Valutazione del rischio chimico

CdL Magistrale Interateneo in
Scienze e Tecnologie per l'Ambiente e il Territorio
Università di Udine e Università di Trieste

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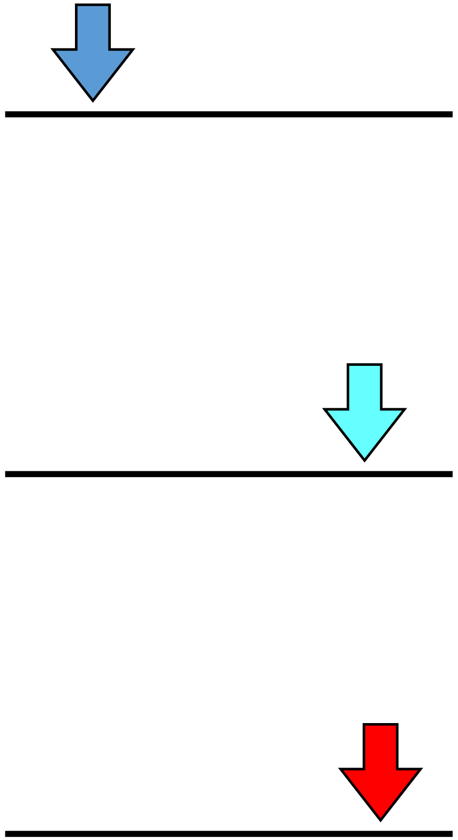
Valutazione del Rischio Ecologico

Approccio Deterministico

Concentrazione soglia di effetto avverso (***T***ossicità)

Concentrazione di ***E***sposizione

TER (E/T)



Evidenze di effetto avverso non sempre evidenti nei casi di esposizione a concentrazioni ambientali basse e per tempi prolungati, su organismi con sensibilità diversa, esaminando effetti non acuti

Servono approcci che considerino sinotticamente le informazioni disponibili, per avere valutazioni di coerenza da linee di evidenza eterogenee e conferme su dati cui è associata incertezza non trascurabile

Uno dei primi approcci alla valutazione sinottica di più linee di evidenza trova applicazione alla caratterizzazione degli impatti sui sedimenti:

Long ER and Chapman PM. **1985**. *A **sediment quality triad**: Measures of sediment contamination, toxicity and infaunal community composition in Puget Sound.* Marine Pollution Bulletin, 16:405-15

A cui è seguito uno sviluppo significativo prima nell'applicazione e con successive generalizzazioni

Chapman PM, McDonald BG & Lawrence GS. **2002**. *Weight-of-Evidence Issues and Frameworks for Sediment Quality (And Other) Assessments*, Human and Ecological Risk Assessment: An International Journal, 8:7, 1489-1515 (http://dx.doi.org/10.1080/20028091057457)

Un esempio:

Preliminar Results From a Sediment Quality Triad Study in the Gulf of Trieste:

the Choice of the Reference Site.

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Title anticipated in the Book of Abstracts:
"Sediment Quality Triads and the Integration of Information from Analytical Chemistry with Ecological Community Structure and Toxicological Data in Risk Assessment of Coastal Sites."
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Environmental quality criteria

Aiming at the classification of ecosystems on the base of their environmental degradation, *environmental quality criteria* (numerical values) are required in order to determine if a zone is degraded or not.

Questions arise when the environmental quality criteria is based only on the assessment of chemical contamination of a certain environmental compartment since *chemical contamination does not necessarily imply effects on biological communities*. Moreover effects on biological communities are related to several factors, conditioning also the concentrations of contaminants, as – in aquatic systems – hydrodynamics, grain size of sediments, species being considered, etcetera.

Sediments

Within aquatic ecosystems, sediments achieve importance in consideration of:

- Accumulation of contaminants (low solubility – affinity for particulate matter
- High residence time of c. (difficult biodegradation in reducing medium) $\rightarrow$ benthic organisms exposed to high levels of c.
- Sediment bound contaminants can be released to water if environmental conditions do vary.

Environmental agencies - as U.S.E.P.A. - thus consider *sediments as key environmental components within aquatic compartments.*

Criteria classically determined for environmental quality characterisation derive from approaches listed in Table 1, where examples and main limitations of each are reported.

