EMA's 2nd Vet Big Data Stakeholder Forum

23 November 2022

Current and future use of omics and other data in food/feed safety assessments

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Trusted science for safe food

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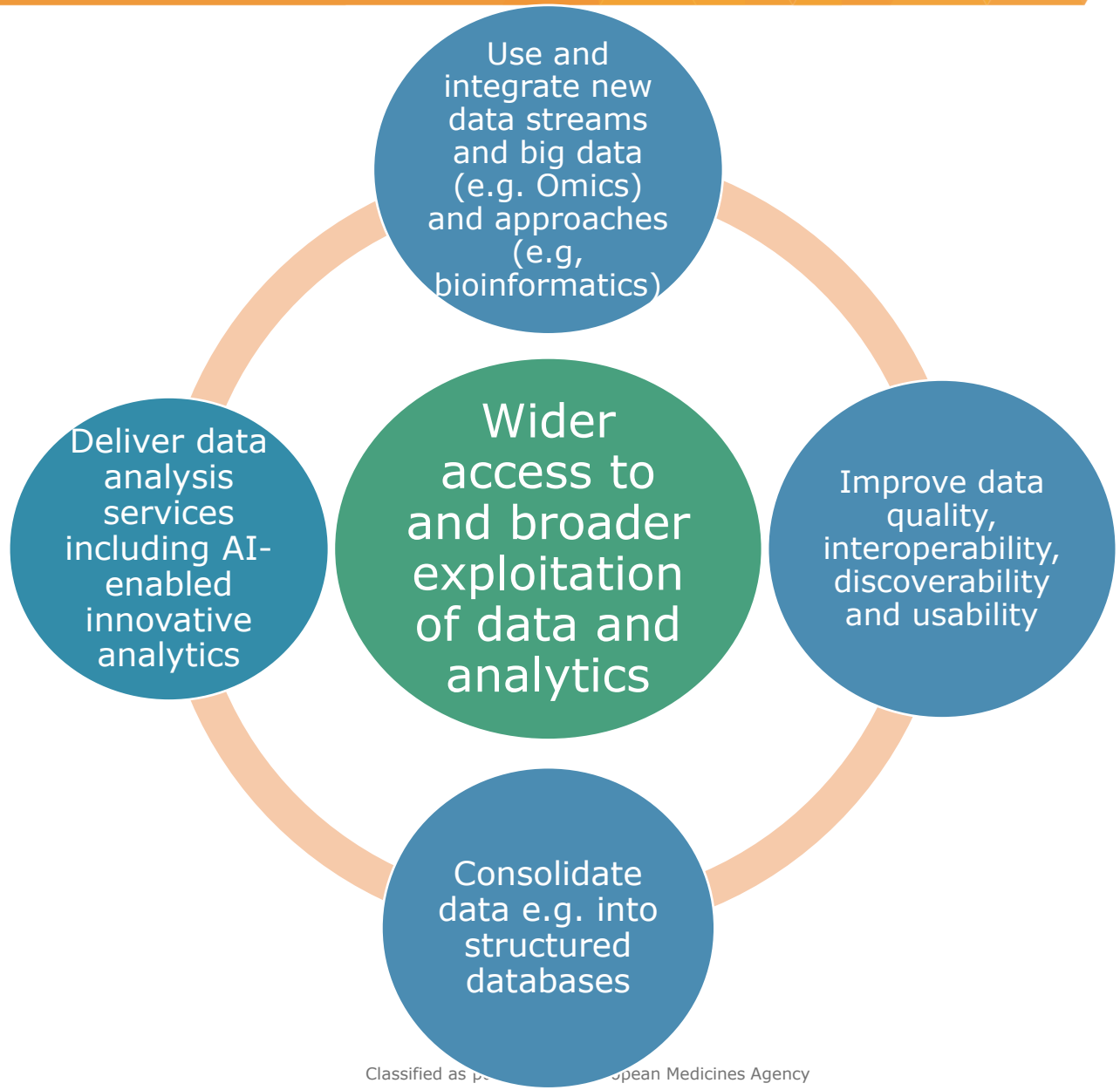
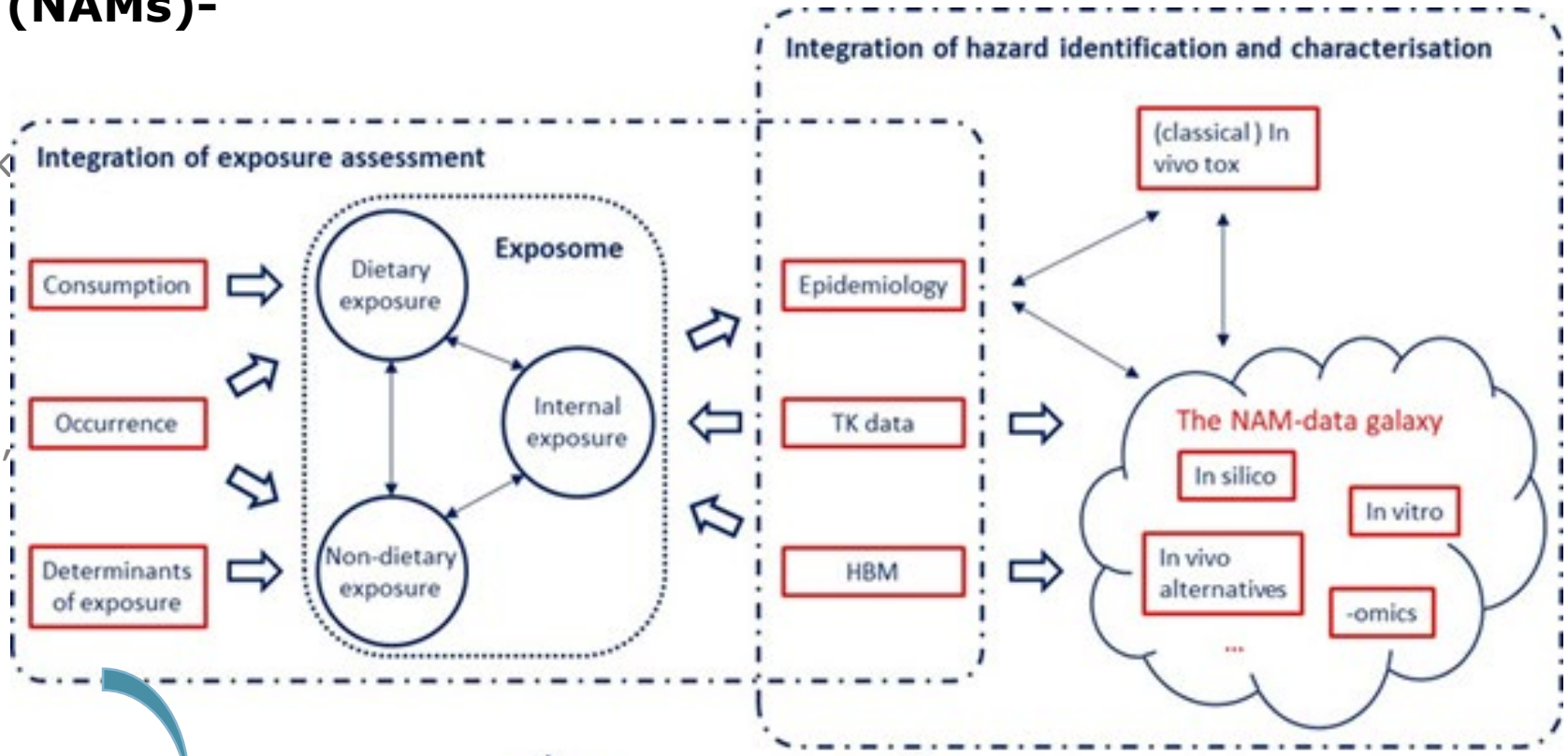
EFSA Strategy 2027



