検索期間：2021年5月～8月

区分ａに分類された文献とその理由

生活環境動植物及び家畜に対する毒性

1. Information on the study

Data point:	CA 8.1.5
Report author	Diaz-Martín R. D. *et al.*
Report year	2021
Report title	Short exposure to glyphosate induces locomotor, craniofacial, and bone disorders in zebrafish (*Danio rerio*) embryos
Document No	Environmental toxicology and pharmacology (2021), Vol. 87, Article No. 103700
Guidelines followed in study	None
Deviations from current test guideline	• No guideline was used / followed
GLP/Officially recognised testing facilities	• No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes (Relevant, Category A acc. EFSA GD 2092, Point 5.4.1 / Reliable with restrictions)

2. Full summary of the study according to OECD format

3. Assessment and conclusion

Assessment and conclusion by applicant:

This article used the zebrafish model to assess the effects of early life glyphosate exposure on the development of cartilage and bone tissues and organismal responses. The evidence suggests functional alterations, including a reduction in the cardiac rate, significant changes in the spontaneous tail movement pattern, and defects in craniofacial development. These effects were concomitant with alterations in the level of the oestrogen receptor alpha osteopontin and bone sialoprotein. Embryos exposed to glyphosate presented spine deformities as adults. These developmental alterations are likely induced by changes in protein levels related to bone and cartilage formation.

This article is of importance for the assessment of the endocrine disrupting properties of glyphosate. It reports the acute and chronic effects on zebra fish. The study seems to have been well conducted and reports a regulatory relevant and reliable endpoint: 96 h NOEC = 1 mg/L (based on the effects on bone sialoprotein (BSPII) relative expression).The study is considered reliable with restrictions because it lacks of analytical verifications of the tested item in the test medium during the exposure phase. Temperature during the test is a bit high for the species tested.

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
1. For guideline-compliant studies (GLP studies): OECD, OPPTS, ISO, and others. The validity/quality criteria listed in the corresponding guidelines are met.	No	Non-guideline study
2. No previous exposure to other chemicals is documented (where relevant).	Yes	Zebrafish embryos used for the present study were generated from individuals obtained from commercial

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
		distributors and cultured in the lab.
3. For aquatic studies, the test substance is dissolved in water or where a carrier is required, it is appropriate (non-toxic) and a carrier control / positive control is considered in the test design.	Yes	Test item dissolved in the buffer solution, no solvent used
4. Glyphosate or its metabolite (test item) are sufficiently documented and reported (i.e. purity, source, content etc.).	Yes	Source, purity and CAS number reported.
5. For tests including vertebrates, there is a compliance of the batches used in toxicity studies compared to the technical specification.	No	Batch specifications are not provided and the assessment of the ecotoxicological equivalence cannot be conducted
6. Species used in the experiment are clearly reported, including source, experimental conditions (where relevant): strain, adequate age/life stage, body weight, acclimatization, temperature, pH, oxygen (dissolved oxygen for aquatic tests) content, housing, light conditions, humidity (terrestrial species) incubation conditions, feeding etc.	Yes	-
7. The validity criteria from relevant test guidelines can be extrapolated across different species but not necessarily across different test designs. If different, then the nature of the difference and impact should ideally be discussed.	No	Non-guideline study
8. Only glyphosate or its metabolite is the test substance (excluding mixture with other substances), and information on application of the test substance is described.	Yes	-
9. The endpoint measured can be considered a consequence of glyphosate (or a glyphosate metabolite).	Yes	-
10. Study design / test system is well described, including when relevant: concentration in exposure media (dose rates, volume applied, etc.), dilution/mixture of test item (solvent, vehicle) where relevant.	Yes	-
11. Analytical verifications are performed in test media (concentration) / collected samples, stability of the test substance in test medium should be documented.	No	Concentrations were analytically verified only in the stock solutions
12. An endpoint can be derived. Findings do deliver a regulatory endpoint, and/or is useful as supporting information.	Yes	Endpoint derived: NOEC (96-h)
13. The test has been tested in several dose levels (at least 3) including a positive/negative control where relevant.	Yes	No positive control tested
14. Suitable exposure throughout the whole exposure period was demonstrated and reported.	No	Concentrations were analytically verified only in the stock solutions
15. A clear concentration response relationship is reported – in studies where the dose response test design is employed.	Yes	-
16. A sufficient number of animals per group was included to facilitate statistical analysis: mortality in control groups reported, observations/findings in positive/negative control clearly reported (where relevant).	Yes	-

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
17. Assessment of the statistical power of the assay is possible with reported data.	Yes	Mean and standard error provided; no raw data
18. If statistical methodology was applied for findings reported, then the data analysis applied should be clearly documented (e.g., checking the plots and confidence intervals).	Yes	Statistical analysis sufficiently described
19. Description of the observations (including time-points), examinations, and analyses performed, with (where relevant) dissections being well documented.	Yes	-
20. For terrestrial ecotox studies in the lab or the field, the substrates used should be adequately described e.g. nature of substrate i.e. species of leaf or soil type.	-	Not applicable, aquatic study
20.1. Field locations are relevant/comparable to European conditions. Soils do not completely match the OECD criteria but are from Europe or to some extent representative for the European Agriculture.	-	Not applicable, aquatic study
20.2. Characterization of soil: texture (sandy loam, silty loam, loam, loamy sand), pH (5.5-8.0), cation exchange capacity, organic carbon (0.5-2-5%), bulk density, water retention, microbial biomass (~1% of organic carbon).	-	Not applicable, aquatic study
20.3. Other soils where information on characterization by the parameters: pH, texture, CEC, organic carbon, bulk density, water holding capacity, microbial biomass.	-	Not applicable, aquatic study
20.4. For tests including agricultural soils, they should not have been treated with test substance or similar substances for a minimum of 1 year.	-	Not applicable, aquatic study
20.5. For soil samples, sampling from A-horizon, top 20 cm layers; soils freshly from field preferred (storage max 3 months at 4 +/- 2°C).	-	Not applicable, aquatic study
20.6. Data on precipitation is recorded.	-	Not applicable, aquatic study
21. For lab terrestrial studies, the temperature was appropriate to the species being tested and generally should fall within the range between 20-25°C and soil moisture / relative humidity was reported.	-	Not applicable, aquatic study
22. For bee studies, temperature of the study should be appropriate to species.	-	Not applicable, aquatic study
23. For lab aquatic studies: 23.1. The source and / or composition of the media used should be described.	Yes	-
23.2. The temperature of the water should be appropriate to the species being tested and generally fall within the 15-25ºC.	Uncertain	Temperature set at 28.5°C for the tests.
24. The residue data can be linked to a clearly described GAP table appropriate in the context of the renewal of approval of glyphosate (crop, application method, doses, intervals, PHI).	No	Concentrations were analytically verified only in the stock solutions, but not during the test
25. Analytical results present residues measurements which can be correlated with the existing residues definition of glyphosate, and where relevant its metabolites.	No	Concentrations were analytically verified only in the stock solutions, but not during the test

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
26. Analytical methods are clearly described and adequate statement of specificity and sensitivity of the analytical methods is included.	Yes	The concentration of glyphosate in-stock solution was determined by liquid chromatography coupled to mass spectrometry (UHPLC-MS/MS)
27. Assessment of the ECX for the width of the confidence interval around the median value; and the certainty on the level of protection offered by the median ECX.	No	No assessment of the ECX median values was conducted.

Overall assessment		
Reliable without restrictions	No	-
Reliable with restrictions	Yes	This article is of importance for the assessment of the endocrine disrupting properties of glyphosate. It reports the acute and chronic effects on zebra fish. The study seems to have been well conducted and reports a regulatory relevant and reliable endpoint: 96-h NOEC = 1 mg/L (based on the effects on bone sialoprotein (BSPII) relative expression). The study is considered reliable with restrictions because it lacks of analytical verifications of the tested item in the test medium during the exposure phase. Temperature during the test is a bit high for the species tested.
Not reliable	No	-

1. Information on the study

Data point:	CP 10.2.1
Report author	Fernandez C. *et al.*
Report year	2021
Report title	Toxic effects of chlorpyrifos, cypermethrin and glyphosate on the non-target organism *Selenastrum capricornutum* (Chlorophyta)
Document No	An Acad Bras Cienc, 2021, 93(4), e20200233
Guidelines followed in study	OECD TG 201 (2011) partially
Deviations from current test guideline	Deviation from OECD TG 201 (2011): • No analytical verifications of the tested item in the test medium during the exposure phase • The test item is not fully documented.
GLP/Officially recognised testing facilities	• No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes (Relevant, Category A acc. EFSA GD 2092, Point 5.4.1 / Reliable with restrictions)

2. Assessment and conclusion

Assessment and conclusion by applicant:

This study evaluates the acute toxic effects of glyphosate on the growth, biovolume and ultrastructure of the green microalgae *Selenastrum capricornutum*. After 48 h, all tested concentrations reduced significantly the population growth. The regulatory relevant endpoint 96-h effective concentration 50 (EC_{50}) was 15.60 mg/L. Cells exposed to glyphosate showed an increase in the cellular size related to the increase in pesticide concentration and exposure time. The most significant damages observed on the ultrastructure of cells included thylakoids and mitochondria disruption, formation of electrodense bodies, accumulation of lipids and increase in the size and number of starch granules.
The study is considered reliable with restrictions because it lacks of analytical verifications of the tested item in the test medium during the exposure phase and the test item is not fully documented.

