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SUMMARY REPORT

Consultation on Tolerable Daily Intake from Food of PCDDs and PCDFs

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EUR/HFA target 19

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TARGET 19

Monitoring, assessment and control of risks in the environment

By 1990, all Member States should have adequate machinery for the monitoring, assessment and control of environmental hazards which pose a threat to human health, including potentially toxic chemicals, radiation, harmful consumer goods and biological agents.

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DIOXINS

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FOOD CONTAMINATION - prevent/control

RISK FACTORS

Introduction

During the past several years, the WHO Regional Office for Europe has been dealing extensively with health risks emanating from exposure to PCDDs and PCDFs. Thus, it initiated a project that included activities to assess exposure levels and possible health risks in infants associated with contamination of breast-milk, and the development of guidelines to prevent accidental and environmental exposure to those chemicals. Within this project, numerous expert consultations and working groups have been organized by the Regional Office in collaboration with other international organizations and national institutions.

An attempt to assess the health risks in infants, based on an evaluation of available research data on exposure levels and on health effects of those chemicals, was made by a working group held in Abano Terme, Italy, in February 1987. While recommending further activities to produce information and collect data in infants, the meeting concluded that a safety margin still exists and recommended promotion and continuation of breastfeeding. Since that time, considerable new research data on exposure levels, health effects and toxicity of these chemicals have been published, and several national and international attempts have been made to develop a quantitative risk assessment.

The present Consultation was organized by the Regional Office in response to a recent request from the Ministry of Welfare, Health and Cultural Affairs of the Netherlands for assistance in setting a tolerable daily intake (TDI) of dioxins from food.

The purpose of the Consultation was to review the scientific evidence and, based on a comprehensive toxicological evaluation, to develop guidelines for tolerable daily intake of PCDDs and PCDFs. Its purpose was also to develop guidelines for risk management, with emphasis on the main sources of food contamination.

The Consultation was attended by 20 experts from 11 countries, one representative of the Netherlands Government, three observers and five staff from the Regional Office and WHO headquarters. Professor U. Ahlborg was elected Chairman, Professor A. Somogyi Vice-Chairman and Dr R. Kimbrough Rapporteur.

Conclusions and recommendations

Exposure

1. For the general population food represents the main route of exposure to PCDDs and PCDFs. The total average daily intake, at least in the industrialized countries, is assessed at 20 pg 2,3,7,8-TCDD/day/person (or 135 pg TEQ/day/person), or approximately 0.3 pg 2,3,7,8-TCDD/kg body weight/day (or 1.9 pg TEQ/kg body weight/day).

Tolerable daily intake

2. There are 135 PCDF and 75 PCDD isomers. The Consultation decided to develop guidelines for a tolerable daily intake based on an evaluation of human health risks of 2,3,7,8-tetrachlorodibenzodioxin (2,3,7,8-TCDD), which is the most studied and most toxic isomer in this mixture of chemicals. Since it is now possible to compare human data and tissue levels with animal data

and tissue levels, the Consultation used a new approach to assess the risk of 2,3,7,8-TCDD that greatly reduces the uncertainties introduced into risk assessments performed in the past.

3. The Consultation compared 2,3,7,8-TCDD tissue levels and health effects in laboratory animals and humans. It was concluded that 2,3,7,8-TCDD is carcinogenic in animals but that the evidence in humans is inconclusive, since for some populations with past high exposures the observation period has not been long enough. Since the compound is considered to be non-genotoxic and acts as a promoter-carcinogen, the Consultation decided to establish a TDI based on general toxicological effects. For pro-carcinogenic liver toxicity, reproductive effects and immunotoxicity tested in the various laboratory animal species, a no-effect level of 1000 pg/kg can be identified. By using kinetic data this can be shown to be equivalent to a dose of 100 pg/kg body weight/day in humans.

4. Because of the insufficient data based on reproductive effects in humans, an uncertainty factor of 10 was employed by the Consultation. Thus a TDI of 10 pg 2,3,7,8-TCDD/kg body weight/day was recommended.

5. It should be recognized that reproductive effects in humans are unlikely to occur at doses substantially different from doses causing other effects. As more data become available, it is likely that the uncertainty factor of 10 could be reduced.

