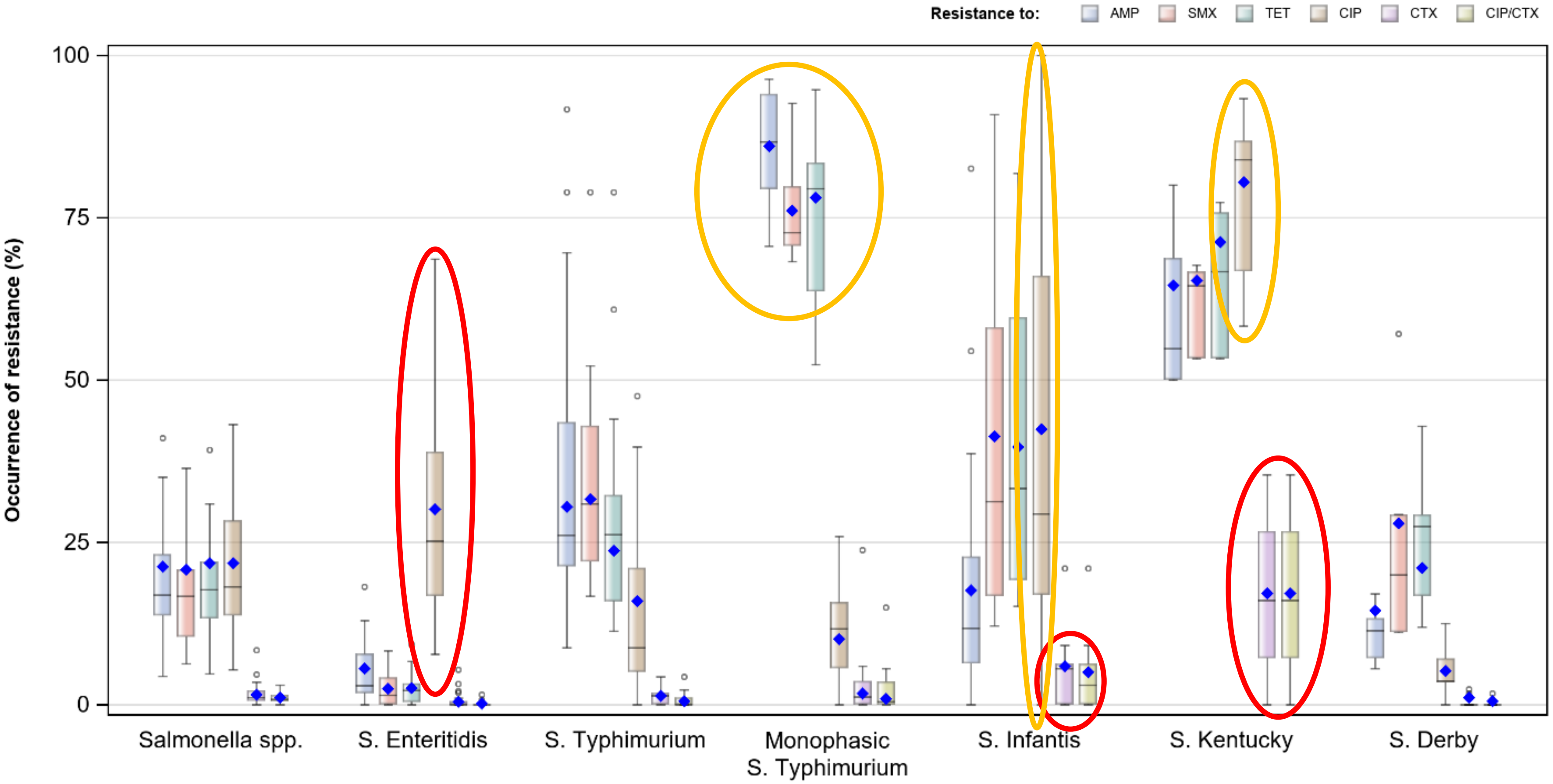
- Multi-drug resistance (≥3 classes) in about 20% of isolates
- ESBL and/or AmpC detected in <1% of isolates
- Decreasing trends in resistance to ampicillin and tetracycline, particularly in *S.* Typhimurium (in 16/24 and 15/24 countries, respectively)



Only countries with >10 isolates were included

Resistance in *Salmonella* spp. from humans, EU/EEA, 2023 - major difference by serovar (2)

