Evaluation from the point of view of health of the presence in drinking water of substances that are not (yet) possible or only partially possible to evaluate

Recommendation of the Federal Environmental Agency after consultation with the Drinking Water Commission at the Federal Environmental Agency

1. Subject of this recommendation and target-group to whom it is addressed[1]

To assess the presence of substances in drinking water in cases in which

- **Data that would allow an assessment of the human toxicology is non-existent or incomplete, *and***
- **Their possible presence in drinking water is not regulated by a limit value, but only by the requirements of Article 6, paragraph 1 of the German Drinking Water Regulation of 21.05.01 (TrinkwV 2001),[2]**

the Drinking Water Commission of the Federal Ministry for Health and Social Security (BMGS) at the Federal Environmental Agency[3] recommends a pragmatic health-based parametric value (HPV) (maximum permitted concentration) of

HPV = 0.1 µg/l.

as the initial basis for evaluation.

The HPV is a precautionary value for substances easily expanding into drinking water, for which an evaluation on the basis of human toxicology is not possible, or only partially possible.[4] Its level is calculated in such a way that a subsequent, complete evaluation of the human toxicology of a

- *non-genotoxic* substance/substance with an effect threshold (⇒section 3.1)

and the majority of

- *genotoxic* substances/substances without an effect threshold (⇒section 3.2.1)

will with certainty produce an equivalent or higher guide value (GV[5]) for lifelong consumption that is tolerable or acceptable in terms of health ($GV \geq HPV$).

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[1] The german version of this recommendation was published *in* Bundesgesundhbl-Gesundheitsforsch-Gesundheitsschutz 45: 249-251 (2003). Cf. also the commentary on this recommendation by Dieter HH (2003): Bundesgesundhbl-Gesundheitsforsch-Gesundheitsschutz 45: 245-248

[2] Regulation amending the German Drinking Water Regulation, BGBl 2001/I, 959-980 (Federal Gazette)

[3] Hereafter referred to as the "Drinking Water Commission"

[4] The HPV refers particularly to substances of the following origin: environmental contaminants that may easily expand into drinking water (supplies), and residues from materials in contact with "water for human consumption ('drinking water and 'water used in the food industry')" as specified in the German Drinking Water Regulation.

[5] The health-based guide value (GV) for a substance is the concentration in drinking water that is acceptable (cf. sections 3.2.1 and 3.2.2) or tolerable (cf. 3.1) for lifelong consumption (70 years), based on 1 to 2 litres of drinking water per day and age-dependent mean body mass.

For the small number of "highly" genotoxic substances that may easily expand into drinking water, we recommend limiting the HPV to a maximum exposure duration of 10 years (⇒section 3.2.2).

This recommendation is intended to provide guidance to public health authorities with responsibility for drinking water on a local or state (*Land*) level. It is designed to be an assessment aid to implementing the German Drinking Water Regulation and satisfies both the scientific evaluation criteria of human toxicology and the health criteria needed for preventive measures to protect human health from substances in drinking water for which an evaluation is not (yet) possible or only partially possible.

2. Purpose of this recommendation

If a water supply company becomes aware of contaminants in its raw or drinking water that have not to date been recorded, or for which a human toxicology-based evaluation is not possible or only partially possible, it must notify the competent public health authority of the name and concentration of the substance.

The public health authority establishes whether, despite the presence of a contaminant of this kind in the drinking water, there is still compliance with the requirements of Article 6 (1) German Drinking Water Regulation. The health-based parametric value (HPV) of this recommendation may be useful as an evaluation aid. There is compliance with the requirements if the actual concentration (C_{actual}) does not exceed the HPV ($\mathbf{C_{actual} \leq HPV}$).

If $\mathbf{C_{actual} > HPV}$, the public health authority instigates action to improve possibilities of assessing the human toxicology of the contaminant, in particular with regard to the following questions:

- Should the contaminant be assessed as genotoxic or not? (see section 3.2 below)
- If "yes:" how high (relatively and absolutely) is its genotoxic potential in drinking water? (see sections 3.2.1 and 3.2.2 below).

