DERIVING EUROPEAN ENVIRONMENTAL QUALITY STANDARDS (EQS): COMPARISONS *WITH USEPA AWQC*

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wca

NUMERICAL CRITERIA/STANDARDS

- SCIENTIFICALLY-BASED VALUES INTENDED TO PROTECT AQUATIC LIFE FROM THE ADVERSE EFFECTS OF CONTAMINANTS WITHOUT CONSIDERATION OF DEFINED WATER BODY USES, SOCIETAL VALUES, ECONOMICS, OR OTHER NON-SCIENTIFIC CONSIDERATIONS.

WATER QUALITY POLICIES DIFFER GLOBALLY

- EU'S WATER FRAMEWORK DIRECTIVE
  - POLICY IS INTENDED TO "…CONTRIBUTE TO PURSUIT OF THE OBJECTIVES OF PRESERVING, PROTECTING, AND IMPROVING THE QUALITY OF THE ENVIRONMENT, IN PRUDENT AND RATIONAL UTILIZATION OF NATURAL RESOURCES, AND TO BE BASED ON THE PRECAUTIONARY PRINCIPAL AND ON THE PRINCIPLES THAT PREVENTIVE ACTION SHOULD BE TAKEN, ENVIRONMENTAL DAMAGE SHOULD, AS A PRIORITY, BE RECTIFIED AT SOURCE AND THAT THE POLLUTER SHOULD PAY."

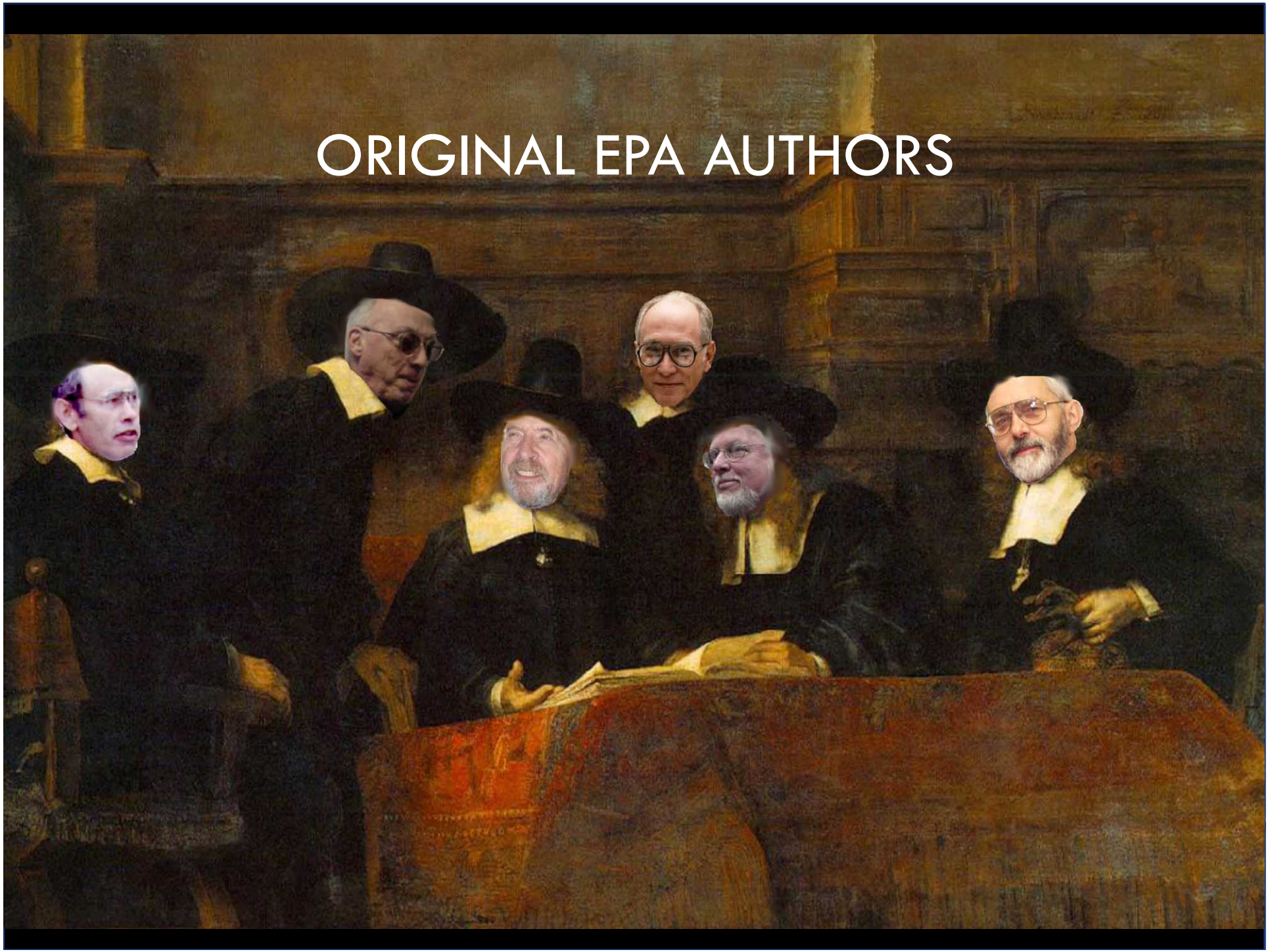
POLICIES DIFFER GLOBALLY (CONT)

- PRECAUTIONARY PRINCIPLE
  - "IN ORDER TO PROTECT THE ENVIRONMENT, THE PRECAUTIONARY APPROACH SHALL BE WIDELY APPLIED BY STATES ACCORDING TO THEIR CAPABILITIES. WHERE THERE ARE THREATS OF SERIOUS OR IRREVERSIBLE DAMAGE, LACK OF FULL SCIENTIFIC CERTAINTY SHALL NOT BE USED AS A REASON FOR POSTPONING COST-EFFECTIVE MEASURES TO PREVENT ENVIRONMENTAL DEGRADATION (RIO CONVENTION 1992)