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Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
1. For guideline-compliant studies (GLP studies): OECD, OPPTS, ISO, and others. The validity/quality criteria listed in the corresponding guidelines are met.	Uncertain	Study conducted according to OECD TG 201 and Environment Canada Series Report EPS 1/RM/25, but not all validity criteria can be checked.
2. No previous exposure to other chemicals is documented (where relevant).	Yes	Cultures were obtained from a culture collection at the Universidad

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
		Federal de São Carlos (São Paulo) and were kept in Bold´s Basic Medium.
3. For aquatic studies, the test substance is dissolved in water or where a carrier is required, it is appropriate (non-toxic) and a carrier control / positive control is considered in the test design.	Yes	Test item dissolved in the test medium, no solvent used
4. Glyphosate or its metabolite (test item) are sufficiently documented and reported (i.e. purity, source, content etc.).	No	Only the name of the product and glyphosate content were reported.
5. For tests including vertebrates, there is a compliance of the batches used in toxicity studies compared to the technical specification.	-	No vertebrate study
6. Species used in the experiment are clearly reported, including source, experimental conditions (where relevant): strain, adequate age/life stage, body weight, acclimatization, temperature, pH, oxygen (dissolved oxygen for aquatic tests) content, housing, light conditions, humidity (terrestrial species) incubation conditions, feeding etc.	Yes	-
7. The validity criteria from relevant test guidelines can be extrapolated across different species but not necessarily across different test designs. If different, then the nature of the difference and impact should ideally be discussed.	Uncertain	Study conducted according to OECD TG 201 and Environment Canada Series Report EPS 1/RM/25, but not all validity criteria can be checked.
8. Only glyphosate or its metabolite is the test substance (excluding mixture with other substances), and information on application of the test substance is described.	Yes	-
9. The endpoint measured can be considered a consequence of glyphosate (or a glyphosate metabolite).	Yes	-
10. Study design / test system is well described, including when relevant: concentration in exposure media (dose rates, volume applied, etc.), dilution/mixture of test item (solvent, vehicle) where relevant.	Yes	-
11. Analytical verifications are performed in test media (concentration) / collected samples, stability of the test substance in test medium should be documented.	No	Analytical verifications were not conducted
12. An endpoint can be derived. Findings do deliver a regulatory endpoint, and/or is useful as supporting information.	Yes	Endpoint derived: EC_{50} (96-h))
13. The test has been tested in several dose levels (at least 3) including a positive/negative control where relevant.	Yes	-
14. Suitable exposure throughout the whole exposure period was demonstrated and reported.	No	Analytical verifications were not conducted
15. A clear concentration response relationship is reported – in	Yes	-

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Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
studies where the dose response test design is employed.		
16. A sufficient number of animals per group was included to facilitate statistical analysis: mortality in control groups reported, observations/findings in positive/negative control clearly reported (where relevant).	Yes	-
17. Assessment of the statistical power of the assay is possible with reported data.	Yes	Mean and standard error provided; no raw data
18. If statistical methodology was applied for findings reported, then the data analysis applied should be clearly documented (e.g., checking the plots and confidence intervals).	Yes	Statistical analysis sufficiently described
19. Description of the observations (including time-points), examinations, and analyses performed, with (where relevant) dissections being well documented.	Yes	-
20. For terrestrial ecotox studies in the lab or the field, the substrates used should be adequately described e.g. nature of substrate i.e. species of leaf or soil type.	-	Not applicable, aquatic study
20.1. Field locations are relevant/comparable to European conditions. Soils do not completely match the OECD criteria but are from Europe or to some extent representative for the European Agriculture.	-	Not applicable, aquatic study
20.2. Characterization of soil: texture (sandy loam, silty loam, loam, loamy sand), pH (5.5-8.0), cation exchange capacity, organic carbon (0.5-2-5%), bulk density, water retention, microbial biomass (~1% of organic carbon).	-	Not applicable, aquatic study
20.3. Other soils where information on characterization by the parameters: pH, texture, CEC, organic carbon, bulk density, water holding capacity, microbial biomass.	-	Not applicable, aquatic study
20.4. For tests including agricultural soils, they should not have been treated with test substance or similar substances for a minimum of 1 year.	-	Not applicable, aquatic study
20.5. For soil samples, sampling from A-horizon, top 20 cm layers; soils freshly from field preferred (storage max 3 months at 4 +/- 2°C).	-	Not applicable, aquatic study
20.6. Data on precipitation is recorded.	-	Not applicable, aquatic study
21. For lab terrestrial studies, the temperature was appropriate to the species being tested and generally should fall within the range between 20-25°C and soil moisture / relative humidity was reported.	-	Not applicable, aquatic study
22. For bee studies, temperature of the study should be appropriate to species.	-	Not applicable, aquatic study
23. For lab aquatic studies: 23.1. The source and / or composition of the media used should be described.	Yes	-
23.2. The temperature of the water should be appropriate to the species being tested and generally fall within the 15-25ºC.	Yes	Temperature set at 24°C for the tests.
24. The residue data can be linked to a clearly described GAP table appropriate in the context of the renewal of approval of glyphosate (crop, application method, doses, intervals, PHI).	No	Analytical verifications were not conducted
25. Analytical results present residues measurements which can be correlated with the existing residues definition of glyphosate,	No	Analytical verifications

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
and where relevant its metabolites.		were not conducted
26. Analytical methods are clearly described and adequate statement of specificity and sensitivity of the analytical methods is included.	No	Analytical verifications were not conducted
27. Assessment of the ECX for the width of the confidence interval around the median value; and the certainty on the level of protection offered by the median ECX.	Yes	95% CI values were reported

Overall assessment		
Reliable without restrictions	No	-
Reliable with restrictions	Yes	This study evaluates the acute toxic effects of glyphosate on the growth, bio volume and ultrastructure of the green microalgae *Selenastrum capricornutum*. The 96-h effective concentration 50 (EC_{50}) was 15.60 mg/L. The study is considered reliable with restrictions because it lacks of analytical verifications of the tested item in the test medium during the exposure phase and the test item is not fully documented.
Not reliable	No	-

1. Information on the study

Data point:	CP 10.1.3
Report author	Goodman R. M. *et al.*
Report year	2021
Report title	Influence of herbicide exposure and ranavirus infection on growth and survival of juvenile red-eared slider turtles (*Trachemys scripta elegans*)
Document No	Viruses, 2021, 13(8), 1440
Guidelines followed in study	None
Deviations from current test guideline	• No guideline was used / followed
GLP/Officially recognised testing facilities	• No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes (Relevant, Category A acc. EFSA GD 2092, Point 5.4.1 / Reliable with restrictions)

2. Assessment and conclusion

Assessment and conclusion by applicant:

In this study, hatchling red-eared slider turtles (*Trachemys scripta elegans*) were exposed to the formulated glyphosate herbicides Roundup ProMax® and Rodeo® to examine direct effects on growth and mortality. Turtles were exposed to herbicides via water bath during the first 3 weeks of a 5-week experiment. Exposure to a NOEC = 2 mg/L concentration of glyphosate (for both products) did not impact growth or survival time of hatchling turtles.
The study cannot be considered as fully reliable because it is uncertain whether and when the samples from the final herbicide solutions that were analysed to verify target concentrations, were taken from the experimental cages. In addition, the test items were not documented and only one concentration of each product was tested.

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
1. For guideline-compliant studies (GLP studies): OECD, OPPTS, ISO, and others. The validity/quality criteria listed in the corresponding guidelines are met.	No	Non-guideline study
2. No previous exposure to other chemicals is documented (where relevant).	Yes	Individuals used for the present study were purchased from a commercial supplier and acclimatized for 3 days to laboratory conditions
3. For aquatic studies, the test substance is dissolved in water or where a carrier is required, it is appropriate (non-toxic) and a carrier control / positive control is considered in the test design.	Yes	Test item dissolved in water, no solvent used

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
4. Glyphosate or its metabolite (test item) are sufficiently documented and reported (i.e. purity, source, content etc.).	No	Just the name of the supplier was reported.
5. For tests including vertebrates, there is a compliance of the batches used in toxicity studies compared to the technical specification.	No	Batch specifications are not provided and the assessment of the ecotoxicological equivalence cannot be conducted
6. Species used in the experiment are clearly reported, including source, experimental conditions (where relevant): strain, adequate age/life stage, body weight, acclimatization, temperature, pH, oxygen (dissolved oxygen for aquatic tests) content, housing, light conditions, humidity (terrestrial species) incubation conditions, feeding etc.	Yes	-
7. The validity criteria from relevant test guidelines can be extrapolated across different species but not necessarily across different test designs. If different, then the nature of the difference and impact should ideally be discussed.	No	Non-guideline study
8. Only glyphosate or its metabolite is the test substance (excluding mixture with other substances), and information on application of the test substance is described.	Yes	-
9. The endpoint measured can be considered a consequence of glyphosate (or a glyphosate metabolite).	Yes	-
10. Study design / test system is well described, including when relevant: concentration in exposure media (dose rates, volume applied, etc.), dilution/mixture of test item (solvent, vehicle) where relevant.	Yes	-
11. Analytical verifications are performed in test media (concentration) / collected samples, stability of the test substance in test medium should be documented.	Uncertain	In two different weeks, samples from the final herbicide solutions were analysed to verify target concentrations, but it is not clear whether and when the samples were taken from the experimental cages.
12. An endpoint can be derived. Findings do deliver a regulatory endpoint, and/or is useful as supporting information.	Yes	Endpoint reported: chronic NOEC (35-d))
13. The test has been tested in several dose levels (at least 3) including a positive/negative control where relevant.	No	Only 1 concentration of each product was tested
14. Suitable exposure throughout the whole exposure period was demonstrated and reported.	Uncertain	Samples from the final herbicide solutions were

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Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
		analysed to verify target concentrations, but it is not clear whether and when the samples were taken from the exposure cages.
15. A clear concentration response relationship is reported - in studies where the dose response test design is employed.	No	Only 1 concentration of each product was tested
16. A sufficient number of animals per group was included to facilitate statistical analysis: mortality in control groups reported, observations/findings in positive/negative control clearly reported (where relevant).	Yes	20 replicates of 1 individual per treatment
17. Assessment of the statistical power of the assay is possible with reported data.	Yes	Mean and standard error provided; no raw data
18. If statistical methodology was applied for findings reported, then the data analysis applied should be clearly documented (e.g., checking the plots and confidence intervals).	Yes	Statistical analysis sufficiently described
19. Description of the observations (including time-points), examinations, and analyses performed, with (where relevant) dissections being well documented.	Yes	-
20. For terrestrial ecotox studies in the lab or the field, the substrates used should be adequately described e.g. nature of substrate i.e. species of leaf or soil type.	-	Not applicable, aquatic study
20.1. Field locations are relevant/comparable to European conditions. Soils do not completely match the OECD criteria but are from Europe or to some extent representative for the European Agriculture.	-	Not applicable, aquatic study
20.2. Characterization of soil: texture (sandy loam, silty loam, loam, loamy sand), pH (5.5-8.0), cation exchange capacity, organic carbon (0.5-2-5%), bulk density, water retention, microbial biomass (~1% of organic carbon).	-	Not applicable, aquatic study
20.3. Other soils where information on characterization by the parameters: pH, texture, CEC, organic carbon, bulk density, water holding capacity, microbial biomass.	-	Not applicable, aquatic study
20.4. For tests including agricultural soils, they should not have been treated with test substance or similar substances for a minimum of 1 year.	-	Not applicable, aquatic study
20.5. For soil samples, sampling from A-horizon, top 20 cm layers; soils freshly from field preferred (storage max 3 months at 4 +/- 2°C).	-	Not applicable, aquatic study
20.6. Data on precipitation is recorded.	-	Not applicable, aquatic study
21. For lab terrestrial studies, the temperature was appropriate to the species being tested and generally should fall within the range between 20-25°C and soil moisture / relative humidity was reported.	-	Not applicable, aquatic study
22. For bee studies, temperature of the study should be appropriate to species.	-	Not applicable, aquatic study

