(RE)ESTABLISH THE USE OF THE GEOMETRIC MEAN AS REFINEMENT OPTION FOR CHRONIC AQUATIC RISK ASSESSMENTS

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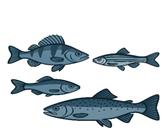
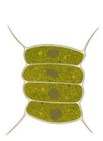
Introduction & problem formulation


Fish

Aquatic invertebrate

Macrophyte


Algae

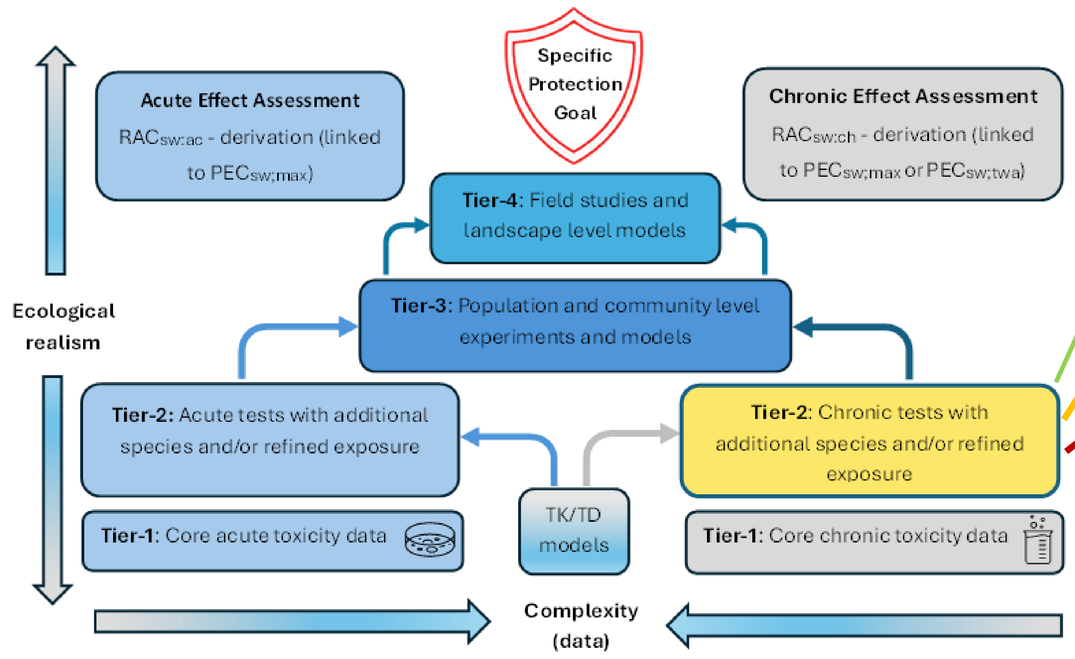


Figure 1: EU Pesticide Risk Assessment Scheme for Aquatic Organisms: Chronic geometric mean calculations are conducted under Tier 2 highlighted in yellow.

$$Geometric\ mean = \sqrt[n]{endpoint\ 1\ *endpoint\ 2\ *endpoint\ n}$$

REGULATORY TIMELINE — CHANGES TO THE CHRONIC GEOMEAN OPTION

EFSA Aquatic Guidance 2013[1]:
Geometric means can be used as refinement for acute and chronic endpoints (Tier 2A)

EFSA Recurring Issues 2019[2]:
Geometric means can only be used as refinement for acute & primary producer endpoints. It is no longer allowed as refinement for chronic invertebrates and fish.

EFSA Member State Expert Meetings 2025:
Chronic geomean is no longer accepted as refinement for chronic invertebrates and fish and is often rejected for macrophytes.

REGULATORY CONCERNS ABOUT CHRONIC GEOMEANS:

- **Comparability:** the lack of comparability between tests regarding duration, endpoints and life stages;
- **Protectiveness:** lack of verification of the protectiveness of the geomean approach.

AIMS AND GOALS
Addressing the concerns from regulatory authorities regarding the chronic geomean approach.

Data collection & analysis

Data Collection
Chronic tier 1 data for fish, invertebrates, macrophytes and algae (NOECs or EC50s) were extracted from EFSA conclusions and RARs. Endpoints > 10-fold different excluded.

Reference Data
Regulatory accepted concentration (RAC) derived from higher tier data (SSDs or mesocosms) were used as reference tier to assesses protectiveness. The lowest chronic NOEC of the data set was used as tier 1 reference.

Protectiveness & Comparability
Geomean was derived for defined standard species of each organism group based on data availability across compounds. The geomean RAC was compared with higher-tier RAC when available, or with the lowest NOEC for the organism group.