Chemical Risk Assessment - a vision for the coming years-EFSA NAMs roadmap for action

New Approach Methodologies (NAMs)- Non animal-based methods

- NAM-based, mechanistic-based risk assessments for chemicals in food and feed (**EMA's regulatory science strategy 2025**)
- *In vitro* and *in silico* alternatives to animal testing, connected to modern technologies and "big data"



Roadmap on Advancing Aggregate Exposure to Chemicals in EU (e.g. explore data generation / connection / collection and tool development in collaboration with sister agencies (EMA, ECHA, EEA)

NAM-based Integrated Assessment and Testing Strategies (IATAs)

Six Prioritised Scientific Areas Requiring Further Scientific Development for NAMs

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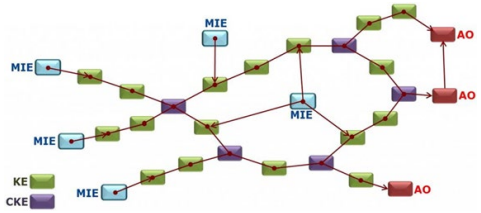
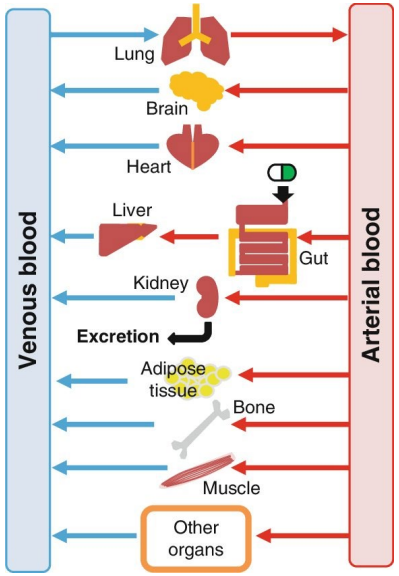
AOPs/AOP networks



Adverse Outcome Pathways e.g. for developmental neurotoxicity

IVIVE-PBK



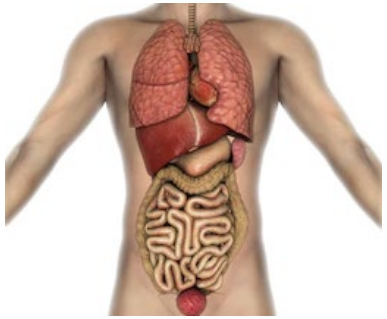
Develop advanced *in vitro/in silico* ADME models/databases

Exposome

Data integration

- Develop NAMs data Integration approaches
- AI4NAMS: AI based data search, extraction, harmonisation and integration

Advanced cell culture systems and OoCs



Susceptible human population

DTU · National Institute for Public Health and the Environment, Ministry of Health, Welfare and Sport · VU Vrije Universiteit Amsterdam · EurA

Escher et al, 2022

A roadmap for action: OMICS & Bioinformatics Approaches: Next Generation Risk Assessment

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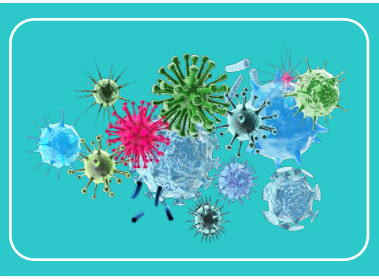
By 2030, EFSA will integrate **omics and associated bioinformatic approaches in its RAs** allowing for an enhanced food chain analytics

- Address challenges (e.g.):
  - Data generation, collection and storage
  - Implementation of the FAIR principles for data
  - Implementation of robust bioinformatic analytical tools and their validation

Improve/facilitate the use of WGS analysis, e.g.:

- In currently applied areas (e.g. foodborne outbreak, AMR monitoring)
- Extend to other areas (e.g. animal/plant health)



Incorporate use of metagenomics into RA for animal, human and environmental health, e.g.:

- Assessment of food additives or novel foods on **human/animal and environmental microbiome**
- Impact of pesticides on biodiversity (bacterial soil communities)

Incorporate other Omics (transcriptomics metabolomics, proteomics, etc) for e.g.:

- Improved assessments of complex products (e.g. Synbio/allergenicity)
- Identify novel biomarkers for the mass screening of contaminants, nutrients, exposures
- Develop methodologies for integrated analysis of multiple omics datasets

Tox pathway analysis to predict target organ toxicity

Inference of Chemical Grouping from Processed OMICS Data

Implementation of a Multi-OMICS and Inter-species Workflow using Quantitative in Vitro Data

WGS applied to foodborne outbreak

Whole genome sequencing in outbreak investigation

- Whole genome sequencing analysis of foodborne pathogens is keystone in outbreak investigation for identifying variants causing the outbreak
- Its application resulted in significant health benefits
  - in US is estimated annually at nearly $500 million, compared to an approximately $22 million investment by public health agencies
- Main challenges for its effective applications
  - Cross-sectoral interaction
  - WGS data comparability
  - Timely data availability
  - Political barriers in data sharing

Feasibility study

Towards WGS-based molecular typing data collection in EFSA

- In 2017, first joint EC mandate for a feasibility study on the collection and analysis of Whole Genome Sequencing (WGS) data from foodborne pathogens from human and non-human isolates


TECHNICAL REPORT

APPROVED: 29 April 2019

doi:10.2903/sp.efsa.2019.EN-1337

https://www.efsa.europa.eu/en/supporting/pub/en-1337

Strategic elements identified by EFSA

- IT architecture
- Transparency
- Engagement
- Data Ownership
- Data confidentiality

Implementation mandate

- In 2019, EFSA and ECDC received a **follow up mandate** for **implementing and managing a One Health system** for the collection and joint analysis of **WGS data** from foodborne isolates from human, food, feed, animal and environmental samples

Requirement from the requestor

Interoperability of the two systems in the public health and the food safety sectors

