

RISK III

Health based and ecotoxicology based recommended exposure limits of dioxin-like substances in the Netherlands

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1. Background

The Core Programme on Priority Substances run by the Ministry of Housing, Spatial Planning and the Environment (VROM) is an essential element of government policy in dealing with the "most environment threatening substances". The aim of the policy is to limit the risk posed by these substances to public health and the structure and functions of ecosystems, at least to a maximum permitted level set by the government, and if possible below the "negligible" level.

The Minister of VROM has requested since 1985 that exposure limits proposed by the National Institute for Public Health and Environmental Protection (RIVM) be assessed by the Health Council. In the case of dioxin-like chemicals, the President of the Health Council of the Netherlands received a joint request to this effect from the Ministers of VROM and of Health, Welfare and Sport. He placed the request before the Committee on the Risk Evaluation of Substances, which was expanded for the study of this question to include experts on the properties and effect of dioxins¹⁾. In accordance with the Ministers' request, the Committee also studied the relevant scientific literature which had appeared after the publication of the RIVM Criteria Document on Dioxins in 1992.

The question whether dioxin-like substances have carcinogenic properties was investigated by the Health Council's Committee on Carcinogenic Risk Assessment, whose findings are included in the present report.

2. Effects and recommended exposure limits

Dioxin-like substances are frequently present in the environment in the form of mixtures of many polychlorinated dibenzo-p-dioxins (PCDDs), dibenzofurans (PCDFs) and the dioxin-like polychlorinated biphenyls (PCBs). Exposure to these compounds may have various adverse health effects, depending on the dose. A great deal of research has been done on the carcinogenic properties of these substances and their effects on reproduction and prenatal and postnatal development. These studies show that developmental effects are the first to be observed as a result of increased exposure, especially in the case of young infants. If exposure increases any further, the promotion of cancer can - after a certain level - no longer be excluded.

The toxic equivalent of a mixture

The effect of the various substances is rather diverse, but it is certain that the many dioxin-like substances act in a similar way on body cells. This finding, together with the fact that the chemicals in question frequently appear in mixtures of highly diverse composition, has led to the adoption of a group approach. One aspect of this approach, supported by the Committee, is the assignment of a toxic equivalency factor (TEF) to each dioxin-like substance. The TEF value expresses toxicity in relation to the most toxic substance of the group, 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD). The toxic equivalent (TEQ_{Total}) of a mixture of PCDDs, PCDFs and dioxin-like PCBs is determined by multiplying the concentration found for each individual compound by the relevant TEF value and adding up the resulting products.

The Committee deems the TEF concept to be applicable to the assessment and limitation of the risks associated with exposure to these substances by humans and by animals and ecosystems. Experimental data on fish and birds show that the TEFs for man, fish and birds can differ substantially. The Committee therefore believes that in estimating the ecotoxicological risk, TEFs other than those used for the toxicological evaluation for humans should be employed. The Committee supports the internationally agreed TEF values for humans; however, it believes that further research is needed before ecotoxicological TEFs can be used.

Humans

It is government policy to guarantee with reasonable certainty that an intake equal to the health based recommended exposure limit for a particular substance will have no adverse effect on the health of the exposed persons or their offspring. Concerning dioxin-like substances the Committee judges an "adverse effect" to be any observable change which immediately or in the longer term is harmful to an organism, as well as any adaptation or response by the organism to exposure to these chemicals which may not with reasonable certainty be regarded to be harmless.

On the basis of animal data, the Committee derives a recommended limit of human exposure to dioxin-like compounds of 1 picogramme of toxic equivalents per kilogramme of body weight per day. This value is lower by a factor of 10 than the figure recommended by the World Health Organization (WHO) and the RIVM. The Committee underpins its proposal with the results of other animal studies, some of which are more recent than those used by the WHO.

The Committee arrived at its proposed health based recommended exposure limit in the following way. Dioxin-like substances are not carcinogenic at low dose levels because they are not genotoxic, but at these intake levels there may be other adverse effects. For instance, changes have been observed in the cognitive development of Rhesus monkeys when the mother was exposed to approximately 100 picogrammes per kilogramme of body weight per day or more. The mothers developed endometriosis. In another study changes of the white blood cells of Marmoset monkeys were observed at a similar level of exposure. The Committee takes the 100 picogramme per kg. level to be the lowest level at which adverse effects have been observed.

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In order to derive a recommended exposure limit for humans from the reported animal studies, the Committee made use of extrapolation and safety factors. Using dose-effect ratios for effects on rats in the lower intake range, it derived an extrapolation factor from "lowest observed adverse effect level" to "no adverse effect level" of 2 for experimental animals. Application of this figure to the above data for monkeys thus gives a "no adverse effect level" of 50 picogrammes per kg. of body weight per day. The committee then selected a factor of 5 for extrapolation from monkey to man. Monkeys appear to be closer to man with regard to the distribution of PCDDs and PCDFs between the liver and fatty tissue than, for instance, rats. Thus, the Committee does not employ the usual factor of 10 for extrapolation from rat data. Differences in sensitivity between humans (intraspecies variation) are accounted for by applying the usual uncertainty factor of 10.

