Key aspects of the information that GRG submitted to address EFSA's request for additional information in the frame of EU glyphosate active ingredient approval renewal, according to Regulation (EC) No 1107/2009

Glyphosate Renewal Group

Regulation (EC) No 1107 /2009, EFSA request for additional information

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Key aspects in the area of environmental fate

- **Assessment of pH dependency and consequences for endpoint selection**
- **Conclusion on representativeness of US field data for the EU – Ecoregion crosswalk**
- **Unknown radioactivity in AMPA-applied water-sediment studies**
- **Monitoring data**

Contents

Summary

The following document summarises points relating to the fate of glyphosate in the environment within the Annex I renewal dossier submitted by the Glyphosate Renewal Group (GRG, applicant). The dossier was evaluated by the Assessment Group for Glyphosate (AGG) acting as RMS consisting of the corresponding competent authorities of France, Hungary, The Netherlands and Sweden.

Following the public commenting period on the draft Renewal Assessment Report (dRAR) from 23rd September to 19th November 2021, an additional information request was received from EFSA on 14th March, 2022 in the context of 'stop-the-clock'. The requests referred to the following areas:

- Position papers to further assess, support and elucidate experimental studies, kinetic evaluations, ecoregion crosswalk of North American field studies, and endpoint selection for modelling.

- Summary of 13 additional public literature articles.

- Update of study information (e.g. addendum to study reports for studies from the applicant that were already submitted).

- Update of risk assessment based on proposed endpoints from EFSA, as well as endpoints selected by the applicant following updated kinetic evaluations.

The following provides targeted summaries of important topics for the ongoing EU Review process regarding environmental fate.

1. Assessment of pH dependency of degradation in soil and consequences for endpoint selection

EFSA requested the applicant to propose an approach for assessing pH-dependence of soil degradation and related endpoints for glyphosate and AMPA based on updated kinetic evaluations arising in view of other requests by EFSA (related to normalising and refitting data from field studies or refitting data from laboratory studies).

pH dependency assessment

For the active substance glyphosate and in the dRAR, Vol. 3, B.8 (AS), the RMS recommended the use of DT_{90} values for better comparability between endpoints derived using SFO kinetics and endpoints derived using biphasic models, where the DT_{90} may arguably be more representative of the overall degradation.

Therefore, the pH dependency assessment performed by the applicant during the 'stop-the clock' phase of the evaluation was based on normalised DT_{90} values. However, it is the understanding that this is not the standard approach in the assessment of plant protection products. It may be justified in specific cases, depending on the distribution of the individual degradation endpoints and their associated kinetic models.

Results of laboratory and field studies were evaluated separately and in combination on the basis of the German Input Decision Tool 3.3. For the combined laboratory and field data sets, there were indications of a weak correlation between pH values and normalised DT_{90} values. Although there is no clear relationship, higher DT_{90} values were observed at acidic pH values of soil (for details see document KCA 7.1.2_anonymous_2022_113898-062_GRG.pdf).

For metabolite AMPA, the pH dependency assessment performed by the applicant during the 'stop-the clock' phase of the evaluation was based on normalised DT_{50} values, since all modelling endpoints were derived using SFO kinetics. The assessment showed a correlation between values of pH in soil and normalised DT_{50} from laboratory studies.

Since a high number of endpoints were derived from the pathway kinetic fit (and the pathway is considered in the PEC_{gw} modelling), the same cut-off pH separating acidic and alkaline regimes as used for glyphosate, was considered appropriate (for details see document KCA 7.1.2_anonymous_ 2022_113898-062_GRG.pdf).

Endpoints for modelling

To conclude on final endpoints for PEC in groundwater and surface water modelling ($PEC_{gw/sw}$), the biphasic nature of degradation kinetics for glyphosate, combined with the weak pH dependence of degradation for glyphosate and AMPA, should be considered. Furthermore, the EFSA $DegT_{50}$ Endpoint Selector was used to demonstrate equivalence between laboratory and field degradation rates of glyphosate and AMPA.