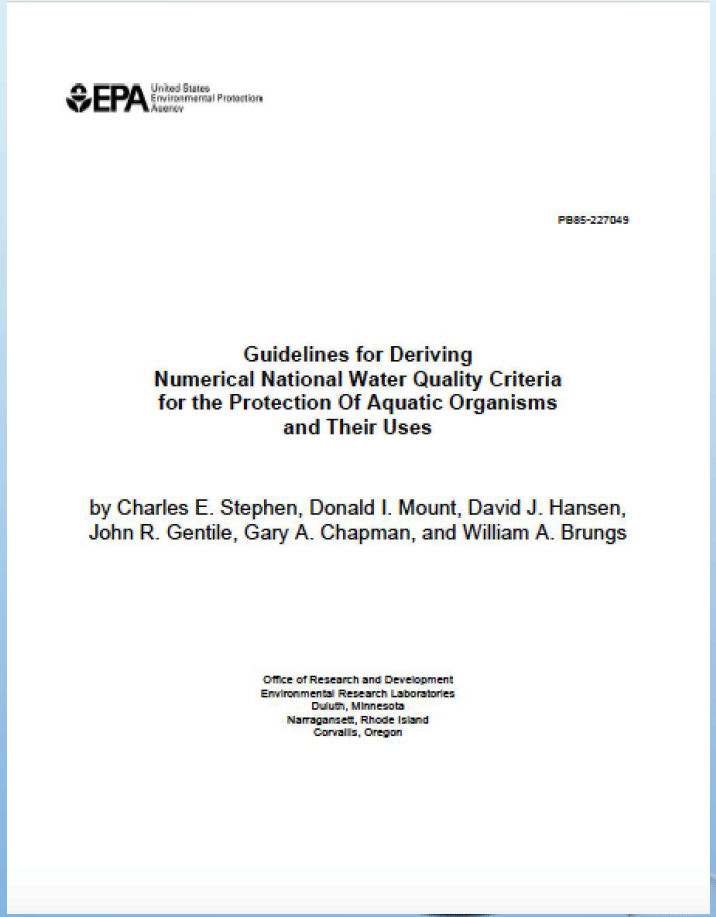
POLICIES DIFFER GLOBALLY (CONT)

- USEPA
  - CONTAINS MANY "PRECAUTIONARY ELEMENTS" BUT DOES NOT ADHERE TO THE PRECAUTIONARY PRINCIPLE. OTHER FACTORS, INCLUDING ECONOMIC CONSIDERATIONS, ARE CONSIDERED IN US ENVIRONMENTAL POLICY.
  - US POLICY DOES NOT ATTEMPT TO PROTECT ALL FORMS OF AQUATIC LIFE AND ALL ASPECTS OF THE AQUATIC LIFE CYCLES AT ALL TIMES BUT DOES CONSIDER "IMPORTANT SPECIES."

ORIGINAL EPA AUTHORS



GUIDELINES FOR DERIVING NUMERICAL NATIONAL WATER QUALITY CRITERIA FOR THE PROTECTIONS OF AQUATIC ORGANISMS AND THEIR USES



EPA United States Environmental Protection Agency

PB85-227049

Guidelines for Deriving Numerical National Water Quality Criteria for the Protection Of Aquatic Organisms and Their Uses

by Charles E. Stephen, Donald I. Mount, David J. Hansen, John R. Gentile, Gary A. Chapman, and William A. Brungs

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Corvallis, Oregon

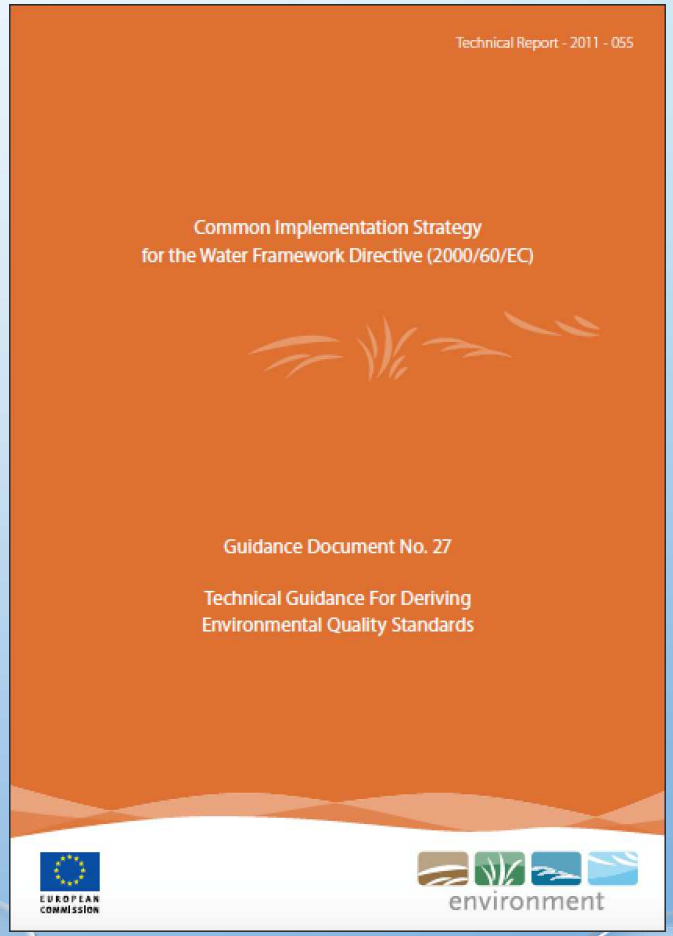

Ye shall follow my Guidance! Lest my wraith be upon you…..

WFD IS A "NEW" REGULATION

- 1995/1996: FUNDAMENTAL RETHINK OF COMMUNITY WATER POLICY
  - THE CURRENT WATER POLICY WAS FRAGMENTED
  - NEED FOR A SINGLE PIECE OF FRAMEWORK LEGISLATION TO RESOLVE THESE PROBLEMS
- 2000: ADOPTION OF THE WATER FRAMEWORK DIRECTIVE (DIRECTIVE 2000/60/EC)
- 2008: PRIORITY SUBSTANCE DIRECTIVE OR ALSO CALLED THE "EQS & MIXING ZONE DIRECTIVE" (DIRECTIVE 2008/105/EC)

GUIDANCE FOR DERIVATION OF EU ENVIRONMENTAL QUALITY STANDARDS

- PREVIOUSLY NATIONAL GUIDANCE AND THEN THE EU TGD
- 2011 DOCUMENT BUT NEW DRAFT TO COME OUT OCT 2015
- AVAILABLE ON LINE AT: CIRCABC.EUROPA.EU/



USE OF EQS

- COMPLIANCE ASSESSMENT:
  - A COMPARISON OF THE ARITHMETIC MEAN OF MONITORED CONCENTRATION OF A CHEMICAL, CALCULATED FROM 12 MONTHLY GRAB SAMPLES AT ONE SITE, WITH AN ANNUAL AVERAGE EQS
  - IF THE EQS IS EXCEEDED THEN THE WATER BODY WILL BE CLASSIFIED AS NOT ACHIEVING GOOD STATUS
- PERMITS TO DISCHARGE ARE:
  - SET IN SUCH A WAY THAT THE EQS WOULD NOT BE EXCEEDED IN ANY EFFLUENT RECEIVING WATER (AFTER DUE CONSIDERATION OF MIXING ZONES)
  - SET DIFFERENTLY BY DIFFERENT AUTHORITIES…..

