Glyphosate Renewal Group's (GRG) Comments on European Commission proposal for a Directive of the European Parliament and of the Council amending Directive 2000/60/EC establishing a framework for Community action in the field of water policy, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration and Directive 2008/105/EC on environmental quality standards in the field of water policy - developments in Glyphosate EQS

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Glyphosate Renewal Group

OWNERSHIP STATEMENT

Comments regarding European Commission proposal for a Directive of the European Parliament and of the Council amending Directive 2000/60/EC establishing a framework for Community action in the field of water policy, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration and Directive 2008/105/EC on environmental quality standards in the field of water policy - developments in Glyphosate EQS setting.

Comments of the GRG

In the EU COM proposal, environmental quality standards (EQS) have been proposed for glyphosate (GLY), including specifically the acute maximum allowable concentration (MAC) and the chronic annual average (AA) as endpoints for freshwater and marine waterbodies. In addition, a quality standard (QS) for surface water (SW) used for the abstraction and preparation of drinking water ($QS_{dw,hh}$) has been suggested for the first time. The following information should be considered in the discussion of the setting of EQS/QS values:

- **The setting of a $QS_{dw,hh}$ for GLY sets an unnecessary precedent for priority substances, which will lead to ambiguity and additional costs for water management in Member States (MS).**
- **Where MS do not abstract drinking water from surface water, a $QS_{dw,hh}$ for glyphosate will not be required at all. Where abstraction of surface water for the production of drinking water takes place, a water treatment factor should be applied to the derivation of any $QS_{dw,hh}$. For glyphosate, this can be set at 10.0 µg/L, given the very high efficiency of treatment methods in place, and as it is allowable for MS to reduce the treatment factor as appropriate to their local water treatment plant conditions.**
- **The very high compliance of real-world drinking water monitoring data strongly suggests that it is unnecessary to set a $QS_{dw,hh}$ for glyphosate for the abstraction of surface water for the generation of drinking water. There is a strong risk that this new requirement would unnecessarily increase workload and costs for water management in MS.**
- **SCHEER have expressed uncertainty relating to the acute and chronic aquatic endpoints proposed for establishing the EQS for surface and marine water bodies. Both regulatory studies and public literature are considered in the proposal using endpoints that are not supported by appropriate chemical analysis to confirm exposure in the corresponding studies. In this document, the GRG highlight robust and scientifically valid studies from which alternate endpoints could be selected for establishing appropriate EQS for freshwater and marine water bodies.**

- **The setting of a $QS_{dw,hh}$ for GLY sets an unnecessary precedent for priority substances.**
  As proposed by EU COM and SCHEER[1], the definition of a $QS_{dw,hh}$ is specific to surface water abstracted for drinking water. It does not replace ecological endpoints such as the freshwater EQS-AA or EQS-MAC. These should be applied to all surface waterbodies as part of an ecosystem risk assessment. As the locations of surface water abstraction points (for deriving drinking water) are rarely made available, public surface water monitoring data should generally be compared with the EQS. The introduction of a $QS_{dw,hh}$ for GLY would be an unnecessary complication with respect to water management. Many MS derive their drinking water from groundwater and hence a $QS_{dw,hh}$ would not be relevant for them. For the others the setting of a $QS_{dw,hh}$ would require a complicated protocol with respect to implementation. For example, how are ‘water extraction zones’ to be

[1] SCHEER (Scientific Committee on Health, Environmental and Emerging Risks), Preliminary Opinion on Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive - glyphosate, 30 September 2022.

defined? Which water is to be considered as 'used for extraction'? There is a strong risk that inconsistent approaches might be established by different MS and confusion reigns. The GRG clearly endorses measures that increase public safety when there can be seen a need to do so. On the other hand, and based on a case by case decision, a $QS_{dw,hh}$ for glyphosate would not contribute to such increase in safety of drinking water for the public (see below). This applies, in particular, for drinking water since the EU pesticide threshold of 0.1 µg/L properly applies at the point of the tap of the consumer. The available drinking water monitoring data clearly indicate that there is no such concern in the context of glyphosate in its residues 'at tap level'.

