codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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POSITION PAPER ON DIOXINS AND DIOXIN-LIKE PCBs, INCLUDING METHODS OF ANALYSIS FOR DIOXINS AND DIOXIN-LIKE PCBs

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 31 January 2002** as follows: Netherlands Codex Contact Point, Ministry of Agriculture, Nature Management and Fisheries, P.O. Box 20401, 2500 E.K., The Hague, The Netherlands (Telefax: +31.70.378.6141; E-mail: info@codexalimentarius.nl, with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: Codex@fao.org).

BACKGROUND

1. At the 31st and 32nd Session of the CCFAC the Netherlands presented a Discussion Paper on Dioxins. The paper described the risk assessment of polychlorinated dibenzo-p-dioxins (PCDDs) and dibenzofurans (PCDFs) (further referred to as 'dioxins') and dioxin-like PCBs. It summarised results from recent activities gathering information on the occurrence of dioxins and dioxin-like PCBs in the general environment and the possible health risks of exposure to these substances through consumption of foods.

2. The 32nd Session of the CCFAC decided that this Discussion Paper should be used as a basis for the elaboration of an additional Position Paper on Dioxins and Dioxin-like PCBs. This Position Paper should include:

- potential range of levels in the food products of interest (including feed stuffs),
- information on available methods of analyses and
- exploration of the arguments for and against setting maximum limits

3. At the 33rd Session of the CCFAC the additional Position Paper was presented. The paper also contained information on recent intake assessments and present regulations of some countries. The Committee agreed that the delegation of the Netherlands would revise the Position Paper on dioxins and dioxin-like PCBs, for circulation, comments and consideration at the 34th CCFAC Session, taking into account the comments and data received, as well as the results of the JECFA evaluation on dioxins and dioxin-like PCBs in June 2001. The Committee also requested governments to submit all available information on methods of analysis for dioxins and dioxin like PCBs in foods and feedingstuffs to the delegation of the Netherlands (ALINORM 01/12A, paras. 176-177).

INTRODUCTION

4. At recent CCFAC meetings the 'dioxin problem' has been discussed. Among the different Codex Member Nations there is general agreement on the necessity to develop and implement source directed measures with the aim of reducing dioxin contamination of foods. A Position Paper about this issue will also be presented at the 34th Session of the CCFAC. Other risk management options, such as the setting of MLs, are still under discussion.

5. The present paper is aimed at giving an overview of available information on occurrence, intake and analysis of dioxins and dioxin-like PCBs, and contributing to the discussion concerning the setting of MLs. Information is presented successively on the occurrence of dioxins an dioxin-like PCBs in feed, occurrence in food and dietary intake, the tolerable intake and comparison of the dietary intake with the PTMI, existing legislation in Codex Member Nations, and methods of analysis. The final chapter presents some points for discussion *(e.g.* the pros and cons of setting MLs) and outlines some proposals to CCFAC.

6. The source of the information presented here are the reports from SCOOP, SCAN, SCF and JECFA, in addition to information submitted by individual countries (The USA, Canada and New Zealand) and a recent study from the Netherlands. Wherever possible the comments received were implemented in the paper.

OCCURRENCE IN FEED

7. The Scientific Committee on Animal Nutrition (SCAN) of the European Commission has been asked to advise the European Commission on the sources of contamination of feedstuffs by dioxins and dioxin-like PCBs. This advice was published in November 2000.

8. The SCAN has obtained available published data and additional information from Member States and other sources about levels of dioxins in feedstuffs in the period of 1999 and 2000. Account has been taken of the environmental sources of pollution resulting in the background contamination of all feed materials and also of any contamination specifically introduced by production conditions, feed processing and during the transport and distribution of feed materials and feedstuffs.

9. Table I summarises the dioxin contents of the main feed materials established by the SCAN on the basis of the available data submitted by Member States to the European Commission or published, or referring to maximum permitted levels according to current European legislation. It includes the “low” and “high” levels identified, and the mean level fixed by the SCAN, as basis to estimate the total dioxin content of each species specific diet. As the database for dioxin-like PCBs is scarce, low, mean and high values were derived only for dioxins.