This reasoning leads to a figure of 1 picogramme per kg. of body weight per day as a public health recommended exposure limit for humans.

Ecosystems

Government policy is to fix an ecotoxicology based recommended limit at which 95% of the species in an ecosystem will not experience adverse effects from exposure to the substance. The Committee uses fixed extrapolation factors in deriving ecotoxicology based recommended limits, taking the data on 2,3,7,8-TCDD for a sensitive species as the basis.

For 2,3,7,8-TCDD in aquatic ecosystems, the Committee has derived a recommended limit of 0.1 picogrammes per litre of water and 13 000 picogrammes per kg. of sediment. In establishing these concentrations it took into account the possibility of accumulation of the chemical in the food chains and the consequences of that on birds and mammals.

The Committee proposes a recommended limit of 2000 picogrammes of 2,3,7,8-TCDD per kg. of dry material for terrestrial ecosystems. Here, too, it has taken accumulation in the food chain into account. It considered data on the common tern and the rat to be appropriate for this purpose. Both sets of data give the same recommended limit.

The recommended limits of 2,3,7,8-TCDD in aquatic ecosystems are in agreement with the limits proposed in the Criteria Document on Dioxins.

3. Comparison of exposure in the Netherlands with the recommended exposure limits

Humans

Most adults in the Netherlands are exposed to approximately 2 picogrammes of toxic equivalents of dioxin-like substances per kilogramme of body weight per day. In general, it may be stated that in excess of 90% of human exposure to PCDDs, PCDFs and dioxin-like PCBs derives from the consumption of animal fats, of which 50% are contained in milk and milk products. Infants are exposed to these substances before birth as well as through the maternal milk. Their exposure through the maternal milk, expressed per kilogramme of body weight, may thus be substantially higher than that of adults.

These exposure figures may be compared to the recommended limits proposed by the Committee. This leads to the conclusion that the possibility that the ingestion of dioxin and dioxin-like compounds causes adverse health effects in the Dutch population cannot be excluded with reasonable certainty. The Committee believes that it is supported in this

conclusion by the correspondences between the degree of prenatal and postnatal exposure to dioxin-like substances and differences in development found in studies of infants up to the age of 18 months. However, the findings of these Dutch studies gave no indication of development in infants outside what is considered to be the normal range. According to the Committee the best way to reduce the exposure of infants is to reduce the life-time exposure of mothers, in fact the exposure of the whole population. Limitation of breastfeeding is not the right way. It was already known and the recent studies confirmed that breastfeeding has a positive effect on the development of infants compared to the alternative formulafeeding. There is no reason to limit the freedom of parents to choose between breastfeeding and formulafeeding for their infant.

Ecosystems

The recommended limit of 2,3,7,8-TCDD in the sediment in aquatic ecosystems is exceeded locally. Particularly in the case of predators dependent on the aquatic environment, effects can be anticipated at current levels of exposure at certain locations. The process of bioaccumulation in the aquatic ecosystem which plays a role in this cannot be predicted with accuracy because of the presence of suspended and dissolved organic material and sediment which affects the availability of PCDDs, PCDFs and dioxin-like PCBs by binding them and releasing them again.

Concentrations of dioxin-like substances greater than the recommended exposure limit for terrestrial ecosystems also occur in the soil at certain locations. The Committee points out that increased binding causes the availability of dioxin-like substances to organisms to decline if these substances and sediment are in contact with each other for long periods. Owing to this "ageing" phenomenon, bioavailability in nature is in most cases lower than in laboratory experiments.

4. Conclusion

Given the current concentrations of dioxin-like substances in the Dutch environment, the recommended exposure limits for both humans and ecosystems are exceeded in many instances. The Committee judges this to be a matter for concern and believes that it constitutes an argument for further reduction of current concentrations, which are caused largely by human activities.

1) The Committee on the Risk Evaluation of Substances/Dioxins of the Health Council of The Netherlands consists of the following persons: LA Clarenburg (chairman), F Balk (BKH), M van den Berg (University of Utrecht), A Brouwer (Agricultural University of Wageningen), JCS Kleinjans (University of Limburg), AGAC Knaap (RIVM), JJ Kolk, WLAM de Kort (TNO), A Opperhuizen (RIKZ), PJJ Sauer (Sophia Childrens Hospital), DTHM Sijm (University of Utrecht), RMC Theelen (TAUW Infraconsult), P van der Torn (GGD Rotterdam), A Wijbenga (Province of Zuid-Holland), JA van Zorge (Ministry of Housing, Spatial Planning and the Environment), JW Dogger and JAG van de Wiel (executive secretary of the committee).