ELEMENTS OF AN USEPA AWQC

- CONCENTRATION OF EXPOSURE: HOW MUCH – AKA: **MAGNITUDE**
- TIME PERIOD OF EXPOSURE: HOW LONG – AKA: **DURATION**
  - ACUTE (1 HR AVG) & CHRONIC (4 DAY AVG)
- FREQUENCY OF EXPOSURE: HOW OFTEN –

  AKA: **FREQUENCY**
  - 1X EVERY THREE YEARS ON AVERAGE

TWO KINDS OF WATER-COLUMN EQS

TO COVER BOTH LONG- AND SHORT-TERM EFFECTS RESULTING FROM EXPOSURE, TWO WATER COLUMN EQSS WILL NORMALLY BE REQUIRED:

- A LONG-TERM STANDARD, EXPRESSED AS AN ANNUAL AVERAGE CONCENTRATION (AA-EQS) AND NORMALLY BASED ON CHRONIC TOXICITY DATA AND
- A SHORT-TERM STANDARD, REFERRED TO AS A MAXIMUM ACCEPTABLE CONCENTRATION EQS (MAC-EQS) WHICH IS BASED ON ACUTE TOXICITY DATA.

- VALUES TYPICALLY EXPRESSED AS "DISSOLVED" CONCENTRATIONS FOR METALS AND TOTAL CONCENTRATIONS FOR ORGANICS

WFD POLLUTANTS

Selected at EU level

- Currently 45 substances (of which 21 are PHSs)
- Selected based on European risk analysis

PRIORITY SUBSTANCES

(ANNEX X)

PRIORITY HAZARDOUS SUBSTANCES

(ANNEX X)

PNEC VS EQS

- A PNEC IS NOT AN EQS……..
- AN EQS IS LEGALLY BINDING, A PNEC IS A TOOL IN RISK ASSESSMENT
  - IF UNDERTAKING A RISK ASSESSMENT, AND EXPOSURES ARE LESS THAN PNEC FOR THE SPECIFIC EXPOSURE SCENARIO(S) BEING CONSIDERED THE RISK ASSESSMENT STOPS. BUT AN EQS MUST BE SUITABLE FOR ALL EXPOSURES OF THAT CHEMICAL…..
- A PNEC DERIVED AS PART OF A RISK ASSESSMENT MAY BE A USEFUL STARTING POINT IN TERMS OF COLLECTING THE EFFECTS)DATA FOR THE DERIVATION OF AN EQS.
  - THE EU RISK ASSESSMENTS WERE AIMED TO COVER 10-90 PERCENTILE OF WATER CHEMISTRY CONDITIONS IN EUROPE – ONLY 80%?
  - AN UNDERLYING REQUIREMENT OF THE WFD IS FOR THE EQS TO PROTECT ALL WATERS IN EUROPE. THEREFORE A REQUIREMENT TO PROTECT A HIGHER PROPORTION OF WATERBODIES. THIS HAS BEEN DEFINED PRACTICALLY AS 95% OF WATERS IN THE MOST SENSITIVE REGION (COUNTRY). TO DO THIS REQUIRES GOOD MONITORING DATA, WHICH FOR MANY MEMBER STATES IS FREELY AVAILABLE

DERIVATION METHODS ARE REMARKABLY SIMILAR

1. Data compilation

2. Data selection
(reliability & relevance criteria)

3. Data aggregation

4. Statistical derivation
of the value

AREAS WHERE U.S. AND EU METHODS DIFFER

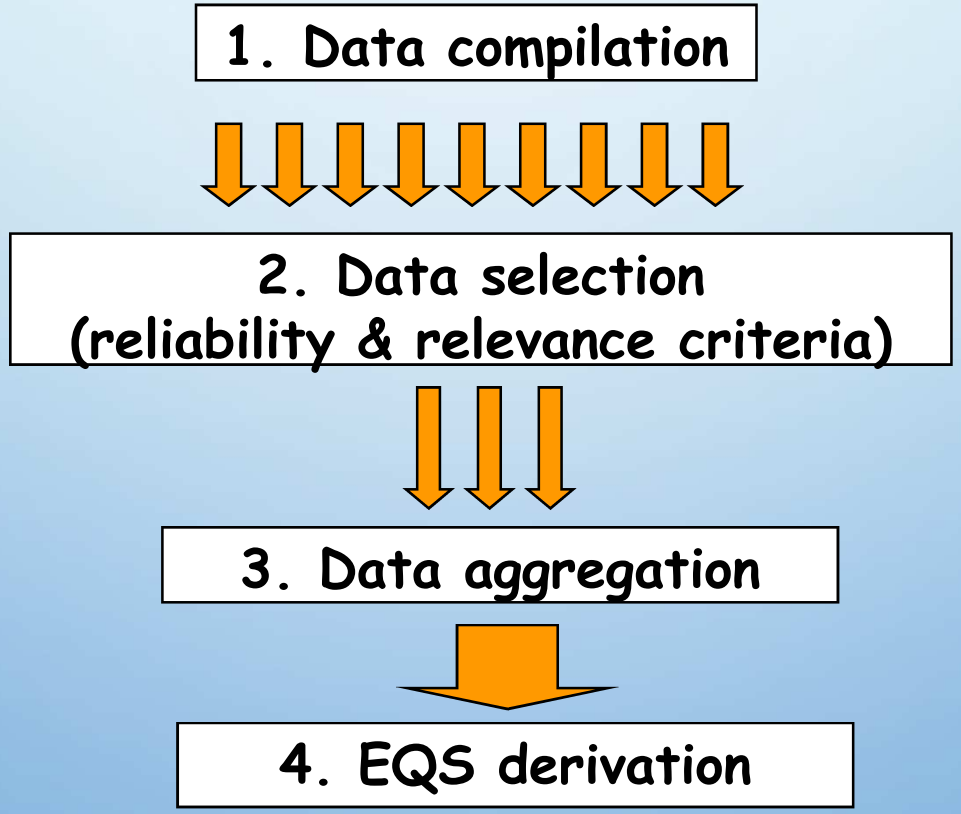
- GUIDING PRINCIPLES
  - BROAD AIM OF PROTECTING ALL ORGANISMS IN ALL WATERS AT ALL TIMES…BUT PRAGMATIC INTERPRETATION OF THIS…
- DATA USED FOR DERIVATION
  - WHAT SPECIES ARE TO BE CONSIDERED IN THE DATABASE? (HOW MANY AND WHICH ONES)
  - APPROACHES FOR LARGE AND SMALL DATA SETS
  - COMBINATION OF FRESH AND SALTWATER DATA (FOR ORGANICS)

AREAS WHERE U.S. AND EU METHODS DIFFER

- WHAT TYPES OF DATA ARE USED?
  - ENDPOINTS (SURVIVAL, GROWTH, REPRODUCTION, OTHER)
  - STATISTICAL ENDPOINTS (EC10, EC20, MATC, NOEC, LOEC)
  - ACUTE:CHRONIC RATIOS
  - CHRONIC DATA ONLY CONSIDERED FOR ANNUAL AVERAGES (CHRONIC EQS)
  - POOR DATA MEAN LARGE ASSESSMENT FACTORS AND NO EQS WILL BE SET
- STATISTICAL METHODOLOGY USED TO DERIVE CRITERIA
  - LOG TRIANGULAR DISTRIBUTION (US EPA)
  - LOG NORMAL DISTRIBUTION (EU)

