COLLATION AND ANALYSIS OF PUBLIC ENVIRONMENTAL MONITORING DATASETS FOR REGULATORY SUBMISSIONS

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Background Pesticide authorization in Europe today requires an overview and assessment of environmental monitoring data, typically compiled from publicly accessible online data repositories and reports. However, there are currently no guidelines for what data should be supplied or how the data should be processed, analysed, presented and interpreted. Data collection and analysis to meet this regulatory requirement draws on existing guidelines, guidance and directives e.g., FOCUSgw, groundwater monitoring guidelines (Gimsing *et al*., 2019), Water Framework (2000/60/EC) and associated directives, QA/QC directive (2009/90/EC) and associated guidelines (e.g. SANTE/2020/12830). Public monitoring data provide valuable insight into the state of the environment and possible impacts; however, caution is required when collating, analysing and interpreting these datasets as these data are sourced from different regions/Member State environment agencies that collect them for:

- different purposes [e.g. incident investigation, compliance assessment],
- using different sampling strategies [e.g. flow proportional/grab],
- by different organisations [e.g. water company, environment agency]
- using different sampling protocols,
- analysed to different standards by different organisations/methods,
- and reported differently [e.g. LOD/LOQ reported; data quality (un)reported].

Observations Using recent example public monitoring data assessments for AIR renewal submissions various issues are illustrated:

- **Data quality and harmonisation**
  - Transparency of data cleaning and harmonisation is important
  - Document/remove erroneous data e.g. duplicate records
  - Identify outliers and assess compliance with/without these (Figure 1)

- **Data analysis**
  - Spatial bias – Country and regional variation (Figure 2)

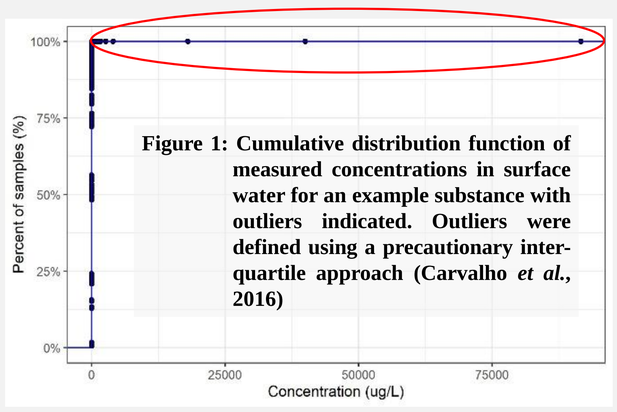


Figure 1: Cumulative distribution function of measured concentrations in surface water for an example substance with outliers indicated. Outliers were defined using a precautionary inter-quartile approach (Carvalho *et al.*, 2016)

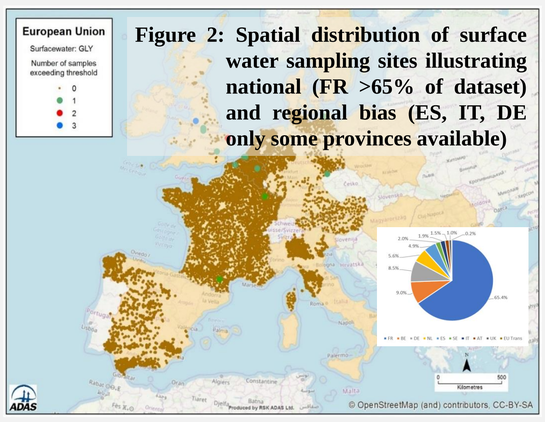


Figure 2: Spatial distribution of surface water sampling sites illustrating national (FR >65% of dataset) and regional bias (ES, IT, DE only some provinces available)