Based on the updated assessments described above, the applicant has proposed that appropriate geometric mean DT_{50} values for $PEC_{gw/sw}$ modelling could be derived as follows:

Active substance glyphosate:

- Geometric mean of normalised slow phase/SFO DT_{50} values from laboratory and field data for acidic soils where glyphosate has a longer, more conservative DT_{50}
- Geometric mean of normalised fast phase/SFO DT_{50} values from laboratory and field data for alkaline soils where glyphosate has a shorter DT_{50}

Metabolite AMPA:

- Geometric mean of normalised SFO DT_{50} values from laboratory and field data for acidic soils where AMPA has a longer, more conservative DT_{50}

For the PEC_{gw} calculations requested by EFSA, the applicant has conducted two sets of simulations using the combination of parent and metabolite endpoints described above. The maximum PEC was used in the risk assessment for parent and metabolite, respectively.

For the PEC_{sw} calculations requested by EFSA, the applicant has considered the geometric mean DT_{50} value from the acidic soils (longer DT_{50} values) at FOCUS Steps 1-2 to calculate conservative PECs of glyphosate and AMPA.

2. Conclusion on representativeness of US field data for the EU - Ecoregion crosswalk

EFSA asked the applicant to provide a comparison of the actual conditions at the field test sites in the North American soil dissipation studies to characteristics of EU ecoregions rather than to use default root ecoregions of the trial soils only.

Within the supplementary dossier (MCA Section 7, June 2020), the applicant submitted an ecoregion crosswalk to assess how representative data obtained in six North American Terrestrial Field Dissipation (TFD) studies are for Europe.

A summary of the assessment is presented in the dRAR, Vol. 3 CA, point B.8.1.1.3.1. Data from 19 field sites, located in the USA and Canada, were evaluated according to the ENASGIPS approach (Europe – North America Soil Geographic Information for Pesticide Studies). Each field site was located within an ecoregion, the so-called root ecoregion. A similarity score was calculated between each root ecoregion and all European ecoregions based on soil and climate parameters such as mean annual temperature, mean annual precipitation, soil pH, soil organic carbon and soil texture. The ecoregion crosswalk resulted in a holistic similarity score of at least 80 % for eight of twelve identified North American ecoregions. Furthermore, a refinement by individual soil and climate scores was conducted. Ecoregions with a low similarity score in terms of temperature conditions were considered as not relevant. Briefly summarised, the conclusion of the evaluation is that nine North American TFD trial sites for glyphosate, represented in five root ecoregions, are representative of European conditions. Details are presented in dRAR, Vol. 3 CA, point B.8.1.1.3.1.

Justification of the ENASGIPS ecoregion crosswalk approach

The ecoregion crosswalk assessment (KCA 7.1.2.2.1-002) was conducted using the ENASGIPS v3.0 (Europe-North America Soil Geographic Information for Pesticide Studies) application. According to the relevant OECD Guidance Document for Conducting Pesticide Terrestrial Field Dissipation Studies, the ENASGIPS tool is strongly recommended in assessing the acceptance of studies conducted in countries outside Europe.

Relevance of similar European ecoregions to agricultural use land areas

In order to determine whether the ecoregions considered relevant in the Ecoregion crosswalk contain agricultural land, a corresponding assessment was conducted (for details see document KCA 7.1.2.2.1_anonymous_2022_113898-060_GRG.pdf). For the determination of agricultural land use area, the Corine Land Cover 2018 European seamless vector database (RELEASE v20 - CLC) was used.

All European ecoregions that are similar to ecoregions of the nine North American trial sites have a relevant share of agricultural use varying from 16.9 % to 49.3 % (refer to KCA 7.1.2.2.1_anonymous_2022_113898-060_GRG.pdf, Table 6). Therefore, the results of the nine trial sites (New York, Ohio, Ontario 1, Ontario 2, California 1, California 2, Iowa, Minnesota and Arizona) are applicable to Europe.

Representativeness of Climate Conditions of nine North American Field Dissipation Trial Sites for Europe

In the absence of further guidance, besides the recommended ENASGIPS approach mentioned above, the actual weather conditions at each trial site were compared to the climate of their North American root ecoregions, to further assess the representativeness of the North American field studies. This resulted in a good to moderate accordance (for details see document KCA 7.1.2.2.1_[redacted]_2022_113898-028_GRG.pdf, section 3.2), which supports the validity of the original ecoregion crosswalk.