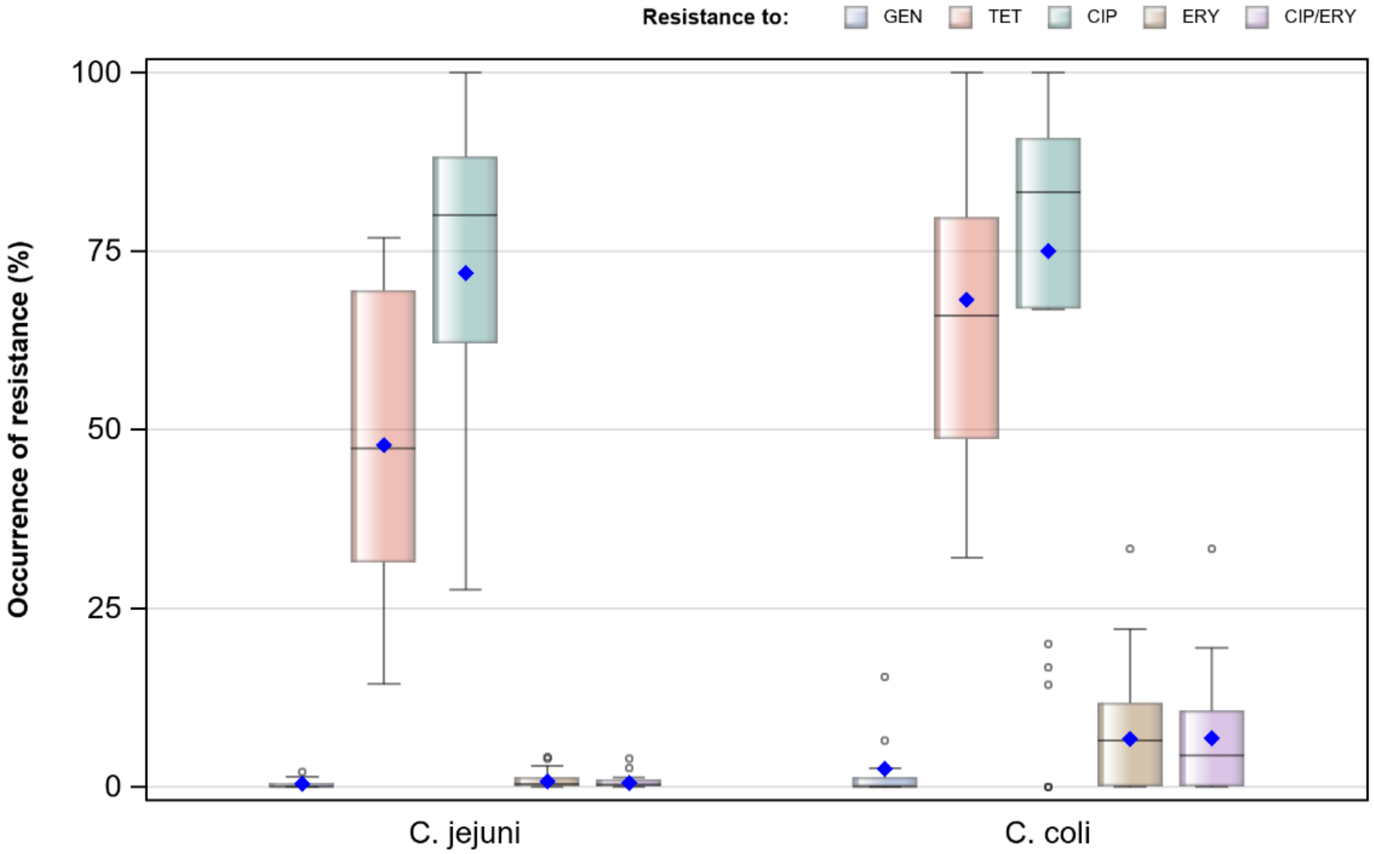
- Multi-drug resistance:
  very high and extremely high in monophasic *S*. Typhimurium and *S*. Kentucky
- Ciprofloxacin resistance: high or extremely high in *S*. Infantis and *S*. Kentucky
- Increasing trends in ciprofloxacin resistance in *S*. Enteritidis in 13/24 countries
- Combined resistance to ciprofloxacin and cefotaxime (often with ESBL)
  5.0% of *S*. Infantis and
  17.2% of *S*. Kentucky



Only countries with >10 isolates were included

Resistance in *Campylobacter jejuni* and *C. coli* from humans, EU/EEA, 2023

- Ciprofloxacin resistance extremely common in both *C. jejuni* (71.9%) and *C. coli* (75.0%)
- Resistance to antibiotics generally higher in *C. coli* than in *C. jejuni*
- Multi-drug resistance in 0.6% of *C. jejuni* and 8.6% *C. Coli* (mostly ciprofloxacin, erythromycin and tettracycline resistance)
- Resistance to both critically-important antimicrobials for treatment, i.e. ciprofloxacin and erythromycin: low in *C. jejuni* (0.6%), but overall 6.8% in *C. coli*
- Erythromycin resistance decreasing in 10/23 and 9/17 countries for *C. jejuni* and *C. coli*, respectively, between 2014 and 2023



