Glyphosate Renewal Group

Glyphosate Monitoring Data

The Glyphosate Renewal Group (GRG) has submitted an 18,000-page dossier to the European Food Safety Authority for consideration by the **Rapporteur Member State (RMS)** Assessment Group on Glyphosate (AGG) (consisting of France, Hungary, The Netherlands, and Sweden) seeking renewal of the active substance glyphosate. The RMS has evaluated this dossier and released a consultation version of their assessment (the Combined Draft Renewal Assessment Report: dRAR).
A brief summary of the 741-page B.8.5 (Monitoring data) section of the dRAR is presented here, including an indication of how the GRG is intending to respond to the issues raised by the RMS, where appropriate.

An extensive assessment of existing public monitoring data has been submitted, based on a collection of public monitoring data (raw data and aggregated data from national authorities and any regional/national agencies – 'raw data' refers to digital data representing official spatially and temporally explicit monitoring data, whereas 'aggregated data' refers to information provided in publicly available reports, *e.g.* from environmental agencies or research institutes) and on a review of open literature. Within the dRAR, the GRG submitted ten new applicant studies, seven existing applicant studies and many published peer-reviewed papers (considered reliable or reliable with restrictions) covering the monitoring of glyphosate and its principal metabolite AMPA (amino methyl phosphonic acid) in soil, groundwater, surface water, transitional water, sediment, drinking water and air.
The studies and publications assessed cover several different spatial extents ranging from pan-EU and country, to regional/provincial, and even specific locations/fields. Similarly, they cover a range of temporal scales ranging from a single sampling occasion to multi-monthly and annual sampling schemes. The assembled EU data set is large and captures a range of agronomic, geographical, pedoclimatic and hydrogeological contexts, as well as providing a good temporal coverage allowing assessment of the state of a compartment in different seasons and hydrological regimes. The data set does not distinguish between different sources of glyphosate and AMPA (which include not only agricultural uses, but also uses on hard surfaces and railways). The data have been collated and analysed by the GRG with reference to regulatory, and other, triggers.

The RMS notes that generally, as it is not possible to directly link public monitoring data to reliable information on the use of glyphosate products (with respect to both location and time), significance of reported concentrations being less than regulatory triggers is difficult to determine. The GRG agrees; comparison of findings to regulatory triggers has been included to help to give some context to the findings, but the anaylses ***do not replace regulatory risk assessments reported elsewhere in the dRAR***.
Public monitoring data cannot be seen as a higher tier risk assessment, but can be viewed as information that helps to confirm the safety indicated in risk assessments, and can also identify where there are issues that require further investigation, stewardship action or local mitigation measures. In this case, though, the analyses are likely to be indicative and given that the data set is very large, do provide a high level of reassurance.

Availability of monitoring data for soil, tidal waters and sediment was very limited – and there were no exceedances of regulatory triggers, and no causes for concern.

For air, there was no monitoring data available for glyphosate and AMPA when the dRAR was submitted. The results of an exploratory French national monitoring campaign conducted 2018 to 2019

became available thereafter. Only 50 sites were monitored in total, and glyphosate and AMPA at only 8 sites: glyphosate was found in air in 56% of samples and AMPA in 1.3%. The RMS suggested that spray drift from glyphosate applications might be the source of these detections, but also conceded that the small number of samples involved make meaningful interpretation difficult. The GRG will undertake further work on this, but it should be noted that the detections were very small (maximum glyphosate concentration was 1.225 ng/m^3, with most concentrations being below 0.25 ng/m^3).

For groundwater, a large monitoring data set was collected, and analysis of these data submitted. In the dRAR results are given for each country, and for the whole combined EU data set. The data set represents >251 000 samples collected from >37 800 sampling sites for glyphosate and >230 000 samples collected from >34 400 sampling sites for AMPA.