- **Where member states do not abstract drinking water from surface water, a $QS_{dw,hh}$ for glyphosate will not be required at all.**
  The introduction of a glyphosate (GLY) $QS_{dw,hh}$ is not required for many MS as they abstract little to no surface water as raw water for the production of drinking water. In the EU, the majority of large water supplies are sourced from groundwater, ranging from 12% in IE to 100% in AT, likewise, the majority of small supplies also exploit groundwater[2]. This is in agreement with the assessment that ~75% of EU inhabitants rely on groundwater for drinking water[3]. Being a MS-specific issue, it should be left to each MS to define a $QS_{dw,hh}$ for drinking water abstraction points if regarded as necessary given the current regulations that allow for such MS level action.
    - In TGD 27[4] on the setting of EQS values the following is noted: "*A treatment factor should be applied to the drinking water threshold so that the $QS_{dw,hh}$ relates to the 'raw' water (i.e. it is an 'environmental' standard). Drinking water thresholds and treatment processes used to achieve them should be taken into account in determining quality standards for water abstraction resources. This should have regard to Article 7 of the WFD with reference **where appropriate** to simple treatment*".
    - The setting of a treatment factor to the lowest common denominator of 'simple treatment' at an EU scale appears not be appropriate when considering that most MS manage the quality of their drinking water in conjunction with adequate water treatment so that quality standards are finally met at the tap of the consumer. In effect, this typically involves very high rates of GLY removal (>90%) by water treatment trains. The latter are already in place for other purposes (see appendix 2). Using the lowest or average treatment factor is problematic as the $QS_{dw,hh}$ would be set too low for MS with a higher removal rate already present. For example, a 50% removal rate would result in a $QS_{dw,hh}$ of 0.2 µg/L while 90% removal would allow for 1 µg/L $QS_{dw,hh}$. **In that the Directive allows MS to establish lower $QS_{dw,hh}$ on a national basis but not a higher value, it would be more appropriate to set the EU-level $QS_{dw,hh}$ at a value arising from a 99% glyphosate removal rate (i.e., 10 µg/L)** with a minimum of 0.125 µg/L (based on a 20% removal rate) and allow each individual MS to determine the value they will use. It is clear that using the worst-case removal value sets an overly precautionary QS for all MS and limits their water management options.

[2] European Commission (EC, 2016). Synthesis Report on the Quality of Drinking Water in the Union examining the Member States' reports for the 2011-13 period, foreseen under Article 13(5) of Directive 98/83/EC. COM (2016) 666 final. 16pp plus Country Reports and Small Supply Summaries. COM (2019) 128 Final. 13pp.

[3] European Commission (EC, 2008). Groundwater Protection in Europe. The New Groundwater Directive – Consolidating the Eu Regulatory Framework. 36pp.

[4] EC (European Commission), 2018. Technical Guidance for Deriving Environmental Quality Standards (TGD). Common Implementation Strategy for the Water Framework Directive. Guidance Document No.27 Updated version 2018.

- **The very high compliance of real-world drinking water monitoring data strongly suggests that it is unnecessary to set a $QS_{dw,hh}$ for glyphosate for the abstraction of surface water for the generation of drinking water.**
  Article 7.3 of WFD: *"Member States shall ensure the necessary protection for the bodies of water identified with the aim of avoiding deterioration in their quality in order to reduce the level of purification treatment required in the production of drinking water... "*. The potential occurrence of GLY in raw drinking water does not automatically trigger the necessity for additional treatment of surface water abstracted for production of drinking water:

  - No evidence has been identified that water companies have to specifically treat raw surface water abstracted for drinking water due to GLY residues, as GLY trace residues are readily removed by existing treatment steps already in place to improve the microbial status of water quality, like bank filtration and chlorination (see appendix 2).

  - There are strong indications that there is no longer a necessity to set removal requirements specific for plant protection products. This is concluded from latest examples given in reports from the association of Dutch water companies (RIWA): in October 2021, RIWA published their Rhine catchment 2020 annual report[5]. In Chapter 2, the report describes a 'Removal Requirement Index', comprising the number and quantity of substances that drinking water companies need to remove to meet the Dutch legal obligations for clean and wholesome drinking water. For the monitoring station Lobith (river Rhine at the German/Netherlands border) the index is given for individual substances, including GLY. The conclusion on page 89 is: *"Since 2015, glyphosate, isoproturon, TCA and the sum of the pesticides no longer have a removal requirement for drinking water purification. In 2020, the removal requirement for the substance group plant protection products, biocides and their metabolites was in fact zero."*

  - The available data from public monitoring and rates of drinking water compliance (see appendix 3) indicate a very high compliance rate to the EU drinking water trigger at the tap of the consumer[6]. Exceedances of the threshold by GLY residues occurred occasionally at very low concentrations and are well below science-based threshold values for human safety[7].