KEY OUTCOME INDICATORS AND TRENDS

KEY OUTCOME INDICATOR COMPLETE SUSCEPTIBILITY IN INDICATOR *E. COLI*

Marked variations among reporting countries

Lower KOI CS were generally observed in countries in eastern and southern Europe and the highest in countries in the northern Europe

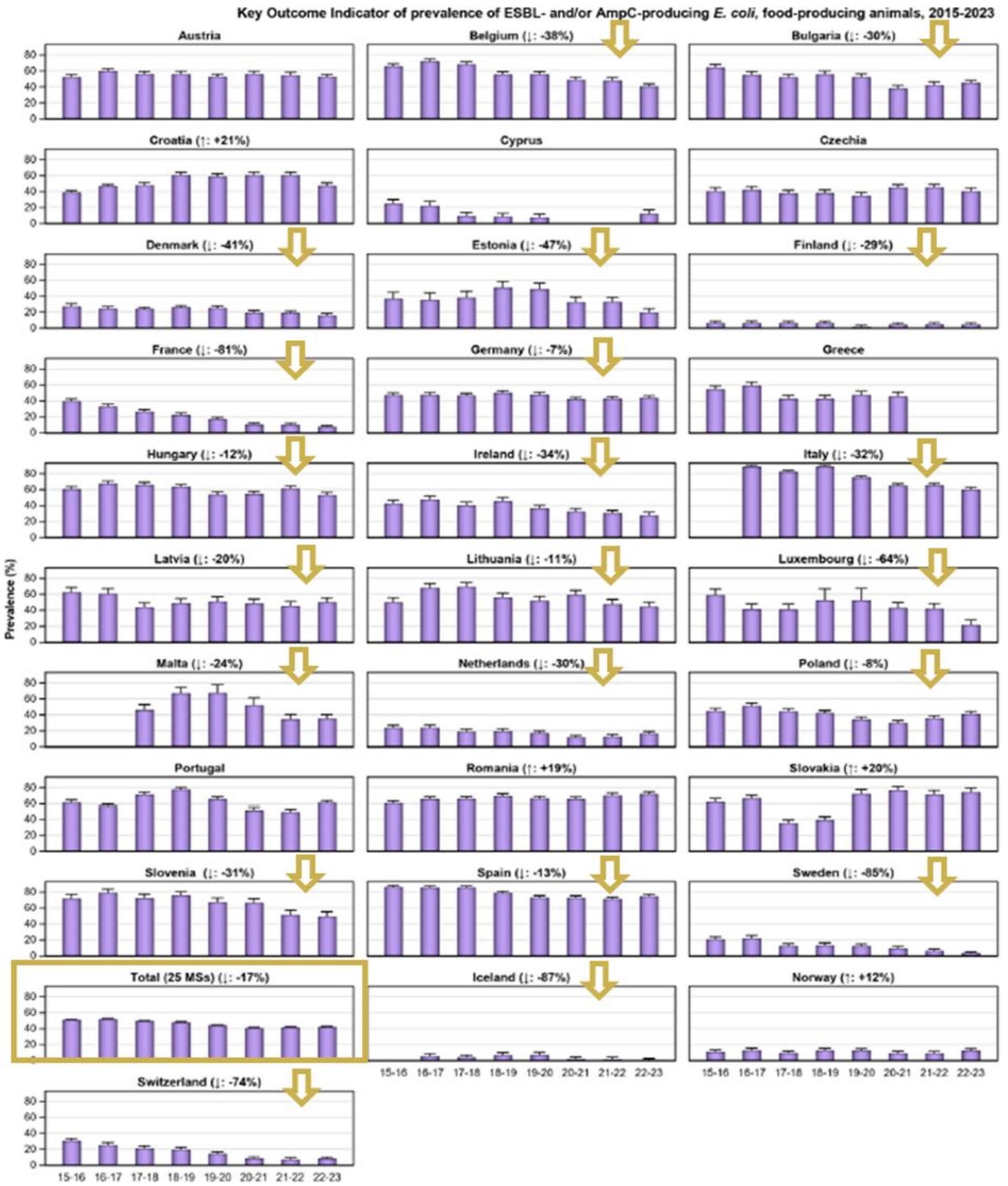
Statistically significant **increasing trends** (from 2014-2023) registered **in 48% of the reporting countries** (14 of 29)