Table I. Dioxin contents of the basic feed materials evaluated by the SCAN from the available data (ng WHO-TEQ/kg dry matter (DM); PCDD/PCDFs only)

Feed materials	**Dioxin levels in feed materials (ng WHO-TEQ/kg DM)**		
	Low	**Mean**	**High**
Roughages	0.1	0.2	6.6
Cereals and seeds (Legumes)	0.01	0.1	0.4
By-products from cereals, seeds and sugar	0.02	0.1	0.7
Vegetable oil	0.1	0.2	1.5
Fish meal Pacific (Chili, Peru)	0.02	0.14	0.25
Fish meal Europe	0.04	1.2	5.6
Fish oil Pacific (Chili, Peru)	0.16	0.61	2.6
Fish oil Europe	0.7	4.8	20
Mixed animal fat	0.5	1	3.3
Meat and bone meal	0.1	0.2	0.5
Milk by-products	0.06	0.12	0.48
Soil	0.5	5	87
Binders, anti-caking agents and coagulants	0.1	0.2	0.5[#]
Trace elements, macrominerals	0.1	0.2	0.5
Premixes	0.02	0.2	0.5

#: according to Commission Regulation n°2439/99 of 17 November 1999

10. On the basis of the data in Table I, and using the percentage of the different feed ingredients in the diets, total contamination levels of typical diets have been calculated. The main conclusions of SCAN are:

- Fish meal and fish oil are the most heavily contaminated feed materials. Products of European fish stocks (respective means of 1.2 and 4.8ng I-TEQ/kg DM) are more heavily contaminated than those from South Pacific (Chile, Peru) stock (respective means 0.14 and 0.61ng I-TEQ/kg DM) by a factor eight.
- Animal fat (mean 1 ng I-TEQ/kg DM) is next in order of dioxins concentration. Values observed depend on the bio-accumulation of dioxins in fatty issues along the feed/food chain.
- All other feed materials of plant (roughages, cereals, legume seeds) and animal (milk by-products, meat and bone meal) origin contain mean concentrations of dioxins around or below 0.2ng I-TEQ/kg DM.
- Roughages present a very wide range of dioxin concentrations depending on location, degree of contamination with soil and exposure to sources of aerial pollution, justifying the use of a worst-case assumption in identifying relatively high mean and upper values.
- The limited data available on the contamination of feed materials by dioxin-like PCBs indicates that their inclusion would increase the TEQ value for feed materials of fish origin by a factor of five and that of other feed materials by a factor of two.
- The contribution of individual feed materials to dioxin content of the whole diet for farmed animals depends on the intrinsic degree of contamination and the proportion used in the diet. Greatest concerns arise from the use of fish meal and fish oil of European origin. These are most critical when used in diets for farmed fish and where fishmeal is incorporated in diets of other food-producing animals.
- The SCAN stresses that depending on the degree and position of chlorinating, the individual dioxins (congeners) exhibit different transfer rates, and that it is not scientifically correct to calculate transfer from feedstuffs to products of animal origin on a TEQ basis only. The exercise must consider the individual congeners.

Additional data from the Netherlands

11. In a series of 108 samples of various animal feed taken in 1998 and 1999 in the Dutch monitoring programme of feed, only 2 samples had a dioxin content above the level of 0.75 ng TEQ/kg (PCDDs and PCDFs).

OCCURRENCE IN FOOD AND DIETARY INTAKE

Sources of information and collection of the data

12. The studies and/or reports that form the basis of this chapter are listed below. It must be noted that in each study or evaluation considerable uncertainties can be identified, for example due to the limited amount of data, difference in sampling strategies, collection of consumption data and analytical methods, and the use of different TEF values. Specific information on these uncertainties can be found in the original reports and documents.

European Union

13. Information on the occurrence of PCDDs, PCDFs and dioxin-like PCBs in food in the European Union, as well as the dietary exposure to these compounds, has been obtained in Scientific Co-operation (EU SCOOP) Task 3.2.5 (SCOOP, 2000). The objectives of this specific task were to provide a scientific basis for the evaluation and management of risks to public health arising from exposure to dioxin and related compounds. Ten Member States participated in this SCOOP task, , *i.e.* Belgium, Denmark, Finland, France, Germany, Italy, The Netherlands, Norway, Sweden and the United Kingdom. The EU SCOOP database includes information on concentrations of dioxins and dioxin-like PCBs in samples of food products, taken from various sites, including rural and industrial sites, and collected in different years covering the period 1982 - 1999.