  - The setting of an EU $QS_{dw,hh}$ for GLY would require water management organisations to establish costly, and complex, GLY monitoring programmes which the current evidence strongly suggests would be unnecessary.

- **Consideration of Aquatic Ecotoxicological endpoint data.**
  Considering Section 7.1 Acute Aquatic Ecotoxicity, SCHEER question reliability scores for acute ecotoxicity data performed with active substance (Tables 10.1.1 & 10.1.4 of draft JRC EQS dossier). Scoring reflects limitations with the studies, that were conducted without analytical confirmation and not according to recognized test guidelines. SCHEER consider that use of the aquatic plant study[8] endpoints proposed for QS setting by JRC was not appropriate for use as the concentration of glyphosate in the test system was not confirmed by chemical analysis. In addition, SCHEER also identified that endpoint (EC_{50} of 4.7 mg/L) from an algal study conducted with *Chlorella vulgaris*[9] should also be excluded as there was also no chemical analysis in the study. It was also considered appropriate to exclude these two (aquatic plant and algal) endpoints from the probabilistic approach

[5] https://www.riwa-rijn.org/wp-content/uploads/2021/10/RIWA-2021-EN-Anual-Report-2020-The-Rhine.pdf.
[6] > 99.9% for unaggregated datasets.
[7] Lifetime health-based ADI (average daily intake) concentration of 1500 µg/L.
[8] conducted with *Myriophyllum sibiricum (PhD thesis - https://atrium.lib.uoguelph.ca/xmlui/handle/10214/24672*)
[9] doi: 10.1006/eesa.2001.2113

to setting of the MAC-$QS_{fw\text{-}eco}$. and that the aquatic plant endpoint should also not be used to establish the AA-$QS_{fw\text{-}eco}$ value (Section 7.2 of SCHEER response).

Uncertainties were raised over the purity of substances tested with stated values (%) suggesting products were tested and not active substance. There are therefore uncertainties relating to the test substances cited in the literature, which appear to have been included in the final reliability scores.

SCHEER highlighted that the next lowest aquatic endpoint for algae from Table 10.1.1 of the JRC EQS dossier, was for the marine alga *Skeletonema costatum* with an EC_{50} of 13.5 mg a.e./L (see GRG-eco[10]), which achieved a reliability score of 1 (therefore, being valid).

SCHEER also discuss that an aquatic plant study conducted with the active substance in 2012 using *Myriophyllum aquaticum* exposed to the active substance submitted for the Annex I renewal (see GRG-eco), suggesting the study be used as an alternative for endpoint selection, although the study was not cited in the list of references. This study was submitted as part of the dossier for re-registration of glyphosate onto Annex I in the EU. The RMS's evaluation concluded the study was invalid due to the wrong plant density in replicate exposure vessels. The registrant (GRG) therefore conducted a repeat study, a fully guideline compliant aquatic plant study with *Myriophyllum spicatum* in 2022, conducted according to OECD 239, 'Water-sediment *Myriophyllum spicatum* toxicity test' test guideline (see GRG-eco). All validity criteria in the test were satisfied and the study was considered valid by the RMS. The 14-d ErC_{50} value achieved for biomass wet weight was 163 mg a.e./L and for total shoot length, the ErC_{50} value was 208 mg a.e./L. These endpoints are considered appropriate alternative endpoints for consideration when establishing a QS for surface water.

For the acute zebrafish toxicity study under section point KCA 8.2.1-015 of the current glyphosate Annex I re-registration dossier (see GRG-eco), the RMS consider the study as 'supportive' due to uncertainties associated with the analytical verification conducted during the 96-hour test. The acute study endpoint from this study does appear in the current list of endpoints in EFSA (2015) Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate[11].