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Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
23. For lab aquatic studies: 23.1. The source and / or composition of the media used should be described.	Yes	-
23.2. The temperature of the water should be appropriate to the species being tested and generally fall within the 15-25ºC.	Yes	Mean temperature set at 24°C (19.5-28°C).
24. The residue data can be linked to a clearly described GAP table appropriate in the context of the renewal of approval of glyphosate (crop, application method, doses, intervals, PHI).	Uncertain	Samples from the final herbicide solutions were analysed to verify target concentrations, but it is not clear whether and when the samples were taken from the exposure cages.
25. Analytical results present residues measurements which can be correlated with the existing residues definition of glyphosate, and where relevant its metabolites.	Uncertain	Samples from the final herbicide solutions were analysed to verify target concentrations, but it is not clear whether and when the samples were taken from the exposure cages.
26. Analytical methods are clearly described and adequate statement of specificity and sensitivity of the analytical methods is included.	No	No analytical methods reported
27. Assessment of the ECX for the width of the confidence interval around the median value; and the certainty on the level of protection offered by the median ECX.	No	No ECx assessment was conducted

Overall assessment		
Reliable without restrictions	No	-
Reliable with restrictions	Yes	This article reports the chronic effects of two glyphosate-based pesticides on growth and survival of juvenile Red-Eared Slider Turtles (*Trachemys scripta elegans*). The study seems to have been well conducted and reports a regulatory relevant endpoint: 35-d chronic NOEC = 2 mg/L (1.952 - 2.292). The study cannot be considered as fully reliable because it is uncertain whether and when the samples from the final herbicide solutions that were analysed to verify target concentrations, were taken from the experimental cages. In addition, the test items were not documented and only one concentration of each product was tested.
Not reliable	No	-

1. Information on the study

Data point:	CP 10.2.1, CP 10.2.2
Report author	Houssou A. M. *et al.*
Report year	2021
Report title	Acute and chronic effects of a glyphosate and a cypermethrin-based pesticide on a non-target species *Eucypris* sp. Vavra, 1891 (Crustacea, Ostracoda)
Document No	Processes, 2021, 9(4), 701
Guidelines followed in study	None
Deviations from current test guideline	• No guideline was used / followed
GLP/Officially recognised testing facilities	• No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes (Relevant, Category A acc. EFSA GD 2092, Point 5.4.1 / Reliable with restrictions)

2. Assessment and conclusion

Assessment and conclusion by applicant:

This article reports the acute and chronic effects of a glyphosate-based pesticide on the fresh-water Ostracoda species *Eucypris* sp. (aquatic invertebrate species other than *Daphnia magna*). The study seems to have been well conducted and reports regulatory relevant and reliable endpoints: 48-h acute LC_{50} = 9.03 mg/L and 28-d chronic LOEC = 0.903 mg/L (10% of the estimated 48-h LC_{50}). However, the study cannot be considered as fully reliable because it lacks of analytical verifications of the tested item in the test medium. In addition, the culture/test medium is not described.

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Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
1. For guideline-compliant studies (GLP studies): OECD, OPPTS, ISO, and others. The validity/quality criteria listed in the corresponding guidelines are met.	No	Non-guideline study
2. No previous exposure to other chemicals is documented (where relevant).	Yes	Individuals used for the present study are fifth generation of a lab culture from a natural sample. They may be considered as non-contaminated individuals by environmental pollutants.
3. For aquatic studies, the test substance is dissolved in water or where a carrier is required, it is appropriate (non-toxic) and a carrier control / positive control is considered in the test design.	Yes	Test item dissolved in distilled water, no solvent used
4. Glyphosate or its metabolite (test item) are sufficiently documented and reported (i.e. purity, source, content etc.).	Uncertain	Source and content reported, but not clear if

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
		the tested formulation Kumark® 480 g/L (Kumark Company Limited, Kumasi, Ghana) contains surfactants.
5. For tests including vertebrates, there is a compliance of the batches used in toxicity studies compared to the technical specification.	No	Batch specifications are not provided and the assessment of the ecotoxicological equivalence cannot be conducted
6. Species used in the experiment are clearly reported, including source, experimental conditions (where relevant): strain, adequate age/life stage, body weight, acclimatization, temperature, pH, oxygen (dissolved oxygen for aquatic tests) content, housing, light conditions, humidity (terrestrial species) incubation conditions, feeding etc.	Uncertain	Culture medium is not described
7. The validity criteria from relevant test guidelines can be extrapolated across different species but not necessarily across different test designs. If different, then the nature of the difference and impact should ideally be discussed.	No	Non-guideline study
8. Only glyphosate or its metabolite is the test substance (excluding mixture with other substances), and information on application of the test substance is described.	Yes	-
9. The endpoint measured can be considered a consequence of glyphosate (or a glyphosate metabolite).	Yes	-
10. Study design / test system is well described, including when relevant: concentration in exposure media (dose rates, volume applied, etc.), dilution/mixture of test item (solvent, vehicle) where relevant.	Yes	-
11. Analytical verifications are performed in test media (concentration) / collected samples, stability of the test substance in test medium should be documented.	No	Concentrations were not analytically verified
12. An endpoint can be derived. Findings do deliver a regulatory endpoint, and/or is useful as supporting information.	Yes	Endpoints reported: acute LC_{50} (24 and 48-h) and chronic LOEC (28-d))
13. The test has been tested in several dose levels (at least 3) including a positive/negative control where relevant.	Yes (acute test) No (chronic test)	For the chronic test only 2 concentrations were tested
14. Suitable exposure throughout the whole exposure period was demonstrated and reported.	No	Exposure concentrations were not analytically verified.
15. A clear concentration response relationship is reported – in studies where the dose response test design is employed.	Yes	-

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
16. A sufficient number of animals per group was included to facilitate statistical analysis: mortality in control groups reported, observations/findings in positive/negative control clearly reported (where relevant).	Yes	Four replicates with seven adults per tested concentration (acute), ten replicates of 1 adult female per concentration (chronic reproduction) and 3 replicates of 10 individuals per concentration (chronic growth)
17. Assessment of the statistical power of the assay is possible with reported data.	Yes	Mean and standard error provided; no raw data
18. If statistical methodology was applied for findings reported, then the data analysis applied should be clearly documented (e.g., checking the plots and confidence intervals).	Yes	Statistical analysis sufficiently described
19. Description of the observations (including time-points), examinations, and analyses performed, with (where relevant) dissections being well documented.	Yes	-
20. For terrestrial ecotox studies in the lab or the field, the substrates used should be adequately described e.g. nature of substrate i.e. species of leaf or soil type.	-	Not applicable, aquatic study
20.1. Field locations are relevant/comparable to European conditions. Soils do not completely match the OECD criteria but are from Europe or to some extent representative for the European Agriculture.	-	Not applicable, aquatic study
20.2. Characterization of soil: texture (sandy loam, silty loam, loam, loamy sand), pH (5.5-8.0), cation exchange capacity, organic carbon (0.5-2-5%), bulk density, water retention, microbial biomass (~1% of organic carbon).	-	Not applicable, aquatic study
20.3. Other soils where information on characterization by the parameters: pH, texture, CEC, organic carbon, bulk density, water holding capacity, microbial biomass.	-	Not applicable, aquatic study
20.4. For tests including agricultural soils, they should not have been treated with test substance or similar substances for a minimum of 1 year.	-	Not applicable, aquatic study
20.5. For soil samples, sampling from A-horizon, top 20 cm layers; soils freshly from field preferred (storage max 3 months at 4 +/- 2°C).	-	Not applicable, aquatic study
20.6. Data on precipitation is recorded.	-	Not applicable, aquatic study
21. For lab terrestrial studies, the temperature was appropriate to the species being tested and generally should fall within the range between 20-25°C and soil moisture / relative humidity was reported.	-	Not applicable, aquatic study
22. For bee studies, temperature of the study should be appropriate to species.	-	Not applicable, aquatic study
23. For lab aquatic studies: 23.1. The source and / or composition of the media used should be described.	No	No information on the composition of

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Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
		the culture/test medium
23.2. The temperature of the water should be appropriate to the species being tested and generally fall within the 15-25ºC.	Uncertain	Temperature set at 27°C for culture and acute tests. No data of the temperature of the chronic tests are reported.
24. The residue data can be linked to a clearly described GAP table appropriate in the context of the renewal of approval of glyphosate (crop, application method, doses, intervals, PHI).	No	Exposure concentrations were not analytically verified
25. Analytical results present residues measurements which can be correlated with the existing residues definition of glyphosate, and where relevant its metabolites.	No	Exposure concentrations were not analytically verified
26. Analytical methods are clearly described and adequate statement of specificity and sensitivity of the analytical methods is included.	No	No analytical methods reported
27. Assessment of the ECX for the width of the confidence interval around the median value; and the certainty on the level of protection offered by the median ECX.	Yes	LC_{50} 95% confidence interval is reported

Overall assessment		
Reliable without restrictions	No	-
Reliable with restrictions	Yes	This article reports the acute and chronic effects of a glyphosate-based pesticide on the fresh-water Ostracoda species *Eucypris* sp. The study seems to have been well conducted and reports regulatory relevant and reliable endpoints: 48-h acute LC_{50} = 9.03 mg/L and 28-d chronic LOEC = 0.903 mg/L (10% of the estimated 48-h LC_{50}). However, the study cannot be considered as fully reliable because it lacks of analytical verifications of the tested item in the test medium. In addition, the culture/test medium is not described.
Not reliable	No	-

1. Information on the study

Data point:	CA 8.2.6.1
Report author	Kaeoboon S. *et al*.
Report year	2021
Report title	Toxicity response of *Chlorella* microalgae to glyphosate herbicide exposure based on biomass, pigment contents and photosynthetic efficiency
Document No	Plant Science Today, 2021, 8(2), 293-300
Guidelines followed in study	None
Deviations from current test guideline	• No guideline was used / followed
GLP/Officially recognised testing facilities	• No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes (Relevant, Category A acc. EFSA GD 2092, Point 5.4.1 / Reliable with restrictions)

2. Assessment and conclusion

Assessment and conclusion by applicant:

This article reports the effects of glyphosate at different concentrations (50-500 mg/L) on three *Chlorella* species including *Chlorella ellipsoidea*, *Chlorella sorokiniana* and *Chlorella vulgaris* in relation to the biomass, pigment contents and photosynthetic efficiency. The study seems to have been well conducted and reports regulatory relevant endpoints: 24-h acute EC_{50} = 449.34, 288.23 and 174.28 mg/L for *Chlorella vulgaris*, *Chlorella ellipsoidea* and *Chlorella sorokiniana*, respectively. Chronic endpoints at 72-h could also be calculated.
The study cannot be considered as fully reliable because it lacks of analytical verifications of the tested item in the test medium and the temperature during the tests and culture are higher than recommended for green algae. Purity of the test item is not given.

