Ann. Ist. Super. Sanità, vol. 29, n. 2 (1993), pp. 355-358

Drinking water health advisory program

Jennifer Orme ZAVALETA, Robert CANTILLI and Edward V. OHANIAN

United States Environmental Protection Agency, Office of Science and Technology, Washington DC, USA

Summary. - The US Environmental Protection Agency prepares Health Advisories (HA) for drinking water contaminants. The HA provide technical guidance to public health officials or other interested groups on many aspects concerning drinking water contamination. The HA contain information on the chemistry, health effects, analytical methods and treatment technologies for specific contaminants. In addition, the HA include a risk assessment section which provides concentrations of the contaminant in drinking water that are not anticipated to cause adverse, noncancer health effects for 1 or 10 days or for longer exposures. Because the HA include risk assessments for less than lifetime exposures, they are useful when accidental spills occur or when regulatory limits are temporarily exceeded. The guidance documents are updated when new information becomes available that would change the previous conclusions.

Key words: health advisories, drinking water contamination, risk assessment.

Riassunto *(Programma per la definizione dei bollettini di consulenza sull'acqua potabile)*. - L'Agenzia per la Protezione dell'Ambiente (EPA) degli Stati Uniti elabora Bollettini di consulenza sulla sanità (*Health Advisories*, detti "HA") sul tema delle sostanze inquinanti dell'acqua potabile. Gli HA forniscono assistenza tecnica su molti aspetti della contaminazione dell'acqua potabile ai responsabili della sanità pubblica od altri gruppi cointeressati. Gli HA contengono informazioni sulla chimica delle sostanze, sugli effetti sulla salute, sui metodi analitici e sulle tecnologie di trattamento dell'acqua. Gli HA forniscono informazioni sulle concentrazioni delle sostanze inquinanti, che non si prevede possano causare effetti avversi, non cancerogeni, per la salute dell'uomo, per esposizioni di 1 giorno, o 10 giorni, o per periodi più lunghi. Poiché gli HA comprendono valutazioni del rischio per esposizioni anche brevi possono essere particolarmente utili in situazioni di emergenza, o quando vengono oltrepassati temporaneamente i limiti di legge. Gli HA sono aggiornati quando si rendono disponibili informazioni nuove tali da modificare le conclusioni precedenti.

Parole chiave: bollettini di consulenza, contaminazione delle acque potabili, valutazione del rischio.

Introduction

Water, unfortunately, is not simply hydrogen and oxygen, but rather a complex mixture of many compounds. These include naturally occurring organic and inorganic substances and those compounds such pesticides, industrial or water treatment contaminants which can be directly or indirectly added to water.

In addition, a variety or microbiological organisms can be found in water. Many of these contaminants may pose a human health concern at certain concentrations.

To avoid toxic outcomes that may result from exposure to these contaminants, government restrictions have been established to limit the concentration of potentially hazardous contaminants in drinking water. Many of these restrictions or regulations developed by the World Health Organization or the US Environmental Protection Agency (EPA) for example, focus on long-term exposures to a few of the more hazardous contaminants. Often, however, guidance is needed for short-term exposures that can result from a spill or contamination situation, or for contaminants that can be found in drinking water that are not regulated.

As a result of this need, the EPA Office of Water developed the Drinking Water Health Advisory Program in 1978. The purpose of this program was to prepare guidance documents for public health officials or other interested groups that would provide assistance in dealing with contamination situations or spills involving drinking water. The *Health Advisories* (HA) are not Federally enforceable. They provide information on the chemical and physical properties of a contaminant, occurrence and environmental fate in water or other pertinent media, the pharmacokinetics and health effects in humans and animals, including reproductive or developmental toxicity, a quantification of toxicological effects for both short and long term exposures, analytical methods, water treatment technologies and other criteria or standards developed for that particular contaminant.

The development of the first HA in 1979 was coordinated with the US National Academy of Sciences (NAS). The NAS provided guidance for 20 contaminants (Table 1). At that time the HA were called suggested-no-adverse-response levels (SNARL). This first group of unregulated contaminants were selected due to an increasing detection of these compounds in US water supplies.

Since the original SNARL were developed EPA renamed the guidance documents as *Health Advisories*. HA have been prepared for over 100 contaminants (Table 2). These include inorganics, organics, pesticides, munition related chemicals and microorganisms such as Legionella.

Many of the HA documents were prepared as part of national water quality surveys conducted in the US. For example, a number of the HA for pesticides were prepared as part of the National Pesticide Survey. This survey was designed to evaluate the presence of pesticides considered likely to leach through soil into ground water throughout the US. The purpose was to determine whether restrictions were needed on the use of some of the pesticides and whether these pesticides should be regulated in drinking water. The HA were prepared to provide guidance in the case of a detection.

HA were also prepared for unregulated drinking water contaminants that were routinely being monitored in public water supplies.

Use of *Health Advisories*

Health Advisories are used only for guidance. They are not enforceable standards and may be updated when new information becomes available. The HA contain estimates of concentrations of a particular contaminant that would not cause adverse, non-cancer health effects for specific durations of exposure. The risk assessments are developed for less-than-lifetime exposures of 1 day, 10 days, a longer-term exposure that covers approximately 7 years or 10% of an individual's lifetime, and a lifetime exposure.