The climatic conditions at nine North American trial sites were compared directly to typical European climate. Similar to the ENASGIPS holistic approach, the long-term average annual temperature and long term average annual sum of precipitation of the nine trial site locations, were compared with the conditions in Europe. The analysis was performed using the MARS FOODSEC ERA-Interim Meteodata – 1978 to 2011 data embedded within ENASGIPS.

The climate of eight out of the nine representative North American TFD trial sites was considered as relevant for Europe. The annual temperature of the North American trial site locations fits very well with European climate and covers large parts of Central and Southern Europe. The annual sum of precipitation of the North American trial site locations is also represented reasonably well within Europe. Areas where both similar temperature and precipitation are overlapping occur on large areas throughout Europe (refer to document KCA 7.1.2.2.1_[redacted]_2022_113898-028_GRG.pdf, section 3.3). Therefore, results from terrestrial dissipation studies at these eight sites are applicable to Europe.

The climate of the trial site 'Arizona' fits well to the root ecoregion, but its hot and dry climate shows no overlap with European climate conditions. Therefore, as a conservative approach, Arizona was considered not representative of European conditions.

Conclusion

The additional information submitted during the 'stop-the-clock' period supports the view that the ecoregion crosswalk as submitted with the supplementary dossier (MCA Section 7) is considered valid. The refinements undertaken fortify the results of the ecoregion crosswalk. As a conservative approach, the field site in Arizona was excluded based on the refinement. The remaining eight trial sites are representative for Europe. Therefore, terrestrial dissipation results from those eight sites can be applied to derive degradation/dissipation information in a European context.

3. Unknown radioactivity in AMPA-applied water-sediment studies

Unknown components P1a (KCA 7.2.2.3-018) and M3.3 (study KCA 7.2.2.3-020) were observed in two of the four AMPA-applied water-sediment studies at levels that potentially trigger further consideration in aquatic risk assessment. Consequently, EFSA requested that the applicant provides the following information:

Unknown P1a

- Data to further address the fraction P1a observed at levels exceeding 10 % AR in the sediment in system Manningtree A. It should be addressed whether this fraction identified at up to 53 % AR in sediment from this AMPA-applied study might reach levels triggering assessment, i.e. whether it could account for amounts above 5 % glyphosate.
- If the information provided to address the data requirement at reporting table comment 4(192) does not exclude the fraction P1a being present above 5 % in sediment, PEC in sediment should be provided for this compound.

Unknown M3.3

- Full details of the approach used to demonstrate the formation of fraction M3.3 for all available water-sediment systems where AMPA was dosed for which a glyphosate dosed study was available for the same system.
- A minor adaptation of the modelling approach proposed by the applicant should be investigated and reported in line with the RMS considerations in column 3 of the reporting table, section 4; 2022-02-17 (comment 4(216)).
- Further information to explain the reasoning for the postulated identity, if it is confirmed that fraction M3.3 exceeds the trigger for risk assessment, should be provided.
- If the information provided to address the data requirement at reporting table comment 4(216) does not exclude the fraction M3.3 being present above 5 % in sediment, PEC in sediment should be provided for this compound.

Occurrence of M3.3/P1a in AMPA-applied studies

In the four water-sediment studies performed with ^{14}C-AMPA applied to the test systems, unknown components were observed in the water, but mainly in the sediment compartment. However, formal identification of transformation products was not undertaken during the studies, as studies with metabolites applied to the test systems were not perceived as route studies at the time they were performed. M3.3 was proposed to be '1-oxo-AMPA' in the study report; however, the applicant does not believe that an unambiguous identification of M3.3 can be deduced based on information given in the study report.

Estimation of maximum occurrences of unknowns in AMPA-applied studies

Two different approaches were considered to estimate the maximum occurrences of M3.3 (study KCA 7.2.2.3-020) and P1a (KCA 7.2.2.3-018). One approach was based on the observed maximum occurrences of unknowns in AMPA-applied studies and the maximum occurrence of 27.1 % AR for AMPA in the total system of glyphosate-applied studies, and in the second approach, kinetic evaluations were performed considering AMPA-applied water-sediment studies to derive the maximum occurrences of the unknown components, M3.3 and P1a. In both approaches, exceedance of the trigger values was observed for P1a and M3.3.