The registrant believes that the chronic zebrafish (*Danio rerio*) toxicity study under section point KCA 8.2.2.1/002 of the current glyphosate Annex I re-registration dossier (see GRG-eco) to be invalid due to many uncertainties associated with the study conduct and reporting, identified in the submitted Annex I reregistration dossier. This includes inadequate reporting and lack of analytical detail, including analysis of test media during the exposure period of the test, in addition to uncertainties associated with the reported test design versus the raw data included in the report.

There are multiple chronic fish study endpoints amongst the ecotoxicology endpoints for glyphosate presented in the current glyphosate Annex I re-registration dossier (see GRG-eco), which includes chronic fish early life stage (ELS) test endpoints conducted with rainbow trout (*Oncorhynchus mykiss*) where no effects on survival, growth and development were observed during an 85-day continuous exposure period to glyphosate, achieving a NOEC of 9.63 mg a.e./L. Additionally, there is a fish full life cycle (FFLC) study and also a fish short-term reproduction assay (FSTRA) both conducted with fathead minnows (*Pimephales promelas*), where there were no significant effects observed after 255 day and 21 day exposure (respectively) to glyphosate, achieving NOEC values of 25.7 mg a.e./L and 3 mg a.e./L, respectively.

[10] GRG-eco: https://www.glyphosate.eu/transparency/scientific-dossier/summary-of-studies/document-m-ca-section-8-ecotoxicological-studies-on-the-active-substance

[11] EFSA Journal 2015; 13(11):4302

Appendix 1 – Sources of Raw Water used for Drinking Water

The sources of water abstracted for the production of drinking water are summarised in Table 1. This indicates that the majority of large water supplies are sourced from groundwater, ranging from 12% in IE to 100% in AT. While the data for small water supplies is not as complete (as MS were not obliged to provide these data) it indicates that the majority of small supplies exploit groundwater. This is in agreement with the assessment that ~75% of EU inhabitants rely on groundwater for drinking water (EC, 2008[12]).

Table 1: Summary of the water sources used for drinking water production (2010) in each country (EC, 2016[13]), including surface water (SW), groundwater (GW) and mixed/other sources. Small supplies are (<1000 m³/day). Other sources include seawater, bank infiltration and artificial groundwater recharge.

Country	Small Water Supply Zone Source			Large Water Supply Zone Source		
	% SW	% GW	% Mixed/ Other‡	% SW	% GW	% Mixed/ Other‡
AT		100			100	
BE		>80		35	65	
BG		>84		63	37	
CY	Mix	Mix	Mix	21	23	56
CZ	Some	Mostly	Few	47	29	24
DE		87		26	74	
DK		100			100	
EE		100		35	65	
EL		95		65	35	
ES	71			70	29	1
FI		>95		45	41	14
FR		>80		29	49	22
HU		>90		8	35	57
IE	Mix	Mix	Mix	88	12	
IT		Mostly		18	80	2
LT		100			93	7
LU	50	50		59	51	
LV		100		22	64	14
MT		100			44	56
NL		100		39	54	7
PL		>96		35	65	
PT	Some	Mostly	Some	39	35	26
RO		>80		67	30	3
SE	NS	NS	NS	24	51	25

[12] European Commission (EC, 2008). Groundwater Protection in Europe. The New Groundwater Directive – Consolidating the Eu Regulatory Framework. 36pp.
[13] European Commission (EC, 2016). Synthesis Report on the Quality of Drinking Water in the Union examining the Member States' reports for the 2011-13 period, foreseen under Article 13(5) of Directive 98/83/EC. COM(2016) 666 final. 16pp plus Country Reports and Small Supply Summaries. COM(2019) 128 Final. 13pp.

SI	>52			31	69	
SK		>85		15	85	
UK	NS	NS	NS	48	19	33
EU	**Some**	**Mostly**	**Few**	**36**	**50**	**14**

Appendix 2 – Removal of Glyphosate and AMPA by Water Treatment Processes

Summary[14]

For drinking water derived from surface water, there is almost always water treatment processes applied to generate the drinking water. The prevalence across the EU of the chemical treatment processes, can be inferred from a publication (van der Hoek *et al*., 2014[15]). This paper was the result of a survey carried out amongst the members of the European Federation of National Associations of Water and Wastewater Services. This organisation covered 23 EU MS's and 405 million European citizens. The report indicates that the vast majority of raw water sources for drinking water production (88%) are subject to disinfection.