Table 1. - Substances for which suggested no adverse response levels (SNARL) was set by EPA

benzene	formaldehyde
carbon tetrachloride	fuel oil 2/kerosene
chlordane	n-hexane
1,2-dichloroethane	methyl ethyl ketone
1,1-dichloroethylene	PCB
cis-1,2-dichloroethylene	tetrachloroethylene
trans-1,2-dichloroethylene	toluene
dichloromethane	1,1,1-trichloroethane
1,4-dioxane	trichloroethylene
ethylene glycol	xylenes

Table 2. - Agents for which current *Health Advisories* are available

Legionella	
antimony	chromium
barium	cyanide
beryllium	mercury
boron	nickel
cadmium	nitrate and nitrite
	thallium
acifluorfen	1,2-dichloropropane
acrylamide	1,3-dichloropropene
alachlor	dieldrin
ammonium sulfamate	dimethrin
atrazine	dinoseb
aldrin	p-dioxane
baygon	diphenamid
bentazon	disulfoton
benzene	diuron
bis(2-chloroisopropyl) ether	endothal
bromacil	endrin
bromochloromethane	epichlorohydrin
bromoform	ethylbenzene
bromomethane	ethylene dibromide
butylate	ethylene glycol
carbamyl	ethylene thiourea
carbofuran	fenamiphos
carbon tetrachloride	fluometron
carboxin	fluorotrichloromethane
chloramben	fonofos
chlordane	glyphosate
chloroethane	heptachlor/epoxide
chloromethane	hexachlorobenzene
chlorothalonil	hexachlorobutadiene
o-chlorotoluene	n-hexane
p-chlorotoluene	isophorone
chlorpyrifos	malathion
cyanazine	maleic hydrazine
2,4-D	MCPA
dacthal	methomyl
dalapon	methoxychlor
diazinon	methyl ethyl ketone
dibromochloropropane	methyl parathion
dicamba	metolachlor
cis-1,2-dichloroethylene	metribuzin
trans-1,2-dichloroethylene	monochlorobenzene
dichlorobenzene	naphtalene
dichlorodifluoromethane	p-nitrophenol
1,2-dichloroethane	oxamyl
1,1-dichloroethylene	paraquat
pentachlorophenol	terbacil
phenol	terbufos
picloram	1,1,1,2tetrachloroethane
prometon	tetrachloroethylene
pronamide	toluene
propachlor	toxaphene
propham	trichlorobenzene
simazine	1,1,1-trichloroethane
styrene	trichloroethylene
2,4,5-T	trifluralin
2,3,7,8-TCDD	
2,4,5-TP	
tebuthiuron	
diisopropyl methylphosphonate	nitroguanadine
1,3-dinitrobenzene	HMX
hexachloroethane	trinitroglycerol
RDX	2,4,6-trinitrotoluene
nitrocellulos	white phosphorous

The less-than-lifetime HA values are particularly useful in situations involving accidental spills. The 1 and 10 day values provide targets for short and long term clean-up goals. They have also been used as target clean-up goals for hazardous waste sites in the United States.

An additional use for the HA is in determining the potential health risks that may result when a drinking water regulatory limit is exceeded such as the US maximum contaminant level (MCL). Under the US Safe Drinking Water Act, the water utilities may appeal to their State for a variance or exemption from an MCL if they are unable to comply with the MCL due to poor source water quality, such that the best available treatment does not effectively remove the contaminant (variance situation), or the utility is unable to install the best available treatment within a given time (exemption situation). Under these conditions, the State can grant the variance or exemption so long as the concentration of the contaminant in question does not present an unreasonable risk to health. The HA are used as reference concentrations to help define what may constitute an unreasonable risk to health for short-term exceedances of the MCL.

Development of *Health Advisories*

The data for each HA are obtained from comprehensive literature searches. Additional information submitted to EPA as confidential business information may be considered if available for pesticides or industrial contaminants. The documents are not comprehensive but contain summaries of pertinent data that are used to determine concentrations that would not pose adverse, non-cancer health effects for different durations of exposure. Each HA value contains a margin of safety to protect sensitive members of the population such as children and the elderly.

The HA values are based on noncancer endpoints of toxicity since these types of effects are more likely to be elicited during short term exposures. Non-carcinogenic effects include those effects such as liver or kidney toxicity, or immunologic or neurotoxic effects that do not lead to an oncogenic outcome. If the contaminant is classified as a human or probable human carcinogen, Lifetime HA values are not determined, since cancer is viewed as a more sensitive endpoint for a lifetime exposure. In these cases, an estimate of cancer risk is presented in the range of one in ten thousand (10^{-4}) to one in one million (10^{-6}).