KEY OUTCOME INDICATOR PREVALENCE OF ESBL- AND/OR AMPC-PRODUCING *E. COLI*

Marked variations among reporting countries

Higher KOI ESBL were generally observed in countries in eastern and southern Europe and the highest in countries in the northern Europe

Statistically significant **decreasing trends** (from 2015-2023) have been observed in **70% of the reporting countries** (21 of 30)



Temporal trends animals - Indicator *E.coli*

- Trends of Resistance to AMP, CIP, CTX and TET

TET: **Decreasing trends** mainly in pigs and broilers

AMP: **Decreasing trends** mainly in broilers and turkeys

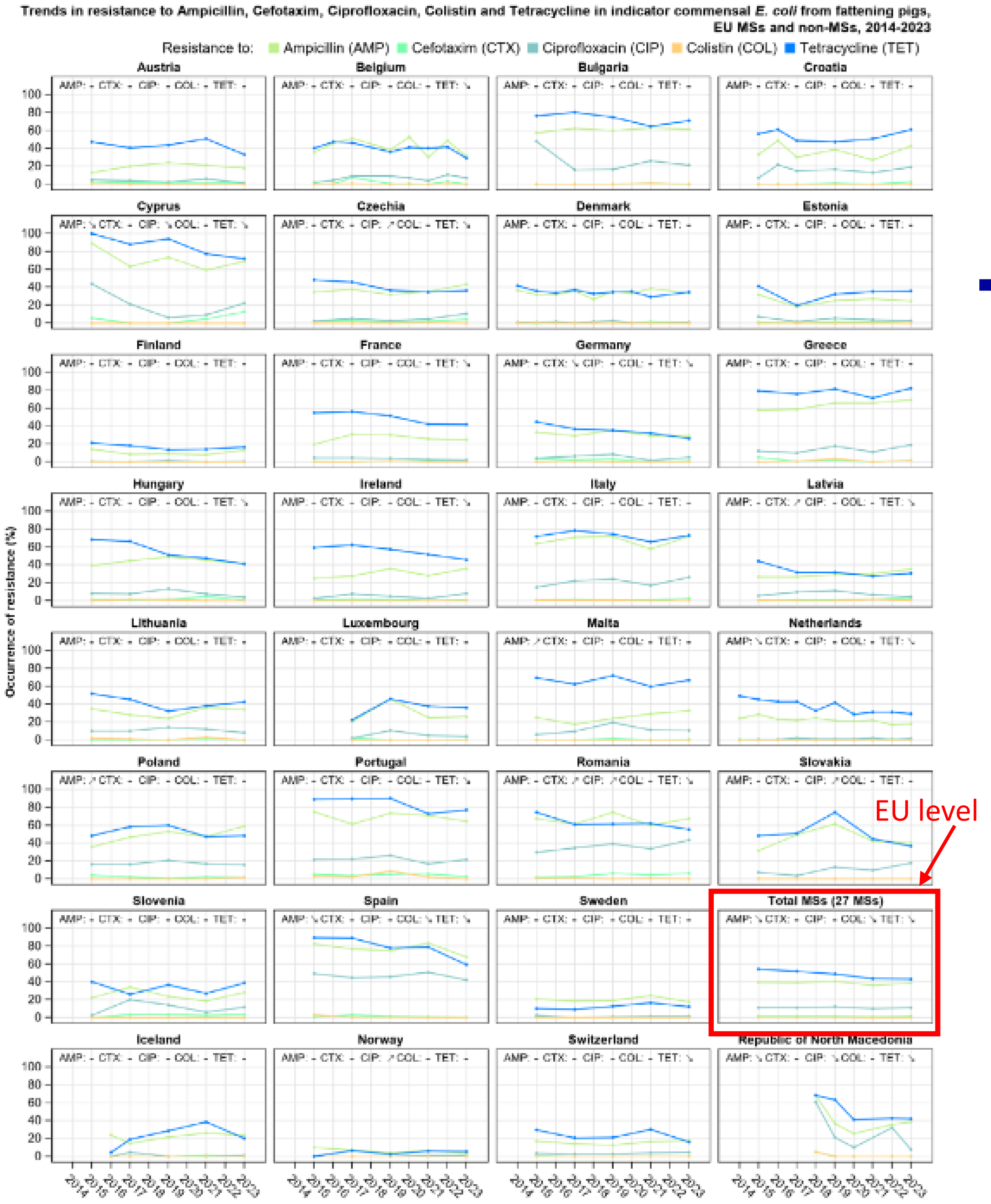
CIP: **Decreasing trends** in broilers and turkeys