Table1

APPROACH	***EXAMPLE OF MEASUREMENTS***	***LIMITATIONS***
Sediment chemical analyses	- Individual contaminants - Complementary analyses (TOC, surface of grains etc.)	- Assumes that all chemical contaminants are measured - Contamination do not inform about biological effects
Organism tissue chemical analyses	- Individual contaminants - Complementary analyses (biometrical etc.)	- *Idem* as above - Organisms mobility
Sediment toxicity tests	- Survival - Sublethal effects (malformation, burial)	- Conditions different from reality; - Assumes that considered tests cover all responses - Toxicity is not linked causally to specific toxic agent
Histopathological alterations	- Individual pathological conditions - Complementary analyses (biometrical etc.)	- Organisms mobility - Disease is not linked causally to specific chemical agent
Structure of the Benthic community	- Taxa (Mollusca, Polichaeta etc.) - Biomass; indices of biodiversity	- Difficult to discriminate between natural and anthropogenic effects

Each single approach presents pros and cons; consequently two or more of the cited type of measurements can be applied on samples acquired simultaneously thus allowing an integrated assessment.

The case study

The growing degree of connection of urban and industrial sites of the Plain of the Isonzo River to the local sewage treatment plants and the high environmental pressure on the coast line of the Gulf of Trieste have brought to *plan the building of a new off-shore diffusor* that will be completed before the end of 2002.

Other diffusors within the same Gulf were demonstrated to bring metals to offshore sediments, thus extending the radius of impact of human activities, beside lowering the environmental strain on the coastline [].

An *integrated environmental assessment* has been performed before the building and exersice of the offshore dispersion device *at four sites located nearby* it - locations are ISO1, ISO2, ISO3 and ISO4 in Figure 1 - so to provide a reference for a future evaluation the possible impact of treated waters on benthic life. *Measurements describing chemical contamination of sediments, ecotoxicity tests with sediment elutriates, and quali-quantitative assessment of macrobenthic population have been produced.*

	Long.	Lat.
ISO1	13°35'.43	45°42'.08
ISO2	13°35'.17	45°41'.86
ISO3	13°35'.91	45°42'.13
ISO4	13°35'.33	45°42'.73

	Depth (m)	Sand %	Silt %	Clay %
ISO1	13.7	0.00	33.47	63.53
ISO2	13.7	0.00	33.16	66.84
ISO3	14.6	0.00	37.05	62.95
ISO4	11.5	0.00	42.82	57.18

Experimental methods:

Samples for chemical and toxicological analyses have been collected by a Kc HAPS bottom corer with a sample area of 127 cm^2; for the analysis of benthos three samples have been collected with a 0.1 m^2 van Veen grab.

Chemical analyses: metals (Cd, Ni, Pb, Ag, Cu, Cr, Fe, Zn, As and Hg) have been released from sediments and analysed according to I.R.S.A. methodologies []. The spectrometer was a PE-5100PC.

PAHs (Phenantrene, Fluoranthene, Pyrene, Benzo(a)anthracene, Crysene, Benzo(b)fluoranthene, Benzo(a)pyrene), PCBs, 4,4’-DDE, 4,4’-DDD, 4,4’-DDT have been extracted again according to I.R.S.A. methods []; PCBs have been quantified as PCB1254 mixture. The separation were conducted by gas chromatography, with ECD for chlorinated compounds and MS for PAHs. PE-AutoSystem XL and HP-6980/5973 instruments were used.

Toxicological analyses on sediment elutriates considered here are the Microtox assay® [] and the assay on the alga Dunaliella tertiolecta [].

In situ alteration of the benthic community has been assessed by the analysis of macrobenthos. Macrobenthic organisms (Mollusca, Polychaeta, Crustacea, Echinodermata) have been determined to species level; furthermore abundance values of specimens were computed. From these data diversity indices (Shannon, Pielou) have been calculated.

Chemistry, Toxicity and Infauna Data from the four different sites can be combined into *the Sediment Quality Triad* (SQT) [] in order to determine the degree of degradation at each site. The normalization of data from the sampling sites towards those of one of them that is considered as an unpolluted reference makes the comparison relatively easy. For each site and for each parameter determined, the datum is converted into a *Ratio To Reference* (RTR) value:

$$(RTR_i)_k = (v_i)_k / (v_i)_0$$

where:

$(RTR_i)_k$ is the RTR for parameter i-me at site k-me;

$(v_i)_k$ is the datum determined for parameter i-me at site k-me;

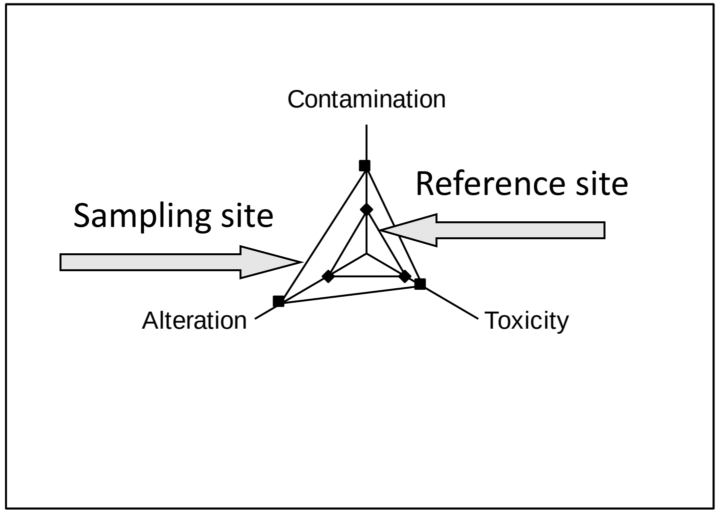
$(v_i)_0$ is the datum determined for parameter i-me at site chosen as reference.