At the same time, it explores possible resource protection measures in conjunction with the water supply company and the authorities and institutions responsible for water management. These would include, for example, voluntary cooperative arrangements, requirements imposed by the authorities or proposing long-term legal provisions to:

- Reduce the contamination of the *raw water* by environmental contaminants that can pass into the drinking water/water treatment works, and/or
- Reduce/prevent pollution of *drinking water* by residues and contaminants from materials that come into contact with drinking water.

The short- to medium-term objective of the measures to be initiated by the public health authority is:

- Compliance with the health-based parametric value (HPV) described in this recommendation, *or*
- Compliance with a GV ≥ HPV which has been determined on a better data base and is correspondingly backed by better justification

for the substance in question.

As soon as it is foreseeable that *resource protection measures* will not make it possible within the time frame stipulated by the public health authority responsible at local or *Land* level to achieve compliance in drinking water with a toxicologically derived guide value for lifelong consumption that is tolerable or acceptable, appropriate technical measures must be introduced by the water supply company, such as additional treatment stages or improvements in the distribution network.

The water supply company can be expected to undertake *more extensive measures* to reduce concentrations of substances to values that are lower than that which is tolerable or acceptable in terms of health for lifelong consumption, provided that, as stipulated in the German Drinking Water Regulation, Article 6 (3) " the generally recognised state of the art makes them [the measures] possible with a reasonable level of expenditure, taking into account the circumstances of the individual case." (Minimization requirement).

3. Justification and practical guidance for the application of this recommendation

3.1 Applying the HPV to substances *with* an effect threshold: HPV tolerable for lifelong consumption without reservation.

Substances with an effect threshold are considered to be **non-genotoxic**. According to assessment experience available in the Federal Environmental Agency, which is also internationally supported, compliance with the HPV with virtual certainty provides lifelong protection from the toxic effects of those environmental contaminants and residues possibly present in drinking water that are not genotoxic and/or (necessarily) possess an effect threshold.

If the HPV is *exceeded* by a substance with an effect threshold, the Drinking Water Commission recommends initiating improvements to the data base for the questionable substance as soon as possible, so that it becomes possible to assess the human toxicity of the substance that is present *in situ* in the decisive concentration range which is higher than the HPV.

Guidance for the public health authority responsible at local or *Land* level
in evaluating the presence of non-genotoxic substances in drinking water at levels higher than the HPV:

Below is a list of indications for substances possibly present in drinking water at concentrations greater than 0.1 µg/l, which it is not possible or only partially possible to evaluate and which can be provisionally tolerated in health terms until the data base is complete.

In the Federal Environmental Agency, and also in the international literature, numerous assessments are documented of daily consumption levels for substances for which *complete* toxicological evaluation is possible. These assessments can be used to draw conclusions synoptically about the maximum levels tolerable for lifelong consumption in terms of health as a function of

- the health significance of the toxic endpoint, *and*
- whether there are gaps in the data base

for those substances possibly present in drinking water for which the database is patchy and likely to remain so for the foreseeable future. With increasing density of data (decreasing level of extrapolation factors for transposing patchy data to humans), the following maximum (safe) values (estimates) for health for lifelong consumption in drinking water can be expected:

- **≤ 0.3 µg/l:** the substance has been proven to be *non-genotoxic*, i.e. the *in vitro* data on genotoxicity and/or initiatory carcinogenic potential of the contaminant are predominantly negative, but otherwise there are no significant experimental toxicological data available;
- **≤ 1 µg/l:** the substance has been proven to be non-genotoxic (see above). In addition, there are significant in *vitro*- and *in vivo* data on the oral neurotoxicity and germ cell damaging potential of the contaminant. However, these data do not produce a value lower than 0.3 µg/l;
- **≤ 3 µg/l:** the substance is neither genotoxic, nor germ cell damaging nor neurotoxic (see above). In addition, there are significant *in vivo* data from at least one study on subchronic-oral toxicity of the contaminant. However, these data do not produce a value lower than 1 µg/l.

Alternatively, we recommend classifying the contaminant in the **entire range > 0.1 µg/l to ≤ 3 µg/l**, if scientifically robust information on the expected relationship between the structure and biochemical-toxicological potential of the contaminant is available ("structure/activity relationship").