CTX: **Decreasing trends** in broilers

- Statistically significant
  - **Decreasing trends** in resistance to AMP, CIP, CTX and TET
  - **Increasing trends** in **CS**

… **reveal progress** towards lower levels of resistance in several countries and in the EU group

- The **improvement** in the situation was most pronounced in **poultry**



DETECTING EMERGING SIGNALS: THE EXAMPLE OF CARBAPENEM RESISTANCE

Carbapenemase-producing *Salmonella* spp. from humans

- Rare – 2017-2023, 19 cases in 2017-2023 from domestic infections (or unknown travel status)
- In 2023, 6 cases identified in 6 different countries.
- Carbapenemase genes: $bla_{\text{OXA-48}}$ most common (14/19), but also $bla_{\text{OXA-181}}$, $bla_{\text{NDM-1}}$, bla_{VIM} and bla_{KPC}
- Serotypes: *S*. Kentucky (5), *S*. Haifa (3), *S*. Typhimurium (2), monophasic *S*. Typhimurium (2), one each of *S*. Abony, *S*. Agona, *S*. Cerro, *S*. Corvallis, *S*. Enteritidis, *S*. Give, *S*. Kottbus, *S*. Rissen and *S. enterica* subsp. *salamae*
- Cases often elderly people with underlying illness
- Hypotheses:
    - Food?
    - Inter-species transfer in healthcare settings?

Carbapenems, a last-resort group of antibiotics

Salmonella spp.: **Carbapenem-R** was found in humans (4 isolates (*bla*$_{OXA-48}$) in 2022 and 6 isolates in 2023 (*bla*$_{OXA-48}$ and *bla*$_{NDM-1}$) but **not** in food-producing animals

E. coli: **Carbapenem-R** was detected in food-producing animals at very low levels

BUT

Presence of carbapenemase-producing bacteria in humans and in food-producing animals in

- Several countries
- Several animal species
- Several genes

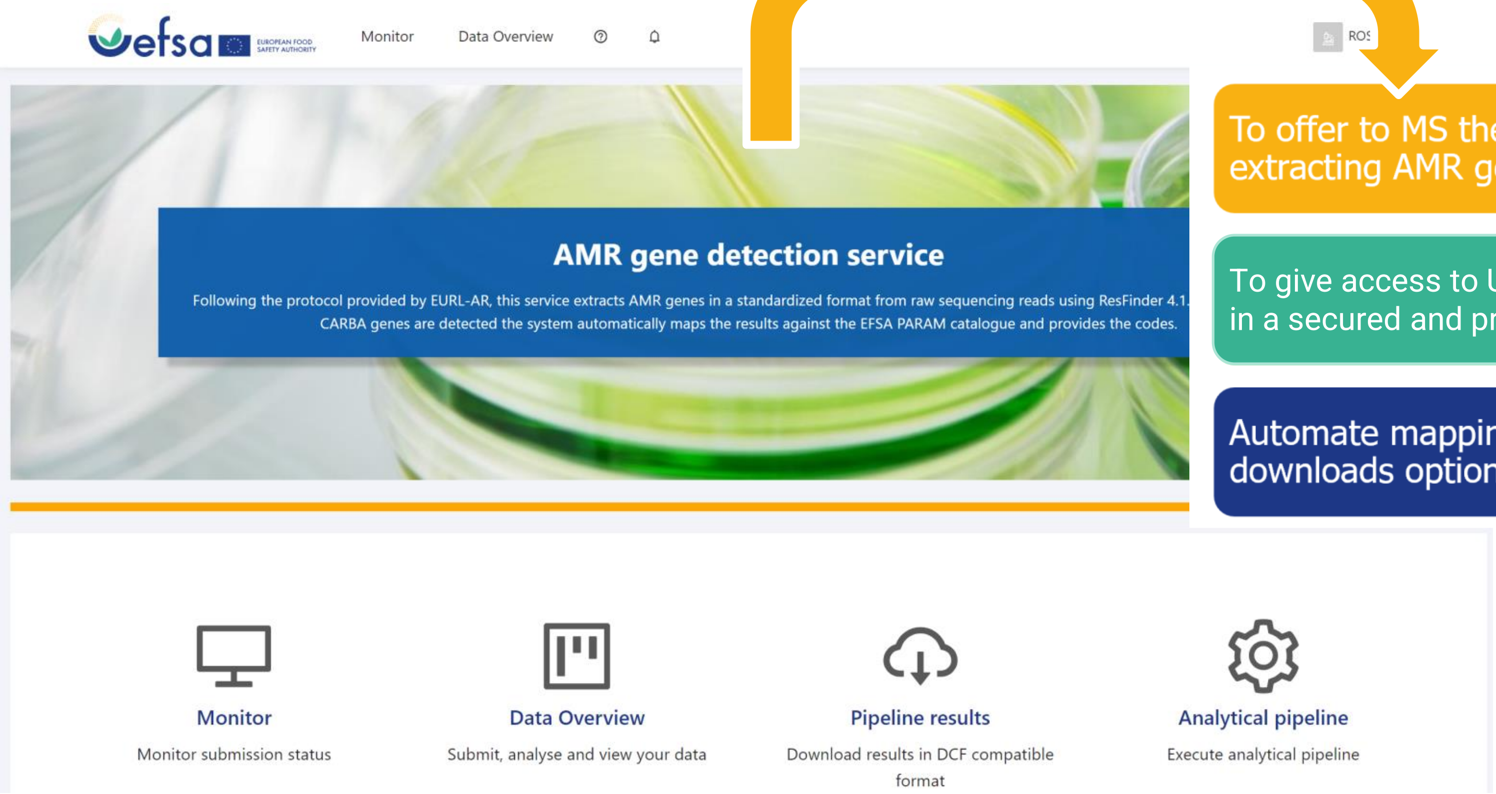
... **highlights the need for continued monitoring and further investigation**

