



SCIENTIFIC OPINION LETTER

## The need of scientific based regulations of chemicals in water: A proposal for Brazil

Gisela de Aragão Umbuzeiro

*Faculty of Technology, Unicamp, Campinas, Brazil.*

In Brazil, as well as other developing countries, it is common to use criteria defined by developed countries in North America or Europe, or those from international agencies. There is a lack regarding methods to define standards used in Brazilian laws. In most of the cases the existing criteria are taken from different organizations or countries, with differences in climate, type of water and soil, treatment and analytical capabilities and public management policies. Among several agencies that define their own criteria there are differences, some of them in a scale of 100 orders of magnitude<sup>1</sup>. Among the parameters used to define those criteria, there are variations between: the calculation algorithm, how priority substances are chosen, how quantitative risk is estimated. In the risk assessment process variations can occur regarding the criteria used for carcinogenic classification or other hazard identification, choice of uncertainty factors, exposure scenarios, acceptable risk levels and others. The use of different variables and calculation may generate, consequently, different numbers with the same initial goal of protection of the human health or biota<sup>2</sup>. The adoption of a list of substances and criteria from different countries and their use in the legal system can lead to conflicts and inconsistency in different norms from the same country. For example, a substance may be considered carcinogenic for the water regulation and not carcinogenic for soil or food regulations, depending from where the criterion was imported. Therefore it seems clear that Brazil needs to develop its own rules for the derivation of environmental criteria in a scientific basis.

In 2009 the Brazilian Society of Environmental Mutagenesis, Carcinogenesis and Teratogenesis (SBMCTA) with the support of the Brazilian Society of Toxicology (SBTox) and Brazilian Ecotoxicology Society (Setac-Br) held the workshop "Strategies to define environmental criteria for the protection of human health and the ecosystem". It was a one-week working meeting with national and international experts to propose a scientific based approach for the establishment of water quality criteria in support

of drinking water and aquatic life protection guidelines for Brazil and maybe other countries of Latin America.

In Brazil, the Ministry of Health is responsible for drinking water regulation while both surface and groundwater, air and soil are regulated by the Ministry of the Environment. The agency that has been defining tolerable daily intakes or reference doses in Brazil is ANVISA, Sanitary Control Agency, which is also responsible for the approval of pesticides. Only for some pesticides tolerable daily intakes are published in monographs available at ANVISA webpage<sup>3</sup>. But there are no official tolerable daily intakes issued for Brazil like the IRIS or EFSA databases. Therefore when one needs to calculate a water quality criterion the first step will be to choose a value from a database. From that start the working group proposed to use tolerable daily intakes (TDI) from worldwide agencies: USEPA Integrated Risk Information System (IRIS); USEPA Office of Pesticide Programs; World Health Organization (WHO) or others, before a critical analysis is performed. More recent and scientifically sound values should be chosen, including mode of action considerations. For carcinogenic substances the recommendation is use of IARC classifications. Defaults of 60Kg body weight and 2L drinking water consumption for adults were recommended following WHO criteria. In the absence of adequate exposure data, the TDI allocated to drinking water should be 20%. Recommendations were made for designating criteria as provisional values as well as for using a health-based parametric value approach for unevaluated substances; the latter follows procedures of the Federal Environmental Agency of Germany. The proposed method (Portuguese and English versions) is available on line<sup>4</sup>.

For aquatic life protection, the scenario is even more complex because the surface regulation is based on the multiple uses of water therefore aquatic life protection is one of those uses. The only Brazilian regulation that is based on single uses is the drinking water norm. As Brazil does not have an established methodology to derive water quality criteria, the developed protocol will provide a first insight on the development of a methodology for the derivation of water quality criteria for the protection of aquatic life. Water quality criteria are intended to be applicable to all water bodies in Brazil, but their application to a particular water body should consider the natural water body

Corresponding Author: Prof. Dr. Gisela de Aragão Umbuzeiro  
Address: Faculdade de Tecnologia, UNICAMP Campus I, Rua Paschoal Marmo 1888,  
ZIP 13484332 Limeira SP, Brasil. Phone: +551921133419.  
E-mail: [giselau@ft.unicamp.br](mailto:giselau@ft.unicamp.br) / [giselau@usp.br](mailto:giselau@usp.br)

characteristics. They can also be used (adopted or modified) to establish water quality objectives to protect a particular water body within specific management plans.

It is important to point out that the suggested methodology considers endpoints or effects on the aquatic community such as survival, light emission inhibition, growth, embryo-larvae development, fertilization and reproduction. Bioaccumulation, alterations of the endocrine system or genotoxicity still need to be considered in the future. The proposed method (Portuguese and English versions) is available on line<sup>4</sup>.

Basically the proposed method followed the framework developed by Lepper<sup>5</sup>. For the derivation of the criteria different databases such as ECOTOX-USEPA, OECD SIDS documents, EU risk assessment reports, TOXLINE literature, Japanese National Institute of Technology and Evaluation (NITE). The data for each substance for which an environmental quality criteria is to be derived should be published in peer-reviewed journals using standardized protocols. An assessment factor (AF) is applied to ensure that the exposure concentration will be protective to aquatic life. The AF can change according with the number of available data. The AF varies from 10 to 10,000. The confidence increases as more data on the toxicity to organisms of different trophic levels, taxonomic groups and lifestyles representing various feeding strategies are available.

When there are sufficient toxicity data, the smallest value is select and an appropriate AF is applied. If there is not sufficient data to derive a criterion, the missing data could be predicted by appropriate Quantitative Structure Activity Relationship (QSAR) models. If no toxicity data is available values can be predicted using QSAR model (fish, invertebrates, algae). The lowest predicted value divided by an assessment factor of 1,000 for freshwater or a factor of 10,000 for marine species is also considered as a preliminary value.

We can conclude that developing water quality criteria is a complex process and should be performed by each country, in a scientifically based platform. The workshop organized by Brazilian toxicological scientific societies for the proposal of protocols for the derivation of water quality criteria generated

two important documents<sup>4</sup> that can be the basis for Brazilian water quality criteria derivation. At least, we observed that during the recent revision of the drinking water norm (MS 2914/2011) the process was more transparent and a report about how the standards were chosen is for the first time available on line<sup>6</sup>.

As future needs the adoption of a defined methodology for prioritizing of chemicals and derivation of water quality criteria by the government should be encouraged and a broad program for monitoring unregulated substances in source and drinking water could be performed to provide occurrence data and basis for the choice of which substances should be included in the national norms.

Also a proactive participation of all social, industrial and governmental stakeholders in constructive dialogue and education should be even more encouraged for a scientifically based derivation of the national water quality criteria.

## References

1. Provoost et al. Parameters causing variation between soil screening values and the effect to harmonization. *Journal of Soils and Sediment* (2008)8(5):298-311.
2. Stouten et al. Reassessment of Occupational Exposure Limits. *American Journal of Industrial Medicine* (2008)51:407-418.
3. <http://portal.anvisa.gov.br/wps/content/Anvisa+Portal/Anvisa/Inicio/Agrotoxicos+e+Toxicologia/Assuntos+de+Interesse/Monografias+de+Agrotoxicos>.
4. <http://www.sbmcta.org.br/documentos/http://www.sbmcta.org.br/documentos/>
5. Lepper P. Manual on the methodological framework to derive environmental quality standards for priority substances in accordance with Article 16 of the Water Framework Directive (2000/60/EC). Fraunhofer-Institute Molecular Biology and Applied Ecology, Schmallenberg, Germany (2005).
6. [www.saude.gov.br/svs/pisast](http://www.saude.gov.br/svs/pisast).