Further, almost all the raw water taken from surface water is subject to disinfection; and where surface water is disinfected, chlorine disinfection is applied to a minimum of 62% of the raw water. Glyphosate and AMPA are known to be transformed by the most common disinfection methods. Transformation products appear to be small molecules, often similar or identical to those found from natural sources.
Other chemical treatment processes are often applied (either for disinfection or for the explicit removal of micro-pollutants), and low chemical processes are also very frequently applied. Monitoring data is usually only available for raw water, before any water treatment processes have been applied, but for contextualising monitoring data, the effects of these processes should be included. Removal rates for glyphosate and AMPA, for various water treatment processes, have been discussed above, and are summarised in Table 2.

Table 2: Summary of removal rates for glyphosate and AMPA following removal processes

Treatment Process	Glyphosate removal (%)	AMPA removal (%)
Bank and dune filtration	20 - >95	25 - >95
Aluminium coagulant and clarification	15 - 40	20 - 85
Iron coagulant and clarification	40 - 70	20 - 85
Activated carbon adsorption	10 - 90	20 - 70
Chlorination	71 - >99	40 - >95
Chlorine dioxide	17 - 93	>99
Ozonation	60 - >99	25 - 95

In addition to disinfection processes, bank filtration can be an effective process for removal of glyphosate and AMPA from water, when sufficient residence time within soil/sediment occurs to allow the normal aerobic/anaerobic soil degradation processes to progress to their full extent (total mineralisation). Generally, drinking water treatment processes are carefully controlled, and the characteristics of a specific source raw water needs to be known – as the water treatment process train needs to be optimised to ensure that quality standards are met at the tap of consumers. Consequently, where glyphosate or AMPA are known to be present in the raw water, the drinking water treatment train can be optimised, where necessary, to ensure removal of these substances below the required threshold values, and therefore, there is a low risk of exceeding the relevant thresholds in drinking water of 0.1 μg/L for glyphosate and 10 μg/L for AMPA, nor for exceeding the life-time health-based ADI concentrations of 1500 μg/L for GLY and 3960 μg/L for AMPA.

[14] Taken from M-CA Section 7 page 1977-1978 (https://www.glyphosate.eu/transparency/scientific-dossier/summary-of-studies/document-m-ca-section-7-fate-and-behaviour-in-the-environment/).
[15] Van der Hoek, JP., Bertelkamp, C., Verliefde, ARD. and Singhal, N. 2014. "Drinking water treatment technologies in Europe: state of the art – challenges – research needs" Journal of Water Supply: Research and Technology, 63.2, 124-130.

Appendix 3 – Drinking Water Compliance

Headline Results[16]

Across all countries the GLY public monitoring dataset compiled comprised >8 300 samples collected from >3 100 sampling sites (see Table 3). Given the limited size of the dataset and the limited number of countries from which it was sourced, a combined European dataset was not created.

Compliance with the drinking water threshold of 0.1 µg/L was high (99.94%) given few exceedances (~0.06%). All 5 samples in SE that are ≥ 0.1 µg/L come from 5 apparently untreated sources (2 drilled wells, 2 dug wells, 1 unspecified GW source). Only 1 site has more than a single sample to assess if exceedance was systematic and for that dug well a further sample 7 weeks later was <LOD. All exceedances are old (≤2007) and significant strides in groundwater protection have been made in SE since the introduction of the water protection regulations in 2004 such that these exceedances do not reflect the current state of the GW environment in SE.

Maximum concentrations were 0.61 µg/L in DE, 0.074 µg/L in IE and 0.17 µg/L in SE. These are well below the life-time ADI based concentration of 1500 µg/L. In addition, GLY exceedances extracted from aggregated data in official reports (see Table 4) range between 0.00% in AT and 0.29% in ES with an average of ~0.16% of samples ≥ 0.1 µg/L. Maximum concentrations were up to 0.92 µg/L in ES. This value is well below the life-time ADI based concentration of 1500 µg/L.