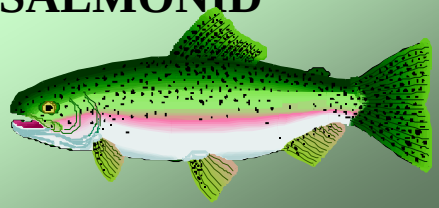
EUROPEAN UNION APPROACH: ENVIRONMENTAL QUALITY STANDARDS (EQS)

GENERAL EU FRAMEWORK

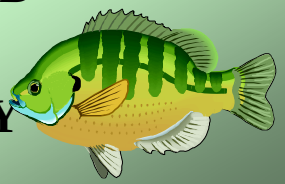


USEPA MINIMUM DATASET FOR FRESHWATER ACUTE CRITERIA DERIVATION – 1985 GUIDELINES METHOD

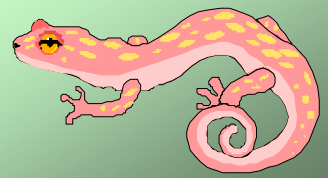
SALMONID



SECOND FISH FAMILY



CHORDATA

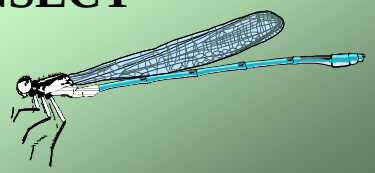


For Chronic – Need 3 chronic tests (minimum) to calculate ACR

PLANKTONIC CRUSTACEAN

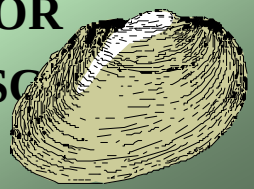
BENTHIC CRUSTACEAN

INSECT



ROTIFERA, ANNELIDA, MOLLUSCA

OTHER INSECT OR MOLLUSC



COMPARISON OF TEST SPECIES REQUIREMENTS

US EPA	EU
the family Salmonidae in the Class Osteichthyes	Fish
A second family of fish in the Class Osteichthyes (preferably a commercially or recreationally important warm-water species)	Second family in the phylum Chordata
A third family in the phylum Chordata	-----
Planktonic crustacean	Crustacean
Insect	Insect
A family in a phylum other than Arthropoda or Chordata	A family in a phylum other than Arthropoda or Chordata
A family in any order of insect, or any phylum not already represented	A family in any order of insect of any phylum not already represented
Benthic crustacean	-----
-----	Algae
-----	Higher plant

DATA QUALITY REVIEW

- SIMILAR TO U.S., BUT BASED ON KLIMSCH (1997) AND POSSIBLY CRED (CRITERIA FOR REPORTING AND EVALUATING ECOTOXICITY DATA) IN THE FUTURE, RATHER THAN APPENDIX A OR EVISTRA
- A RIGOROUS ASSESSMENT OF THE DATA NORMALLY ENTAILS A REVIEW OF THE ORIGINAL STUDY REPORT, ESPECIALLY FOR CRITICAL DATA THAT ARE LIKELY TO HAVE A MAJOR IMPACT ON THE EQS.
  - **RELIABILITY** REFERS TO THE INHERENT QUALITY OF THE METHOD USED TO CONDUCT THE TEST.
  - **RELEVANCE** MEANS THE EXTENT TO WHICH A TEST PROVIDES USEFUL INFORMATION ABOUT THE HAZARDOUS PROPERTIES OF A CHEMICAL.
- ONLY RELIABLE, RELEVANT DATA CONSIDERED VALID FOR USE IN SETTING A QUALITY STANDARD.
- NOT LIMITED TO ONLY PUBLISHED DATA OR GLP TESTS

DATA REQUIREMENTS

- DATA REQUIREMENTS DIFFER FROM U.S.
- DATA ENDPOINTS ARE EC_{10} OR NOEC FOR ANNUAL AVERAGES (CHRONIC EQS)
- EC50/LOECS, ETC USED FOR MAC – MAXIMUM ACCEPTABLE CONCENTRATIONS, USED TO ASSESS SHORT-TERM OR INTERMITTENT RELEASES.
- NON-NATIVE SPECIES NOT REJECTED IN EU – CONSIDERED BETTER TO USE ALL DATA TO START WITH, THEN ASSESS FOR RELEVANCE

