ANALYSIS OF PUBLIC ENVIRONMENTAL MONITORING DATASETS FOR THE LISTING AND DELISTING OF PRIORITY SUBSTANCES

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Background The procedure for analysing public environmental monitoring data to assess the listing and delisting of chemical compounds as priority substances (PS) under the associated directive (2455/2001/EC amended by 2013/39/EU) draws on the Watch List approach (Carvalho *et al*., 2016). This compounds a series of worst-case assumptions resulting in an unrealistic risk assessment, notably, the manner in which it (i) deals with outliers and non-detections; (ii) considers all available data to assess the current state of the environment whilst ignoring changes in policy and associated changes in product registrations/usage and their impact on environmental residues; (iii) compares a single worst case predicted no-effect concentration (PNEC) against the 95th percentile (P95) measured environmental concentration (MEC) when deriving the hazard quotient ignoring associated Water Framework Directive guidance and the available annual average (AA) and maximum acceptable concentration (MAC) environmental quality standards (EQS).

Observations Using a dataset for an example compound, compiled using readily available, recent public monitoring datasets (given the dataset used in the PS dossier is not available owing to Member State data access restrictions) as well as recent PS public monitoring data assessments various issues are illustrated:

- **Data availability**
  - Data used in analyses should be freely available to stakeholders to ensure transparency
  - The reason(s) why Member States do not collect monitoring data, especially during a watch list period, should be determined and documented as rather than this being a source of uncertainty, it may instead be a measure of assessed no/low risk
- **Data analysis**
  - Combining all years of available data into a single exposure metric or considering decades old data should be justified, especially when policy changes have restricted uses and product sales have decreased in response (Figure 1).

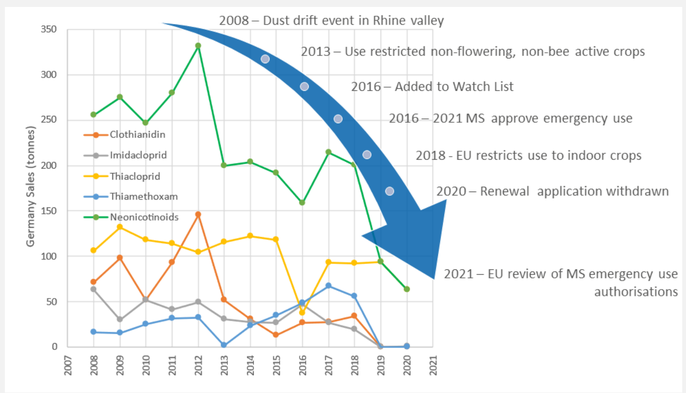


Figure 1: Illustration of the change in German usage of pesticides containing neonicotinoids, frequently used as seed treatments (see below), as a backdrop to key dates for regulatory and policy changes in Europe that would have driven this overall reduction.

- Outlier identification should be considered as the current approach is highly precautionary (Figure 2), especially for monitoring data collected under the Water Framework Directive (WFD) where it is almost certainly collected to ISO standards, e.g. ISO 5667-6 and 5667-14, and analysed according to validated methods, e.g. ISO17025, as mandated under this regulation (WFD Technical Guidance Document 19). Approaches are increasingly harmonised between MSs and Regulations (e.g. SANTE/2020/12830).

Samples with LOQ ≤ EQS	Measured Environmental Concentration (µg/L)				Number of outliers using UFL1	Number of outliers using UFL2
	MLE[1] Q25	MLE Q75	UFL1[2] K = 1.5	UFL2 K = 1000		
EQS-AA	0.00065	0.0114	0.0274	10.72	13,655	23
EQS-MAC	0.00042	0.0051	0.012	4.65	23,987	56

1 Maximum Likelihood Estimation (MLE)
2 Upper Fence Limit (UFL) = Q75 + (K * (Q75 – Q25))

Figure 2: Illustration of the change in the number of potential outliers considering different values of K using the inter-quartile range approach.

- The way left-censored data (concentration data below LOD/LOQ) should be taken into consideration (Figure 3) when calculating annual averages or 95th percentiles seems to be evolving with the substitution approach outlined by the QA/QC (2009/90/EC) and EQS (2008/105/EC) directives used in some PS dossiers while the Kaplan-Meier approach (implemented using US EPA software ProUCL v5.1) was used in others.

Year	Number of samples	Removal rate % samples with LOQ > EQS-MAC	Number of samples with LOQ ≤ EQS-MAC	Censoring rate % samples < LOQ
2005	3901	0.8	3871	99.5
2006	5882	4.4	5622	99.7
2007	10948	5.0	10398	99.2
2008	9790	6.9	9110	94.8
2009	12550	1.2	12394	96.4
2010	15488	13.7	13367	94.8
2011	17774	12.6	15539	95.2
2012	19104	0.1	19078	88.1
2013	25451	0.3	25377	86.7
2014	25630	0.3	25552	85.7
2015	30879	0.4	30760	84.5
2016	31264	0.01	31260	79.7
2017	32959	0.06	32884	81.0
2018	37486	0.4	37337	79.7
2019	34920	0.4	34094	77.0
2020	11137	0.04	11133	81.2
2021	459	0.00	459	60.8

LOQ – Limit of quantification; MAC – maximum acceptable concentration; EQS – Environmental quality standard

Figure 3: Illustration of annual left-censoring rates that are encountered in available public monitoring datasets.

- Confirmation of the exposure endpoints is required - the MEC-P95 is typically being used in the PS listing approach, while the current PS de-listing approach (JRC, 2022) outlines the use of an MEC-AA and MEC-P99.

- The number of samples required for the calculation of a site MEC AA or P95 needs clarification (figure 4) as at present there seems to be no minimum number.

