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Health risk characterisation for environmental pollutants with a new concept of overall risk probability

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ABSTRACT

In health risk assessment, risk is commonly characterised by calculating a simple hazard quotient (HQ), which cannot reflect the actual distribution of exposure and health effect values. This study aimed to develop a new risk characterisation method, the overall risk probability (ORP) method based on probabilistic techniques. Exposure exceedence values were calculated to obtain an exposure exceedence curve (EEC). The area under the EEC was calculated as the ORP value to represent the risk. This method was demonstrated by a case study for two steroidal EDCs, 17β-estradiol (E2) and 17α-ethinylestradiol (EE2) for fish in surface water. It was found that the risk probability of fish exposed to E2 (ORP, 8.1%) and EE2 (ORP, 27%) were both above the reference value of 2.5%, which was consistent with the results of HQ method. Assuming independent action of individual EDCs, a combined risk probability of 33% was obtained for the mixture effects of E2 and EE2. Our results implicated that the adverse health effects imposed by E2 and EE2 were significant for fish in surface water worldwide.

1. Introduction

Each year, large quantities of chemicals are released into the environment contaminating land, water, air and food sources. As a result, various adverse health effects such as cancers, birth defects and reproductive abnormalities have been observed in many wildlife species and humans. For example, a particular group of pollutants termed as endocrine disrupting chemicals (EDCs) is able to cause endocrine disruption in living organisms. Evidence of this includes increased vitellogenin (VTG) levels in male and juvenile female fish, reproductive abnormalities, altered sexual ratios and neuroendocrine disruption in some aquatic species [1–5]. Research has also revealed possible links between EDCs (e.g., DDT and DES) and adverse human health effects such as female breast cancers, male testicular and prostate cancers [6–13].

With more evidences on adverse health effects appeared in the scientific communities and public media, the health risks of emerging or existing environmental pollutants are subjected to close scrutiny by many regulatory authorities. Thus, the assessment of these health risks becomes a crucial step for any further regulatory actions. The principle goal of a risk assessment is to define a 'safe' exposure level, which can protect the majority of organisms at most of the time with minimum costs. In this context, the concept of 'risk' generally has three core elements, exposure, adverse effects and likelihood or probability of adverse effects. The risk will be zero without any of these three elements [14,15]. Risk assessment using probabilistic techniques will enable the risk assessor to express the risk in terms of probability distribution, rather than the traditional deterministic methods using a single-point risk estimation approach.

Historically, probabilistic techniques have been applied to engineering problems since the 1970s, such as the estimation of seismic risk and assessment of nuclear power plant safety [16,17]. Recently it has been applied to assess the risk of environmental pollutants [18–22]. In this method, the exposure and effect values are expressed in cumulative probability distributions (CPD) and plotted in the same diagram. For simple risk estimation, the risk can be expressed as a hazard quotient (HQ) value (also referred to as risk quotient), which is the ratio of an exposure concentration to an adverse effect concentration [19]. The estimated HQ values are compared with a reference value of one to show whether the risk caused by the target pollutant is significant or not. However, this risk characterisation method is a single-point risk estimation method, which cannot reflect the actual shape and distribution of the CPD curves.

The aim of this article was to propose a new health risk characterisation method by using the concept of overall risk probability (ORP), which is capable of reflecting the shape and distribution of

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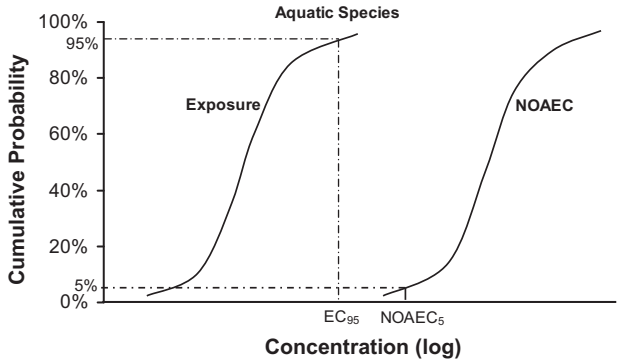

Fig. 1. Cumulative probability distribution of exposure and NOAEC values for aquatic species.

CPD curves. As an example, a case study of health risk characterisation with this new concept was conducted for two typical steroidal EDCs, 17β-estradiol (E2) and 17α-ethinylestradiol (EE2) for fish in surface water.

2. Methodology

2.1. Risk assessment using probabilistic techniques

The use of probabilistic techniques in risk assessment has gained increasing popularity in the area of environmental science, which proved its usefulness and applicability. A detailed description of conducting probabilistic risk assessment was published in two US EPA guidance documents [23,24]. Its application was also demonstrated elsewhere in a number of case studies [18,20,21]. Briefly, the exposure and adverse effect values (measured or simulated) are cumulatively distributed in the same plots, which were illustrated in Fig. 1 for aquatic species and Fig. 2 for humans and mammals. In Fig. 1, aqueous phase concentration is used for the measure of exposure, whereas in Fig. 2, daily dose of exposure is used. The risk is evaluated from the overlapped region between the exposure and effects CPD curves. Generally, the closer the two CPD curves, the higher is the level of risk.

