National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

The sharing of NGS-data for the control of food-borne disease

Towards a legal framework

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Content

- Stakeholders
- 2 key barriers in the food domain
- Recent experience in the Netherlands
- Cross border collaboration: some legal issues and perspectives.

Background:
EU Funded COMPARE project 2014 – 2019
EU Funded VEO project 2020 –
RIVM collaboration with NVWA Food Health Authority 2018-2020

Tracing and Control of Foodborne Diseases

Public Health / Food Health Authorities
- protecting the community
- Source tracing & Control/Enforcement

Public Law
- GDPR
- National Public Health Act

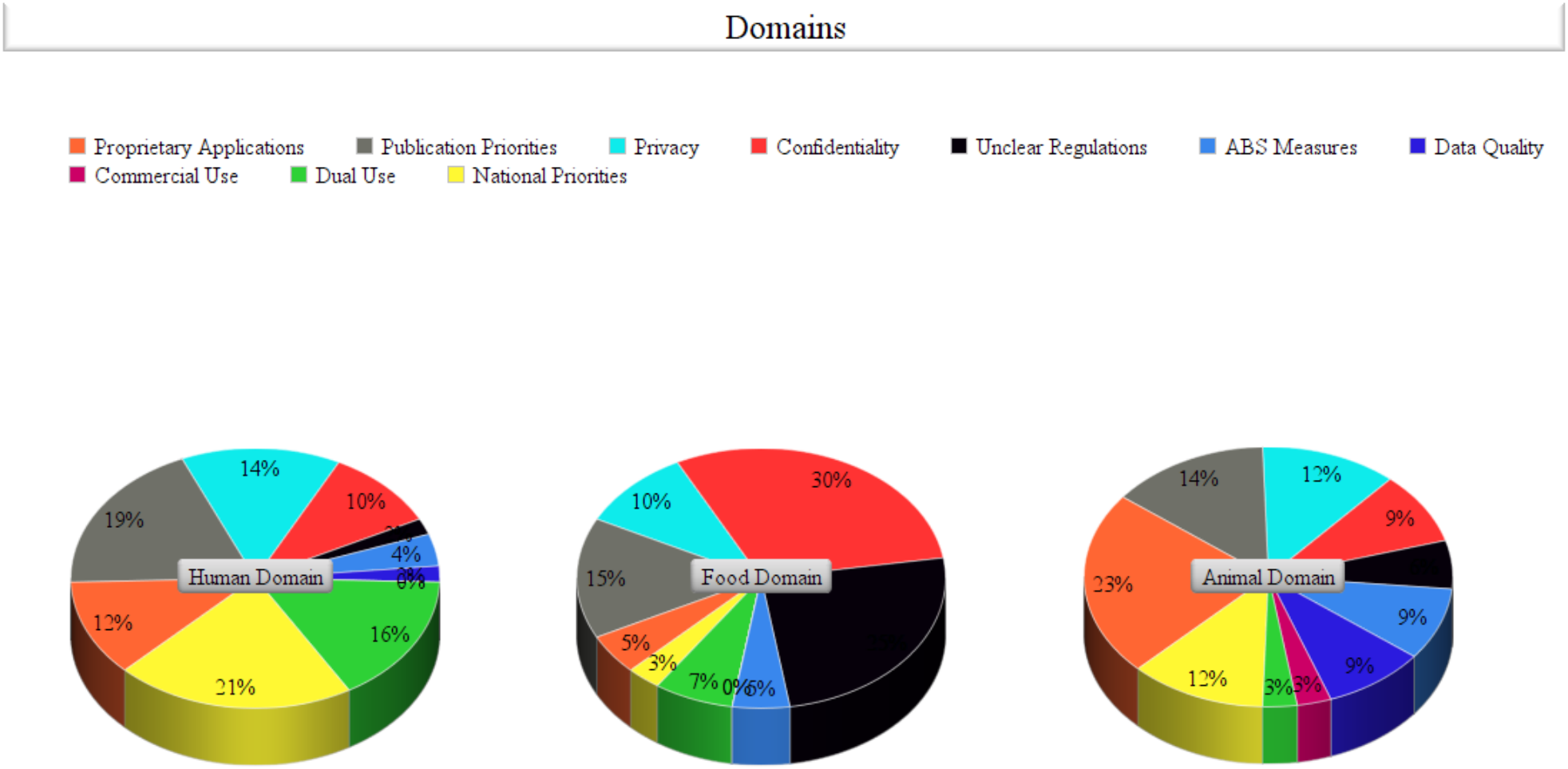
Public Law
- EU food/feed Regulations
- National food/feed legislation

Citizen's / Patient's rights
- Privacy
- Safe products
- Timely information

Producer's / Retailers
- Obligations / responsibilities
- Company's Economic interests
- Good name & fame

Private Law
Compensation claims

BARRIERS PER DOMAIN



Ribeiro et al 2018

Confidentiality
NGS and source tracing

Individual/Patient

- Identity is protected (GDPR | Public Health Act)
- Classic epidemiology: patient knows provided information
- NGS? Clusterdetection may reveal ‘secret’ information

Food Producers

- No GDPR protection (unless family business)
- Accidents may happen: contamination is not always misconduct
- Unjustified blame/shame; Economic damage

Public Health – Food Health Authorities

- When sharing, I loose grip on data for which I am responsible
- The sharing of data outside ‘my’ domain is not explicitly regulated

Unclear Regulations

Public Health and Food Health Authorities

- The sharing of data is not explicitly regulated
- Change in traditional roles and tasks (PH-epi -> food production)
- Anyone can jump to incorrect conclusions
- Am I still in charge of the decisions I am responsible for?