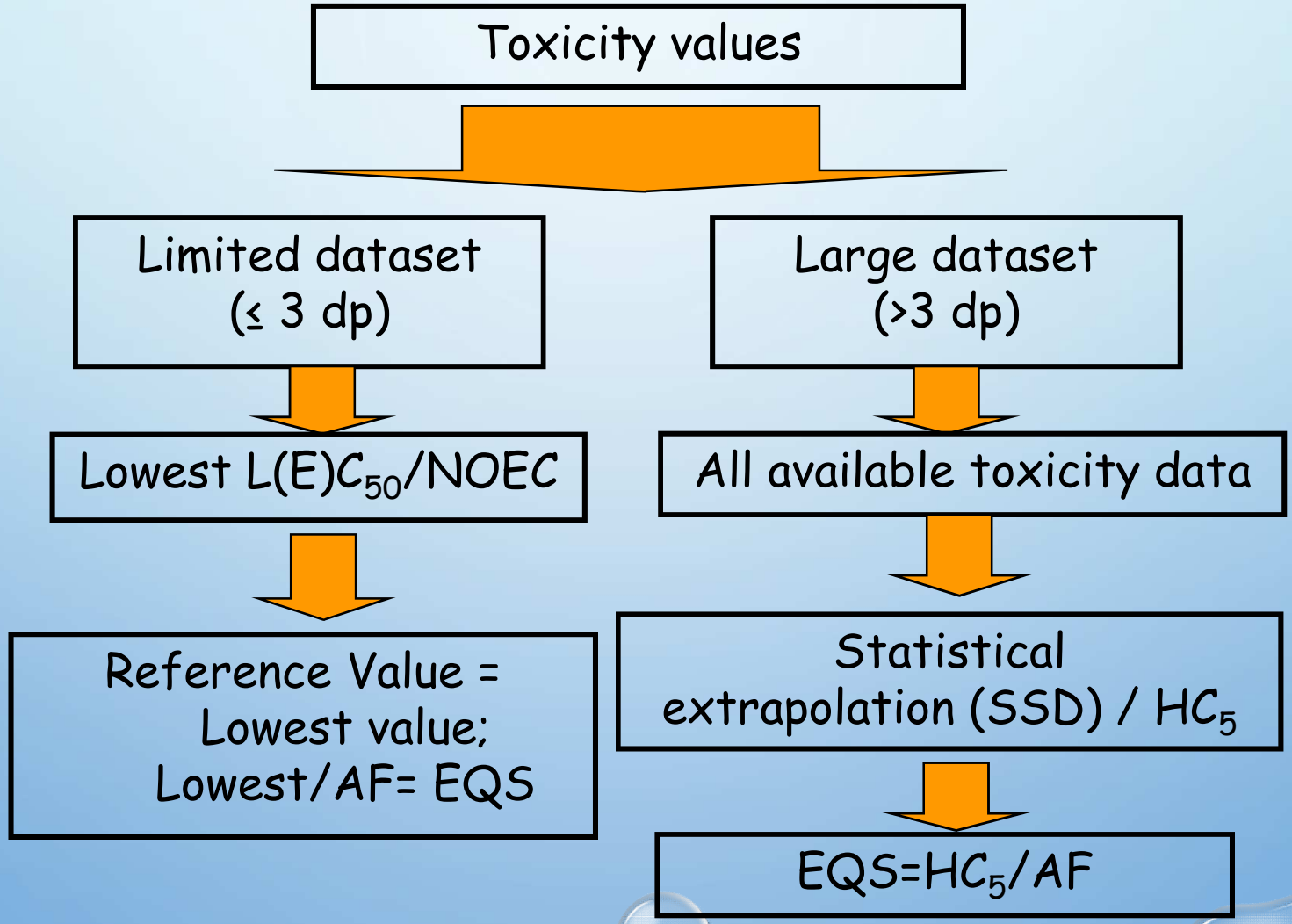
FRESHWATER/SALTWATER DATA POOLING

- IN PRINCIPLE, ECOTOXICITY DATA FOR FRESHWATER AND SALTWATER ORGANISMS SHOULD BE POOLED FOR ORGANIC COMPOUNDS, IF STATISTICAL CRITERIA ARE MET. POOLED DATASETS ARE THEN USED TO DERIVE BOTH FRESHWATER AND SALTWATER EQS, BUT WITH DIFFERENT ASSESSMENT FACTORS
- FRESHWATER AND SALTWATER TOXICITY DATA FOR METALS SHOULD BE SEPARATED *A PRIORI*. DATASETS SHOULD ONLY BE COMBINED WHEN THERE IS NO DEMONSTRABLE DIFFERENCE IN SENSITIVITY.

METHODS FOR EQS DERIVATION

- WHERE DATA PERMIT, THE $EQS_{FW, ECO}$ CAN BE DERIVED IN THREE WAYS:
  - **DETERMINISTIC APPROACH**: ASSESSMENT FACTOR APPLIED TO THE LOWEST CREDIBLE DATUM (SMALL DATA SETS)
  - **PROBABILISTIC APPROACH** USING SPECIES SENSITIVITY DISTRIBUTION (SSD) MODELING (LARGE DATA SETS)
  - UNDER SOME CIRCUMSTANCES DERIVATION FROM FIELD DATA – SUCH AS FOR IRON
- METHODOLOGY IS CONSISTENT WITH THE REACH REGULATIONS.
- IF THE CONDITIONS TO USE THE SSD-METHOD FOR THE DERIVATION OF QUALITY STANDARDS ARE MET, IT SHOULD ALWAYS BE USED.

EQS DERIVATION



EQS DERIVATION – FRESHWATER CHRONIC

1. DATA POOR SUBSTANCES
   - ADDITIONAL TESTING OR
   - USE OF EMPIRICALLY DERIVED ASSESSMENT FACTORS ON THE LOWEST ACUTE/CHRONIC VALUE
   - EQS WON'T BE SET IF AF >50

Available Data	Assessment factor
At least one short-term L(E)C50 for each of three trophic levels of the base set (fish, Daphnia and algae	1000
One long-term NOEC (either fish or Daphnia)	100
Two long-term NOECs from species representing 2 trophic levels (fish and/or Daphnia and/or algae)	50
Long-term NOECs from at least 3 species (normally fish, Daphnia and algae) representing three trophic levels	10

EQS DERIVATION – SALTWATER CHRONIC

Available Data	Assessment factor
Lowest short-term L(E)C50 from freshwater or saltwater representatives of 3 taxonomic groups (algae, crustaceans and fish, i.e., base set) of 3 trophic levels	10,000
Lowest short-term L(E)C50 from freshwater or saltwater representatives of 3 taxonomic groups (algae, crustaceans and fish) of 3 trophic levels, plus 2 additional marine taxonomic groups (e.g., echinoderms, molluscs)	1000
1 long-term results (e.g., EC10 or NOEC) (from freshwater or saltwater crustacean reproduction or fish growth studies)	1000
2 long-term results (e.g., EC10 or NOEC) from freshwater or saltwater species representing 2 trophic levels (algae and/or crustaceans and/or fish)	500
Lowest long-term (EC10 or NOECs) from 3 freshwater or saltwater species (normally algae and/or crustaceans and or fish) representing 3 trophic levels	100
2 long-term results (EC10 or NOECs) from freshwater or saltwater species representing 2 trophic levels (algae and/or crustaceans and/or fish) plus 1 long-term result from an additional marine taxonomic group (echinoderms, molluscs)	50
Lowest long-term results (EC10 or NOECs) from 3 freshwater or saltwater species (normally algae and/or crustaceans and/or fish) representing 3 trophic levels + 2 long-term results from additional marine taxonomic groups (echinoderms, molluscs)	10

EQS DERIVATION – FRESHWATER ACUTE

Available Data	Additional information	Assessment factor
Base set not complete		Cannot be derived
At least one short-term L(E)C50 from each of 3 trophic levels of the base set (fish, Daphnia and algae)		100
At least one short-term L(E)C50 from each of 3 trophic levels of the base set (fish, Daphnia and algae)	Acute toxicity data for different species do not have a higher standard deviation than a factor of 3 in both directions OR known mode of toxic action and representative species for most sensitive taxonomic group included in data set	10