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Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
1. For guideline-compliant studies (GLP studies): OECD, OPPTS, ISO, and others. The validity/quality criteria listed in the corresponding guidelines are met.	No	Non-guideline study
2. No previous exposure to other chemicals is documented (where relevant).	Yes	-
3. For aquatic studies, the test substance is dissolved in water or where a carrier is required, it is appropriate (non-toxic) and a carrier control / positive control is considered in the test design.	Yes	The culture medium was directly used as diluent
4. Glyphosate or its metabolite (test item) are sufficiently documented and reported (i.e. purity, source, content etc.).	No	The producer is provided, but not the purity
5. For tests including vertebrates, there is a compliance of the batches used in toxicity studies compared to the technical specification.	-	No vertebrate study
6. Species used in the experiment are clearly reported, including source, experimental conditions (where relevant): strain, adequate age/life stage, body weight, acclimatization, temperature, pH, oxygen (dissolved oxygen for aquatic tests) content, housing, light conditions, humidity (terrestrial	Yes	-

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
species) incubation conditions, feeding etc.		
7. The validity criteria from relevant test guidelines can be extrapolated across different species but not necessarily across different test designs. If different, then the nature of the difference and impact should ideally be discussed.	No	Validity criteria cannot be assessed because no raw data are available
8. Only glyphosate or its metabolite is the test substance (excluding mixture with other substances), and information on application of the test substance is described.	Yes	-
9. The endpoint measured can be considered a consequence of glyphosate (or a glyphosate metabolite).	Yes	-
10. Study design / test system is well described, including when relevant: concentration in exposure media (dose rates, volume applied, etc.), dilution/mixture of test item (solvent, vehicle) where relevant.	Yes	-
11. Analytical verifications are performed in test media (concentration) / collected samples, stability of the test substance in test medium should be documented.	No	No analytical verifications of the concentration of glyphosate in the test media were conducted
12. An endpoint can be derived. Findings do deliver a regulatory endpoint, and/or is useful as supporting information.	Yes	Endpoint reported: EC_{50} (24-h)
13. The test has been tested in several dose levels (at least 3) including a positive/negative control where relevant.	Yes	5 concentrations tested
14. Suitable exposure throughout the whole exposure period was demonstrated and reported.	Uncertain	No analytical verifications of the concentration of glyphosate in the test media were conducted
15. A clear concentration response relationship is reported - in studies where the dose response test design is employed.	Yes	-
16. A sufficient number of animals per group was included to facilitate statistical analysis: mortality in control groups reported, observations/findings in positive/negative control clearly reported (where relevant).	Yes	3 replicates for each treatment group were tested
17. Assessment of the statistical power of the assay is possible with reported data.	Yes	Mean and standard deviation were provided. No raw data
18. If statistical methodology was applied for findings reported, then the data analysis applied should be clearly documented (e.g., checking the plots and confidence intervals).	Yes	Statistical analysis sufficiently described
19. Description of the observations (including time-points), examinations, and analyses performed, with (where relevant) dissections being well documented.	Yes	-
20. For terrestrial ecotox studies in the lab or the field, the substrates used should be adequately described e.g. nature of substrate i.e. species of leaf or soil type.	-	Not relevant, aquatic study
20.1. Field locations are relevant/comparable to European conditions. Soils do not completely match the OECD criteria but are from Europe or to some extent	-	Not relevant, aquatic study

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
representative for the European Agriculture.		
20.2. Characterization of soil: texture (sandy loam, silty loam, loam, loamy sand), pH (5.5-8.0), cation exchange capacity, organic carbon (0.5-2-5%), bulk density, water retention, microbial biomass (~1% of organic carbon).	-	Not relevant, aquatic study
20.3. Other soils where information on characterization by the parameters: pH, texture, CEC, organic carbon, bulk density, water holding capacity, microbial biomass.	-	Not relevant, aquatic study
20.4. For tests including agricultural soils, they should not have been treated with test substance or similar substances for a minimum of 1 year.	-	Not relevant, aquatic study
20.5. For soil samples, sampling from A-horizon, top 20 cm layers; soils freshly from field preferred (storage max 3 months at 4 +/- 2°C).	-	Not relevant, aquatic study
20.6. Data on precipitation is recorded.	-	Not relevant, aquatic study
21. For lab terrestrial studies, the temperature was appropriate to the species being tested and generally should fall within the range between 20-25°C and soil moisture / relative humidity was reported.	-	Not relevant, aquatic study
22. For bee studies, temperature of the study should be appropriate to species.	-	No bee study
23. For lab aquatic studies: 23.1. The source and / or composition of the media used should be described.	Yes	-
23.2. The temperature of the water should be appropriate to the species being tested and generally fall within the 15-25ºC.	No	Temperature was 30ºC (should have been in the range 21-24ºC)
24. The residue data can be linked to a clearly described GAP table appropriate in the context of the renewal of approval of glyphosate (crop, application method, doses, intervals, PHI).	Uncertain	No analytical verifications of the concentration of glyphosate in the test media were conducted
25. Analytical results present residues measurements which can be correlated with the existing residues definition of glyphosate, and where relevant its metabolites.	Uncertain	No analytical verifications of the concentration of glyphosate in the test media were conducted
26. Analytical methods are clearly described and adequate statement of specificity and sensitivity of the analytical methods is included.	No	No analytical methods reported
27. Assessment of the ECX for the width of the confidence interval around the median value; and the certainty on the level of protection offered by the median ECX.	No	No ECx assessment was conducted

Overall assessment		
Reliable without restrictions	No	-
Reliable with restrictions	Yes	This article reports the effects of glyphosate at different concentrations (50-500 mg/L) on three *Chlorella* species including *Chlorella ellipsoidea*, *Chlorella sorokiniana* and *Chlorella vulgaris* in relation to the biomass, pigment contents and photosynthetic efficiency. The study seems to have been well

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria			Criteria met? Yes / No / Uncertain	Comment / Justification
		conducted and reports regulatory relevant endpoints: 24-h acute EC_{50} = 449.34, 288.23 and 174.28 mg/L for *Chlorella vulgaris*, *Chlorella ellipsoidea* and *Chlorella sorokiniana*, respectively. Chronic endpoints at 72-h could also be calculated. The study cannot be considered as fully reliable because it lacks of analytical verifications of the tested item in the test medium and the temperature during the tests and culture are higher than recommended for green algae. Purity of the test item is not given.		
Not reliable	No	-		

1. Information on the study

Data point:	CA 8.2.2, CP 10.2.2
Report author	Le Du -Carrée J. *et al.*
Report year	2021
Report title	Developmental effect of parental or direct chronic exposure to environmental concentration of glyphosate on the larvae of rainbow trout, *Oncorhynchus mykiss*
Document No	Aquatic Toxicology, 2021, 237, 105894
Guidelines followed in study	None
Deviations from current test guideline	• No guideline was used / followed
GLP/Officially recognised testing facilities	• No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes (Relevant, Category A acc. EFSA GD 2092, Point 5.4.1 / Reliable with restrictions)

2. Assessment and conclusion

Assessment and conclusion by applicant:

This study investigates the impact of parental and direct exposure to 1 µg/L of glyphosate using the active subtance alone or one of two Glyphosaet-Based Herbicide formulations (i.e. Roundup Innovert® and Viaglif Jardin®) in the early developmental stages of rainbow trout. Three different modes of exposure on the F1 generation were studied: (1) intergenerational (i.e. fish only exposed through their parents); (2) direct (i.e. fish exposed only directly) and (3) multigenerational (i.e. fish both exposed intergenerationally and directly). The impact of chemical treatments on embryo -larval development (survival, biometry and malformations), swimming behaviour, biochemical markers. Chemical exposure did not affect the survival of F1 embryos or malformation rates. Direct exposure to the a.s. induced some biometric changes, such as reduction in head size (with a 10% decrease in head length), independently of co -formulants. Intergenerational exposure to the a.s. or the Roundup GBH increased swimming activity of the larvae, with increase of between 78 and 102% in travel speeds. Therefore, 1 generation LOEC = 1 µg/L.
The study is not considered fully reliable because although it presents analytical verifications of the tested item in the water in the exposure phase, it does not fully follow any agreed guidance and only one concentration was tested. Temperature of the test could have been a bit low for the tested species at some time points of the experiment.