The overall maximum occurrence of 14.4 % AR calculated with the simple approach from the RMS was used as a conservative endpoint for the unknown component, together with default modelling input parameters to estimate the exposure in sediment. Using these results, no risk was shown for aquatic or sediment-dwelling organisms in the risk assessment. Details on the exposure modelling can be found in documents KCP 9.2.5_anonymous_2022_113898-034_GRG.pdf and KCP 9.2.5_anonymous_2022_113898-035_GRG.pdf, and details of the ecotoxicological risk assessment can be found in the documents KCP10_anonymous_2022_113898-238_GRG.pdf and KCP 10_anonymous_2022_113898-239_GRG.pdf.

Comparison of unknown metabolites P1a and M3.3

A comparison of chromatographic methods and peak retention times for P1a and M3.3 from their respective studies indicates that the two components could possibly be the same.

The HPLC column static phase was identical in both studies (Hamilton PRP-X400, 250 mm × 4.1 mm; 7µm). Although the buffers used as mobile phase for separation were different, they were both buffered to pH 1.9. The flow rates were also different, with the rate used in study KCA 7.2.2.3-020 being faster than the rate used in study KCA 7.2.2.3-018. In study KCA 7.2.2.3-020, the absolute retention times for AMPA and M3.3 were shorter than those for AMPA and P1a in study KCA 7.2.2.3-018. These differences can be explained by the faster flow rate used in study KCA 7.2.2.3-020, which results in shorter retention times for AMPA and M3.3 than those for AMPA and P1a in study KCA 7.2.2.3-018. In both studies, the unknowns had similar retention and eluted earlier than AMPA.

When considering that AMPA has a relatively simple chemical structure, together with the similarities observed in relative retention times of the unknowns to AMPA after accounting for the minor differences in chromatographic methods, it is quite possible that P1a and M3.3 share the same identity.

4. Monitoring data

An assessment of publicly available monitoring data is currently not a routine practise in regulation. There is no guidance on how the data should be generated, nor on how to assess the data. There exists, for example, no 'best monitoring practise' that allows for an evaluation of results according to consistent criteria. Furthermore, such data are collected for a variety of different purposes (e.g., to assess compliance with other existing regulations, identify emerging issues) in the context of various protection goals.
While a large number of results are documented in various formats (e.g., electronic data bases or summarizing documents), very little is known about procedures followed for selection of sampling sites, or how samples were taken. The data must be regarded generally, therefore, as of unknown quality and reliability in the context of evaluation. Although this lack of detail means that the demanding requirements of regulatory risk assessment for the use of such data directly in the risk assessment process are not fulfilled, it is possible to get information with respect to the chemical status of the environment at a local scale.

Within the ongoing EU review process, a comparison of monitoring data for GLY and AMPA to regulatory triggers has been included to put the findings into context. Although public monitoring data cannot be seen as a higher tier risk assessment, they can be viewed as supportive information that helps to confirm the safety as indicated in risk assessments (in the case of GLY and AMPA it is important to note that safety in accordance with risk assessment frameworks is demonstrated at the conservative lower tier level). Public monitoring data may also identify whether local issues could exist that would require further investigation through stewardship action or local mitigation measures; a process to which the applicant is committed.

In this case, though, the analyses are likely to provide a comprehensive picture of the chemical state of the environment, given that 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; and, overall, the data do provide a high level of reassurance.