This is straightforward for chemical parameters, while toxicological and infaunal parameters have been transformed so to show increase with biological damage. For instance, in a Microtox® test the result (endpoint) is expressed as EC20, the percentage of interstitial water sample causing a 20% inhibition of bioluminescence of the population of *Vibrio Fisheri;* this means that EC20 is low when sediment is highly polluted; the inverse ($EC20^{-1}$) is thus considered.

$(RTR_i)_k$ for all i parameters describing chemical contamination are averaged, thus providing a single *Index of Contamination for each site, IC ;* the same is done for parameters describing sediment toxicity and *in situ* alteration; The result is a *Index of Toxicity (IT) and a Index of Alteration (IA) for each site*.

The three indices for each sampling site can be displayed in graphical form as three segments (for Contamination, Toxicity and Alteration) departing from a central point, where the lenghts of each segment equals the averaged values of the RTR for the three group of determined parameters.

Two triangles are identified; the inner one represents the reference site, the outer is one of the site for whom the environmental quality must be assessed. The difference between the areas of the outer and inner triangles can be retained as a synthetic **index of degradation** with respect of the reference site []. The difference between the sums of the three indices IC, IT and IA. for the site under investigation and the reference is a measure of degradation as well.



Del Valls et al. [] proposed a modified normalization procedure, where:

$$(RTM_i)_k = (RTR_i)_k / RTRmax_i$$

$(RTM_i)_k$ is the new normalized value for parameter i-me at site k-me;
$(RTR_i)_k$ is the RTR for parameter i-me at site k-me;
$RTRmax_i$ is the maximum value of RTR for parameter i-me;
The new indices of Contamination, Toxicity and Alteration for site k are computed as:
$NIC_k=(\Sigma RTM_{ic})_k / (\Sigma RTM_{i\,c})_0$; ic = index running between chemical parameters;
$NIT_k=(\Sigma RTM_{it})_k / (\Sigma RTM_{i\,t})_0$; it = index running between toxicological parameters;
$NIA_k=(\Sigma RTM_{ia})_k / (\Sigma RTM_{i\,a})_0$; ia = index running between alteration parameters

It is clear how results depend on the choice of the reference site, but no formal procedure has been proposed to select it, at the best of our knowledge.

The problem is not trivial, since in practical cases it is frequent to choose the reference site between stations which are not "completely unpolluted"; the quest for a "truly unpolluted" reference could lead to select a station being too heterogeneous from others.

A formal procedure for selecting the reference site is as follows:

1) for each possible reference site i

compute IC, IT, IA (or NIC, NIT, NIA) and index of degradation P_{ij} (based on

areas of triangle or on sums of indices) for each sampling site j

2) the selected reference site <u>i</u> is the one for which

a) $P_{\underline{ii}} = \min P_{ij}$;