EQS DERIVATION – SALTWATER ACUTE

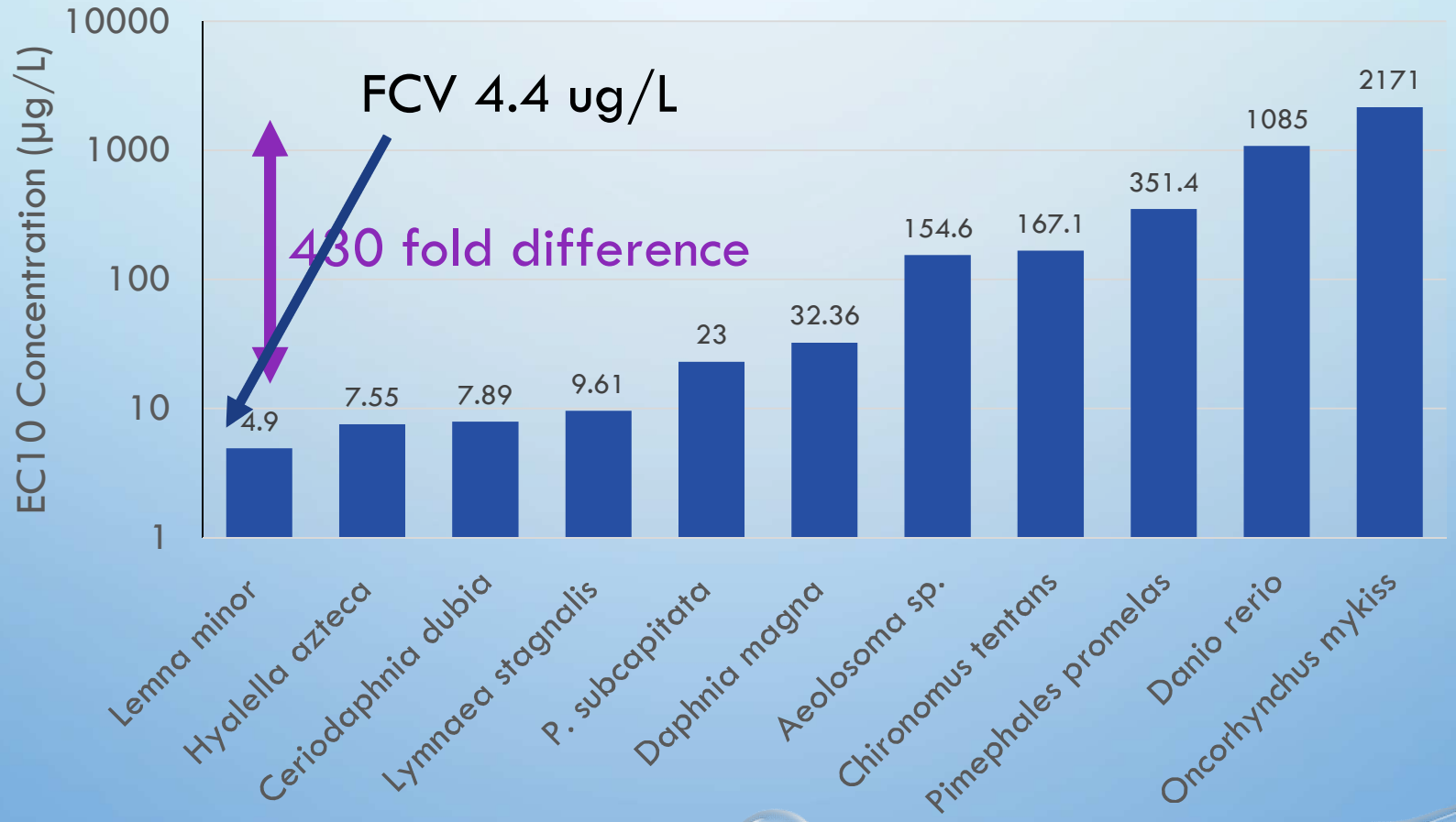
Toxicity data	Additional information	Assessment factor
Base set not complete	–	Cannot be derived
At least one short-term L(E)C50 from each of three trophic levels of the base set (fish, crustaceans and algae)		1000
At least one short-term L(E)C50 from each of three trophic levels of the base set (fish, crustaceans and algae)	Acute toxicity data for different species do not have a higher standard deviation than a factor of 3 in both directions OR known mode of toxic action and representative species for most sensitive taxonomic group included in data set	100
At least one short-term L(E)C50 from each of three trophic levels of the base set (fish, crustaceans and algae) + one short-term L(E)C50 from an additional specific saltwater taxonomic group		500
At least one short-term L(E)C50 from each of three trophic levels of the base set (fish, crustaceans and algae) + one short-term L(E)C50 from an additional specific saltwater taxonomic group	Acute toxicity data for different species do not have a higher standard deviation than a factor of 3 in both directions OR known mode of toxic action and representative species for most sensitive taxonomic group	50

EQS DERIVATION – DATA RICH SUBSTANCES

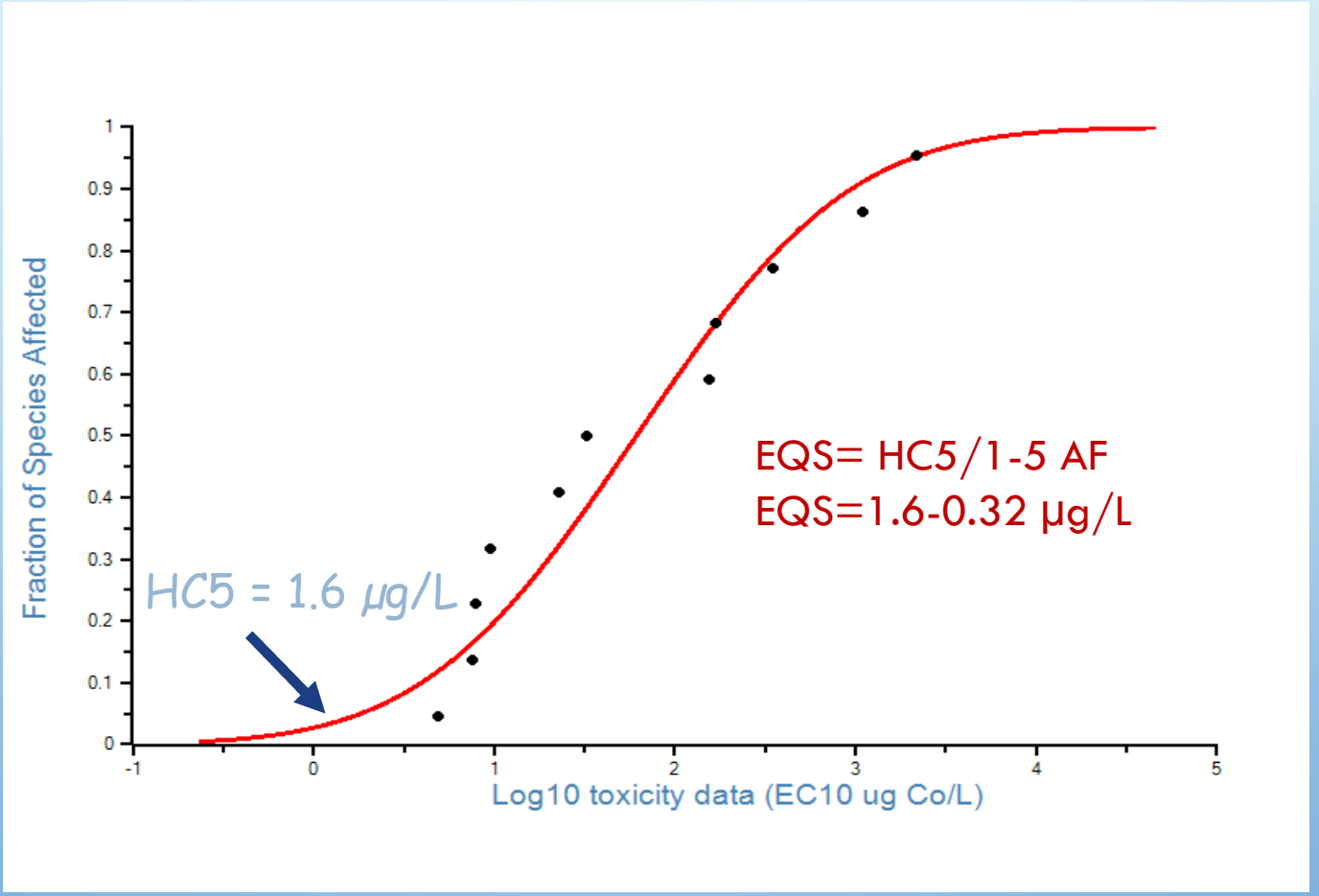
- IDEALLY THE SSD SHOULD COVER AT LEAST 8 TAXONOMIC GROUPS CONTAINING AT LEAST 10 NOECS (PREFERABLY MORE THAN 15) FOR DIFFERENT SPECIES.
- USE OF STATISTICAL EXTRAPOLATION METHOD (WITH BIOAVAILABILITY CORRECTION AS APPROPRIATE)
- LOG NORMAL OR LOG LOGISTIC APPROACH IS "STRONGLY" RECOMMENDED, "ALTHOUGH OTHERS ARE PERMISSIBLE."
  - CAREFULLY EVALUATION OF GOODNESS-OF-FIT (PREFERENCE TO A/D TESTS)
- EQS = HC5 X AF (1-5)
- SAME APPROACH FOR MAC-EQS EXCEPT DATA ARE LC50 AND AF = 10