GRG conclusion: The analysis of the large groundwater dataset for glyphosate and AMPA indicates they are both occasionally detected, however, compliance against regulatory endpoints and thresholds is very high. The environmental concentrations typically encountered do not pose a risk for ecosystems or human health from drinking water. The RMS broadly accepted the extensive nature of the assembled data set and the high compliance of concentrations against thresholds and considers that glyphosate contamination of groundwater >0.1 µg/L via direct leaching following agricultural use is not expected but seeks further reassurance with respect to the underlying issues of representivity of the monitoring data. The GRG intends to address the concerns of the RMS.

Although representing 14 EU countries (capturing the bulk of glyphosate sales in the EU), the monitoring dataset was dominated by French data (~80%) with smaller contributions from Denmark (~6%), Germany (~6%) and Austria (~4%). Data from additional EU countries is currently being collected and will be added to the analyses and submitted to the RMS.
Detection of glyphosate above the limit of quantification in groundwater samples was ~2%, ranging from as low as 0.2% in Austria to as high as 10.3% in Spain. Compliance with the 0.1 µg/L trigger value, of the combined EU data set, was 99.4% of samples from 97% of sites, indicating just a few exceedances (~0.6% of samples from ~3.0% of sites). Investigations exploring elevated rates of groundwater detection in Spain and the UK have been initiated, and first findings suggest these are local issues from direct contamination (e.g. a pollution event at a UK plant-cultivation nursery) and the GRG expects to arrive at appropriate specific mitigation measures in the near future, once investigations are complete. Detection of AMPA above the limit of quantification was ~2.9%, ranging from as low as 0.4% in Spain to 19.5% in Belgium. Compliance with the 10 µg/L threshold for a non-relevant metabolite was 99.998% of samples from 99.994% of sites.
The RMS notes that key information on description of monitoring locations is often missing in public monitoring data and it is not possible to evaluate the vulnerability to leaching represented by these sampling sites. Frequency and regularity of sampling have also not been included as criteria in the data analysis; this means the temporal distribution of the overall data set is unknown, but also that the spatial distribution of the sampling results might be affected by this heterogeneous sampling effort. The GRG considers that although further information on use and detailed data on sampling sites may on rare occasions be available in underlying reports available at national level, practically it would not be possible to collate a consistent set of site characteristics for such a large number of sampling sites. Nevertheless, where there are anomalous results, detailed investigations have been initiated to understand the results better. The RMS has also requested further investigation of the data to confirm that the low number of exceedances are not related to long-term contamination in some locations, and additional investigations and analyses will be submitted by the GRG. Overall, as indicated by the

groundwater monitoring data, the RMS considers that systematic groundwater contamination > 0.1 µg/L via direct leaching is not expected.

For surface water, a large monitoring data set was collected, and analysis of these data submitted. In the dRAR results are given for each country, and for the whole combined EU data set. The data set represents >291 000 samples collected from >13 800 sampling sites for glyphosate and >269 000 samples collected from >12 400 sampling sites for AMPA.

GRG conclusion: Analysis of the large glyphosate and AMPA surface water datasets indicates they are both frequently detected, however, compliance against regulatory endpoints and thresholds is extremely high. The environmental concentrations typically encountered do not pose a risk for biota or ecosystems. The RMS agrees that the number of detections tends to indicate that glyphosate is widely and regularly found in surface water and that this reflects the spread and diversity of use of glyphosate containing products, and seeks further reassurance with respect to the underlying issues of representivity of the monitoring data. The RMS considers that these levels of detection highlight the necessity of implementing better-reasoned practices for glyphosate containing products, in order to limit environmental contamination. The GRG intends to address the concerns of the RMS.