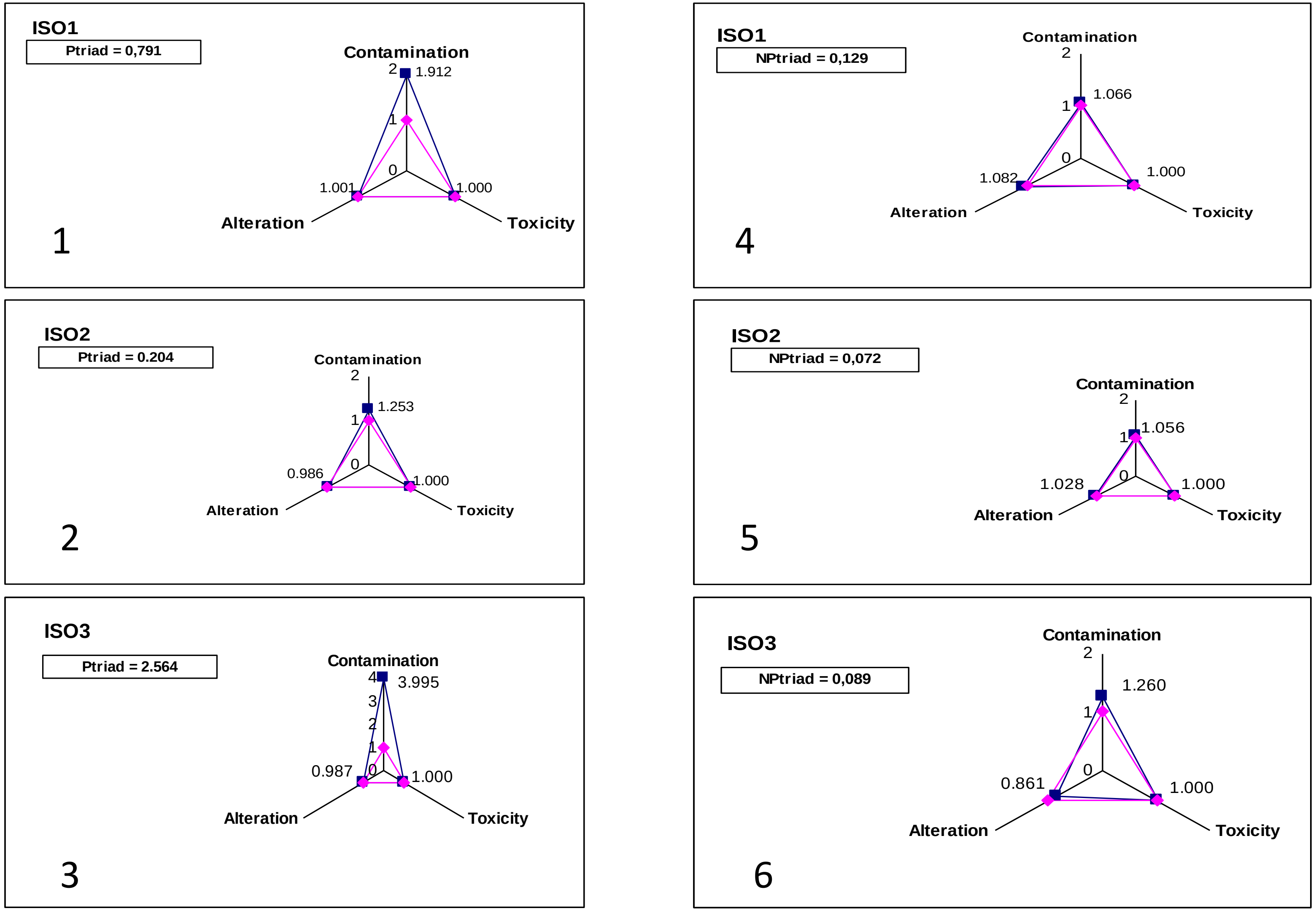
b) $P_{ij} \geq 0$.

The results of the procedure described above for our data, using RTR, the areas for defining the index of degradation, are as follows:

Rif.	ISO1				ISO2				ISO3				ISO4			
	ISO1	**ISO2**	**ISO3**	**ISO4**	**ISO1**	**ISO2**	**ISO3**	**ISO4**	**ISO1**	**ISO2**	**ISO3**	**ISO4**	**ISO1**	**ISO2**	**ISO3**	**ISO4**
IC	1.000	0.989	1.760	0.908	1.193	1.000	2.423	0.903	1.193	1.000	2.423	0.903	1.912	1.253	3.995	1.000
IT	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000
IA	1.000	0.992	0.791	0.939	1.016	1.000	1.001	1.015	1.016	1.000	1.001	1.015	1.001	0.986	0.987	1.000
Ptriad	**0.000**	**-0.017**	**0.407**	**<u>-0.131</u>**	**0.181**	**0.000**	**1.233**	**<u>-0.073</u>**	**0.181**	**0.000**	**1.233**	**<u>-0.073</u>**	***0.791***	***0.204***	***2.564***	***<u>0.000</u>***

Underlined numbers stand for condition (a), Italics stand for condition (b); from the table above, *ISO4 is selected as reference site*.

Sediment Quality Triad Plots



Plots 1, 2, 3 report results derived after RTR normalization; plots 4, 5, 6 report results derived after RTM normalization; Degradation Indices (P or NP) are differences between areas of triangles defined for the sampling sites ISO1, ISO2, ISO3 , and the reference site ISO4.

Conclusions

Examining the plots it can be seen how the three sites are very similar to the reference station; some differencies can be appreciated with respect to the chemical contamination, but they seem not to be severe enough to alter in a significative way population of macrobenthos, and neither to determine a significative toxicity of sediments. This scenario will be compared with SQT analysis obtained when the wastewater diffusor will be operative.

From a methodological point of view, the SQT approach present an interesting way of synthetising complementary information, providing a rich -informative- comparison between sites of a certain area.

In order to gain more widespread acceptance of the methodology, detailed guidelines are needed so to apply SQT “on objective bases”.

Clear indications (“how to”) on the selection of contaminants to be considered, on ecotoxicological tests to be applied, and on measures of the *in situ* alteration should be set. Moreover an exaustive study on benefits of the different normalization procedures and a general criterium for the selection of the reference site are required.