  - Temporal bias – inter- (Figure 3)/intra-(Figure 4) annual variation

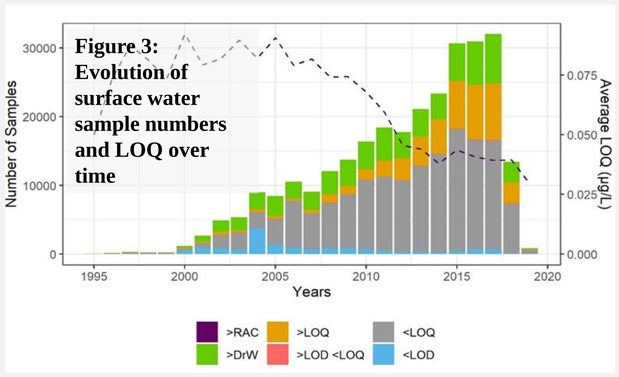


Figure 3: Evolution of surface water sample numbers and LOQ over time

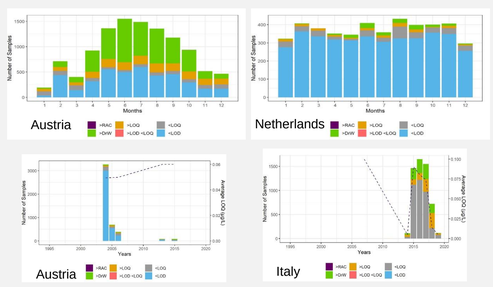


Figure 4: Examples illustrating monthly and annual temporal bias in the datasets that comprise the combined European dataset.

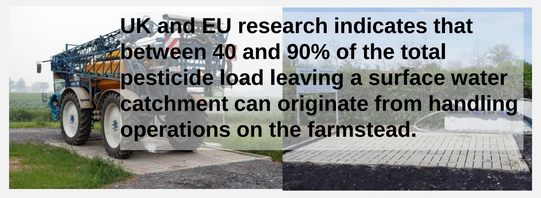
  - Dealing with left-censored data?
    - ❖ Substitution, Kaplan-Meier, Maximum Likelihood Estimation, other?
    - ❖ Which software - NADA package in R, ProUCL v5.1 of US EPA, other?

- **Data Interpretation**
  - Where are compounds measured in the environment coming from?

Figure 5: Chemicals may be registered under different directives and used in different settings including a wide range of professional and amateur users

  - What issue is the data highlighting?

Figure 6: Point sources within a catchment can be significant



  - What sources are the data capturing?
    - ❖ Urban, agricultural, rail, road usage

Figure 7: Emissions from Waste Water Treatment Works and sewer overflows may be similar or higher than losses from agriculture.

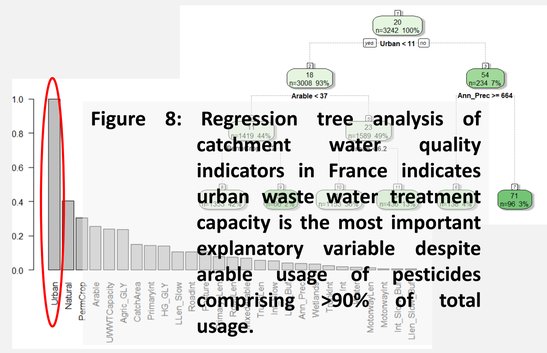


Figure 8: Regression tree analysis of catchment water quality indicators in France indicates urban waste water treatment capacity is the most important explanatory variable despite arable usage of pesticides comprising >90% of total usage.

    - ❖ Transboundary contributions

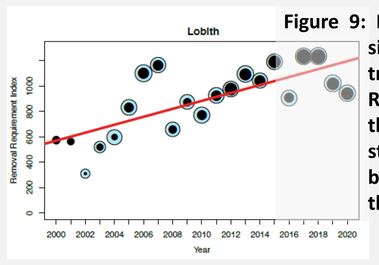


Figure 9: RIWA (2021) report a significant increasing trend in their Removal Requirement Index at the Lobith monitoring station on the border between Germany and the Netherlands

    - ❖ Shared metabolites

Figure 10: Metabolites may be present from other chemicals, legacy pesticides, other parent pesticides