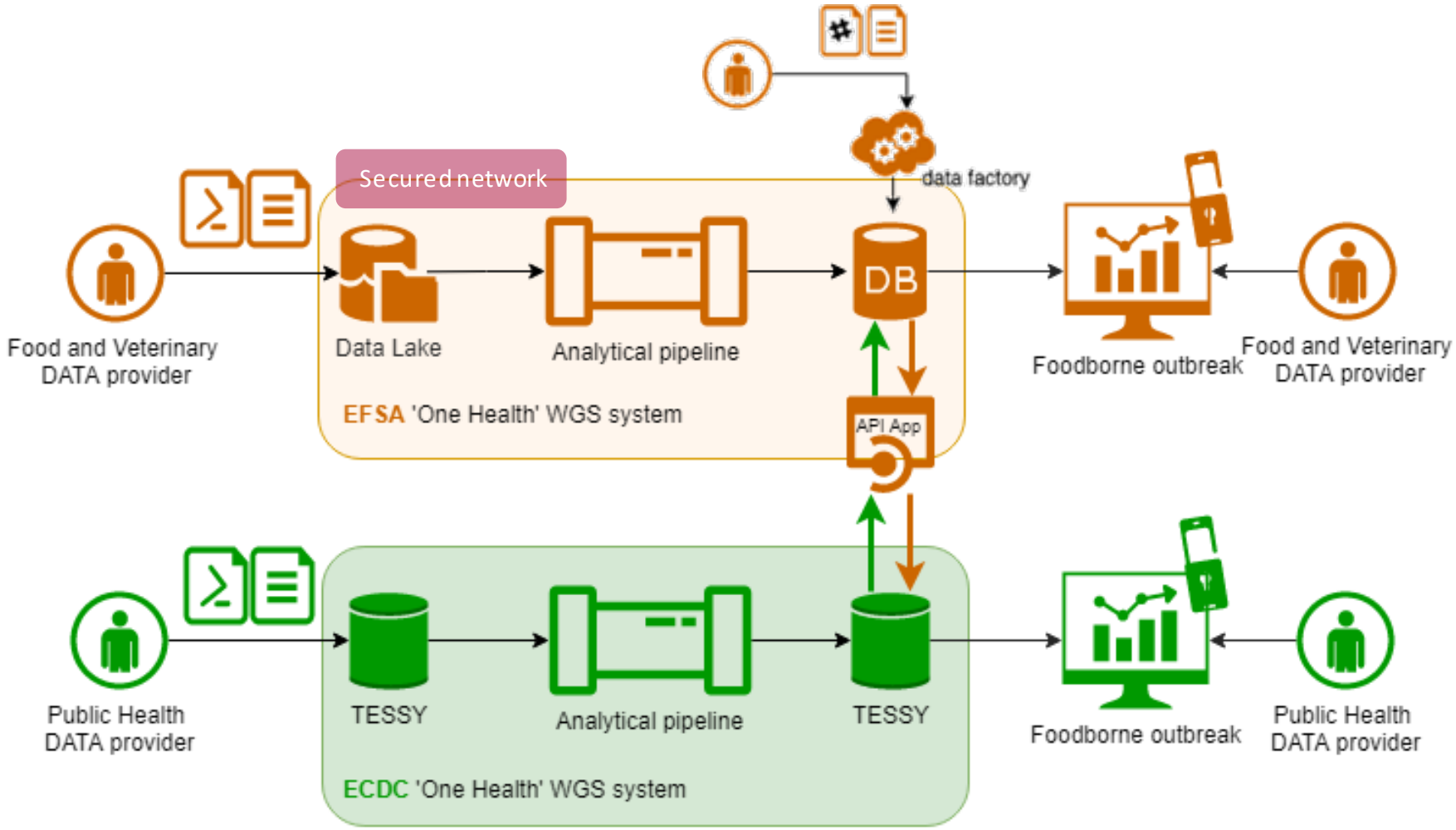
- Detection of **joint microbiological clusters of human and non-human food-borne pathogens isolates**
- **Data exchange on demand** when matches have been found
- Automatic **exchange of WGS-based typing data** and **epidemiological data** between the two systems

The EFSA One Health WGS System

Interoperability

Cross-sector matches

Machine-to-machine



Objective of the EFSA One Health WGS System

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To collect genomic profile of foodborne pathogens and associated epidemiological data of isolates from food, feed, animals and related environment

Build a database of genome profiles that can be queried in case of food-borne outbreaks
EU/EEA countries are invited to submit WGS-based typing data on a voluntary basis at any time throughout the year