In this work we have proposed a procedure for the choice of the reference station.

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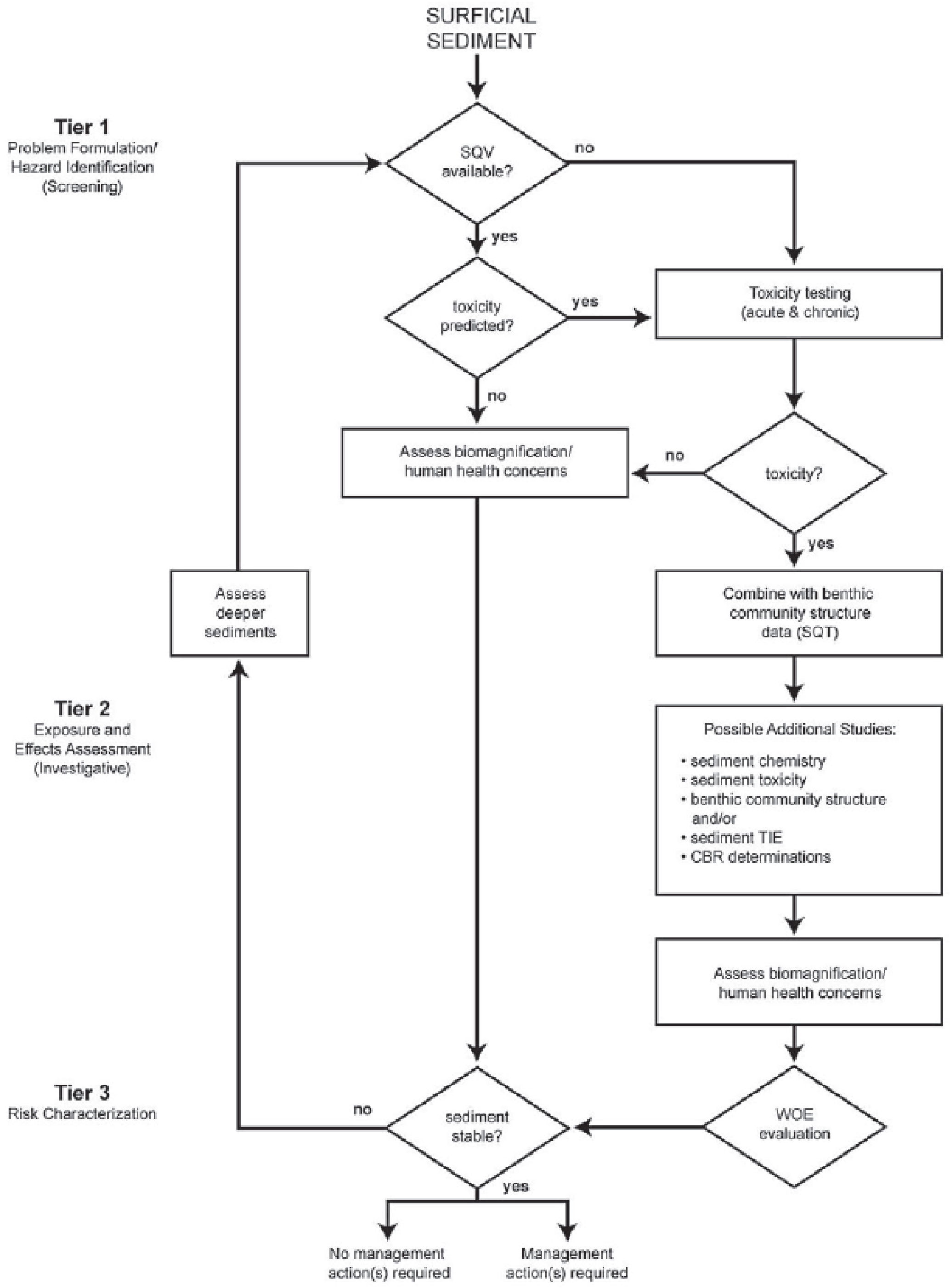
- **Relative Taxa Sensitivity (RTS) of aquatic invertebrates with respect to organic and metal compounds. (39)**
- **Von der Ohe, P. & Liess, M. 2004. Environmental Toxicology and Chemistry. 23, 150-156.**
- In the field, a multitude of species can be exposed to numerous toxicants; thus, the sensitivity of individual species to particular toxicants must be known to predict effects and to analyze changes in species composition. For most species, no information about their toxicant sensitivity is available. To address this limitation, we have grouped the available information to assign sensitivities to aquatic invertebrate taxa relative to Daphnia magna. With respect to organic compounds, most taxa of the orders Anisoptera, Basommatophora, Coleoptera, Decapoda, Diptera, Ephemeroptera, Eulamellibranchiata, Heteroptera, Hirudinea, Isopoda, Oligochaeta, Prosobranchia, Trichoptera, Tricladida, and Zygoptera are less sensitive than D. magna. Some taxa of the Amphipoda, Plecoptera, and Cladocera (other than D. magna) are significantly more sensitive. For organic compounds, approximately 22% of the investigated taxa were more sensitive than D. magna. Most taxa of the orders Amphipoda, Basommatophora, Diptera, Ephemeroptera, Eulamellibranchiata, Heteroptera, Isopoda, Oligochaeta, and Tricladida are significantly less sensitive than D. magna to metal compounds. The taxa belonging to the Crustacea, with the exception of the order Isopoda, are much more sensitive. For metal compounds, approximately 30% of the investigated taxa were more sensitive than D. magna. Hence, D. magna is among the most sensitive taxa regarding both groups of toxicants. The sensitivities for several taxa are listed, and use of the relative sensitivity distribution to link toxicant effects in mesocosm studies and field investigations is discussed.