[16] Taken from M-CA Section 7 page 1919 (https://www.glyphosate.eu/transparency/scientific-dossier/summary-of-studies/document-m-ca-section-7-fate-and-behaviour-in-the-environment/).

Table 3: Summary of unaggregated drinking water (DrW) data for glyphosate (GLY) sourced from Germany, Ireland and Sweden[17]

GLY						
Country	**DE**		**IE**		**SE**	
Threshold	**DrW: 0.1 µg/L**	**LTHAC: 1500 µg/L**	**DrW: 0.1 µg/L**	**LTHAC: 1500 µg/L**	**DrW: 0.1 µg/L**	**LTHAC: 1500 µg/L**
Number of sites	16	16	1027	1027	2335	2369
Number of samples	18	18	2215	2215	6917	7135
Number of samples > threshold	3	0	2	0	5	0
% of samples > threshold	16.7	0.00	0.09	0.00	0.072	0.0
Number of sites > threshold	3	0	2	0	5	0
% of sites > threshold	18.8	0.0	0.2	0.0	0.21	0.0
Number of consecutive samples > threshold	0	0	0	0	0	0
% of samples that are consecutive samples > threshold	0.0	0.0	0.00	0.0	0.00	0.0
Max number of samples > threshold at a single site	1	0	1	0	1	0
Max number of consecutive samples > threshold at a single site	1	0	1	0	1	0

LTHAC - lifetime health-based ADI concentration

[17] Taken from Table 7.5-216 from M-CA Section 7 page 1922 (https://www.glyphosate.eu/transparency/scientific-dossier/summary-of-studies/document-m-ca-section-7-fate-and-behaviour-in-the-environment/).

Table 4: Summary of drinking water (DrW) monitoring data aggregated in reports for glyphosate (GLY) and AMPA[18]

MS	Substance	Number of reports identified	Reports with data relating to threshold						Maximum value (µg/L)
			Number of reports	Date range	Number of samples	Threshold (µg/L)	Samples above threshold	% samples above threshold	
AT	AMPA	ND	ND	ND	ND	ND	ND	ND	ND
	GLY	2	2	2011 - 2017	2020	0.1	0	0.00	NS
BE	AMPA	1	1	2016	1169	0.1	1	0.09	0.087
	GLY	1	1	2016	1157	0.1	2	0.2	0.051
DE	AMPA	3	3	2011-2016	9525	0.1	5	0.05	NS
	GLY	3	3	2011-2014	4531	0.1	9	0.20	NS
DK	AMPA	1	1	2014-2016	1336	0.1	0	0.00	NS
	GLY	1	1	2014-2016	1337	0.1	1	0.07	NS
ES	AMPA	ND	ND	ND	ND	ND	ND	ND	ND
	GLY	10	9	2008-2018	>5313	0.1	>10	0.22/0.29†	0.92
EU Trans	AMPA	ND	ND	ND	ND	ND	ND	ND	ND
	GLY	ND	ND	ND	ND	ND	ND	ND	ND
FR	AMPA	ND	ND	ND	ND	ND	ND	ND	ND
	GLY	ND	ND	ND	ND	ND	ND	ND	ND
IE	AMPA	ND	ND	ND	ND	ND	ND	ND	ND
	GLY	1	0	NA	NA	NA	NA	NA	NS
IT	AMPA	ND	ND	ND	ND	ND	ND	ND	ND
	GLY	ND	ND	ND	ND	ND	ND	ND	ND
NL	AMPA	11	0	NA	NA	NA	NA	NA	3.0
	GLY	11	0	NA	NA	NA	NA	NA	0.3
SE	AMPA	ND	ND	ND	ND	ND	ND	ND	ND
	GLY	ND	ND	ND	ND	ND	ND	ND	ND
UK	AMPA	ND	ND	ND	ND	ND	ND	ND	ND
	GLY	9	0	NA	NA	NA	NA	NA	NS

† Report data includes sample counts and % values – The first value is the average using count data only while the second is the average of report averages
NA – No data available; ND – No data identified; NS – Not specified; > as missing values to calculate total

[18] Taken from Table 7.5-217 from M-CA Section 7 page 1923 (https://www.glyphosate.eu/transparency/scientific-dossier/summary-of-studies/document-m-ca-section-7-fate-and-behaviour-in-the-environment/).