TABLE 23 Summary table on carbapenemase-encoding genes reported in *Escherichia coli* sampled in the routine monitoring, the specific monitoring of ESBL-/AmpC-/CP-produ-cers and the specific monitoring of CP-producers in 2022–2023.

Year	Matrix	Gene	Number of isolates	Countries detecting the isolates (*n*)
Routine monitoring of indicator commensal *E. coli*				
2022	Fattening turkeys	*bla*$_{OXA-181}$	1	IT (1)
Specific monitoring of ESBL-/AmpC-/CP-producing *E. coli*				
2022	Broilers	*bla*$_{VIM-1}$	3	AT (2), IT (1)
2023	Cattle under 1 year of age	*bla*$_{VIM-1}$	1	DE (1)
		bla$_{NDM-5}$	1	IT (1)
	Fattening pigs	*bla*$_{OXA-181}$	3	ES (1), IT (1), PT (1)
		bla$_{OXA-181}$ + *bla*$_{NDM-5}$	1	PT (1)
Specific monitoring of CP-producing *E. coli*				
2022	Fattening turkeys	*bla*$_{OXA-181}$	1	IT (1)
2023	Fattening pigs	*bla*$_{OXA-181}$	24	ES (4), IT (19), PT (1)
		bla$_{NDM-5}$	5	CZ (5)
		bla$_{OXA-48}$	21	ES (19), PT (1), RO (1)
		bla$_{OXA-181}$ + *bla*$_{NDM-5}$	4	PT (4)
		bla$_{OXA-244}$	1	PT (1)
	Cattle under 1 year of age	*bla*$_{OXA-181}$	4	IT (4)
		bla$_{OXA-48}$	1	ES (1)
	Meat from pigs	*bla*$_{NDM-5}$	1	ES (1)

RECENT IMPROVEMENTS IN METHODOLOGY AND DATA-MINING TOOLS

THE EFSA AMR GENE DETECTION SERVICE



To offer to MS the opportunity to use EFSA computing resources for extracting AMR genes from WGS data

To give access to User-Friendly interface for accessing and managing the data in a secured and private environment, no sharing of data

Automate mapping against the PARAM catalogue and different downloads options for the results