BISOGNA PORRE LE DOMANDE GIUSTE !!! Da Chapman, 2002

1. Are contaminants present at levels of concern? (sediment chemistry)
2. Are the contaminants capable of causing toxicity? (laboratory toxicity tests)
3. Are resident biotic communities altered? (community structure analyses)
4. Are the contaminants causing the observed toxicity and/or community alterations (manipulative/investigative studies, *e.g.*, TIE [toxicity identification evaluation], CBR [contaminant body residues] determinations)
5. Are any contaminants of concern capable of and likely to biomagnify? (sediment chemistry and tissue analyses, food chain modeling)
6. Is the sediment stable or is it liable to erosion resulting in exposure of deeper, more contaminated sediments and/or contamination down-current? (shear stress and cohesion measurements relative to possible and unusual events) *ndr rischi differiti temporalmente o spazialmente*

Alberi decisionali /diagrammi di flusso per la valutazione di rischi e necessità di mitigazione per sedimenti contaminati (da Chapman, 2002)

Tiered sediment assessment framework. "SQV available?" assumes appropriate ability to predict no toxicity and recognizes the reality that reasonably reliable SQVs do not exist for all contaminants. SQV = sediment quality value. SQT = sediment quality triad; TIE = toxicity identification evaluation; CBR = contaminant body residue; WOE = weight-of-evidence.



Esempi da Chapman, 2002

Table 2. Ordinal ranking scheme applied for weight of evidence categorizations in Example 1 (Table 3). SQV = sediment quality value; SEL = severe effect level; LEL = lowest effect level; EC = effective concentration.

	●	◉	○
Chemistry (Bulk sediment)	Exceeds upper-bound SQV (>SEL)	Exceeds lower-bound SQV (>LEL)	All contaminant concentrations below lower-bound SQV (<LEL)
Toxicity	EC50 (Study 1); 50% of "warning level" from Great Lakes references (Study 2)	EC20 (Study 1); Less than the "warning level" (Study 2)	Negligible effects compared to references, controls, and/or warning levels
Bioaccumulation	10-fold difference compared to references	2-fold difference compared to references	No increase in contaminant uptake
Benthos Assemblages (multivariate assessment)	"different" or "very different" from reference stations	"possibly different" from reference stations	"equivalent" to reference stations
Overall Risk	High - Significant adverse effects predicted for these sediments	Moderate - Effects possible, but unlikely and/or small in magnitude	Low - No significant adverse effects predicted for these sediments

Table 3. Example 1: Weight of evidence for sediment bioavailability and toxicity at a freshwater contaminated site in the Great Lakes. Note: Two different studies for sediment chemistry (1,2) and two rounds of toxicity tests (1,2) were conducted. NA = not assessed.