Values > 3 µg/l can, from the health point of view, be tolerated for lifelong consumption without further review, if at least one chronic-oral study is available, on the grounds of which (almost) **complete** toxicological **evaluation** of the contaminant is possible and the evaluation does not produce a value lower than 3 µg/l.

However, indications of this kind for concentrations that can provisionally be tolerated in health terms for substances which it is not possible or only partially possible to evaluate, and which are present in drinking water at levels greater than HPV = 0.1 µg/l, should only be approved on a case-by-case basis. This approval should be granted on a nationwide basis by the Federal Environmental Agency.

3.2 Application of HPV to substances *without* an effect threshold (genotoxic substances)

Substances that do not have an effect threshold are considered to be **genotoxic**. For substances of this kind, it is not possible from a human toxicology point of view to give guide values that are tolerable in health terms, but only limit values that are acceptable in health terms, i.e. **risk-based guide values for health (GV).**[5]

As a rule, a risk-based GV for a genotoxic substance in drinking water reflects a socially acceptable, calculated additional risk (AR) of developing cancer as a result of lifelong consumption of the questionable substance in drinking water of up to $\mathbf{AR_{GV} = 10^{-6}}$. The scientific basis for calculations of this kind is either epidemiological data or (as a substitute) quantified structure-activity relationships or dose-incidence relationships.

3.2.1 Genotoxic substances, for which the HPV is acceptable in terms of health *for lifelong consumption without reservation*

In the opinion of the Drinking Water Commission of the Federal Environmental Agency of Germany, the HPV for substances that are both genotoxic and present in drinking water is only acceptable in health terms for lifelong consumption on the condition that the **GV ≥ HPV**.

If genotoxic substances, to which the condition GV ≥ HPV does not apply, are present in drinking water, the recommendations of section 3.2.2 should be followed.

3.2.2 Genotoxic substances, for which the HPV is *not acceptable* in terms of health *for lifelong consumption*

For a small number of "highly" genotoxic substances that can occur in raw water and thus also in drinking water, it is possible to calculate on a scientific basis guide values that are acceptable in health terms for lifelong consumption where GV < HPV.[6] Here, the Drinking Water Commission considers a risk-based GV of 0.01 µg/l as the (still) realistic lower limit of concentration.

According to the preamble to the German Drinking Water Regulation, the health requirement expressed in Article 6 (1) consists, on the one hand, of preventing occurrences where *damage* to human health is *sufficiently probable*. On the other hand, the "remedial action required to restore water quality," which, according to Article 9 (4), must also be taken to restore the requirement of Article 6 (1), aims at a drinking water quality which is acceptable in health terms *for lifelong consumption*.

For that reason, when assessing the presence of "highly" genotoxic substances, the HPV of this recommendation should be roughly equated in health terms with the risk-based *ten-year* action value AV_{10} stipulated in the parallel recommendation of the Drinking Water Commission: *"Action values (AV) for substances in drinking water given permissible deviations from limit values in accordance with Article 9, paragraph 6-8 of the German Drinking Water Regulation"*[7].

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6 The *risk-based* GV^5 = LV > HPV stipulated in the German Drinking Water Regulation as a limit value (LV) for *lifelong* exposure accepted by society, should comply with an additional lifetime risk of $AR_{GV} = AR_{LV} = 10^{-6}$ of developing cancer as a result of lifelong consumption of drinking water in the case of the following contaminants: acrylamide, benzene, 1.2-dichlorethane, vinyl chloride. For benzo(a)pyrene LV = GV < HPV, for 2.6-dinitrotoluene (et al.) a risk-based GV < HPV was also calculated. For bromate with its GV < LV the $AR_{LV} = 3 \cdot 10^{-5}$

7 Bundesgesundhbl-Gesundheitsforsch-Gesundheitsschutz 45: 707-710

According to this, the presence of "highly" genotoxic substances would – depending on their actual concentrations C_{actual} *lower than* the HPV – be acceptable in drinking water only for exposure durations that are *not lifelong*, but in the ratio C_{actual}/HPV arithmetically shorter than 70 years.

At the latest at the end of this period of time of less than 70 years, a "highly" genotoxic substance must no longer be detectable in drinking water at levels greater than its risk-based GV < HPV, as a result of the remedial action taken as prescribed in Article 9(4) German Drinking Water Regulation.