Patients

- Stress their right on information that formerly did not exist
- Can they demand the evidence of their personal contamination?

Food Producers are in doubt

- NGS provides proof beyond doubt. Dataprotection? does this lead to claims?
- NGS proofs also non-contamination, which clears my product from suspicion

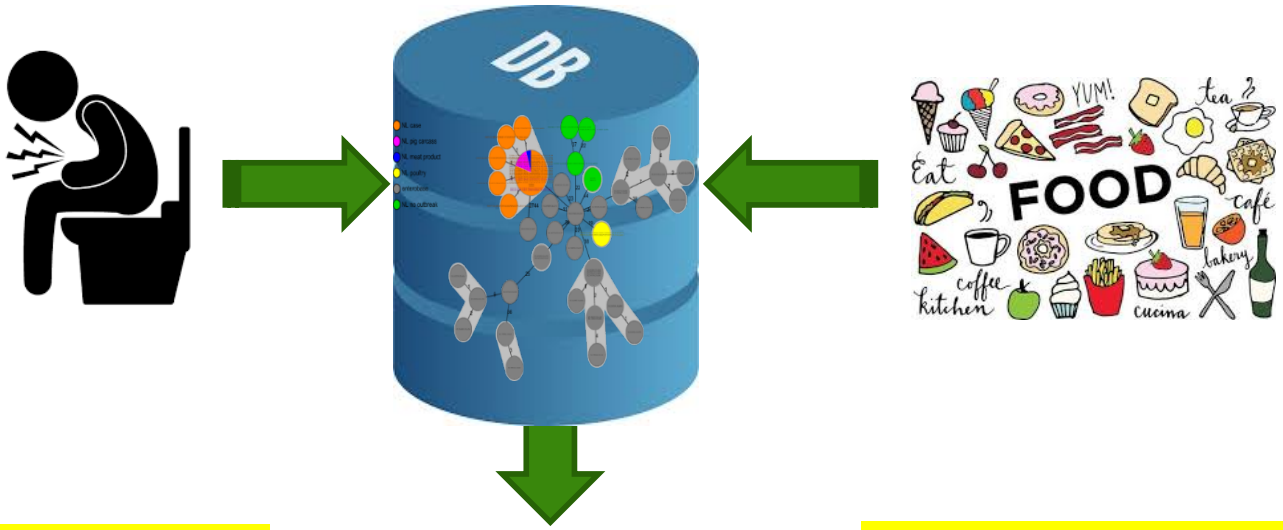
NGS Sharing

RIVM National Institute for Public health

NVWA Netherlands Food Health Authority

Patient's Epi-data

Producer's Meta-data



- Outbreak detection
- Epidemiological source tracing

Cluster **human and foodisolates.**
Focus on active outbreaks

- (re)Inspection and sampling
- Control & Enforcement

A joint NGS databse
Roles and tasks

2019: Listeria cluster detected through NGS matching

40 reported patients in a period of a few months

1 isolate provided by a commercial lab matches with 25 patients

Agreements on roles and tasks:

- RIVM and NVWA compare results of different NGS-methods
- NVWA is leading in decisions and in actions towards Producer
- RIVM researches background epi-data
- NVWA decides on inevitability of disclosure to the public (recall)

- RIVM: information to patients, only request (part of cluster?)
- Patient's right to know only when producer is disclosed to the public
- NVWA/RIVM-evidence against Producer is kept confidential …..
- Unless court order.

Cross border collaboration

Some Legal Issues and perspectives

Startingpoint:

- A OneHealth NGS database with minimum metadata
- As a default, identifying or sensitive epi/meta data of individuals and companies must stay under the responsible national authorities
- NGS and the epi/metadata silos are connected through a codenumber. Ergo, the NGS database contains pseudonomized data and should only be accessable by competent authorities (GDPR)
- A code of conduct and confidentiality agreement must guard the roles and responsibilities of each MS's authorities and ECDC/EFSA

Cross border collaboration

Some Legal Issues and perspectives

- When serious threats/clusters are detected, sensitive epi/metadata can be shared - in a best protected way and only within the Union
  - Criteria/protocols for decision making?
  - Each MS should identify one authority who can 'put the red flag'
  - Sharing is limited to the MS's involved + ECDC / EFSA
  - Protected datahubs can be used

- Public health mandates/powers for source tracing, interventions and enforcement are given for the protection of the public's health, not for forensic or claim purposes. The court should decide on the release of evidence, on pain of loosing trust of producers. Proper legislation would be welcome.

- Declaring a source to be the cause of a cluster only on sequence matching (without minimal epi-investigation) is juridicaly riskful

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Thank you

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