To **allow ECDC to query the EFSA database** for finding possible matches between human and non-human isolates

Support the real-time investigation of multi-country food-borne outbreaks

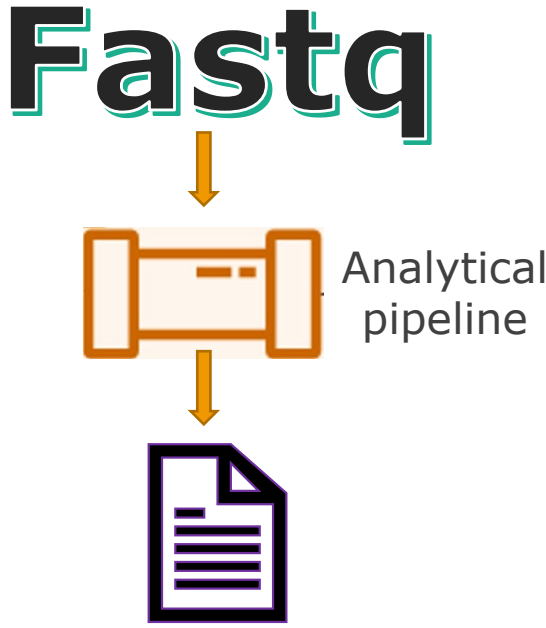
To offer a **set of services through a user-friendly interface** for the analysis and managing of the submitted data

Type of data collected

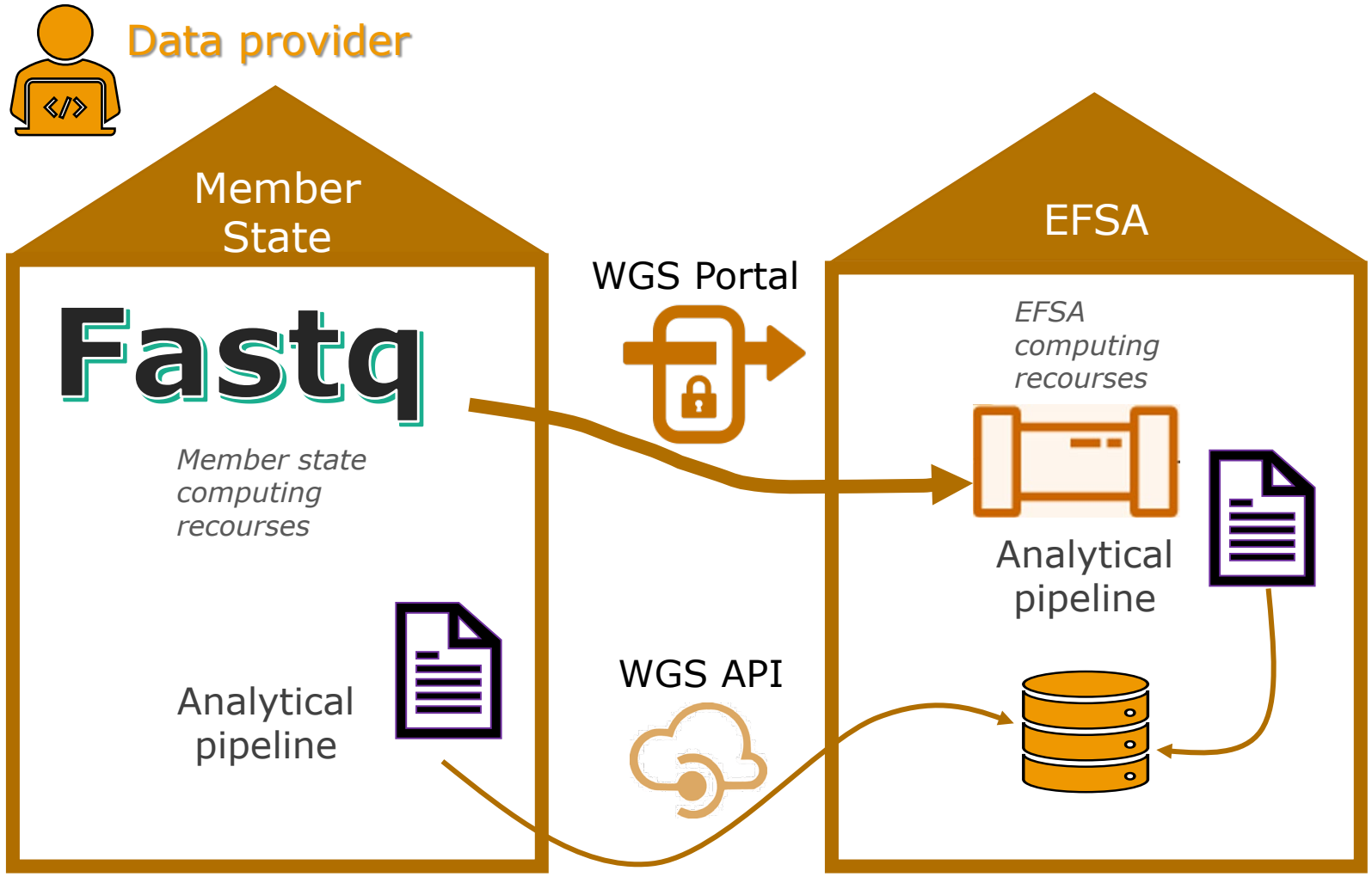
Experimental data: information related to the experiment *(raw sequencing reads)*