SITE	BULK SEDIMENT CHEMISTRY: METAL (1,2) – PAH – PCB	*Chironomus* TOXICITY: SURVIVAL (1,2) – GROWTH (1,2)	*Hexagenia* TOXICITY: SURVIVAL (1,2)- GROWTH (1,2)	*Hyalella* TOXICITY: SURVIVAL- GROWTH	FATHEAD MINNOW: SURVIVAL- BIOACCUM	*Tubifex* TOXICITY: SURVIVAL - # COCOONS- % HATCH- -# YOUNG	MULTIVARIATE EVALUATION OF BENTHIC COMMUNITY STRUCTURE	OVERALL RISK RATING
1	**○**-**○**-**○**-**○**	○-○-○-○	○-○-○-○	○-○	NA-NA	○-○-**○**-**○**	○	Low
2	●-●-**○**-**○**	○-○-○-○	○-○-○-○	○-○	NA-NA	○-○-○-○	○	Very Low
3	NA-**○**-NA-NA	NA-○-NA-○	NA-○-NA-○	NA-NA	○-○	○-○-○-●	○	Low
4	NA-●-NA-NA	NA-○-NA-○	NA-○-NA-○	NA-NA	○-○	○-○-**○**-●	**○**	Moderate
5	●-●-●-**○**	○-○-○-○	○-○-○-○	○-○	NA-NA	○-○-○-**○**	○	Very Low
6	●-●-**○**-**○**	○-○-**○**-○	○-○-**○**-○	○-○	NA-NA	○-○-○-○	○	Low
7	NA-●-NA-NA	NA-○-NA-○	NA-○-NA-○	NA-NA	○-○	○-○-○-○	○	Very Low
8	**○**-**○**-**○**-**○**	**○**-○-○-○	○-○-○-○	○-○	NA-NA	○-○-**○**-●	○	Low
9	NA-●-NA-NA	NA-○-NA-○	NA-○-NA-○	NA-NA	○-○	○-○-**○**-**○**	**○**	Low
10	**○**-**○**-**○**-**○**	○-○-○-○	○-○-○-○	○-○	NA-NA	○-○-**○**-●	○	Low
Ref A	**○**-**○**-○-○	NA-○-NA-○	NA-○-NA-○	○-○	NA-NA	○-○-○-○	**○**	Low
Ref B	NA-**○**-NA-NA	NA-○-NA-○	NA-○-NA-○	NA-NA	○-○	○-○-○-○	**○**	Low

Da SCHEER, 2018

Term	Definition
Weight of evidence	WHO, (2009) "A process in which all of the evidence considered relevant for a risk assessment is evaluated and weighted" ECHA, (2010) "Weight-of-Evidence can be defined as 'the process of considering the strengths and weaknesses of various pieces of information in reaching and supporting a conclusion concerning a property of the substance" Also in ECHA, (2010) "An evidence based approach involves an assessment of the relative values/weights of different pieces of the available information that have been retrieved and gathered in previous steps. To this end, a value needs to be assigned to each piece of information. These weights/values can be assigned either in an objective way by using a formalised procedure or by using expert judgement. The weight given to the available evidence will be influenced by factors such as the quality of the data, consistency of results, nature and severity of effects, relevance of the information for the given regulatory endpoint"

Generalizzazione dell'approccio di valutazione sinottica di diverse «lines of evidence» di alterazione o impatto dell'inquinamento:

European Food Safety Agency

Reliability, Relevance and Consistency are the basic considerations for weighting evidence

doi: 10.2903/j.efsa.2017.4971

EFSA Journal

SCIENTIFIC OPINION

ADOPTED: 12 July 2017

doi: 10.2903/j.efsa.2017.4971

Guidance on the use of the weight of evidence approach in scientific assessments

EFSA Scientific Committee,

EFSA requested the Scientific Committee to develop a guidance document on the use of the weight of evidence approach in scientific assessments for use in all areas under EFSA's remit. The guidance document addresses the use of weight of evidence approaches in scientific assessments using both qualitative and quantitative approaches. Several case studies covering the various areas under EFSA's remit are annexed to the guidance document to illustrate the applicability of the proposed approach. Weight of evidence assessment is defined in this guidance as a process in which evidence is integrated to determine the relative support for possible answers to a question. This document considers **the weight of evidence assessment as comprising three basic steps: (1) assembling the evidence into lines of evidence of similar type, (2) weighing the evidence, (3) integrating the evidence.** The present document identifies reliability, relevance and consistency as three basic considerations for weighing evidence.

Table 5: Scale proposed by EFSA's Guidance on the weight of evidence (2017) for harmonised use in EFSA to express the probability of uncertain outcomes

Probability term	Subjective probability range
Extremely likely	99-100%
Very likely	90-99%
Likely	66-90%
As likely as not	33-66%
Unlikely	10-33%
Very unlikely	1-10%
Extremely unlikely	0-1%

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A WEIGHT OF EVIDENCE FRAMEWORK FOR ENVIRONMENTAL ASSESSMENTS: INFERRING QUALITIES

Glenn Suter[1,†], **Susan Cormier**[‡], and **Mace Barron**[§]

Abstract

The weighing of heterogeneous evidence such as conventional laboratory toxicity tests, field tests, biomarkers, and community surveys is essential to environmental assessments. Evidence synthesis and weighing is needed to determine causes of observed effects, hazards posed by chemicals or other agents, the completeness of remediation, and other environmental qualities. As part of its guidelines for WoE in ecological assessments, the U.S. Environmental Protection Agency has developed a generally applicable framework. Its basic steps are: assemble evidence, weight the evidence, and weigh the body of evidence. Use of the framework can increase the consistency and rigor of WoE practices and provide greater transparency than ad hoc and narrative-based approaches.

