On the use of science-based thresholds for the interpretation of public environmental monitoring data:

Demonstrating glyphosate (GLY) residues in European surface, ground and drinking water pose no risk to biota, ecosystems or human health

S. Mayer[1#], G. Hughes[4,5], P. Manson[2], D. Saltmiras[3,] M. Al Ramahi[1]
1 Bayer AG Crop Science Division, Monheim, DE #Corresponding author: simon.mayer1@bayer.com
2 Bayer Crop Science, Environmental Safety, Chesterfield MO, USA; 3 Bayer Crop Science, Human Safety, Chesterfield MO, USA; 4 Cambridge Environmental Assessments, Cambridge, UK; 5 GeoSpatial Analytics Ltd, Wolverhampton, UK.

Background

In accordance with the Regulation (EC) No. 1107/2009, pesticide authorisation 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 regulatory expectations draws on existing guidelines, guidance and directives e.g., FOCUSgw, groundwater monitoring guidelines[2], 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 sourced from different organisations:

Purpose – different organisations, like water companies and environment agencies, collect the monitoring data for a range of purposes, e.g. incident investigation or compliance assessment.

Collection – consequently, different sampling protocols and strategies, e.g. flow proportional versus grab sampling, are likely.

Analytics – these differences include being analysed to different standards by different organisations using varying methods and reporting criteria, e.g. LOD/LOQ reported, data quality (un)reported, or LOD (un)validated.

In order to determine whether remedial actions are necessary to ensure protection of human and environmental health, the underpinning basis for establishing threshold limits for impact assessment, should be whether they were arbitrarily established, or science-based and data-derived.

Regulatory Threshold vs Human/Ecological Risk

The arbitrary regulatory threshold value for most pesticide active substances in drinking water is 0.1 µg/L (total of 0.5 µg/L), under the EU Drinking Water Directive (DWD). These are not health-based values but were intended to represent essentially no detectable residues at that time (1990s).

Surface water (SW)

- Ecotoxicological endpoint relevant for GLY registration in Europe is EC50 = 40,000 µg/L (Pacific oyster)
  - European acute risk assessment factor: AF = 100 (data requirements under EU Regulation No. 1107/2009)
  - Regulatory Acceptable Concentration: RAC = Endpoint / AF = 400 µg/L
- RAC used as surrogate threshold for assessing impact of surface water detects on non-target aquatic biota
- No European level Environmental Quality Standard (EQS) currently available for glyphosate (but in preparation).

Groundwater (GW)

- DWD threshold: 0.1 µg/L for pesticide active substances
- Groundwater dependent terrestrial ecosystem (GWDTE) endpoint: No values, to our knowledge, have been set at EU/MS level for use under the WFD for GWDTEs.
- Health-based concentration: The lifetime safe drinking water limit used for consumer risk assessment under the PPPD for GLY of 1500 µg/L (see below) was used.

Drinking water (DrW)

- DWD threshold of 0.1 µg/L for pesticide active ingredients
- Health-based concentration: The lifetime health-based Acceptable Daily Intake (ADI) in water assuming 10% of the ADI in drinking water for a 60 kg person consuming 2 L/day [1],[3],[4]
  - Lifetime health-based ADI (water) = (0.1 x ADI x body weight) / (daily water consumption)
    = (0.1 x 0.5 mg/kg bw/day x 60 kg) / 2 L/day = 1.5 mg/L = 1500 ug/L
  - This is more conservative than the current WHO guidelines (2011) which apply 20% of ADI to water

Results

A GLY Annex I renewal dossier was recently submitted in Europe. Public monitoring data collection/analysis for all Member States (MS) across environmental compartments was included, comprising

Surface Water: comprehensive dataset (>300k samples from >15k sites) versus the regulatory acceptable concentration (RAC) of 400 µg/L, shows very high regulatory compliance (>99.99%). Assessment of MS monitoring data against MS EQS endpoints (given there is no official EU EQS) indicates very high regulatory compliance (>99.96%).