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Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
1. For guideline -compliant studies (GLP studies): OECD, OPPTS, ISO, and others. The validity/quality criteria listed in the corresponding guidelines are met.	No	Non -guideline study
2. No previous exposure to other chemicals is documented (where relevant).	Yes	Individuals were cultured in the lab.
3. For aquatic studies, the test substance is dissolved in water or where a carrier is required, it is appropriate (non -toxic) and a carrier control / positive control is considered in the test design.	Uncertain	Pre -dilution of pure glyphosate was done in pure methanol in a concentration so

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full -text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
		the final dose of methanol exposure was kept under 4 µL/L
4. Glyphosate or its metabolite (test item) are sufficiently documented and reported (i.e. purity, source, content etc.).	Yes	Source, purity, CAS number and content reported
5. For tests including vertebrates, there is a compliance of the batches used in toxicity studies compared to the technical specification.	No	The assessment of the ecotoxicological equivalence was not conducted
6. Species used in the experiment are clearly reported, including source, experimental conditions (where relevant): strain, adequate age/life stage, body weight, acclimatization, temperature, pH, oxygen (dissolved oxygen for aquatic tests) content, housing, light conditions, humidity (terrestrial species) incubation conditions, feeding etc.	Yes	-
7. The validity criteria from relevant test guidelines can be extrapolated across different species but not necessarily across different test designs. If different, then the nature of the difference and impact should ideally be discussed.	No	Non -guideline study
8. Only glyphosate or its metabolite is the test substance (excluding mixture with other substances), and information on application of the test substance is described.	Yes	-
9. The endpoint measured can be considered a consequence of glyphosate (or a glyphosate metabolite).	Yes	-
10. Study design / test system is well described, including when relevant: concentration in exposure media (dose rates, volume applied, etc.), dilution/mixture of test item (solvent, vehicle) where relevant.	Yes	-
11. Analytical verifications are performed in test media (concentration) / collected samples, stability of the test substance in test medium should be documented.	Yes	Concentrations were analytically verified just before and 2-h after restarting the water flow approximately two months after the beginning of the experiment and a standard curve of the mean glyphosate concentrations as a function of time was generated.
12. An endpoint can be derived. Findings do deliver a regulatory endpoint, and/or is useful as supporting information.	Yes	Endpoint derived: LOEC (1 generation)
13. The test has been tested in several dose levels (at least 3) including a positive/negative control where relevant.	No	Just 1 concentration was tested

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Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
14. Suitable exposure throughout the whole exposure period was demonstrated and reported.	Yes	Concentrations were analytically verified just before and 2 h after restarting the water flow approximately two months after the beginning of the experiment and a standard curve of the mean glyphosate concentrations as a function of time was generated.
15. A clear concentration response relationship is reported – in studies where the dose response test design is employed.	No	Only 1 concentration was tested
16. A sufficient number of animals per group was included to facilitate statistical analysis: mortality in control groups reported, observations/findings in positive/negative control clearly reported (where relevant).	Yes	-
17. Assessment of the statistical power of the assay is possible with reported data.	Yes	Mean and standard error provided; no raw data
18. If statistical methodology was applied for findings reported, then the data analysis applied should be clearly documented (e.g., checking the plots and confidence intervals).	Yes	Statistical analysis sufficiently described
19. Description of the observations (including time -points), examinations, and analyses performed, with (where relevant) dissections being well documented.	Yes	-
20. For terrestrial ecotox studies in the lab or the field, the substrates used should be adequately described e.g. nature of substrate i.e. species of leaf or soil type.	-	Not applicable, aquatic study
20.1. Field locations are relevant/comparable to European conditions. Soils do not completely match the OECD criteria but are from Europe or to some extent representative for the European Agriculture.	-	Not applicable, aquatic study
20.2. Characterization of soil: texture (sandy loam, silty loam, loam, loamy sand), pH (5.5 -8.0), cation exchange capacity, organic carbon (0.5 -2 -5%), bulk density, water retention, microbial biomass (~1% of organic carbon).	-	Not applicable, aquatic study
20.3. Other soils where information on characterization by the parameters: pH, texture, CEC, organic carbon, bulk density, water holding capacity, microbial biomass.	-	Not applicable, aquatic study
20.4. For tests including agricultural soils, they should not have been treated with test substance or similar substances for a minimum of 1 year.	-	Not applicable, aquatic study
20.5. For soil samples, sampling from A -horizon, top 20 cm layers; soils freshly from field preferred (storage max 3 months at 4 +/ - 2°C).	-	Not applicable, aquatic study

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Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
20.6. Data on precipitation is recorded.	-	Not applicable, aquatic study
21. For lab terrestrial studies, the temperature was appropriate to the species being tested and generally should fall within the range between 20 -25°C and soil moisture / relative humidity was reported.	-	Not applicable, aquatic study
22. For bee studies, temperature of the study should be appropriate to species.	-	Not applicable, aquatic study
23. For lab aquatic studies: 23.1. The source and / or composition of the media used should be described.	Yes	River water filtered
23.2. The temperature of the water should be appropriate to the species being tested and generally fall within the 15 -25ºC.	Uncertain	Temperature set at 8°C during the embryonic development and at 11°C for the swimming behaviour analysis. Main test temperature not reported
24. The residue data can be linked to a clearly described GAP table appropriate in the context of the renewal of approval of glyphosate (crop, application method, doses, intervals, PHI).	No	-
25. Analytical results present residues measurements which can be correlated with the existing residues definition of glyphosate, and where relevant its metabolites.	Yes	Concentrations were analytically verified just before and 2 h after restarting the water flow approximately two months after the beginning of the experiment and a standard curve of the mean glyphosate concentrations as a function of time was generated.
26. Analytical methods are clearly described and adequate statement of specificity and sensitivity of the analytical methods is included.	Yes	The concentration of glyphosate in water was determined by HPLC and fluorometric methods
27. Assessment of the ECX for the width of the confidence interval around the median value; and the certainty on the level of protection offered by the median ECX.	No	No assessment of the ECX median values was conducted.

Overall assessment		
Reliable without restrictions	No	-

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full -text documents

Criteria		Criteria met? Yes / No / Uncertain	Comment / Justification
Reliable with restrictions	Yes	This study investigates the impact of parental and direct exposure to 1 µg/L of glyphosate using the AS alone or one of two GBH formulations (i.e. Roundup Innovert® and Viaglif Jardin®) in the early developmental stages of rainbow trout. Three different modes of exposure on the F1 generation were studied: (1) intergenerational (i.e. fish only exposed through their parents); (2) direct (i.e. fish exposed only directly) and (3) multigenerational (i.e. fish both exposed intergenerationally and directly). The impact of chemical treatments on embryo -larval development (survival, biometry and malformations), swimming behaviour, biochemical markers. Chemical exposure did not affect the survival of F1 embryos or malformation rates. Direct exposure to the AS induced some biometric changes, such as reduction in head size (with a 10% decrease in head length), independently of co -formulants. Intergenerational exposure to the AS or the Roundup GBH increased swimming activity of the larvae, with increase of between 78 and 102% in travel speeds. Therefore, 1 generation LOEC = 1 µg/L. The study is not considered fully reliable because although it presents analytical verifications of the tested item in the water in the exposure phase, it does not fully follow any agreed guidance and only one concentration was tested. Temperature of the test could have been a bit low for the tested species at some time points of the experiment.	
Not reliable	No	-	

1. Information on the study

Data point:	CA 8.2.2, CP 10.2.2
Report author	Le Du-Carrée J. *et al.*
Report year	2021
Report title	Generational effects of a chronic exposure to a low environmentally relevant concentration of glyphosate on rainbow trout, *Oncorhynchus mykiss*
Document No	Science of the Total Environment, 2021, 801, 149462
Guidelines followed in study	None
Deviations from current test guideline	• No guideline was used / followed
GLP/Officially recognised testing facilities	• No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes (Relevant, Category A acc. EFSA GD 2092, Point 5.4.1 / Reliable with restrictions)

2. Assessment and conclusion

Assessment and conclusion by applicant:

This study investigates the impact of an environmentally relevant concentration of glyphosate on a F2 generation issued from exposed generations F0 and F1. Trans, inter and multigenerational toxicity of 1 µg/L of the active substance was evaluated on early stages of development and juvenile rainbow trout (*Oncorhynchus mykiss*) using different molecular, biochemical, immuno-hematologic, and biometric parameters, behaviour analysis, and a viral challenge. Reproductive parameters of generation F1 were not affected. However, developmental toxicity in generation F2 due to glyphosate alone or co -formulated was observed with head size changes (e.g. head surface up to +10%), and metabolic disruptions (e.g. 35% reduction in cytochrome -c -oxidase). Therefore, LOEC = 1 µg/L.
The study is not considered fully reliable because although it presents analytical verifications of the tested item in the water in the exposure phase, it does not fully follow any agreed guidance and only one concentration was tested. Temperature of the test could have been a bit low for the tested species at some time points of the experiment.

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Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
1. For guideline -compliant studies (GLP studies): OECD, OPPTS, ISO, and others. The validity/quality criteria listed in the corresponding guidelines are met.	No	Non -guideline study
2. No previous exposure to other chemicals is documented (where relevant).	Yes	Individuals were cultured in the lab.
3. For aquatic studies, the test substance is dissolved in water or where a carrier is required, it is appropriate (non-toxic) and a carrier control / positive control is considered in the test design.	Uncertain	Pre -dilution of pure glyphosate was done in pure methanol in a concentration so the final dose of methanol exposure was

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full -text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
		kept under 4 µL/L
4. Glyphosate or its metabolite (test item) are sufficiently documented and reported (i.e. purity, source, content etc.).	Yes	Source, purity, CAS number and content reported
5. For tests including vertebrates, there is a compliance of the batches used in toxicity studies compared to the technical specification.	No	The assessment of the ecotoxicological equivalence was not conducted
6. Species used in the experiment are clearly reported, including source, experimental conditions (where relevant): strain, adequate age/life stage, body weight, acclimatization, temperature, pH, oxygen (dissolved oxygen for aquatic tests) content, housing, light conditions, humidity (terrestrial species) incubation conditions, feeding etc.	Yes	-
7. The validity criteria from relevant test guidelines can be extrapolated across different species but not necessarily across different test designs. If different, then the nature of the difference and impact should ideally be discussed.	No	Non -guideline study
8. Only glyphosate or its metabolite is the test substance (excluding mixture with other substances), and information on application of the test substance is described.	Yes	-
9. The endpoint measured can be considered a consequence of glyphosate (or a glyphosate metabolite).	Yes	-
10. Study design / test system is well described, including when relevant: concentration in exposure media (dose rates, volume applied, etc.), dilution/mixture of test item (solvent, vehicle) where relevant.	Yes	-
11. Analytical verifications are performed in test media (concentration) / collected samples, stability of the test substance in test medium should be documented.	Yes	Concentrations were analytically verified just before and 2 h after restarting the water flow approximately two months after the beginning of the experiment and a standard curve of the mean glyphosate concentrations as a function of time was generated.
12. An endpoint can be derived. Findings do deliver a regulatory endpoint, and/or is useful as supporting information.	Yes	Endpoint derived: LOEC (2 generations)
13. The test has been tested in several dose levels (at least 3) including a positive/negative control where relevant.	No	Just 1 concentration was tested
14. Suitable exposure throughout the whole exposure period was demonstrated and reported.	Yes	Concentrations were analytically verified just before and 2 h