The service is available for

Salmonella enterica
Escherichia coli
Campylobacter jejuni
Campylobacter coli

For access, please send email to mirko.rossi@efsa.europa.eu

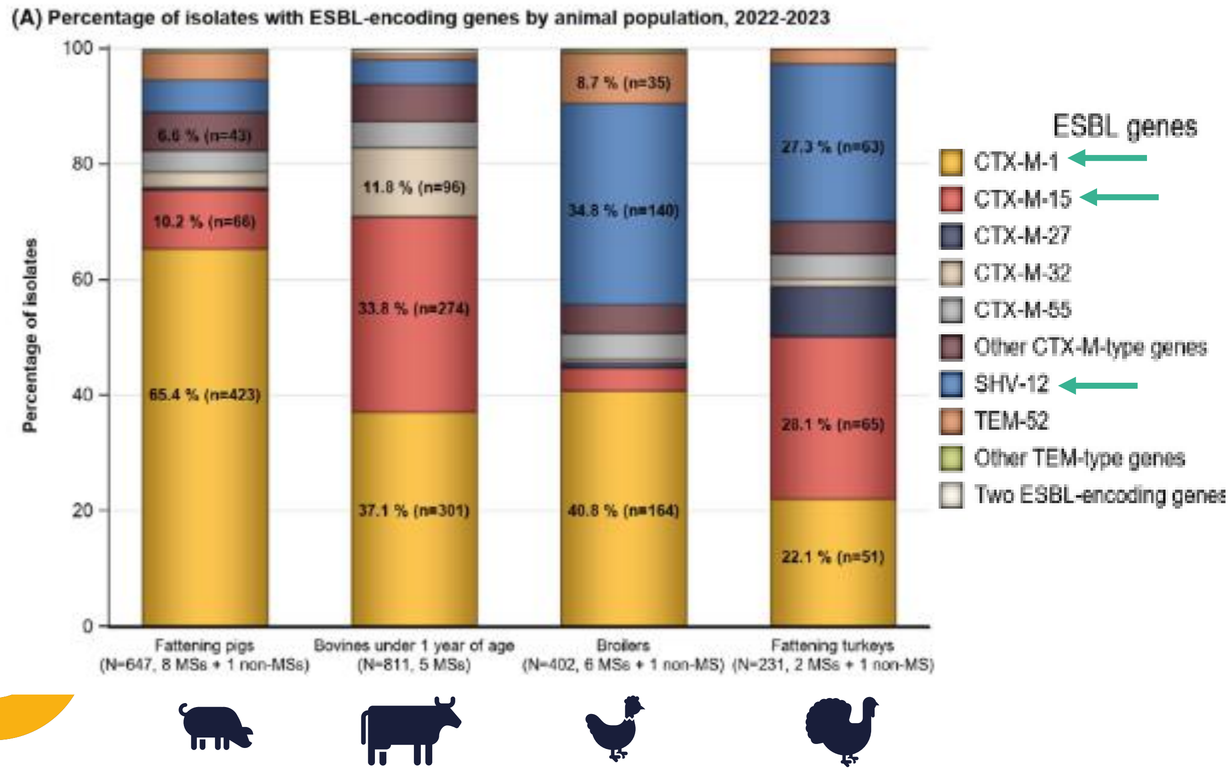
WGS: ESBL and/or AMPC- producing *E.coli* from animals

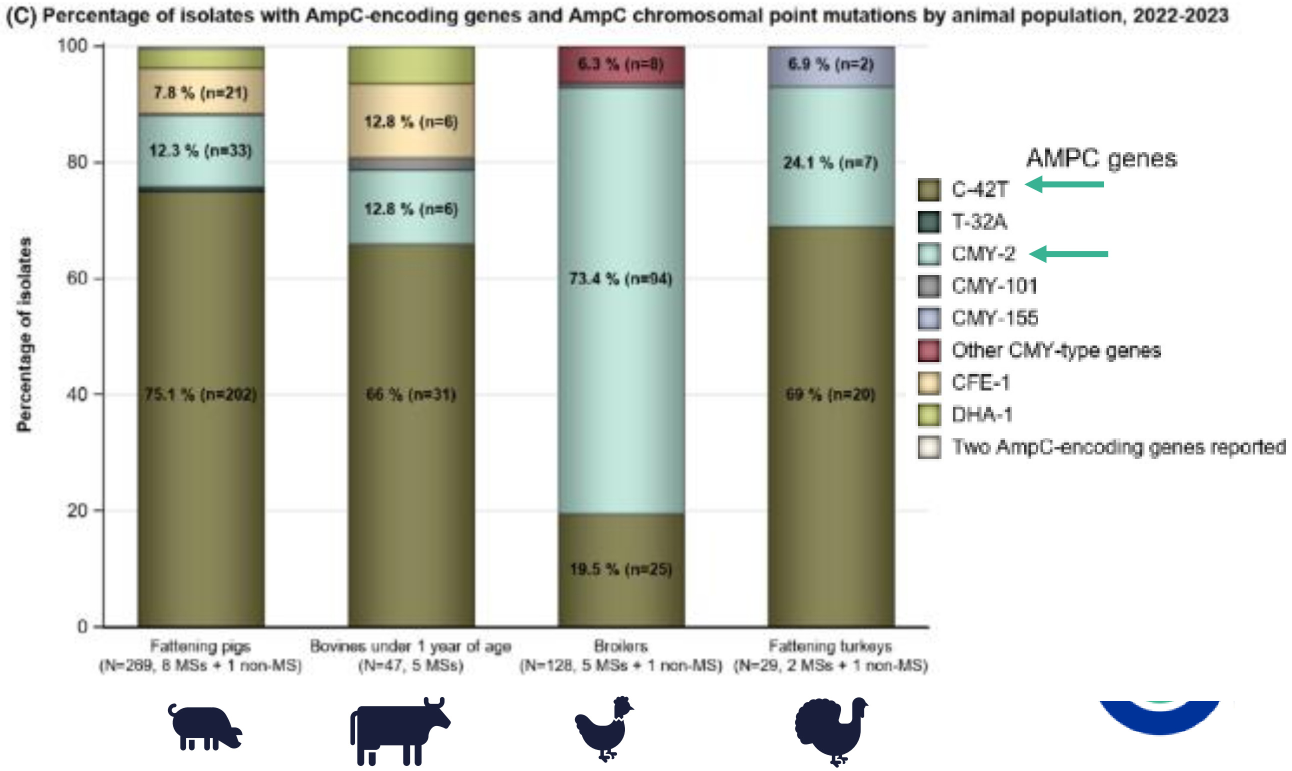
Genotypic data from:

