German Drinking Water Regulations, Pesticides, and Axiom of Concern

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ABSTRACT / The limit value of 0.1 µg/liter for "substances used in plant treatment and pest control including their main toxic degradation products" (PBSM) established in the German Drinking Water Regulations (Trinkwasserverordnung) serves comprehensively to protect drinking water from unexpected toxicological risks and thus corresponds to the axiom of concern (Besorgnisgrundsatz) contained in §11.2 of the Federal Communicable Diseases Control Act (Bundesseuchengesetz), which is an essential cornerstone of the Drinking Water Regulations. Furthermore, precautionary values that are specific to the particular substance and near the valid limit can be found for about 10% of all registered active substances. The goal of the PBSM Recommendations of the Federal Health Office (BGA) issued in July 1989 is to preserve and restore groundwater and drinking water through measures to be taken by the causal party, while reducing consumer health risks to the greatest extent possible. The EC commission's drawbacks on these recommendations and the imminent EC-wide directive for the uniform registration of pesticides being based solely on Article 43 of the European Treaty would seriously endanger this goal. Therefore, a situation threatens in Europe similar to that in the United States, where at least 18 active ingredients have been detected in groundwater in concentrations of up to 1000 times the toxicologically established limits for drinking water.

The basic purpose of any scientific consultatory and health-related precautionary policies is not to establish limits, but rather to reach a consensus concerning modes of procedure and technology aimed at preventing futile burdens for man and environment. This results in giving the examination of beneficial effects priority over assessing the risks connected with the implementation of such effects (Dieter 1989a).

Anyone can experience this sequence of priorities as commonplace. For example, the common type of advertising basically tries to convince the consumer of the products' benefits and not their risks. The complexity of the scientific as well as the psychological aspects to be considered in the context of making the risk-benefit discussions clear for society is reflected apparent in the article by Covello (1989). Something beneficial for one may be detrimental to others. I do not wish to become involved, either in my capacity as a toxicologist or as a drinking water hygienist, in a deep discussion of what the objective or case-related majority definition of "beneficial" is supposed to be. Fortunately, there is a consensus on the uselessness of pesticides in drinking water. In the context of the basic purpose of health policy, pesticides should be applied in such a manner that they do not gain access to groundwater from the utilized compartment, topsoil, because 70% of German drinking water consists of untreated groundwater.

A series of legal and technical agreements between the sectors involved (i.e., governments, agriculture, environmental hygiene, toxicology, equipment and application technology, manufacturers of plant protection products) are aimed at avoiding useless contamination of groundwater by products used in plant treatment and pest control (pesticides). I do not need to go into detail about these agreements here. The term, good agricultural practice, should be included among them, at least according to the World Health Organization (WHO 1987a).

The German Plant Protection Act also aims in the same direction by affording specific protection for groundwater, regardless of the use made of the top soil (Federal Republic of Germany 1986). This is why the limits specified in the Drinking Water Regulations (Federal Republic of Germany 1990) are applied to new registrations of pesticides. Since 1986, an essential registration criterion for pesticides is the limit of the Drinking Water Regulations for "products used in plant treatment and pest control and their main toxic degradation products" (PBSMs); the concentration of 0.10 µg/liter and the anticipated adherence to this value in groundwater beneath agriculturally utilized surface areas will be the most important environmental criterion for the authorization of pesticides.

KEY WORDS: Drinking water regulations; Pesticides; Germany; Axiom of concern

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Axiom of Concern

The axiom of concern (Besorgnisgrundsatz) is a legal provision in §11, 2 of the Federal Communicable Diseases Control Act from 18 December 1979 (Federal Republic of Germany 1979). This provision demands that the properties of drinking water be such that its consumption and use may not give rise to concern about damage of human health, especially through pathogenic agents, for which latter no exceptions at all are permitted.

The official reasons given for §11, 1 of the Federal Communicable Diseases Control Act from 1961 underline the term concern with the fact that drinking water must be of a quality that "excludes any damage to human health." The substantiation of the fourth amendment to the Federal Communicable Diseases Control Act from 1979 (§11, 2) expresses in the same context "that damage to human health be implausible."

The precautionary measures taken in adhering to this provision among PBSMs differ greatly from substance to substance, because PBSMs are a very heterogeneous class of substances when seen from a chemical, ecological, and toxicological point of view. To obtain the safety margin necessary for drinking water in protecting human health, we cannot directly apply the precautionary principles of environmental protection, as expressed for example in Article 130 r, Para. 2 of the EC Treaty (Einheitliche Europäische Akte 1986), but first §11, 2 of the Federal Communicable Diseases Control Act.

If one assumes that the demands established by the choice of the word excludes in the official substantiation of §11 from 1961 can only be fulfilled by the total absence of a substance that is possibly detrimental to health, a methodologically impracticable situation, then the official statement made in 1979 appears to be a thoroughly achievable objective from a toxicological point of view. However, this far exceeds the principles of determining the acceptable daily intakes (ADI values) that usually allow an uncertainty of $10 \times 10 = 100$ (Ohnesorge 1984, WHO 1990) in findings for noncarcinogenic substances for which "no observable effect levels" (NOELs) were obtained in animal testing.

The allocation of 1% or 10% of a respective ADI value to drinking water does not represent an additional safety factor of 10 or 100. Rather, it is only a very arbitrary attempt to take into consideration the burden on the consumers via various paths, which are hardly known in the single cases (WHO 1984, 1988). The following toxicological arguments should be included with respect to the special demands placed on the protection of drinking water that is legally established by the axiom of concern of the Federal Communicable Diseases Control Act.

1. The above-mentioned uncertainty in findings of 10 or 100 also can be correlated to even higher factors (Cothern and others 1986, Hayes 1987).

There are many examples that illustrate the existing differences within and between various experimental animal species with respect to pharmacokinetics and metabolism, which individually cover much larger areas than would be represented by the conventional factor of 10. Here, we can list the elimination half-life of 2,3,7,8-TCDD, for which the value in rats is only about 1/20 of that in humans (Pirkle and others 1989). Other examples are the metabolism of progesterone by the hepatic cytochrome P-450 of NZW rabbits (Dieter and Johnson 1982, Dieter and others 1982) or of debrisoquine by humans (Davies and others 1981).

The differences between individuals of the same species in these two cases cover factors of more than 100 and are genetically determined. As is the case with the majority of metabolic diseases, there are only a few individuals afflicted to such an extent. In a toxicological context, this emphasizes the precept of protecting the individual, which has its rudiments in ethics and constitutional law.

2. If a suspicion exists that the degradation and decomposition products of active substances stemming from anaerobic soil passage and oxidative treatment of drinking water are genotoxic, not having been recognized during the registration phase, the PBSM limits in the Drinking Water Regulations of 0.10 µg/liter acquire an explicit toxicological significance.

Available structure-activity relations cause the following substance classes to appear suspicious: chlorinated aromatic substances, chlorinated phenols, alkyl aniline and anilides, chlorinated anilines and anilides, nitro aromatic substances, unsaturated halogenated compounds and side chains (Dieter 1989b).

As an example, we should point out the numerous degradation products that form in open regions from herbicides containing dinitroaniline and from herbicides with phenylurea (Smith 1988). MCPA forms the metabolite, 2-methyl-4-chlorophenol, in open regions from chlorophenoxy herbicides. It has not yet been examined to what extent other herbicides of this class form chlorophenols in subsoil. Biochemical toxicology proves that there is a specific genotoxic and, therefore, also mutagenic or even carcinogenic potential for many