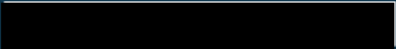




# *Input for Aquatic Hazard Classification Consideration*

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Glyphosate Renewal Group (GRG), Ecotoxicology Technical Working Group Lead  
**ECHA RAC 60 Meeting, 16<sup>th</sup> March, 2022**

BAYER IS ACTING AS LEAD REGISTRANT ON BEHALF OF THE GLYPHOSATE RENEWAL GROUP (GRG).

THE GRG IS A COLLECTION OF COMPANIES SEEKING THE RENEWAL OF THE EU AUTHORISATION OF THE ACTIVE SUBSTANCE GLYPHOSATE.

CURRENT MEMBERS OF THE GRG ARE ALBAUGH EUROPE SARL, BARCLAY CHEMICALS MANUFACTURING LTD., BAYER AGRICULTURE BV, CIECH SARZYNA S.A., INDUSTRIAS AFRASA S.A., NUFARM GMBH & Co.KG, SINON CORPORATION, SYNGENTA CROP PROTECTION AG.

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# Glyphosate Technical - Aquatic Chronic Hazard Classification

## ➤ Applicant is rebutting current Aquatic Chronic 2 classification

- Classification currently based on chronic fish **NOEC = 1 mg a.e./L** (████████, 2000; 168 h study conducted ) with *Brachydanio rerio* (zebra fish)
- **Applicant strongly believes** this study should not be used for hazard classification nor risk assessment purposes
  - Study **unreliable** due to concerns with **test design, chemical analysis** and **age of fish** used

## ➤ Applicant **proposal** for alternate **aquatic plant species endpoint** to inform chronic hazard classification

- New (valid) ***Myriophyllum spicatum*** (OECD 239) technical material study - **NOEC (gr) = 4.69 mg a.e./L**

## ➤ Available study endpoints support low chronic toxicity to **aquatic vertebrates** - fish & amphibians:

- Fish short term reproduction assay (FSTRA): **21 day NOEC = 33 mg a.e./L**
- Amphibian metamorphosis assay (AMA): **21 day NOAEC = 90 mg a.e./L**
- Fish early life stage test (ELS): **85 day NOEC = 9.6 mg a.e./L**
- Fish full life cycle test (FFLC): **255 day NOEC = 26 mg a.e./L**

## (2000) Chronic Fish Study – Concerns with Test Design

### ➤ Non-guideline study - relevant parameters not measured - set-up not suitable

- **Test design does not reflect chronic test design;**
  - Developmental parameters e.g., hatching success / growth / behaviour (e.g., *feeding*) not considered
  - Fish mortality per replicate recorded
  - Presence / absence of lethargy recorded by treatment group; no individual fish numbers recorded
  - Size of fish unknown – no terminal wet weights & body lengths recorded

### ➤ Static (168 h) test design – raw data does not support semi-static / 48 h renewal interval

- **Report claims semi-static** with 48 h renewal interval – whilst raw data (included in report) supports only static
  - Test media prepared once (day 0) during 168 h study duration
  - Water quality recorded for single set of replicate vessels each day (**no new media WQs**)
  - No record of fish addition / transfer to freshly prepared test media on reported renewal occasions

## (2000) Chronic Fish Study – Concerns with Chemical Analysis

### ➤ **No test media analysis in definitive test – only concentrated stocks analysed - analytical results do not support exposure duration – no analytical method reported**

- Concentrated stocks (100 & 1000 mg a.e./L) prepared **only on day 0** & analysed 0, 24, 72 and 120 h only
- 168 h duration not supported by stock analysis.
- Stock concentrations decline after 72 and 120 h
- Deflection in measured glyphosate concentrations in stock solution > nominal test concentrations
- **No analytical method details in report / raw data**
  - Quality of chemical analysis not confirmable

### ➤ **CLP guidance for analytical data in chronic exposure studies:**

- **Static test design** – *test media* analysis required at test start **and end of test (168 h)**
- *...'If measured concentrations are absent, no valid interpretation can be made and the test should be considered as invalid for classification purposes.'*



## ██████████ (2000) Chronic Fish Study – Concerns with Age of Fish in Study

### ➤ Information to confirm age of fish on addition to test media - not in raw data

- Evidence of embryo's at 48 h pf being added and 'Presence - absence of yolk sac'
  - Not in raw data

- **Embryos added at 48 h pf** cannot be confirmed from raw data – *reporting error*
  - Information on the age, size and quality of fish used NOT presented in raw data
  - Raw data states only that '**larvae**' were added at test start – no other data / No biometric data, so fish loading cannot be confirmed
- **Presence / absence of yolk sac** cannot be confirmed from raw data

### ➤ Conclusion to ██████████ (2000) *Brachydanio rerio* chronic fish study rebuttal

- **The Applicant strongly** believes the presented evidence on uncertainties relating to the **test design, chemical analysis** and to the **quality of fish**, used in the ██████████ (2000) Chronic fish exposure study, are more than sufficient to **exclude the use of endpoint data from** the study to inform on the chronic hazard classification.



## ➤ Proposal for Alternate Aquatic Plant Species Endpoint to Inform Hazard Classification

### ▪ New valid aquatic macrophyte study available conducted with technical material

- *Myriophyllum spicatum* (OECD 239) - ██████████, 2022 – conducted due to data gap identified by RMS in ██████████, 2012 (*M. aquaticum* vs. technical material) – invalid due to poor control growth (Coefficient of Variation > 35%)
- Final fully GLP report and Tier II study summary available
  - Current study **valid** against all OECD 239 TG validity criteria
  - **Coefficient of variation** between control replicates was <35% (=13.5%)
- **Chemical analysis of test media** - overlying water: 86.5 – 108.2% of nominal
- Endpoints:
  - Growth rate (shoot length)                      ErC<sub>50</sub> = 208 mg a.e./L                      NOEC g.r. = 12.7 mg a.e./L
  - Growth rate (biomass)                              ErC<sub>50</sub> = 163 mg a.e./L                      **NOEC g.r. = 4.69 mg a.e./L**

- The relevant & reliable aquatic species chronic exposure endpoints (NOEC values) based on technical material study endpoints are >> 1 mg a.e./L (...including ██████████, 2022).
- Applicant proposal is that Chronic aquatic hazard classification of glyphosate is not required.