> *"A sampling rate of **12–20** samples per year is the mathematical equivalent of assuming that the MAC is an annual 90 or 95-percentile".*
>
> *"If the MAC is used as an absolute 'maximum', serious and arbitrary errors will result. These lead to a biased classification of water bodies, and wrong decisions on action to secure compliance." UKTAG (2013)*

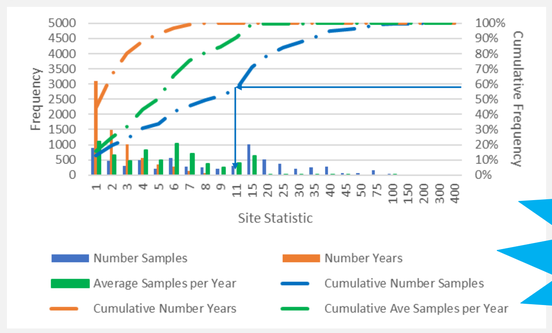
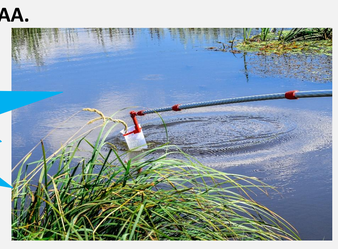


Figure 4: Illustration of the number of samples available at each site for the determination of an MEC-Ave using an expanded May 2021 European Environment Agency (EEA) Waterbase dataset and measured environmental concentrations where LOQ/D ≤ EQS-AA.

~57% of sites have ≤ 11 samples total let alone 12 per year



- The data requirements for trend assessment and the way in which this should be conducted and assessed are similarly unclear.

- **Risk Assessment**
  - Revision of the environmental quality standards (EQS) to levels below the LOQs that MS have used for analyses, especially during the Watch List period, thereby invalidating much of the monitoring data collected is problematic.
  - The exposure endpoints that should be compared with the ecotoxicological endpoints need to be clarified/justified. The PS listing approach compares an MEC-P95 with the PNEC (≈ EQS-AA) which is not in keeping with the existing EQS directive. While the de-listing approach embraces the statistical methods allowed under the directive comparing the MEC-AA to the EQS-AA and an overly precautionary MEC-P99 to the EQS-MAC. Alignment between the different approaches and existing Regulations is required.

> The EQS Directive (2013/39/EU, Annex 1 Part B) considers that:
>
> "*For any given surface water body, **applying the AA-EQS means** that, for each representative monitoring point within the water body, the **arithmetic mean of the concentrations** measured at different times during the year does not exceed the standard*".

Example

- Comparison of annual MEC-P95s with the EQS-MAC (Figure 5) indicates compliance in all years.

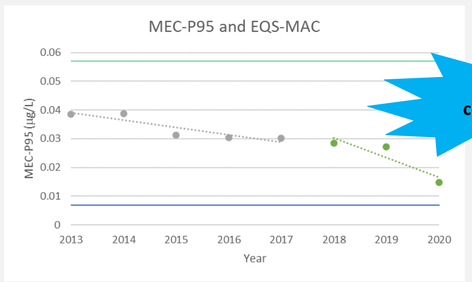


Figure 5: Illustration of the annual 95th percentile (P95) measured environmental concentrations (MEC) calculated using non-substitution based statistical techniques. The EQS-AA is the blue line while the EQS-MAC is the green line. Trendlines are fitted considering key dates for neonicotinoid registration changes in 2013 and 2018.

- Comparison of annual MEC-AAs with the EQS-AA (Figure 6) indicates compliance in the most recent year with the downward trend in MEC-AAs expected to continue as residues already in the environment decrease further. This highlights the importance of using recent data and considering trends within the assessment.

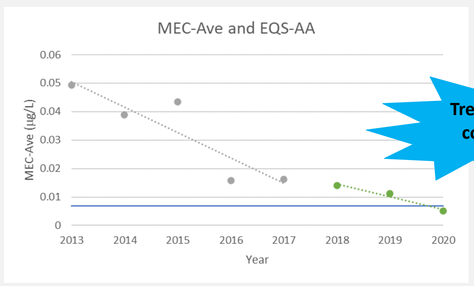


Figure 6: Illustration of the annual average (AA) measured environmental concentrations (MEC) calculated using non-substitution based statistical techniques. The EQS-AA is the blue line. Trendlines are fitted considering key dates for neonicotinoid registration changes in 2013 and 2018.

Summary, Conclusions & Recommendation

- Public monitoring data collected by regional/national environment agencies and water companies is a valuable source of information regarding the state of the environment, however, caution is required when using these data as they are collected and analysed for diverse purposes using an array of approaches.
- The examples presented demonstrate how evolving data analysis methodologies, that seem to compound overly precautionary assumptions, may lead to an assessment of risk that will require Member States to invest precious resources monitoring for a compound that does not present a risk to their surface waterbodies.
- Further dialogue between EU/MS regulatory agencies, chemical/pharmaceutical industries and data analysts/statisticians is required to define data collection and analysis approaches that are better aligned with existing regulation, make the most of public monitoring data and account for the inherent challenges when doing so. This will ensure better science-based decisions are made when listing and de-listing priority substances that will allow Member States to target their limited resources to tackle their most pressing water quality issues in local river basins.

References:
1 Carvalho, R.N., Marinov, D., Loos, R., Napierska, D., Chirico, N. and Lettieri, T., 2016. Monitoring-based Exercise: Second Review of the Priority Substances List under the Water Framework Directive. European Commission, Joint Research Centre. 301pp
2 JRC, 2022. Deselection of existing Priority Substances v05. 189pp.