SSD FITTING PROCEDURES

EXAMPLE DATA SET



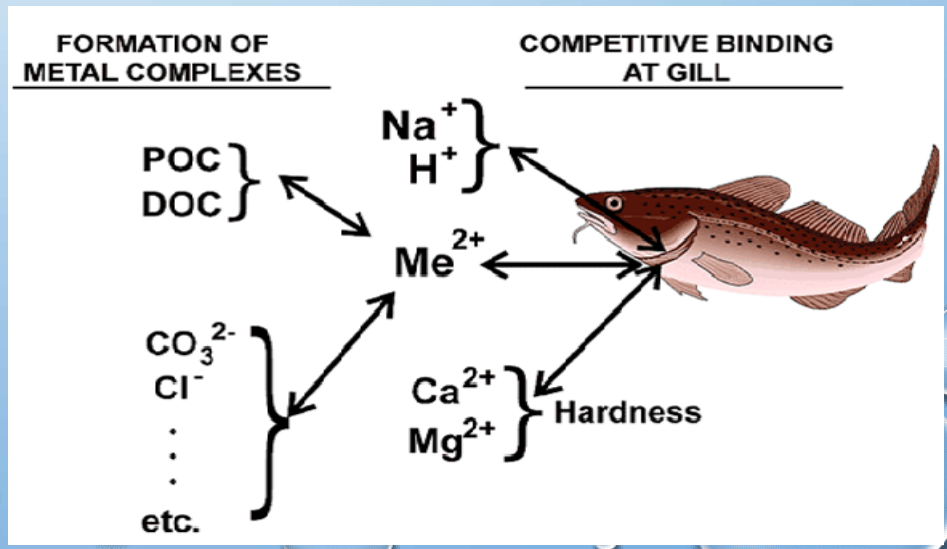
RESULTS USING RIVM ETX



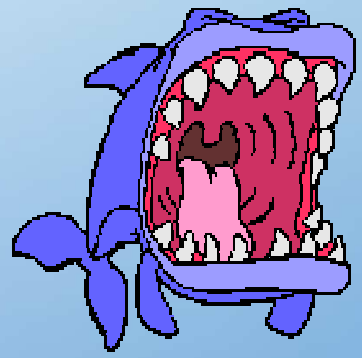
A BIT ABOUT INCLUSION OF BIOAVAILABILITY FOR TRACE ELEMENTS

HARDNESS BASED AWQC

- IN DERIVING STANDARD HARDNESS BASED AWQC TOXICITY DATA ARE NORMALIZED TO HARDNESS OF 50 MG/L AS $CACO_3$ BASED ON THE HARDNESS:TOXICITY RELATIONSHIP PRIOR TO FAV/FCV CALCULATION.
- NOW BIOTIC LIGAND MODEL



BUT WHAT MAKES AN ACCEPTABLE BLM?



USEPA GUIDANCE FROM THE 1985 AWQC GUIDE

- "IF THE ACUTE TOXICITY OF THE MATERIAL TO AQUATIC ANIMALS APPARENTLY HAS BEEN SHOWN TO BE RELATED TO A WATER QUALITY CHARACTERISTIC SUCH AS HARDNESS OR PARTICULATE MATTER FOR FRESHWATER ANIMALS OR SALINITY OR PARTICULATE MATTER FOR SALTWATER ANIMALS, A FINAL ACUTE EQUATION SHOULD BE DERIVED BASED ON THAT WATER QUALITY CHARACTERISTIC."
- "WHEN ENOUGH DATA ARE AVAILABLE TO SHOW THAT ACUTE TOXICITY TO TWO OR MORE SPECIES IS SIMILARLY RELATED TO A WATER QUALITY CHARACTERISTIC THE RELATIONSHIP SHOULD BE TAKEN INTO ACCOUNT AS DESCRIBED ……"
- "IF USEFUL SLOPES ARE NOT AVAILABLE FOR AT LEAST ONE FISH AND ONE INVERTEBRATE OR IF THE AVAILABLE SLOPES ARE TOO DISSIMILAR OR IF TOO FEW DATA ARE AVAILABLE TO ADEQUATELY DEFINE THE RELATIONSHIP BETWEEN ACUTE TOXICITY AND THE WATER QUALITY CHARACTERISTIC," RETURN TO HOME DO NOT COLLECT $200…….