Although representing 8 EU countries and 2 large transboundary catchments relating to the Rhine and Danube river basins, the monitoring dataset was dominated by French data (~67%) with smaller contributions from Belgium (9%), Germany (~9%), The Netherlands (~6%) and Spain (~5%). Data from additional EU countries is currently being collected and will be added to the analyses and submitted to the RMS.
Detection of glyphosate above the limit of quantification in surface water samples was ~40%. Compliance of the concentration results with the glyphosate aquatic regulatory trigger was 99.994% of samples and 99.90% of sites, and the exceedances (0.006% of samples; 0.10% of sites) were on separate non-consecutive occasions (0.003% of samples being consecutive). This analysis was performed using a Regulatory Acceptable Concentration (RAC; derived from experimental toxicity levels to relevant aquatic organisms). Analyses were also carried out against more conservative EQS values (Environmental Quality Standards; predicted no effect concentrations arrived at by considering the appropriate aquatic organism toxicity data and including margins of safety linked to quality and number of data points available, derived to support activities under the EU Water Framework Directive), where available for individual Member States (no EU-wide agreed EQS value is currently available) of 28 – 196 µg/L (annual average EQS) and 64 – 398 µg/L (maximum allowable concentration EQS). Compliance rates were also very high against these (>99% of samples). Detection of AMPA above the limit of quantification in surface water samples was ~64%. Compliance of the concentration with the AMPA aquatic regulatory trigger was very high (99.999% of samples; 99.976% of sites). There was no specific pattern or bias to the distribution of the exceedances for either glyphosate or AMPA (and it should be noted that there are other non-glyphosate sources of AMPA in the environment, such as detergents).
Glyphosate and AMPA residues are frequently detected in surface water, but the monitoring data indicate that they do not pose risk to the environment. The RMS notes that although glyphosate containing products are widely used, the lack of information with respect to the temporal and spatial aspects of this use mean that it is difficult to determine the extent to which actual peak concentration and exceedance of the triggers in relation to pesticide use of glyphosate is caught by these monitoring programs. The GRG maintains that the scale of the public monitoring datasets collated for this assessment likely captures a broadly representative range of potential surface water concentrations and

the near absence of surface water concentrations above the triggers suggests this does not occur very often.
Where surface water is abstracted for the generation of drinking water, 99.9% (in the EU) is subject to disinfection, and glyphosate and AMPA are readily degraded by the most common disinfection methods. Rates of removal by chemical disinfection for glyphosate and AMPA are very high for optimised processes (93 – 95%), and water treatment processes at specific abstraction sites are carefully controlled to ensure that quality standards are met at consumers' taps. Consequently, where glyphosate or AMPA are known to be present in surface water, the water treatment processes can be optimised to ensure there is a low risk of exceeding thresholds in drinking water.

For **drinking water**, availability of monitoring data for glyphosate and AMPA was limited and not recently collected; a total of ~8000 samples for glyphosate (from ~3 100 sites) and ~7 000 for AMPA (2 300 sites). The bulk of the data (~86% for glyphosate and 99% for AMPA) came from Sweden (1998 – 2014), with only data for glyphosate available in Ireland for 2017 (14% of the data), and a small dataset from Germany (2012 – 2018). Compliance with the drinking water threshold (0.1 µg/L) was very high for glyphosate (99.9%), and for AMPA with the non-relevant metabolite threshold (10 µg/L) was 100%. Additionally, the RMS reported that for France (2007 – 2016), for glyphosate the annual number of analyses for drinking water were between 4 293 and 15 003, and the proportion of yearly observed exceedance of 0.1 µg/L was 0.09% – 0.30%; for AMPA there were 4 138 – 14 422 annual analyses, and the observed yearly exceedance of 0.1 µg/L was 0.08% – 0.27%. Overall, the evidence points to isolated detections, most likely due to contamination at the sampling stage or problems with analyses, rather than any indication of a persistent presence in drinking water. The RMS notes that the definition, and origin of the drinking water sampled (e.g. groundwater or surface water), does not appear to be available – the GRG will provide any additional relevant reported information, but also notes that this data is rarely in the public domain (possibly due to security considerations), and that the source of drinking water is somewhat irrelevant as compliance is required at the consumers' tap, and the available monitoring data strongly suggests that compliance is achieved.