All accessible public monitoring data for glyphosate (GLY) and its primary metabolites amino methyl phosphonic acid (AMPA) and hydroxy methyl phosphonic acid (HMPA) from public monitoring databases in the EU (including UK, Switzerland, Norway and Iceland) were collected. No data for HMPA was identified for any country or compartment, and very little data was available for GLY or AMPA in sediment and soil, but what was available didn't indicate levels are of concern. The monitoring data obtained was subjected to detailed and comprehensive analysis as reported in KCA 7.5-002 and updated in document KCA 7.5_[redacted]_2022_CEA.2365_GRG.pdf. Further detailed analysis included, particularly, investigations of consecutive detections, especially undertaken for consecutive trigger exceedances. It also included a 'vulnerability of the sites analysis' for both groundwater and surface water as performed in Appendix 1 of document KCA 7.5_[redacted]_2022_CEA.2365_GRG.pdf. For a case study focussing on France, regression tree and random forest statistical models were developed and applied to predict total and consecutive rates of detection (%) for values above 0.1 µg/L in surface waters. Predictor variables were used describing potential sources of GLY/AMPA and factors affecting emission and detection. This is reported in Chapter 10 of document KCA 7.5_[redacted]_2022_CEA.2365_GRG.pdf. A potential influence of the sources of drinking water (SW vs GW, and 'small water supply' vs 'large water supply') was also investigated and reported in Section 5.8 of document KCA 7.5_[redacted]_2022_CEA.2365_GRG.pdf.

The following more general principles were applied for data evaluation:

- The approaches taken for any data processing were precautionary in that they preserved data-points in the analysis where there was any doubt regarding their reliability.
- An outlier analysis[1] was performed on the combined EU dataset, and to ensure complete transparency, statistics were presented for the combined dataset (i) with all of the data and (ii) with outliers excluded.
- Analyses of the datasets sought to assess the chemical state of the environmental compartment and also to consider potential impacts on biota, ecosystems and human health by using regulatory endpoints and thresholds from a range of European (EU) Directives (Water Framework Directive (Directive 2000/60/EC) and associated Groundwater (2006/118/EC), Drinking Water (1998/83/EC) and Priority Substances (2008/105/EC28) Directives, in addition to the Plant Protection Products Directive (1107/2009/EC).

Groundwater

For groundwater (GW), monitoring data from 21 countries were analysed for compliance against non-scientific thresholds of 0.1 µg/L[2] for GLY and 10 µg/L[3] for AMPA.

- The GLY public monitoring dataset was large (> 251 700 samples collected from > 40 000 sampling sites). Detection of GLY in GW samples was ~2 % and compliance with the 0.1 µg/L threshold was very high (99.4 % samples from 97 % of sites). The maximum concentration (excluding 10 outliers[4]) was 39.2 µg/L. This value is well below the SW RAC[5] for groundwater fed ecosystems and it is also clearly below the life-time health-based ADI[6] concentration of 1500 µg/L.
- The AMPA public monitoring dataset was also large (> 228 400 samples collected from > 35 900 sampling sites). Detection of AMPA in GW samples was ~2.9 % and compliance with the arbitrary 10 µg/L regulatory threshold was very high (99.998 % of samples from 99.994 % of sites). The maximum concentration of 16 µg/L was well below the SW RAC (for groundwater fed ecosystems) and the lifetime health-based ADI concentration of 3960 µg/L.
- For GLY, only 0.21 % of samples were consecutively above the threshold of 0.1 µg/L allowing the conclusion that exceedances were rare and not caused by systematic factors. Analysis indicated that these sites are likely anomalous, sampling karstic terrain or alluvial gravels which were in direct contact with surface water or, in some cases, incorrectly assigned to groundwater when in fact they were surface water monitoring sites. Similar observations were noted for outliers with sites influenced by surface water and/or the data was historic (i.e., from the early 2000s, hence of less relevance to a current assessment of the state of the environment).

[1] The Inter-Quartile-Range approach was used, such that an upper fence limit is defined by Q75 + K * (Q75 – Q25), where Q75 is the upper quartile, Q25 the lower quartile and K typically has a value of 1.5. In order to ensure that a precautionary approach was taken, a K value of 1000 was used to define the upper fence limit
[2] From Drinking Water Directive (Directive 98/83/EC)
[3] Arbitrary threshold in drinking water for non-relevant metabolite in SANCO/221/2000-rev.10 (25 Feb 2003)
[4] Given the conservative nature of the procedure for identifying outliers, and the small number identified, it is believed that this should be regarded as a reasonable process.
[5] RAC – Regulatory Acceptable Concentration; 400 µg/L for GLY, and 1200 µg/L for AMPA
[6] ADI – Acceptable Daily Intake

- Case studies were carried out to explore potential reasons for locally elevated rates of groundwater detection in ES, IT and the UK. Several dozen monitoring sites were elucidated predominately by a desk-based approach (45 sites in ES, 13 in IT, and 5 in UK) while this was followed up for Spain for 16 sites with field visits. The investigations suggest the reasons for the findings at these sites are most likely due to deteriorated monitoring locations, poor or specific local agronomic practice, and pollution events. The applicant has initiated the implementation of further stewardship measures to improve compliance in the future.