Austria
Belgium
Czechia
Germany
Finland
Italy
The Netherlands
Norway
Sweden
Northern Ireland

Genotypic data reported

2022 ➡ Provided by 7 MSs
2023 ➡ Provided by 9 MSs + 1non-MSs

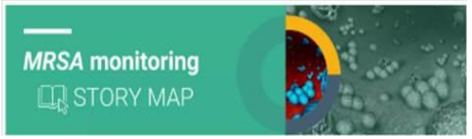




ONLINE VISUALISATION TOOLS: DASHBOARDS & STORY MAPS

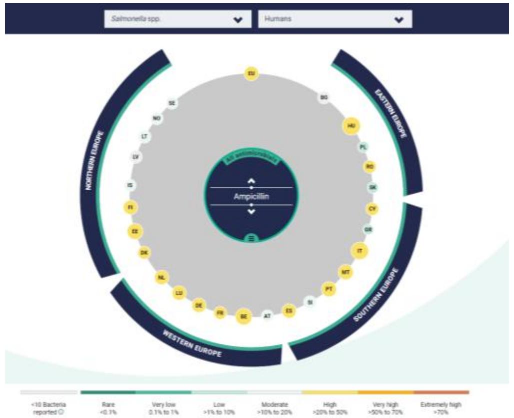
- **2022 visualisation tools**

STORY MAPS

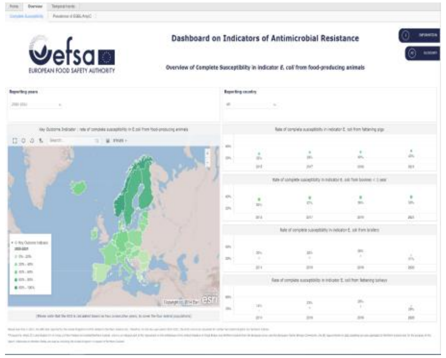


Data VIZ

Levels of the resistance of *Salmonella* spp., *E. coli and Campylobacter* spp. in **food, animals** and **humans**

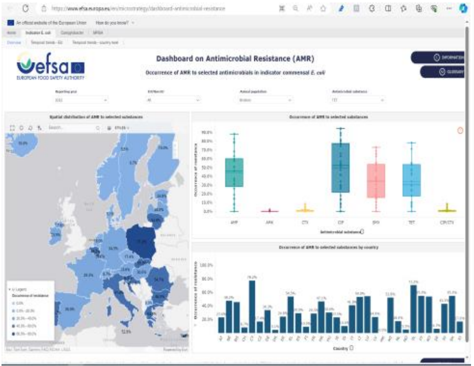


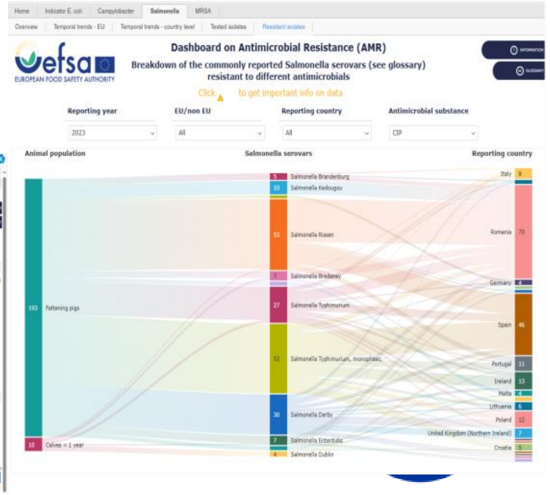
DASHBOARDS



- **2023 Visualisation tools**

New: story map on AMR in *Salmonella* spp.





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