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Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
		after restarting the water flow approximately two months after the beginning of the experiment and a standard curve of the mean glyphosate concentrations as a function of time was generated.
15. A clear concentration response relationship is reported – in studies where the dose response test design is employed.	No	Only 1 concentration was tested
16. A sufficient number of animals per group was included to facilitate statistical analysis: mortality in control groups reported, observations/findings in positive/negative control clearly reported (where relevant).	Yes	-
17. Assessment of the statistical power of the assay is possible with reported data.	Yes	Mean and standard error provided; no raw data
18. If statistical methodology was applied for findings reported, then the data analysis applied should be clearly documented (e.g., checking the plots and confidence intervals).	Yes	Statistical analysis sufficiently described
19. Description of the observations (including time -points), examinations, and analyses performed, with (where relevant) dissections being well documented.	Yes	-
20. For terrestrial ecotox studies in the lab or the field, the substrates used should be adequately described e.g. nature of substrate i.e. species of leaf or soil type.	-	Not applicable, aquatic study
20.1. Field locations are relevant/comparable to European conditions. Soils do not completely match the OECD criteria but are from Europe or to some extent representative for the European Agriculture.	-	Not applicable, aquatic study
20.2. Characterization of soil: texture (sandy loam, silty loam, loam, loamy sand), pH (5.5 -8.0), cation exchange capacity, organic carbon (0.5 -2 -5%), bulk density, water retention, microbial biomass (~1% of organic carbon).	-	Not applicable, aquatic study
20.3. Other soils where information on characterization by the parameters: pH, texture, CEC, organic carbon, bulk density, water holding capacity, microbial biomass.	-	Not applicable, aquatic study
20.4. For tests including agricultural soils, they should not have been treated with test substance or similar substances for a minimum of 1 year.	-	Not applicable, aquatic study
20.5. For soil samples, sampling from A -horizon, top 20 cm layers; soils freshly from field preferred (storage max 3 months at 4 +/ - 2°C).	-	Not applicable, aquatic study
20.6. Data on precipitation is recorded.	-	Not applicable, aquatic study

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full -text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
21. For lab terrestrial studies, the temperature was appropriate to the species being tested and generally should fall within the range between 20 -25°C and soil moisture / relative humidity was reported.	-	Not applicable, aquatic study
22. For bee studies, temperature of the study should be appropriate to species.	-	Not applicable, aquatic study
23. For lab aquatic studies: 23.1. The source and / or composition of the media used should be described.	Yes	River water filtered
23.2. The temperature of the water should be appropriate to the species being tested and generally fall within the 15 -25ºC.	Uncertain	Temperature varied from 6 to 15°C (it should have been 12 to 15.
24. The residue data can be linked to a clearly described GAP table appropriate in the context of the renewal of approval of glyphosate (crop, application method, doses, intervals, PHI).	No	-
25. Analytical results present residues measurements which can be correlated with the existing residues definition of glyphosate, and where relevant its metabolites.	Yes	Concentrations were analytically verified just before and 2 h after restarting the water flow approximately two months after the beginning of the experiment and a standard curve of the mean glyphosate concentrations as a function of time was generated.
26. Analytical methods are clearly described and adequate statement of specificity and sensitivity of the analytical methods is included.	Yes	The concentration of glyphosate in water was determined by HPLC and fluorometric methods
27. Assessment of the ECX for the width of the confidence interval around the median value; and the certainty on the level of protection offered by the median ECX.	No	No assessment of the ECX median values was conducted.

Overall assessment		
Reliable without restrictions	No	-
Reliable with restrictions	Yes	This study investigates the impact of an environmentally relevant concentration of glyphosate on a F2 generation issued from exposed generations F0 and F1. Trans, inter and multigenerational toxicity of 1 µg/L of the active substance was evaluated on early stages of development and juvenile rainbow trout (*Oncorhynchus mykiss*) using different molecular,

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full -text documents

Criteria			Criteria met? Yes / No / Uncertain	Comment / Justification
		biochemical, immuno-hematologic, and biometric parameters, behaviour analysis, and a viral challenge. Reproductive parameters of generation F1 were not affected. However, developmental toxicity in generation F2 due to glyphosate alone or co -formulated was observed with head size changes (e.g. head surface up to +10%), and metabolic disruptions (e.g. 35% reduction in cytochrome -c -oxidase). Therefore, 2 generations LOEC = 1 µg/L. The study is not considered fully reliable because although it presents analytical verifications of the tested item in the water in the exposure phase, it does not fully follow any agreed guidance and only one concentration was tested. Temperature of the test could have been a bit low for the tested species at some time points of the experiment.		
Not reliable	No	-		

1. Information on the study

Data point:	CA 8.2.7
Report author	Mendes E. J. *et al.*
Report year	2021
Report title	Isolated and combined effects of glyphosate and its by-product aminomethylphosphonic acid on the physiology and water remediation capacity of *Salvinia molesta*
Document No	Journal of Hazardous Materials, 2021, 417, 125694
Guidelines followed in study	None (partially based on OECD TG 221)
Deviations from current test guideline	• No guideline was used / followed
GLP/Officially recognised testing facilities	• No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes (Relevant, Category A acc. EFSA GD 2092, Point 5.4.1 / Reliable with restrictions)

2. Assessment and conclusion

Assessment and conclusion by applicant:

This study evaluates the isolated and combined effects of glyphosate and its by-product aminomethylphosphonic acid (AMPA) on the aquatic macrophyte *Salvinia molesta*. Plants were exposed to environmentally relevant concentrations of glyphosate (0, 20, 40, 60, 80 and 100 µg/L) or AMPA (0, 10, 20, 30, 40 and 50 µg/L) for seven days. Then, based on the effective concentrations of glyphosate found to reduce photosynthetic rates by 10% (EC_{10}) and 50% (EC_{50}), the plants were exposed to combinations of 0, 16 and 63.5 µg glyphosate/L and 0, 5, 15, 25 µg AMPA/L. The EC_{10} and EC_{50} were lower for AMPA (6.1 µg/L and 28.4 µg/L, respectively) than for glyphosate (16 and 63.5 µg glyphosate/L, respectively). When occurring together, the deleterious effects of those chemicals to plants increased.
The study is considered not fully reliable because it is not possible to identify the number of plants tested for each treatment and because plants were collected from the field in Brazil with no record of previous pesticide exposure (although they were maintained in the lab for 60 days for depuration).

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Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
1. For guideline-compliant studies (GLP studies): OECD, OPPTS, ISO, and others. The validity/quality criteria listed in the corresponding guidelines are met.	Uncertain	Study conducted according to OECD TG 221, but validity criteria cannot be verified because the measured variables (mainly photosynthetic rate) are different from those stated in the OECD GD (inhibition of growth).

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
2. No previous exposure to other chemicals is documented (where relevant).	Uncertain	Plants were collected from the field in Brazil with no record of previous pesticide exposure, but were maintained in the lab for 60 days for depuration
3. For aquatic studies, the test substance is dissolved in water or where a carrier is required, it is appropriate (non-toxic) and a carrier control / positive control is considered in the test design.	Yes	Test item dissolved in water, no solvent used
4. Glyphosate or its metabolite (test item) are sufficiently documented and reported (i.e. purity, source, content etc.).	Yes	Analytical grade glyphosate and AMPA (Pestanal®, Sigma-Aldrich, Canada) were used in all experiments
5. For tests including vertebrates, there is a compliance of the batches used in toxicity studies compared to the technical specification.	-	No vertebrate study
6. Species used in the experiment are clearly reported, including source, experimental conditions (where relevant): strain, adequate age/life stage, body weight, acclimatization, temperature, pH, oxygen (dissolved oxygen for aquatic tests) content, housing, light conditions, humidity (terrestrial species) incubation conditions, feeding etc.	Yes	-
7. The validity criteria from relevant test guidelines can be extrapolated across different species but not necessarily across different test designs. If different, then the nature of the difference and impact should ideally be discussed.	Uncertain	Study conducted according to OECD TG 221, but validity criteria cannot be verified
8. Only glyphosate or its metabolite is the test substance (excluding mixture with other substances), and information on application of the test substance is described.	Yes	-
9. The endpoint measured can be considered a consequence of glyphosate (or a glyphosate metabolite).	Yes	-
10. Study design / test system is well described, including when relevant: concentration in exposure media (dose rates, volume applied, etc.), dilution/mixture of test item (solvent, vehicle) where relevant.	Yes	-
11. Analytical verifications are performed in test media (concentration) / collected samples, stability of the test substance in test medium should be documented.	Yes	The concentrations of glyphosate and AMPA in the water medium and plants (initial and final concentrations) were determined

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
12. An endpoint can be derived. Findings do deliver a regulatory endpoint, and/or is useful as supporting information.	Yes	Endpoint derived: EC_{50} (7-d) for both glyphosate and AMPA
13. The test has been tested in several dose levels (at least 3) including a positive/negative control where relevant.	Yes	-
14. Suitable exposure throughout the whole exposure period was demonstrated and reported.	Yes	Analytical verifications were conducted at the beginning and the end of the test
15. A clear concentration response relationship is reported – in studies where the dose response test design is employed.	Yes	-
16. A sufficient number of animals per group was included to facilitate statistical analysis: mortality in control groups reported, observations/findings in positive/negative control clearly reported (where relevant).	Uncertain	A density of 15 g plant/L was used in the bioassays, but the number of replicates is not known.
17. Assessment of the statistical power of the assay is possible with reported data.	Yes	Mean and standard deviation provided; no raw data
18. If statistical methodology was applied for findings reported, then the data analysis applied should be clearly documented (e.g., checking the plots and confidence intervals).	Yes	Statistical analysis sufficiently described
19. Description of the observations (including time-points), examinations, and analyses performed, with (where relevant) dissections being well documented.	Yes	-
20. For terrestrial ecotox studies in the lab or the field, the substrates used should be adequately described e.g. nature of substrate i.e. species of leaf or soil type.	-	Not applicable, aquatic study
20.1. Field locations are relevant/comparable to European conditions. Soils do not completely match the OECD criteria but are from Europe or to some extent representative for the European Agriculture.	-	Not applicable, aquatic study
20.2. Characterization of soil: texture (sandy loam, silty loam, loam, loamy sand), pH (5.5-8.0), cation exchange capacity, organic carbon (0.5-2-5%), bulk density, water retention, microbial biomass (~1% of organic carbon).	-	Not applicable, aquatic study
20.3. Other soils where information on characterization by the parameters: pH, texture, CEC, organic carbon, bulk density, water holding capacity, microbial biomass.	-	Not applicable, aquatic study
20.4. For tests including agricultural soils, they should not have been treated with test substance or similar substances for a minimum of 1 year.	-	Not applicable, aquatic study
20.5. For soil samples, sampling from A-horizon, top 20 cm layers; soils freshly from field preferred (storage max 3 months at 4 +/- 2°C).	-	Not applicable, aquatic study
20.6. Data on precipitation is recorded.	-	Not applicable, aquatic study