Surface water

For surface water (SW), data from 22 countries were analysed for compliance against RAC[7]. Additional analyses against country specific annual average (AA) and Maximum Allowable Concentration (MAC) EQS[8] values were also undertaken.

- The GLY public monitoring dataset was large (> 308 000 samples collected from > 15 000 sampling sites) and detection of GLY above the limit of quantification (> LOQ; average 0.43 µg/L, 0.0.1 – 1000 µg/L) in SW samples was ~37 %. Compliance with the GLY RAC of 400 µg/L was extremely high (99.994 % of samples; 99.90 % of sites) and the very occasional exceedances (0.006 % of samples; 0.10 % of sites) were largely on separate non-consecutive occasions (only 0.003 % of samples being consecutive). The maximum concentration of 77.2 µg/L (excluding outliers), was well below the RAC (mean measured concentration 0.06 µg/L (0.000 – 77.2 µg/L)).
- Distribution of locations that exceed the GLY RAC did not indicate any specific pattern or bias. Consideration of the country GLY data against country EQS values indicated a near total compliance (~99.96 % of samples) across the large EQS-MAC dataset. Similarly, compliance for the large EQS-AA dataset (~13 000 site-years from ~2 500 sites) was very high (99.96 % site-years at 99.98 % of sites).
- The AMPA public monitoring dataset (> 270 000 samples collected from > 12 600 sampling sites) was large and detection of AMPA > LOQ (average 0.07 µg/L, 0.01 – 10 µg/L) in SW samples was ~62 %, however, compliance with the AMPA RAC of 1200 µg/L was very high (99.999 % of samples; 99.98 % of sites) with infrequent exceedances (0.001 % of samples from 0.02 % of sites) occurring on 3 separate non-consecutive occasions. A small number of high maximum concentrations were confirmed to be outliers and once excluded the maximum concentration was 224.4 µg/L, which is well below the RAC (mean measured concentration 0.10 µg/L (0.000 – 224.4 µg/L)).
- Distribution of locations that exceed the AMPA RAC did not indicate any specific pattern or bias. Consideration of the country AMPA surface water data against country EQS values indicated that the presence of AMPA, from GLY or other sources (e.g., detergents, fire retardants or textile industry chemicals) is not expected to have any impacts with 100 % compliance for the large EQS-MAC (~218 000 samples from ~9 100 sites) and EQS-AA (~10 900 site-years from ~1 600 sites) datasets.
- For surface water destined to be drinking water, it is a routine of water works to apply **Water Treatment Processes** to remove bacteria and viruses and other organic micro-pollutants. In the EU, 88 % of raw water sources for drinking water production are subject to disinfection. Raw drinking water taken from surface water is practically quantitatively disinfected (99.9 % by volume). For disinfected surface water, chlorine disinfection is applied to a minimum of 62 % of

[7] 400 µg/L for GLY and 1200 µg/L for AMPA
[8] EQS – Environmental Quality Standard; this has not yet been set for GLY at the EU-level, although there are ongoing considerations in that direction.

the raw water. GLY and AMPA are known to be very readily transformed by the most common disinfection methods, ranging from 60 to 99 % for GLY and from 25 to 95 % for AMPA. Chlorination results in small molecules as transformation products, often similar or identical to those found from natural sources. Drinking water treatment processes are carefully controlled and the water treatment process train at any given abstraction site is optimised to ensure that quality standards are met at the tap of consumers (e.g., GLY < 0.1 µg/L).

Drinking water

For drinking water (DrW), monitoring data were identified and evaluated for the four countries DE, IE (GLY only), SK and SE.