6. Based primarily on short-term in vivo and in vitro studies, an international toxicity equivalence factor (I-TEF) has been developed to compare the presumed toxic effects of PCDD and PCDF isomers to the toxicity of 2,3,7,8-TCDD where more information is available. In making these comparisons, it is assumed that all PCDD and PCDF isomers given as a mixture are equally well absorbed, and that the toxic effects of the components in the mixture would be additive. However, such assumptions are simplistic and do not take into account toxicokinetic principles. Until adequate data are available, therefore, the I-TEF scheme should be used only as an interim approach for risk management purposes. Based on present information, it appears that the I-TEF approach may overestimate the risk.

Breastfeeding

7. The TDI of 10 pg 2,3,7,8-TCDD/kg body weight/day for the general population should not be applied to infants who are breastfed, since the TDI concept for these substances is based on a lifetime intake. In most countries breastfed infants between 0 and 6 months of age have an average daily intake estimated to be at about 13 pg 2,3,7,8-TCDD/kg body weight (or 90 pg TEQ/kg body weight). This exposure does not result in high concentrations in target organs or fatty tissues, and levels in tissues of breastfed infants are lower than in their respective mothers during the whole nursing period. It is estimated that the PCDD and PCDF intake during a six month nursing period corresponds to less than 5% of the lifetime intake.

8. No disease has been associated in infants with the levels of these chemicals now found in human milk. Whenever possible, however, exposure to these compounds must be minimized in order to reduce the accumulation of PCDDs and PCDFs in breastfed infants.

9. Lactating mothers should not intentionally try to lose weight. This practice may induce nutritional deficiencies in the mother and/or the infant.

Moreover, PCDDs and PCDFs might be mobilized from fat stores during excessive weight reduction and transferred to the infant via breast-milk.

Risk management of sources

10. It may be observed that the present exposure evaluation provides an estimate that is somewhat lower than the proposed TDI for 2,3,7,8-TCDD of 10 pg/kg body weight. However, since PCDDs and PCDFs are known to be without any use to humans and to persist in the environment so that their levels tend to increase as a result of continuous release, the Consultation considered that the introduction of these compounds into the environment should be reduced to the extent possible consistent with sound engineering practices judged to be reasonable. The following actions are therefore strongly recommended.

11. Incinerators. Because it is well documented that incinerators may emit significant amounts of dioxins and furans into the environment, it is recommended that these emissions should be reduced to levels as low as technically achievable (e.g. 0.1 ng TEQ/m³). This should be applied to all kinds of incinerators, including municipal solid waste incinerators. Special attention should be paid to fly ash so as to avoid contamination of the environment.

12. Metal industry. In several instances it has been demonstrated that metal producing and recycling industries emit high amounts of PCDDs and PCDFs. These emissions should be minimized by optimizing technical procedures and equipment.

13. Motor vehicles. Use of scavengers for leaded petrol results in the formation of considerable levels of halogenated dioxins and furans. It is therefore recommended that the use of leaded petrol should be phased out as soon as possible.

14. Sewage sludge. Since it is well known that the application of sewage sludge on pastures may lead to elevated levels of PCDDs and PCDFs in cows' milk, its use for this purpose should be banned. Moreover, it should be banned for all agricultural practices that may result in the bioaccumulation of PCDDs and PCDFs. The disposal of sludge should be done in such a manner as to prevent any introduction of PCDDs and PCDFs into the food chain.

15. Pulp and paper industries. PCDDs and PCDFs have been found in significant levels in association with chlorine-based bleaching processes. Other bleaching processes should therefore be adopted in order to minimize the presence of these contaminants in pulp and paper products and effluents and wastes. The aim should be to reduce the levels in paper products to below 1 ppt (ng/kg) TEQ (which has been shown to be feasible), so that migration into food in contact with these products is significantly reduced.

16. Pentachlorophenol. Pentachlorophenol (PCP) may contain considerable amounts of PCDDs and PCDFs. The widespread use of this chemical has resulted in broad contamination of the environment and direct exposure to human beings. Therefore, PCP production and use should be banned for such uses where safer substitutes are available.

17. Flame retardants. It is known from the literature that polybrominated dibenzodioxins and dibenzofurans are also of similar toxicity to the chlorinated ones. The use of brominated flame-retardants especially, as potential precursors, should be carefully reevaluated.

18. Other sources. Since the origin of a large fraction of PCDDs and PCDFs is not known, every effort should be made to identify other sources and contamination pathways in order to take appropriate measures.