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Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
21. For lab terrestrial studies, the temperature was appropriate to the species being tested and generally should fall within the range between 20-25°C and soil moisture / relative humidity was reported.	-	Not applicable, aquatic study
22. For bee studies, temperature of the study should be appropriate to species.	-	Not applicable, aquatic study
23. For lab aquatic studies: 23.1. The source and / or composition of the media used should be described.	Yes	-
23.2. The temperature of the water should be appropriate to the species being tested and generally fall within the 15-25ºC.	Yes	Temperature set at 20°C for the tests.
24. The residue data can be linked to a clearly described GAP table appropriate in the context of the renewal of approval of glyphosate (crop, application method, doses, intervals, PHI).	Yes	Analytical verifications were conducted at the beginning and the end of the test
25. Analytical results present residues measurements which can be correlated with the existing residues definition of glyphosate, and where relevant its metabolites.	Yes	Analytical verifications were conducted at the beginning and the end of the test
26. Analytical methods are clearly described and adequate statement of specificity and sensitivity of the analytical methods is included.	Yes	Analytical methods were described
27. Assessment of the ECX for the width of the confidence interval around the median value; and the certainty on the level of protection offered by the median ECX.	No	95% CI values were not reported

Overall assessment		
Reliable without restrictions	No	-
Reliable with restrictions	Yes	This study evaluates the isolated and combined effects of glyphosate and its by-product aminomethylphosphonic acid (AMPA) on the aquatic macrophyte *Salvinia molesta*. Plants were exposed to environmentally relevant concentrations of glyphosate (0, 20, 40, 60, 80 and 100 µg/L) or AMPA (0, 10, 20, 30, 40 and 50 µg/L) for seven days. Then, based on the effective concentrations of glyphosate found to reduce photosynthetic rates by 10% (EC_{10}) and 50% (EC_{50}), the plants were exposed to combinations of 0, 16 and 63.5 µg glyphosate/L and 0, 5, 15, 25 µg AMPA/L. The EC_{10} and EC_{50} were lower for AMPA (6.1 µg/L and 28.4 µg/L, respectively) than for glyphosate (16 and 63.5 µg glyphosate/L, respectively). When occurring together, the deleterious effects of those chemicals to plants increased. The study is considered not fully reliable because it is not possible to identify the number of plants tested for each treatment and because plants were collected from the field in Brazil with no record of previous pesticide exposure (although they were maintained in the lab for 60 days for depuration).

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Criteria			Criteria met? Yes / No / Uncertain	Comment / Justification
Not reliable	No	-		

1. Information on the study

Data point:	CA 8.2.8
Report author	Vera M. S. *et al.*
Report year	2021
Report title	First evaluation of the periphyton recovery after glyphosate exposure
Document No	Environmental Pollution, 2021, 290, 117998
Guidelines followed in study	None
Deviations from current test guideline	• No guideline was used / followed
GLP/Officially recognised testing facilities	• No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes (Relevant, Category A acc. EFSA GD 2092, Point 5.4.1 / Reliable with restrictions)

2. Assessment and conclusion

Assessment and conclusion by applicant:

This is a higher tier study for aquatic organisms with two glyphosate concentrations tested (0.4 and 4 mg/L) on aquatic microcosms. The study is structured in two phases: 7 days of exposure to treated water and 21 days of recovery in clean water (both of them under static conditions). It evaluates the potential of freshwater periphyton to recover from glyphosate exposure using microcosms under laboratory conditions. Dry weight, ash-free dry weight, chlorophyll *a*, and periphyton abundances were analysed. The periphyton affected with the lowest concentration recovered most of the structural parameters within 7 days in clean water, but the taxonomic structure did not entirely recover towards the control structure. Periphyton exposed to 4 mg/L could not recover during 21 days in herbicide-free water, reaching values almost four times higher in % of dead diatoms and four times lower in ash-free dry weight concerning the control at the end of the study. Results suggest a long lasting effect of the herbicide due to the persistence within the community matrix even after translocating periphyton to decontaminated water. The study concludes that the exposure concentration modulates the recovery potential of impacted periphyton.
The study is considered reliable with restrictions. Analytical verifications of the tested item in the test medium were conducted at the beginning and the end of the exposure phase.

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Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
1. For guideline-compliant studies (GLP studies): OECD, OPPTS, ISO, and others. The validity/quality criteria listed in the corresponding guidelines are met.	No	Non-guideline study
2. No previous exposure to other chemicals is documented (where relevant).	Yes	The periphytic colonization was conducted in a pond that has never been contaminated with glyphosate or any other pesticide.

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
3. For aquatic studies, the test substance is dissolved in water or where a carrier is required, it is appropriate (non-toxic) and a carrier control / positive control is considered in the test design.	Uncertain	It's not clear whether the test item dissolved in distilled water, filtered pond water or a solvent was used
4. Glyphosate or its metabolite (test item) are sufficiently documented and reported (i.e. purity, source, content etc.).	Yes	Source, content and CAS number were reported.
5. For tests including vertebrates, there is a compliance of the batches used in toxicity studies compared to the technical specification.	-	No vertebrate study
6. Species used in the experiment are clearly reported, including source, experimental conditions (where relevant): strain, adequate age/life stage, body weight, acclimatization, temperature, pH, oxygen (dissolved oxygen for aquatic tests) content, housing, light conditions, humidity (terrestrial species) incubation conditions, feeding etc.	Yes	-
7. The validity criteria from relevant test guidelines can be extrapolated across different species but not necessarily across different test designs. If different, then the nature of the difference and impact should ideally be discussed.	No	Non-guideline study
8. Only glyphosate or its metabolite is the test substance (excluding mixture with other substances), and information on application of the test substance is described.	Yes	-
9. The endpoint measured can be considered a consequence of glyphosate (or a glyphosate metabolite).	Yes	-
10. Study design / test system is well described, including when relevant: concentration in exposure media (dose rates, volume applied, etc.), dilution/mixture of test item (solvent, vehicle) where relevant.	Yes	-
11. Analytical verifications are performed in test media (concentration) / collected samples, stability of the test substance in test medium should be documented.	Yes	Glyphosate concentration was measured at the beginning and the end of the exposure period
12. An endpoint can be derived. Findings do deliver a regulatory endpoint, and/or is useful as supporting information.	Yes	Endpoints reported: LOEC immediately after the exposure phase (7-d) and after the recovery phase (28-d)
13. The test has been tested in several dose levels (at least 3) including a positive/negative control where relevant.	No	Only 2 concentrations were tested
14. Suitable exposure throughout the whole exposure period was demonstrated and reported.	Yes	Glyphosate concentration was measured at the beginning and the end of

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
		the exposure period
15. A clear concentration response relationship is reported – in studies where the dose response test design is employed.	Yes	-
16. A sufficient number of animals per group was included to facilitate statistical analysis: mortality in control groups reported, observations/findings in positive/negative control clearly reported (where relevant).	Yes	3 microcosms per treatment to determine physical, chemical and biological parameters
17. Assessment of the statistical power of the assay is possible with reported data.	Yes	Mean and standard deviation provided; no raw data
18. If statistical methodology was applied for findings reported, then the data analysis applied should be clearly documented (e.g., checking the plots and confidence intervals).	Yes	Statistical analysis sufficiently described
19. Description of the observations (including time-points), examinations, and analyses performed, with (where relevant) dissections being well documented.	Yes	-
20. For terrestrial ecotox studies in the lab or the field, the substrates used should be adequately described e.g. nature of substrate i.e. species of leaf or soil type.	-	Not applicable, aquatic study
20.1. Field locations are relevant/comparable to European conditions. Soils do not completely match the OECD criteria but are from Europe or to some extent representative for the European Agriculture.	-	Not applicable, aquatic study
20.2. Characterization of soil: texture (sandy loam, silty loam, loam, loamy sand), pH (5.5-8.0), cation exchange capacity, organic carbon (0.5-2-5%), bulk density, water retention, microbial biomass (~1% of organic carbon).	-	Not applicable, aquatic study
20.3. Other soils where information on characterization by the parameters: pH, texture, CEC, organic carbon, bulk density, water holding capacity, microbial biomass.	-	Not applicable, aquatic study
20.4. For tests including agricultural soils, they should not have been treated with test substance or similar substances for a minimum of 1 year.	-	Not applicable, aquatic study
20.5. For soil samples, sampling from A-horizon, top 20 cm layers; soils freshly from field preferred (storage max 3 months at 4 +/- 2°C).	-	Not applicable, aquatic study
20.6. Data on precipitation is recorded.	-	Not applicable, aquatic study
21. For lab terrestrial studies, the temperature was appropriate to the species being tested and generally should fall within the range between 20-25°C and soil moisture / relative humidity was reported.	-	Not applicable, aquatic study
22. For bee studies, temperature of the study should be appropriate to species.	-	Not applicable, aquatic study
23. For lab aquatic studies: 23.1. The source and / or composition of the media used should be described.	Yes	Water variables were continuously verified