- Compared to groundwater and surface water, the GLY dataset was comparatively small (~9 500 samples collected from ~3 700 sampling sites). Compliance with the DrW threshold of 0.1 µg/L was very high (99.90 % of samples). All of the exceedances reported are old (2007 and earlier).
- The AMPA monitoring dataset was similarly small (~7 250 samples collected from ~2 650 sampling sites). Compliance with the threshold of 10 µg/L was absolute at 100 %. Compliance with the DrW threshold of 0.1 µg/L was very high (99.90 % of samples).
- Approximately 75 % of EU inhabitants rely on drinking water from groundwater, 25 % on surface water. The high compliance rates in drinking water somewhat confirm that the treatment methods in place (e.g., for SW as drinking water) are effective at removing GLY and AMPA.

Air

For **air**, a small number of GLY and AMPA monitoring results (381 each from 8 sites) were collected from FR and analysed. The maximum measured concentration of 1.225 ng/m^3 for GLY and 0.014 ng/m^3 for AMPA are extremely low[9]. Current understanding is that air transport of GLY could occur either for short distances via spray drift (up to 100 m) or via wind-eroded soil sediment over larger distances. Very little relevant and reliable air monitoring data is currently available. Also, there are no relevant regulatory ecotoxicological endpoints against which the monitoring data might be evaluated.

[9] Considering the health-based reference values ADI, AOEL and AAOEL covering exposures from acute to lifetime duration, inhalation exposures at these combined maximum concentrations are several orders of magnitude lower even for the most sensitive group (children). Therefore, preliminary and very conservative calculations strongly suggest that air-borne exposure to GLY and AMPA would not result in adverse health effects.

References

1. KCA 7.1.2_anonymous_2022_113898-062_GRG.pdf – Response to Request FATE 2, Applicant to propose an assessment of the pH-dependence endpoints selected for modelling.

2. KCA 7.1.2.2.1_anonymous_2022_113898-060_GRG.pdf - Response to Request FATE 6, Applicant to provide a more accurate comparison of the actual conditions of fields tested to the characteristics of EU ecoregions, instead of default root ecoregions of the trial soils.

3. KCA 7.1.2.2.1_[redacted]_2022_113898-028_GRG.pdf – Report on representativeness of climate conditions of nine North American field dissipation trial sites for Europe.

4. KCA 7.2.2.3_anonymous_2022_113898-022_GRG.pdf – Response to Requests FATE 30, 35 and 36, Applicant to provide data to further address the fraction P1a observed at levels exceeding 10 % AR in sediment; Applicant to provide full details of the approach to demonstrate the formation of fraction M3.3; Applicant to provide further information to explain the reasoning for the postulated identity of M3.3.

5. KCA 7.5_[redacted]_2022_CEA.2365_GRG.pdf – Glyphosate (GLY) and the primary metabolites Aminomethylphosphonic acid (AMPA) and Hydroxymethylphosphonic acid(HMPA): Public monitoring data assessment and interpretation

6. KCP 9.2.5_anonymous_2022_113898-034_GRG.pdf – Response to Request FATE 41, Applicant to provide updated PEC_{sw} and PEC_{sed} for glyphosate and its relevant metabolites using endpoints for soil proposed by EFSA.

7. KCP 9.2.5_anonymous_2022_113898-035_GRG.pdf - Response to Request FATE 42, Applicant to provide updated PEC_{sw} and PEC_{sed} for glyphosate and its relevant metabolites using endpoints for soil proposed by the GRG.

8. KCP10_anonymous_2022_113898-238_GRG.pdf - Response to ECOTOXICOLOGY Requests 32 and 47 – Applicant to provide an update of the aquatic risk assessment for sediment dwelling organisms from exposure to an unknown metabolite (related to Request FATE 41).

9. KCP 10_anonymous_2022_113898-239_GRG.pdf - Response to ECOTOXICOLOGY Requests 32 and 47 – Applicant to provide an update of the aquatic risk assessment for sediment dwelling organisms from exposure to an unknown metabolite (related to Request FATE 42).

10. KCA 7.2.2.2-002_[redacted]_2021_232126_GRG.pdf – Report on characterisation of unidentified material in aerobic mineralisation in surface water study.