It is important to note that, in the calculation of cumulative probabilities for exposure values, those values that are reported to be below the detection limit should also be counted as part of the total number of exposure values. Solomon et al. [19] assigned a dummy value of zero for these values to obtain the correct position of each point in the CPD curve. Cao [25] suggested using random values between zero and the detection limit to simulate random sampling, which was regarded as an improvement in data treatment.

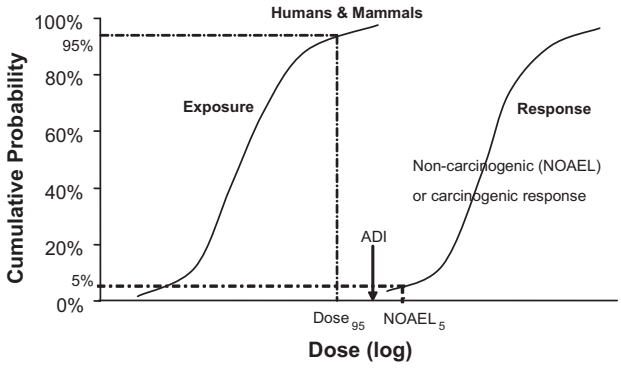

Fig. 2. Cumulative probability distribution of exposure and NOAEL values for humans and mammals.

In the assessment of adverse effects for aquatic organisms (e.g., fish), the *no-observed-adverse-effects-concentration* (NOAEC) values are collated and ranked to calculate cumulative probabilities (CP) (Fig. 1). Similarly in dose–response assessment for humans and mammals, the *no-observed-adverse-effects-level* (NOAEL) values are used for non-carcinogenic effects, whilst other indicative levels can be used for carcinogenic effects (Fig. 2). Due to experimental difficulties and sensitive ethical issues [26,27], NOAEL values are not always available for humans. Thus, NOAEL values obtained in animal studies can be used to extrapolate NOAEL values for humans with appropriate methods. Currently, there are three interspecies extrapolation methods: extrapolation based on caloric demand, body weight and body surface area [29]. These methods have been reviewed and compared by several authors [29–32]. The body surface area method has been recommended by the US Food and Drug Administration [33], which is described in Eq. (1).

$$\mathrm{NOAEL_{HED}} = \mathrm{NOAEL_{animal}} \times \frac{K_{\mathrm{m\ animal}}}{K_{\mathrm{m\ human}}} \quad (1)$$

where $\mathrm{NOAEL_{HED}}$ is the human equivalent daily dose (ng kg $\mathrm{BW^{-1}\ d^{-1}}$), $\mathrm{NOAEL_{animal}}$ is the animal dose (ng kg $\mathrm{BW^{-1}\ d^{-1}}$), K_m is a factor calculated as the body weight (BW) divided by body surface area ($\mathrm{m^2}$). Some typical values of K_m were set by the US Federal Drug Administration for humans and some common mammals used in laboratory studies [33].

The measured or extrapolated human NOAEL values can be used to determine a reference dose value (RfD) or an *acceptable daily intake* (ADI) by dividing a safety factor ranging from 10 to 1000 (Fig. 2). Due to experimental difficulties in the determination of NOAEL and NOAEC values, Bailer and Oris [34] suggested that the *lowest-observed-adverse-effects-level* (LOAEL) values or the *lowest-observed-adverse-effects-concentration* (LOAEC) values can also be used in effects assessment in the absence of NOAEL and NOAEC values.

2.2. Risk characterisation by single-point methods

Commonly, risk is characterised by the hazard quotient ($\mathrm{HQ_{95/5}}$) method for non-carcinogenic effects and the 'slope factor' method for carcinogenic effects. The $\mathrm{HQ_{95/5}}$ method is a single-point comparison between exposure and non-carcinogenic effect values, which is generally expressed as an exposure value divided by an effects value [35]. For the protection of the majority of population under most exposure conditions, a $\mathrm{HQ_{95/5}}$ value is calculated as an exposure value at 95% of CP divided by an adverse effects value at 5% of CP, which is described by Eqs. (2) and (3).

$$\mathrm{HQ_{95/5}} = \frac{\mathrm{EC_{95}}}{\mathrm{NOAEC_5}} \quad \text{(Aquatic species)} \quad (2)$$

where $\mathrm{EC_{95}}$ is the exposure concentration at 95% of CP and $\mathrm{NOAEC_5}$ is the adverse effects concentration at 5% of CP.

$$\mathrm{HQ_{95/5}} = \frac{\mathrm{Dose_{95}}}{\mathrm{NOAEL_5}} \quad \text{(Humans and mammals)} \quad (3)$$

where $\mathrm{Dose_{95}}$ is human or mammals daily dose at 95% of CP and $\mathrm{NOAEL_5}$ is the adverse effects level at 5% of CP.

The $\mathrm{HQ_{95/5}}$ value of one can be regarded as a reference value to assess whether a significant level of health risk occurs or not. If $\mathrm{HQ_{95/5}}$ is less than 1, it means that less than 5% of organisms will be affected by 95% of exposure concentrations, or the majority of exposure concentrations will affect only a minority of the population. If $\mathrm{HQ_{95/5}}$ is larger than 1, it means that more than 5% of fish will be affected by 95% of exposure concentration, or the population affected by most exposure concentrations is significant (>5%).