Table 1: Overview on extracted data

Organism Group	No. Compounds	Comparison
Fish	4	NOEC
Invertebrates	1	Mesocosm
Algae	3	Mesocosm, SSD, NOEC
Macrophytes	3	Mesocosm, SSD, NOEC

Protectiveness

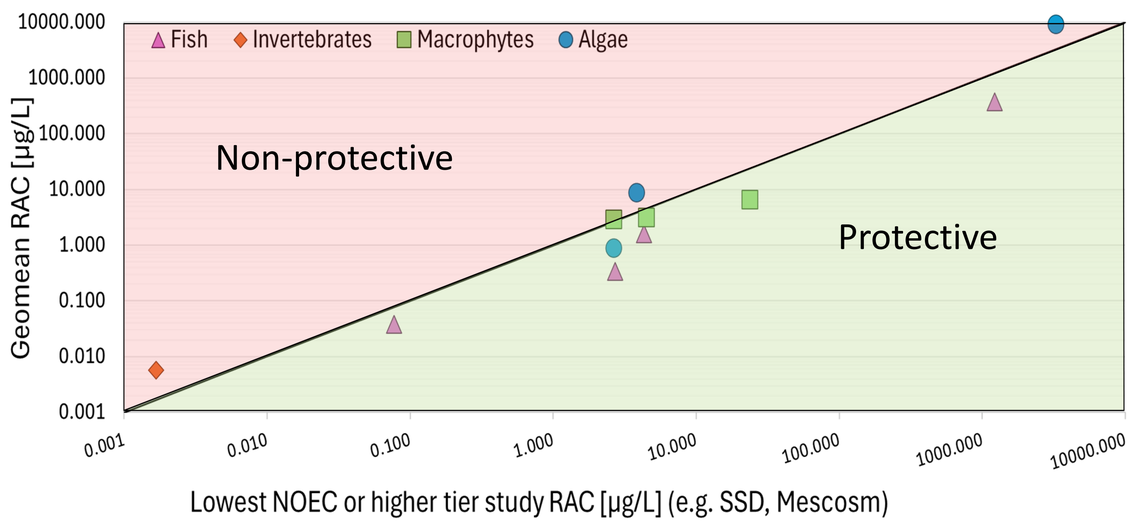
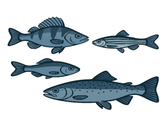


Figure 2: Geomean RAC plotted against comparison endpoint

→ **Green area:** Geomean RAC is more conservative than comparison RAC or NOEC
→ **Red area:** Geomean RAC is less conservative than comparison RAC or endpoint
→ **Black trendline:** Geomean RAC equal to comparison RAC or endpoint

Comparability of endpoints



- **Standard species** *Onchorhynchus mykiss*, *Pimephales promelas*
- **Tests** OECD 210 (ELS), OECD 204 (Prolonged Toxicity Test), FFLC (Full fish life cycle)
- **Endpoint** Lowest NOEC (based on species-specific measurements)

- **Standard species** *Daphnia magna*, *Chironomus riparius*
- **Tests** OECD 211 (*D. magna*), OECD 219 (*C. riparius*)
- **Endpoint** Lowest NOEC (based on species-specific measurements)

- **Standard species** *Lemna gibba*, *Ceratophyllum demersum*, *Myriophyllum* sp., *Elodea densa*, *Glyceria maxima*
- **Tests** OECD 221 (*L. gibba*), OECD 239 (rooted, submerged and emergent macrophytes)
- **Endpoint** Lowest E_rC_{50} (based on species-specific measurements)

- **Standard species** *Raphidocelis subcapitata*, *Desmodesmus subspicatum*, *Navicula pelliculosa*
- **Tests** OECD 201 (Freshwater Algae)
- **Endpoint** E_rC_{50}

Conclusions

Comparability: For most organism groups, different variables are measured to determine endpoints. In principle the same or similar variables should be used for the calculation of the geometric mean (e.g. NOEC weight for fish, or E_rC_{50} for no. shoots). In praxis, this is often not possible (e.g. the variable 'Total No. of Neonates' does not exist in chronic tests with chironomids). Therefore, current praxis is to use the lowest NOEC/ E_rC_{50} per study. Although this praxis is decreasing comparability, this approach includes an additional level of conservatism which should be considered.

Protectiveness: Protectiveness was observed for fish and macrophytes. The geomean RACS were lower than those of the higher tiers or the lowest NOEC used for comparison. For invertebrates no conclusion can be drawn currently due to the limited number of substances evaluated so far. Therefore, more cases would be needed for a clearer picture.

References:
1 EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues) (2013). Scientific Opinion - Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013; 11(7): 3290.
2 EFSA (European Food Safety Authority), 2019. Technical report on the outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology. EFSA supporting publication 2019:EN-1673. 117 pp.

Internal