As mentioned above, the HA values are determined for different durations of exposure (1 day, ten days, longer), term and lifetime. These exposure durations are comparable to the duration of exposure from the experimental studies that serve as the basis for the HA value. The One-day HA represents a concentration of the contaminant in drinking water that is considered protective of adverse non-cancer health effects for up to 5 consecutive days of exposure. The One-day HA is usually derived from experimental studies of 7 days duration or less. The Ten-day HA is considered protective of these effects for up to 14 days of continuous exposure and may be based on experimental studies of 30 days duration or less. The Longer-term HA, based on subchronic exposure studies covering 10% of the animals lifetime, is considered protective of an exposure period in humans for up to seven years, (i.e., 10% of an individual's lifetime). The Lifetime HA is, of course, considered protective of lifetime exposures and is usually based on chronic or subchronic or other, more relevant experimental data.

The less-than-lifetime HA are derived for a 10 kg child drinking 1 l water/day as children are viewed to be more sensitive than adults in short-term exposures. The Longer-term HA is derived for both children and adults. The adult is assumed to weigh an average of 70 kg, consuming 2 l water /day.

The HA levels are generally based on available, well conducted studies involving humans or animals. Data from drinking water studies are preferred; however, data from dietary or gavage studies can also be used. In the absence of oral data, studies by other routes of exposure such as inhalation or injection are considered.

From the available data of appropriate exposure duration, the highest no-observed-adverse-effect level (NOAEL) or, in absence of a NOAEL, the lowest-observed-adverse effect level (LOAEL) is identified from a sensitive species or population. For example, in calculating a Ten-day HA, consider that two 30 day studies are available, one in rabbits, one in rats. A NOAEL of 5 mg/kg/d is reported in rabbits with developmental effects noted at 15 mg/kg/d. The rats, exposed for 30 days show no adverse effects at 30 mg/kg/d. In this situation, the NOAEL from the rabbit study would be selected as the basis for the HA calculation since effects were noted in this species at a dose lower than the NOAEL from the rat study.

In addition to species sensitivity, other factors that are considered in the selection of a NOAEL or LOAEL include the magnitude of the NOAEL/LOAEL selected in comparison to others within the same exposure duration or for other HA levels, the degree of confidence in the conduct of the study and whether the NOAEL or LOAEL are supported by other dose-response data.

Once the NOAEL or LOAEL are identified, the HA values are derived from the following formula:

$$HA = \frac{\text{(NOAEL or LOAEL in mg/kg/d)} \times \text{(BW)}}{\text{(UF)} \times \text{(WC)}} = \text{---- mg/l}$$

where:

NOAEL or LOAEL = no- or lowest-observed adverse effect level

BW = body weight of protected individual (10 kg for a child or 70 kg for an adult)

UF = uncertainty factor

WC = water consumption (1 l/day for a child; 2 l/day for an adult).

The uncertainty factor used in the calculation provides the margin of safety in the HA derivation. They may range from 1 to 10,000 depending on the nature and quality of the data. A factor of 1 to 10 is usually applied to a NOAEL from a human study. This factor accounts for different responses to toxicity within the human population. If a LOAEL from a human study is used, then a factor of 100 may be applied to account for the lack of a NOAEL and intraspecies variation. A UF of 100 may also be used for a NOAEL from an animal study. This would account for intraspecies variation as well as extrapolation from animal data to predict human health effects. If a LOAEL from an animal study is used, then a factor of 1,000 would be applied to account for the lack of a NOAEL.

In the Lifetime HA calculation, the uncertainty factors may increase to as much as 10,000 if a LOAEL from an animal study of less-than-lifetime duration is used as the basis for the Lifetime HA value. The additional factor accounts for the extrapolation of subchronic effects to predict chronic toxicity outcomes. The Lifetime HA value may also include an addition factor of 1-10 to account for possible carcinogenicity if the contaminants is considered a possible human carcinogen.

For each of the less-than-lifetime HA values, it is assumed that all of an individuals exposure to a contaminant comes from a drinking water source. The calculation of the Lifetime HA differs from the less-than-lifetime values in that a relative source contribution factor is included. This factor adjusts the exposure to reflect that portion which is likely to be contributed from drinking water. Unless actual exposure data are available, a default factor of 20% is used to reflect the assumed contribution to exposure from drinking water.

For contaminants considered human or probable human carcinogens, mathematical models are used to estimate the theoretical upper-bound cancer risk for humans from human or animal data. The data used in these estimates usually come from lifetime ingestion studies, although in some cases epidemiological studies are available. The excess cancer risk estimates may be calculated from a number of different models such as the one-hit, Weibull, logit, multistage or probit models. These models employ different assumptions. There is no evidence to indicate that one model is more accurate in predicting risk than another since the mechanism of carcinogenicity is often not understood. As a result, EPA has generally considered that there is no safe threshold for carcinogenicity, and thus uses the linearized multistage model to estimate risk. This model fits linear dose response curves to low doses to calculate a cancer potency value called the q_1^*. The potency factor is then used to determine concentrations of the contaminant in drinking water that are associated with excess cancer risks of 10^{-4} to 10^{-6}. The public health official or risk manager may then use this information to make decisions regarding carcinogenic contaminants in drinking water.

Copies of the HA documents may be obtained from the EPA Water Resource Center, 401 M St SW, Washington DC 20460 USA, free of charge.

Submitted on invitation.
Accepted on 5 February 1993.