Typing data: genomic profile and other typing data extracted from the raw sequencing reads

Epidemiological data: information related to the food, feed and animal samples from which the pathogen isolates linked to genomic profiles originated



Move code as alternative of moving big data



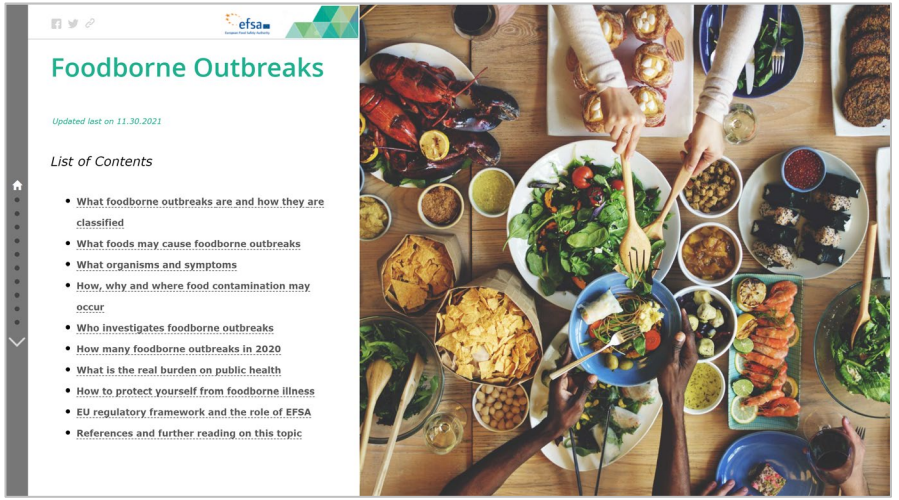
Other examples of digital data in EFSA One Health assessments

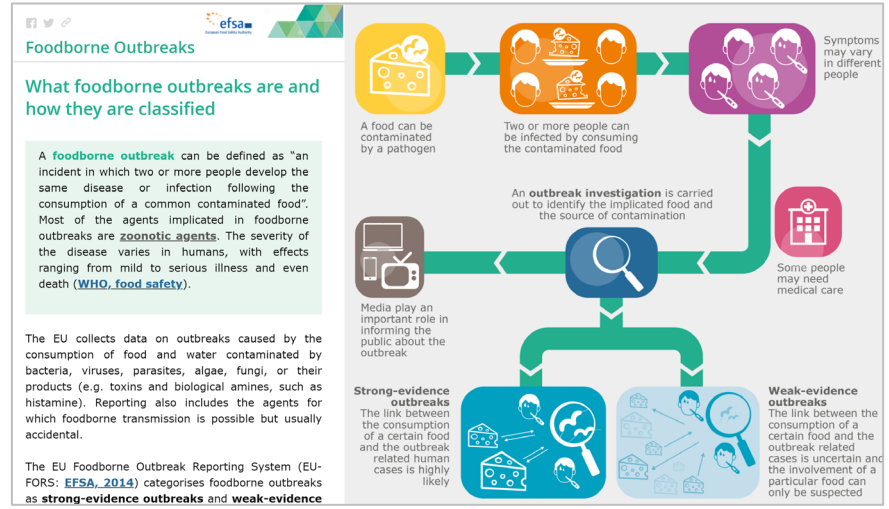
New communication & data visualisation online tools: EFSA story map and dashboard on foodborne outbreaks