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Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
23.2. The temperature of the water should be appropriate to the species being tested and generally fall within the 15-25ºC.	Yes	Temperature set at 25°C for culture and tests.
24. The residue data can be linked to a clearly described GAP table appropriate in the context of the renewal of approval of glyphosate (crop, application method, doses, intervals, PHI).	Yes	Glyphosate concentration was measured at the beginning and the end of the exposure period
25. Analytical results present residues measurements which can be correlated with the existing residues definition of glyphosate, and where relevant its metabolites.	Yes	Glyphosate concentration was measured at the beginning and the end of the exposure period
26. Analytical methods are clearly described and adequate statement of specificity and sensitivity of the analytical methods is included.	Yes	Analytical methods reported (ion chromatography)
27. Assessment of the ECX for the width of the confidence interval around the median value; and the certainty on the level of protection offered by the median ECX.	No	LC_{50} 95% confidence interval is reported

Overall assessment		
Reliable without restrictions	No	-
Reliable with restrictions	Yes	This is a higher tier study for aquatic organisms with two glyphosate concentrations tested (0.4 and 4 mg/L) on aquatic microcosms. The study is structured in two phases: 7 days of exposure to treated water and 21 days of recovery in clean water (both of them under static conditions). It evaluates the potential of freshwater periphyton (a complex of bacteria, fungi, algae and protozoa) to recover from glyphosate exposure using microcosms under laboratory conditions. Dry weight, ash-free dry weight, chlorophyll *a*, and periphyton abundances were analysed. The periphyton affected with the lowest concentration recovered most of the structural parameters within 7 days in clean water, but the taxonomic structure did not entirely recover towards the control structure. Periphyton exposed to 4 mg/L could not recover during 21 days in herbicide-free water, reaching values almost four times higher in % of dead diatoms and four times lower in ash-free dry weight concerning the control at the end of the study. Results suggest a long lasting effect of the herbicide due to the persistence within the community matrix even after translocating periphyton to decontaminated water. The study concludes that the exposure concentration modulates the recovery potential of impacted periphyton. The study is considered reliable. Analytical verifications of the tested item in the test medium were

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria			Criteria met? Yes / No / Uncertain	Comment / Justification
		conducted at the beginning and the end of the exposure phase.		
Not reliable	No	-		

1. Information on the study

Data point:	CP 10.4.2.1
Report author	Wee J. *et al.*
Report year	2021
Report title	Temperature and Aging Affect Glyphosate Toxicity and Fatty Acid Composition in *Allonychiurus kimi* (Lee) (Collembola)
Document No	Toxics, 2021, 9, 126
Guidelines followed in study	None (partially based on OECD TG 232)
Deviations from current test guideline	• OECD TG 232 validity criteria cannot be fully checked.
GLP/Officially recognised testing facilities	• No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes (Relevant, Category A acc. EFSA GD 2092, Point 5.4.1) / Reliable with restrictions

2. Assessment and conclusion

Assessment and conclusion by applicant:

This study examined the toxicity of glyphosate with the temperature (20ºC and 25ºC) and aging times (0 day and 7 days) in soil using a collembolan species, *Allonychiurus kimi* (Lee). The degradation of glyphosate in soil was investigated. Fatty acid composition of *A. kimi* was also investigated. The half-life of glyphosate was 2.38 days at 20ºC and 1.69 days at 25ºC. At 20ºC with 0 day of aging, the EC_{50} and NOEC were estimated to be 93.5 and 3.7 mg/kg, respectively. As the temperature and aging time increased, the glyphosate degradation also increased, so no significant toxicity was observed on juvenile production. The proportions of the arachidonic acid and stearic acid decreased and increased with the glyphosate treatment, respectively, even at 37.1 mg/kg, at which no significant effects on juvenile production were observed. The study was conducted according to OECD TG 232 Collembolan Reproduction Test in Soil and is considered reliable with restrictions, the validity criteria cannot be fully checked.

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
1. For guideline-compliant studies (GLP studies): OECD, OPPTS, ISO, and others. The validity/quality criteria listed in the corresponding guidelines are met.	Uncertain	As no raw data are provided not all validity criteria can be checked
2. No previous exposure to other chemicals is documented (where relevant).	Yes	The species has been cultured for years in the lab and the soil is according to guidance
3. For aquatic studies, the test substance is dissolved in water or where a carrier is required, it is appropriate (non-toxic) and a carrier control / positive control is considered in the test design.	-	No aquatic study

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
4. Glyphosate or its metabolite (test item) are sufficiently documented and reported (i.e. purity, source, content etc.).	Yes	-
5. For tests including vertebrates, there is a compliance of the batches used in toxicity studies compared to the technical specification.	-	No vertebrate study
6. Species used in the experiment are clearly reported, including source, experimental conditions (where relevant): strain, adequate age/life stage, body weight, acclimatization, temperature, pH, oxygen (dissolved oxygen for aquatic tests) content, housing, light conditions, humidity (terrestrial species) incubation conditions, feeding etc.	Yes	-
7. The validity criteria from relevant test guidelines can be extrapolated across different species but not necessarily across different test designs. If different, then the nature of the difference and impact should ideally be discussed.	Uncertain	As no raw data are provided not all validity criteria can be checked
8. Only glyphosate or its metabolite is the test substance (excluding mixture with other substances), and information on application of the test substance is described.	Yes	-
9. The endpoint measured can be considered a consequence of glyphosate (or a glyphosate metabolite).	Yes	-
10. Study design / test system is well described, including when relevant: concentration in exposure media (dose rates, volume applied, etc.), dilution/mixture of test item (solvent, vehicle) where relevant.	Yes	-
11. Analytical verifications are performed in test media (concentration) / collected samples, stability of the test substance in test medium should be documented.	Yes	Analytical verifications of the concentration of glyphosate in soil samples were conducted
12. An endpoint can be derived. Findings do deliver a regulatory endpoint, and/or is useful as supporting information.	Yes	Endpoint reported: 28-d EC_{50} and NOEC
13. The test has been tested in several dose levels (at least 3) including a positive/negative control where relevant.	Yes	-
14. Suitable exposure throughout the whole exposure period was demonstrated and reported.	Yes	Analytical verifications of the concentration of glyphosate in soil samples were conducted
15. A clear concentration response relationship is reported – in studies where the dose response test design is employed.	Yes	-
16. A sufficient number of animals per group was included to facilitate statistical analysis: mortality in control groups reported, observations/findings in positive/negative control clearly reported (where relevant).	Yes	5 replicates of 10 individuals for each treatment group
17. Assessment of the statistical power of the assay is possible with reported data.	Yes	Mean and standard deviation were provided. No raw data
18. If statistical methodology was applied for findings reported, then the data analysis applied should be clearly documented (e.g., checking the plots and confidence intervals).	Yes	Statistical analysis

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria	Criteria met? Yes / No / Uncertain	Comment / Justification
		sufficiently described
19. Description of the observations (including time-points), examinations, and analyses performed, with (where relevant) dissections being well documented.	Yes	-
20. For terrestrial ecotox studies in the lab or the field, the substrates used should be adequately described e.g. nature of substrate i.e. species of leaf or soil type.	Yes	OECD substrate
20.1. Field locations are relevant/comparable to European conditions. Soils do not completely match the OECD criteria but are from Europe or to some extent representative for the European Agriculture.	-	Lab study
20.2. Characterization of soil: texture (sandy loam, silty loam, loam, loamy sand), pH (5.5-8.0), cation exchange capacity, organic carbon (0.5-2-5%), bulk density, water retention, microbial biomass (~1% of organic carbon).	Yes	OECD artificial soil used
20.3. Other soils where information on characterization by the parameters: pH, texture, CEC, organic carbon, bulk density, water holding capacity, microbial biomass.	Yes	OECD artificial soil used
20.4. For tests including agricultural soils, they should not have been treated with test substance or similar substances for a minimum of 1 year.	-	Lab study
20.5. For soil samples, sampling from A-horizon, top 20 cm layers; soils freshly from field preferred (storage max 3 months at 4 +/- 2°C).	-	Lab study
20.6. Data on precipitation is recorded.	-	Lab study
21. For lab terrestrial studies, the temperature was appropriate to the species being tested and generally should fall within the range between 20-25°C and soil moisture / relative humidity was reported.	Yes	2 temperatures (20 and 25°C) set
22. For bee studies, temperature of the study should be appropriate to species.	-	No bee study
23. For lab aquatic studies: 23.1. The source and / or composition of the media used should be described.	-	Not aquatic study
23.2. The temperature of the water should be appropriate to the species being tested and generally fall within the 15-25ºC.	-	Not aquatic study
24. The residue data can be linked to a clearly described GAP table appropriate in the context of the renewal of approval of glyphosate (crop, application method, doses, intervals, PHI).	Yes	Analytical verifications of the concentration of glyphosate in soil samples were conducted
25. Analytical results present residues measurements which can be correlated with the existing residues definition of glyphosate, and where relevant its metabolites.	Yes	Analytical verifications of the concentration of glyphosate in soil samples were conducted
26. Analytical methods are clearly described and adequate statement of specificity and sensitivity of the analytical methods is included.	Yes	Analytical methods reported
27. Assessment of the ECX for the width of the confidence interval around the median value; and the certainty on the level of protection offered by the median ECX.	Yes	95% confidence intervals of the

ECOTOXICOLOGY: Reliability criteria for the detailed assessment of full-text documents

Criteria		Criteria met? Yes / No / Uncertain	Comment / Justification
			EC_{50} were calculated
Overall assessment			
Reliable without restrictions	No	-	
Reliable with restrictions	Yes	This study examined the toxicity of glyphosate with the temperature (20ºC and 25ºC) and aging times (0 day and 7 days) in soil using a collembolan species, *Allonychiurus kimi* (Lee). The degradation of glyphosate in soil was investigated. Fatty acid composition of *A. kimi* was also investigated. The half-life of glyphosate was 2.38 days at 20ºC and 1.69 days at 25ºC. At 20ºC with 0 day of aging, the EC_{50} and NOEC were estimated to be 93.5 and 3.7 mg/kg, respectively. As the temperature and aging time increased, the glyphosate degradation also increased, so no significant toxicity was observed on juvenile production. The proportions of the arachidonic acid and stearic acid decreased and increased with the glyphosate treatment, respectively, even at 37.1 mg/kg, at which no significant effects on juvenile production were observed. The study was conducted according to OECD TG 232 Collembolan Reproduction Test in Soil and is considered reliable with restrictions, the validity criteria cannot be fully checked.	
Not reliable	No	-	