Groundwater: comprehensive dataset (>251k samples from >40k sites) versus the EU arbitrary regulatory threshold (0.1 µg/L) shows very high regulatory compliance rates (>99.4%). Excluding a small number of high outlier maximum concentrations that were well below the lifetime health-based Acceptable Daily Intake (ADI) water concentration (1500 µg/L). Case studies exploring local elevated detection rates in Spain (ES), Italy (IT) and the United Kingdom (UK), suggest these findings are most likely a function of poor monitoring locations, poor or specific local agronomic practice and pollution events. Local farmer surveys in southern ES have identified several stewardship measures to improve practices. The Glyphosate Renewal Group (GRG) proactively initiates stewardship measures with the aim to achieve compliance going forward.

Drinking Water: small dataset (>9.5k samples from >3.7k sites) versus the EU regulatory arbitrary threshold (0.1 µg/L) shows very high regulatory compliance (>99.9%) and is in good agreement with a large number of aggregated data summaries in published reports. Where threshold exceedances occur, the maximum concentrations are low and well below the lifetime health-based ADI concentration. This is unsurprising as GLY is readily removed by conventional water treatment processes already in place to ensure microbiological safety.

Conclusions

Analysis of a comprehensive database of GLY residue analyses, that exists within the public monitoring of national and regional environment agencies in Europe with robust science-based thresholds suggest no issues for the state of the environment, nor to human health via drinking water.

References

[1] EFSA, 2010. Scientific Opinion on Dietary Reference Values for water. EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA) EFSA Journal 2010; 8(3):1459

[2] Gimsing, A.L. 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

[3] WHO, 1993. Guidelines for drinking-water quality, 2nd edition: Volume 1 – Recommendations. 202pp.

[4] WHO, 2011. Guidelines for drinking-water quality, 4th edition. 564pp.

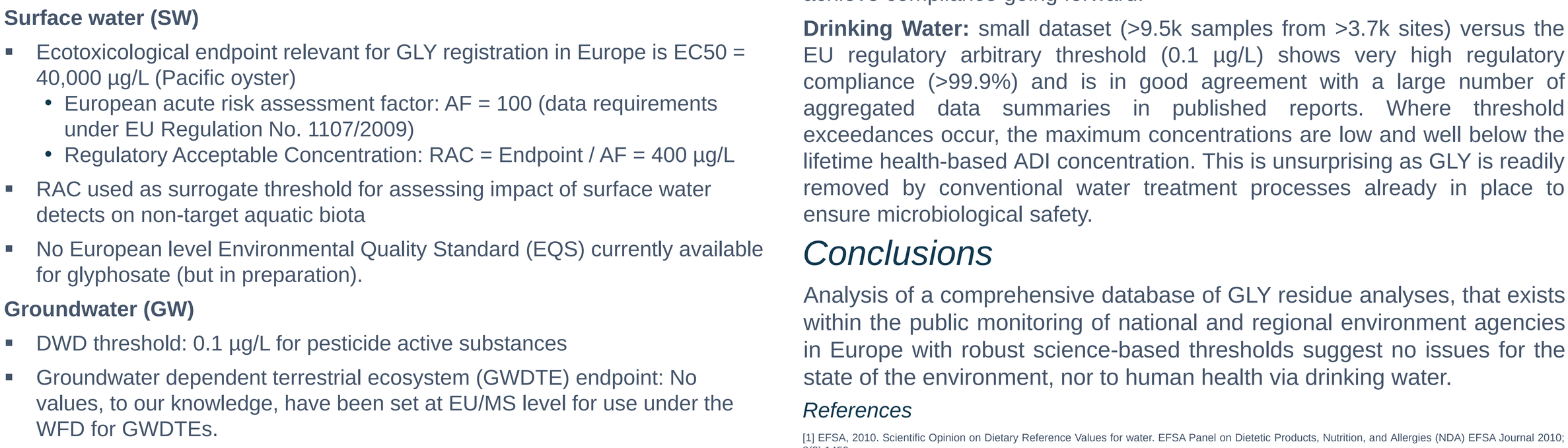

Figure 1: Cumulative distribution function (CDF) of glyphosate measured concentrations (excluding outliers) in surface water (left) and groundwater (right) to facilitate interpretation of the combined Europe dataset using different thresholds and regulatory acceptable concentrations (RACs). The X- and/or Y-axes of the inset CDFs have been constrained to illustrate the lower concentration ranges.