Potential benefits of WoE

1. WoE provides greater confidence in results obtained by considering all relevant and reliable evidence. For example, it is not uncommon for causal assessments to consider only statistical evidence of co-occurrence of an effect and its potential causes. That approach provides much less confidence than one that also considers evidence of temporal sequence, specific alterations, and other characteristics of causal relationships. In many cases, no single type of evidence is sufficient to reach a conclusion.

2. A formal WoE method increases defensibility by demonstrating that all relevant evidence has been considered and no credible evidence has been arbitrarily dismissed. Without an explicit process planned in advance, reviewers might criticize or even dismiss an assessment for excluding data or evidence that they believe deserved greater consideration.

3. Transparency of the processes also increases defensibility of assessments. A formal WoE method enables reviewers and readers to understand and critique the processes of assembling, weighting, and weighing the evidence.

Attenzione

A formal WoE process may be unclear to readers or may discourage engagement. To avoid this, conclusions of each section may be presented as a short narrative up front, and details of evidence and analysis may follow, for those who are engaged by the conclusions. If scoring and WoE tables are large or numerous, they may be presented in an appendix.

https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_014.pdf

Scientific Committee on Health, Environmental and Emerging Risks

SCHEER

ABSTRACT

This Memorandum is focussed on how to use the weight of evidence approach (WoE) to conduct a risk assessment for stressors to which humans and/or the environment may be exposed. It is intended to complement the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) report on the identification of emerging issues and the work on the challenges in future risk assessment. The aim of this document is to support the use of the WoE, wherever appropriate, for the risk assessment activities of the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER). In addition, it should support the consistency in the work of different EU bodies performing risk assessments.

Memorandum on weight of evidence and uncertainties

Revision 2018

Scientific Committees

on Consumer Safety

on Health, Environmental and Emerging Risks

Scientific evidence consists of observations, experimental and model results and expert judgements that serve to support, refute, or modify a scientific hypothesis or theory. The search for relevant information and data for the SCHEER comprises of identifying, collecting and selecting possible sources of evidence in order to perform a risk assessment and/or to answer the specific questions being asked. According to the issue being addressed, the SCHEER may utilise data provided by the DG tasking the SCHEER, or provided by a third party (e.g. stakeholder reports, submissions such as confidential data provided by companies or applicants), reports and Opinions of other scientific, governmental or international bodies, scientific (peer-reviewed) publications, meta-analysis and systematic reviews or personal communications.

The WoE is an iterative process involving:

- Problem formulation
- Identification, collection and selection of the possible sources of evidence
- Assessment and weighing of individual lines of evidence
- Integration of lines of evidence
- Description of uncertainties
- Conclusion and reporting

For each line of evidence, the criteria of validity, reliability and relevance need to be applied and the overall quality has to be assessed. Several tools for the analysis and description of uncertainties are presented. In the integration of the different lines of evidence, the strength of the overall evidence depends on the consistency and the quality of the results. The weighing of the total evidence should be presented in a standard format. A system is proposed that classifies results of analysis for human and environmental risks in terms of:

- Strong weight of evidence: Coherent evidence from a primary line of evidence (human, animal, environment) and one or more other lines of evidence (in particular mode/mechanistic studies) in the absence of conflicting evidence from one of the other lines of evidence (no important data gaps)
- Moderate weight of evidence: good evidence from a primary line of evidence but evidence from several other lines is missing (important data gaps)
- Weak weight of evidence: weak evidence from the primary lines of evidence (severe data gaps)
- Uncertain weight of evidence: due to conflicting information from different lines of evidence that cannot be explained in scientific terms
- Weighing of evidence not possible: No suitable evidence available

- Reporting

Strong weight of evidence: coherent evidence from a primary line of evidence (human, animal, environment) and one or more other lines of evidence (in particular mode/ mechanistic studies) in the absence of conflicting evidence from one of the other lines of evidence (no important data gaps).

Moderate weight of evidence: good evidence from a primary line of evidence but evidence from several other lines is missing (important data gaps).

Weak weight of evidence: weak evidence from the primary lines of evidence (severe data gaps).

Uncertain weight of evidence: uncertain evidence due to conflicting information from different lines of evidence that cannot be explained in scientific terms.

Weighing of evidence not possible: no suitable evidence available.

In each case, free text is required to explain the assignment. It is important to identify studies that appear to have been well conducted but generate findings that are very different (outliers) from those of other studies in the same line of evidence. Inconsistencies between apparently very similar, good quality studies also need to be addressed in the final risk assessment along with comments on possible unknowns.

anche

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Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

Weight of Evidence:
General Principles and Current Applications at Health Canada

PREPARED FOR: Task Force on Scientific Risk Assessment

PREPARED BY: Weight of Evidence Working Group