European Food Safety Authority

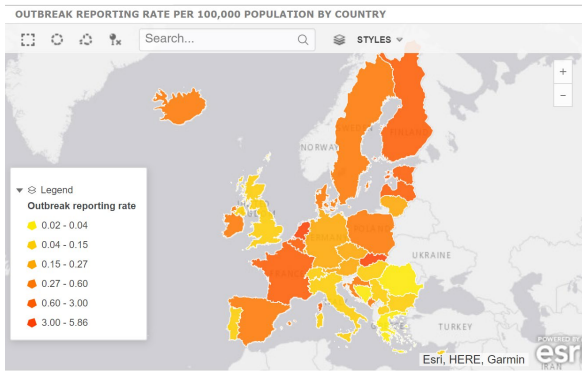
- **EFSA's story map on foodborne outbreaks**

https://multimedia.efsa.europa.eu/fbo-storymaps/index.html

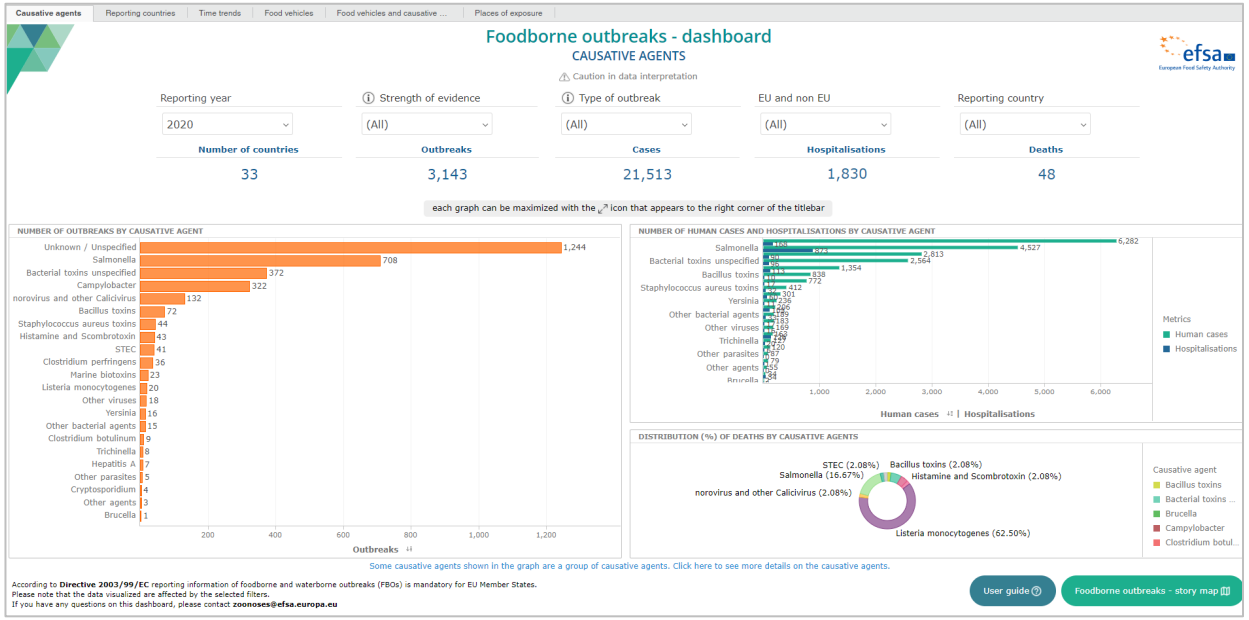


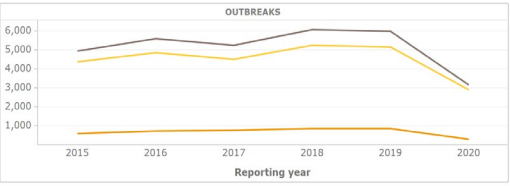


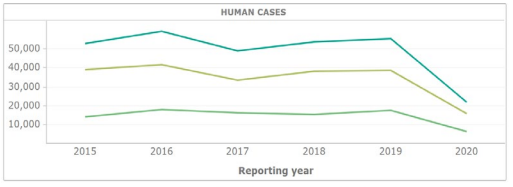
- **EFSA's dashboard on foodborne outbreaks**



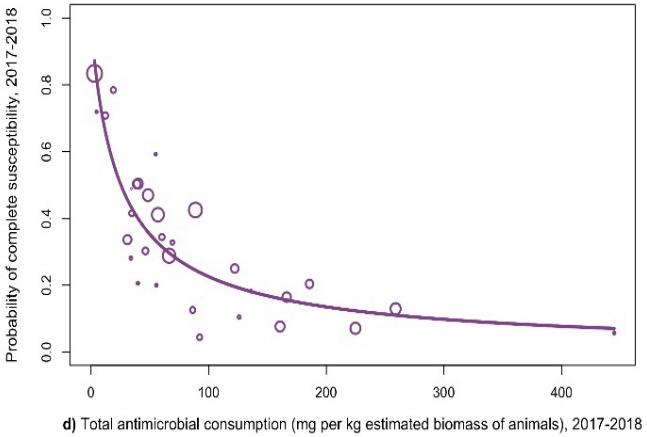
https://www.efsa.europa.eu/en/microstrategy/FBO-dashboard



