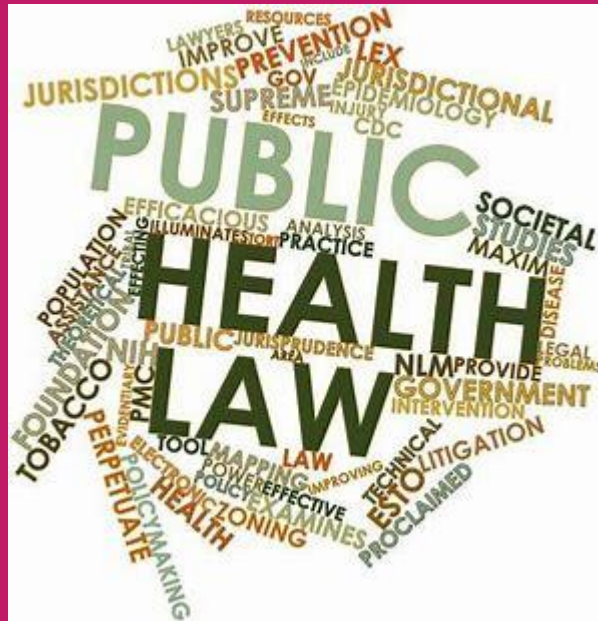




National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport



Cross border Sharing of NGS Data of Human Pathogens

Public Health in Europe
Legal Developments and implications
2020 - 2023

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European Public Health Law – what's new?

Legislation:

New Regulation On Cross Border Health Threats

2022/2371/EU entry into force Dec 26 2022
Replacing Decision 2013/1082/EC

Amended Regulation On Establishing the ECDC

2022/2370/EU entry into force Dec 26 2022
Amending Regulation 851/2004/EU

Jurisprudence:

Judgement of 26 April 2023 of the General Court of the EU in Case T-557/20 of the Single Resolution Board v the European Data Protection Supervisor

Regarding, inter alia, the concept of pseudonymization when processing personal data

ECLI:EU:T:2023:219

Appeal Case before the EU Court of Justice no. C-413/23, filed July 6 2023



Legislation: Extended role for EU, ECDC & Interoperability

The new regulation in general:

- Inter alia ...
- Establishes coordinating EU and national health crisis and pandemic plans
 - Including for One Health approach with i.a. zoonotic, food & water born diseases
- Includes biological, chemical, environmental threats and unknown origin events
- Extends the role and capacities of ECDC to provide scientific advice, guidance and support to the member states and HSC/Commission.
- Improves harmonization through enforced digital interoperability of data exchange
 - New: interoperability of EWRS for source & contact tracing
- Establishes a system for EU Reference Laboratories, cooperating with WHO RefLabs



Sharing human pathogens data in the EU Surv. Network

Network = Competent National Authorities + Commission + ECDC (coordinator)

The National Competent Authorities [...] shall communicate the following information, based on agreed indicators and standards, to the participating authorities of the network (*)

- (a) [...] the epidemiological data (i.e. Tessa data)
- (b) information about the progression of epidemic situations, including for modelling [...];
- (c) unusual or new epidemic phenomena including those in third countries;

New:

- (d) *molecular pathogen data, if required for detecting or investigating serious cross-border threats;*
- (e) *health systems data required for managing serious cross-border threats; and*
- (f) *information about contact-tracing monitoring systems developed at national level.*

*Shall provide through the ECDC-curated Digital Platform for Surveillance
the detailed EPI data & molecular data as adopted by Commission's delegated act
in accordance with procedure of art. 31 of the Regulation*

(*) the same m.m. for ad hoc monitoring

i.e. code included



Interim conclusion on the new Regulation 2022/2371

- Epidemiological data & lab-data (classical typing/WGS/NGS data) of pathogens & AMR on the EU list of notifiable diseases, must be shared with
 - EC & ECDC
 - Competent Authorities of all Member States
- A list of mandatory data per disease will be supplemented to the Regulation
 - after adoption by the Commission through procedure of art. 31 (Experts, EP & Council)
- If domestic legislation (e.g. medical law) prohibits the collection/sharing of mandatory data, the Member States must provide in implementing law.

*How about the sharing of these data under pseudonymization (return code)
- necessary for collaborative source tracing, national and international?*



Jurisprudence

Judgement of the General Court of the EU of 26 April 2023
in the Case of the Single Resolution Board –v- the European Data Protection Supervisor
(ECLI:EU:T:2023:219)

The Court held that pseudonymized data transmitted to a data recipient will not be considered personal data if the data recipient does not have the decoding key nor any other legally valid means to re-identify the data subjects

- *One should put oneself in the position of the recipient*
- *The fact that the sender of data has the decoding key is considered irrelevant*

The judgement is consistent with the 2016 ruling of the EU Court of Justice in the case *Breyer v BRD* under the old Privacy Directive

! EDPS appealed on July 6 against this judgement of the General Court



Consequences

GC judgement is now prevailing rule: a pending appeal at the EU Court of Justice has no suspensory effect.

Consequences both for the European Institutions' and General Data Protection Regulations:

- Dually pseudonymised data fall outside the scope of the GDPR
- Reduction of administrative burden: extensive data impact assessments less applicable
- Dually pseudonymised data can be shared, also outside the Union

Caveat!

The assessment of yes/no pseudonymized data is, like anonymized data, context sensitive

Special caution when $N = \text{small}$

New assessment required each time data-sets are linked by means of a code

New dynamics foreseen: Double coding highly recommended



Sharing Network WGS/NGS data with 3rd Parties without prior Member State's consent

- With other EU and International Rapid Alert Systems (e.g. and in particular RASFF):
through implementing acts (art.29(2) of the Commission
- Partial access to the Digital Platform for 3rd Countries and International Organizations:
through delegating acts (art. 31), conferred to the Commission, which means
 - after consultation of experts of each MS, and
 - no objection raised by the EU Parliament or the Council
- On all other requests (academia, industry, public databases, etc.) Member States decide on the sharing of their own Network data *(Regl. on Access to EU Documents art. 4(5))*
- EU appointed Reference Laboratories?
 - > Collaboration between EU and National Ref. Laboratories is on a voluntary basis



Concluding

Decision -> Regulation : Discussion about the duty to report which data is closed:

- Sharing all (NGS/WGS) detailed data between 27 Competent Authorities, EC and ECDC is mandatory
- If necessary, MS must undertake national implementing acts

Status of pseudonymized data is changed in 2023, (but appeal pending):

- Dually pseudonymized data fall outside the scope of GDPR
- *Double pseudonymization is highly recommendable*

The sharing of data from ECDC with other International rapid alert systems is allowed after implementing act of the Commission, in particular for an efficient One Health approach

Partial access to the Network's Digital Platform can be granted to 3rd Countries and International Organizations, when such delegated act is endorsed by the Council & EU Parliament

In all other cases MS's decide with whom or which database to share their own Network data

- Respecting (inter)national rulings on Open Science/Open Data & Freedom of Information



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Thank you !

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