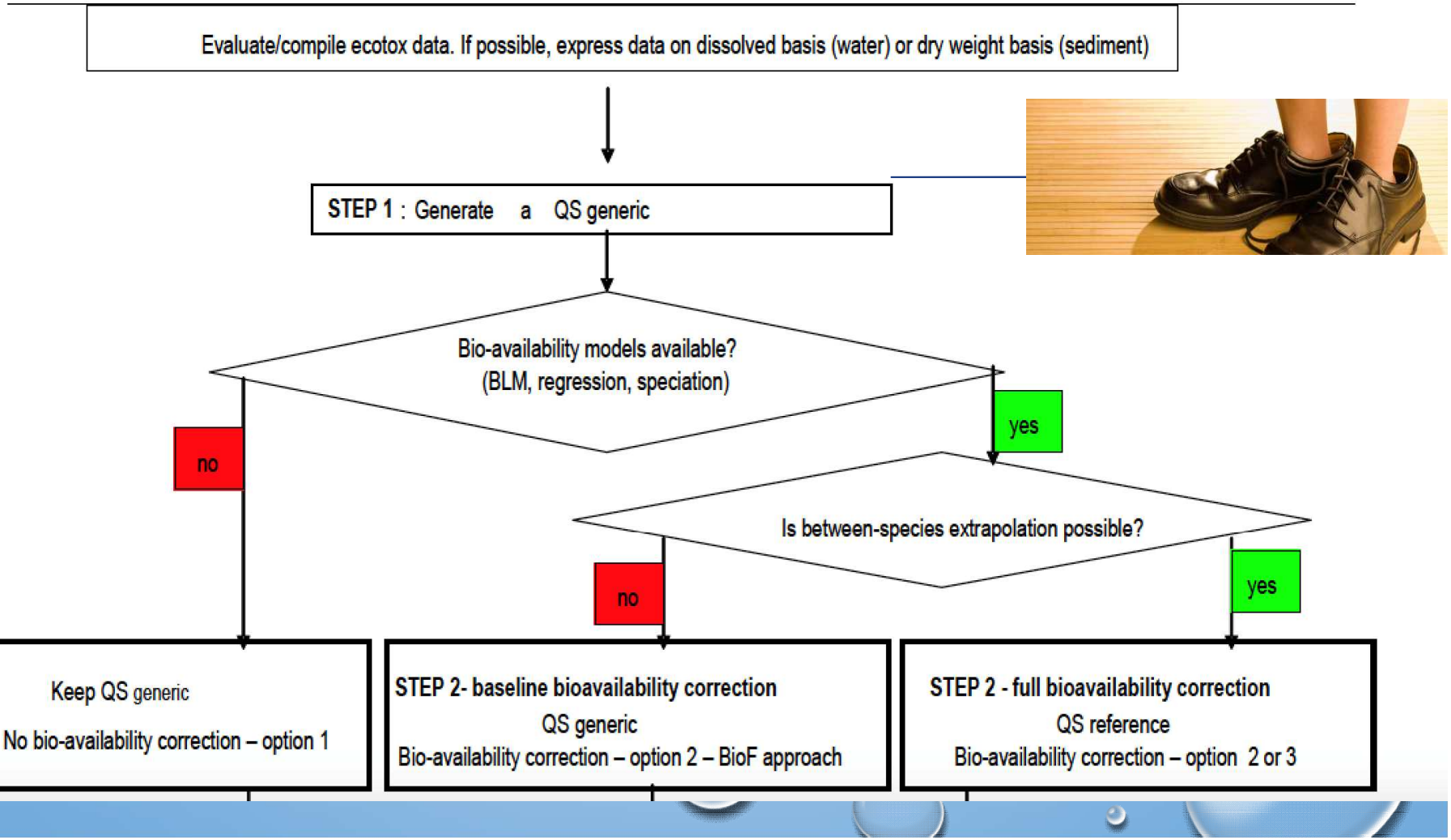
EU BLM REQUIREMENTS

- IF MODELS ARE AVAILABLE THAT INVOLVED BIOAVAILABILITY CORRECTION (BLM'S), THE **MODELS MAY BE SPECIES-SPECIFIC** AND, THEREFORE, BIOAVAILABILITY CORRECTION IS ONLY POSSIBLE IF THE BLM MODELS HAVE BEEN DEVELOPED AND VALIDATED FOR **AT LEAST THREE HIGHER TAXONOMIC GROUPS, INCLUDING AN ALGAE, AND INVERTEBRATE, AND A FISH SPECIES**.
  - THIS TYPICALLY REQUIRES TESTING IN NATURAL WATERS AND AN EVALUATION OF THE PREDICTIVE CAPABILITY OF THE BLM.

EU BLM REQUIREMENTS

- FULL BLM NORMALIZATION OF THE ENTIRE NOEC DATASET IS JUSTIFIED AND FULL BIOAVAILABLE CORRECTION CAN BE PERFORMED ONLY IF MODELS ARE AVAILABLE AND IF ADDITIONAL QUANTITATIVE EVIDENCE IS AVAILABLE TO **CONFIRM THE APPLICABLE AT THE OF THE THREE BLM'S TO AT LEAST THREE ADDITIONAL TAXONOMIC GROUPS** (AT LEAST AT THE LEVEL OF CLASS, BUT PREFERABLY AT THE LEVEL OF PHYLUM.
  - THIS REQUIRES "SPOTCHECK" TESTS WITH ADDITIONAL SPECIES AND COMPARISON TO PREDICTIONS FROM THE ORIGINAL BLM DATABASE.

INCORPORATION OF BIOAVAILABILITY CORRECTION



WHAT IS THE RIGHT $EQS_{BIOAVAILABLE}$?

- COLLECT MONITORING DATA FROM ACROSS EU, MATCHED SAMPLE SITE DATA – INCLUDING PH, DOC AND CA (I.E. EACH SAMPLE HAS THESE FOR AN EXTENDED PERIOD – 10 YEARS). MANY MEMBER STATES HAVE THESE DATA.....
- RUN THROUGH RELEVANT INTEGRATED BLM TO PREDICT HC5 PER SAMPLE
- DERIVE FREQ DIST FOR HC5S FOR EACH REGION.....
- PRAGMATIC DECISION $EQS_{BIOAVAILABLE}$ TO BE PROTECTIVE OF 95% OF MOST SENSITIVE REGION
- FOR NICKEL, MOST SENSITIVE REGION TO POTENTIAL NICKEL EXPOSURES AUSTRIA. THE 5^{TH} PERCENTILE FOR THESE WATERS 4 UG/L
- THIS A BIOAVAILABLE EQS – IT IS OPERATIONALLY DEFINED, IT CAN ONLY BE USED WITH CONSIDERATION WITHIN A BIOAVAILABILITY FRAMEWORK

ALTERNATIVE CRITERIA APPROACH

- CURRENT AWQC EQUATION:
  - AWQC = $e^{(1.0166\ (\text{LN HARDNESS}) - 3.924)}$
- EQS APPROACH
  - EQS = $[M^{+}]\ UG_{BIOAVAILABLE}\ /L$
  - $EQS_{BIOAVAILABLE}$ TO BE PROTECTIVE OF 95% OF MOST SENSITIVE REGION
  - CORRECTIONS FOR BIOAVAILABILITY MADE ON THE EXPOSURE SIDE DATA

BLMS COMPLEX, RESOURCE HUNGRY, TOUGH TO INTERPRET OUTPUTS IN ROUTINE REGULATORY FRAMEWORKS

A TIERED APPROACH TO CLASSIFICATION / INVESTIGATIONS