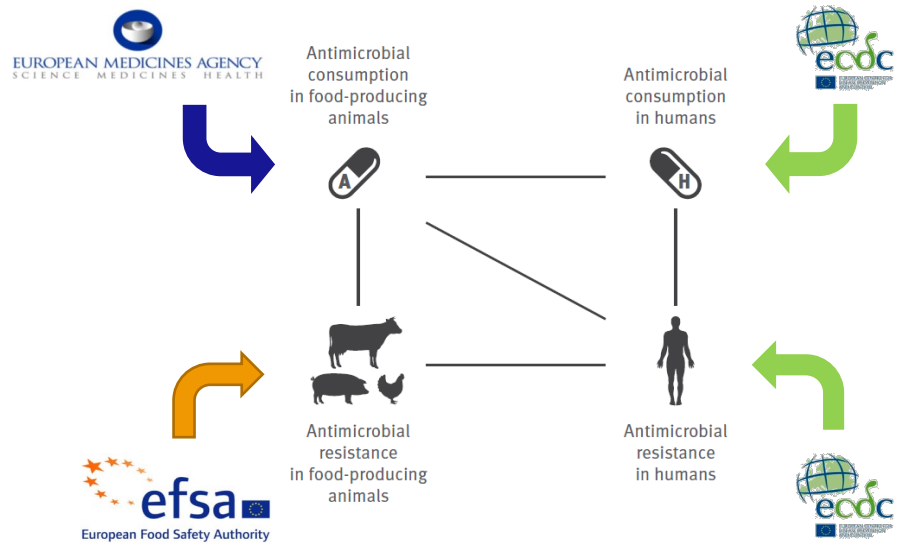


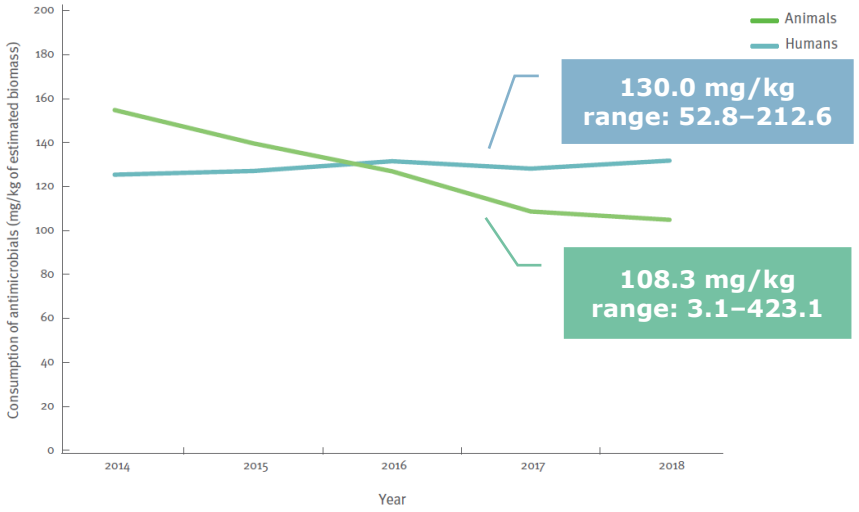


JIACRA: integrated analysis of Ab consumption and AMR



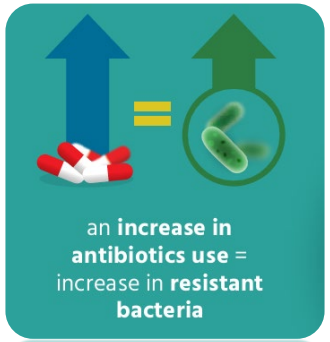
A consistently **lower probability** of detecting completely susceptible indicator *E. coli* in animals when AMC was higher





Overall Conclusions

- Interventions to **reduce AMC** will have a **beneficial impact** on **AMR**
- Need to promote, in both humans and food-producing animals:
  - ✓ **prudent use** of antimicrobial agents
  - ✓ **infection prevention and control**
- High levels of AMC and AMR still reported: **interventions to be reinforced**



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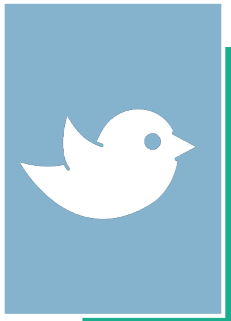

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