- **Impact assessment**
  - Which threshold or approach is best to assess potential impact (Figure 11)?
    - ❖ PPP directive –Regulatory acceptable concentration (RAC) designed for edge of field waterbody risk assessment; Lifetime health-based ADI concentration for consumers *via* drinking water
    - ❖ Priority substance directive - Environmental quality standards (EQS) for all catchment waterbodies
      - ➢ maximum allowable concentration (MAC)
      - ➢ average annual concentration (AA)
    - ❖ Drinking water directive – tap water standard
  - Defining robust science-based thresholds for many compounds takes effort

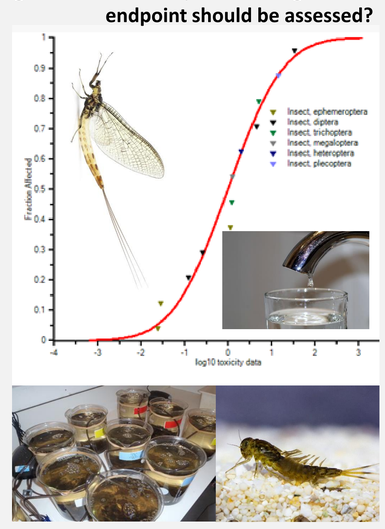


Figure 11: Which protection goal and endpoint should be assessed?

- **Response**
  - Public monitoring is a valuable resource for identifying residues of chemicals in the environment and emerging issues.
  - Important that the underlying causes for residue detection are understood and right measures are targeted at correct use/source/pathway/time
  - Mitigation options and their effectiveness are well understood. Plenty of existing resources to draw on to facilitate this approach (Figure 12).
  - Impact of approach at catchment scale is proven (e.g. stewardship catchments in Belgium).
  - Most effective response is the use of local measures and stewardship targeting local issues rather than blunt national policy instruments.

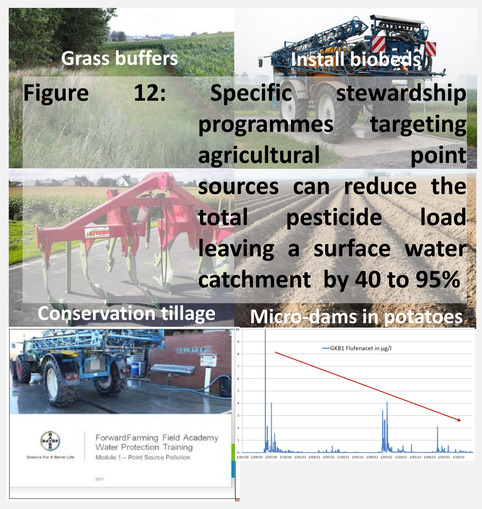


Figure 12: Specific stewardship programmes targeting agricultural point sources can reduce the total pesticide load leaving a surface water catchment by 40 to 95%

Summary, Conclusions & Recommendation

- Public monitoring data provide valuable insight into the state of the environment, emerging issues and possible impacts, and are therefore in principle good data sources to fulfil the regulatory requirement.
- Caution is required when analysing and interpreting monitoring datasets.
- Extensive data exploration should be undertaken that all aspects of the dataset characteristics on the resulting conclusions is appreciated.
- Important that underlying causes for residue detection are understood and the right mitigation measures targeted at the correct use, source, pathway, time.
- Impact assessment should be undertaken using robust science-based thresholds.
- Most effective response to chemical residue detection in the first instance is the use of local measures and stewardship programmes targeting local issues rather than less targeted national policy interventions.
- Guidance that clarifies the data to be used and analytical approach required would be useful.

References:
1 Gimsing *et al*., 2019. Conducting Groundwater monitoring studies in Europe for pesticide active substances and their metabolites in the context of Regulation (EC) 1107/2009, Journal of consumer protection and food safety, https://doi.org/10.1007/s00003-019-01211-x.
2 RIWA, 2021. Annual Report 2020 – The Rhine. 144pp. RIWA-2021-EN-Anual-Report-2020-The-Rhine.pdf (riwa-rijn.org)