United States of America

14. The data submitted by the USA are from a market basket survey carried out by the U.S. Food and Drug Administration (FDA). Samples from dairy products and commercial fish and shellfish, collected in 1998 and 1999, were analysed for 17 dioxin/furan congeners (2,3,7,8-congeners). The food products were selected based on 1) the their potential to be dietary sources for dioxins and 2) their relatively high consumption (1987-1988 Nation-wide Food Consumption Survey, United States Department of Agriculture), and 3) their having been dietary sources of dioxin in the past.

Canada

15. Canada submitted information on dioxin-like compounds in market basket (total diet) food samples from 5 major cities, in the period 1992-1995. Data outlined below are mean values of the data from these 5 cities.

New Zealand

16. The New-Zealand ministry of for the Environment conducted a dietary study in 1995 with the objective to determine the level of PCDDs, PCDFs and PCBs contaminants in meat, dairy products and other key foods in the new Zealand market place, and to estimate the dietary intake for the New Zealand population of these compounds.

17. The sampling strategy for this survey was designed to assess the levels of PCDDs, PCDFs and PCBs in food products commonly eaten by New Zealanders and which are widely available through retail outlets nationally. The criteria for selection of foods for this dietary study were as follows:

- Foods found to be significant contributors to dietary exposure to PCDDs, PCDFs and PCBs from overseas surveys.
- Foods known to be significant sources of energy in the New Zealand diet
- Frequently consumed staple foods, some popular high fat foods such as 'take-away' foods, and foods such as livers and tinned fish which, while not so popular, might be important contributors to the dietary exposure to PCDDs, PCDFs and PCBs.

The Netherlands

18. A recent study carried out by the National Institute of Public Health and the Environment (RIVM) and the State Institute for Quality Control of Agricultural Products (RIKILT) was designed to obtain information on the occurrence and dietary intake of dioxins and dioxin-like PCBs at the end of the 20th century. The data for this assessment were extracted from two monitoring programmes carried out by RIVM and RIKILT in 1998/1999, where concentrations of dioxins (PCDDs and PCDFs) and dioxin-like PCBs (non-ortho PCBs and mono-ortho PCBs) were measured in Dutch primary agricultural products and in composite consumer food categories. Concentrations measured in consumer foods were combined with food consumption data to assess the dietary intake of dioxins and dioxin-like PCBs in the general population. Only part of the data generated in this study were incorporated in the SCOOP database since the PCB analyses were not finished yet at the time.

JECFA

19. JECFA made a compilation of submitted data on occurrence of dioxins and coplanar PCBs in different countries and regions and calculated the dietary intake in the different regions. In addition to the countries already mentioned in the Introduction, the JECFA report also contained data from Japan.

Occurrence of dioxins and dioxin-like PCBs in foodstuffs

20. A summary of the available information on the occurrence of dioxins and dioxin-like PCBs in several food groups are outlined below. Unless otherwise noted, the TEQ is calculated using the limit of detection (LOD) for the non-detects (ND).

Eggs

21. In Europe eggs are characterised by a rather consistent PCDD and PCDF presence, with means between 0.5 and 2.7 pg I-TEQ/g, lipid basis, and only a slightly higher value of the upper confidence limit. The USA reported a dioxin content of 0.29 pg WHO-TEQ/g product. Canada reported values of 0.044 pg TEQ (dioxins) and 0.029 ng TEQ (non-ortho PCBs)/kg whole weight (eggs: 10.10% lipid). Only a few studies give information on dioxin-like PCBs, the limited information shows PCB-TEQ contributions in the same range as for the I-TEQ. A recent study in the Netherlands shows a level of dioxin-like PCBs of 0.6 pg WHO TEQ/g, lipid basis (dioxin content of the same sample was 1.2 pg WHO TEQ/g fat). Limited data from the Netherlands, Belgium and Germany (SCOOP) show elevated levels of dioxins in biological or free-range eggs. Data from New-Zealand show dioxin content of 0.12 pg I-TEQ/g fat (ND=0.5LOD) and a PCB content of 0.11 pg PCB-TEQ/g fat (ND=0.5LOD).

Fish

22. Fish and fish-products form a most inhomogeneous food group, due to the large number of different species and geographical differences in the level of contamination of the various fishing grounds. The concentrations of dioxins and PCBs vary considerably. Many fish species contain dioxins and dioxin-like PCBs at a level below 1 pg I-TEQ/g and 1 pg PCB-TEQ/g wet weight respectively. In some fish species, such as crab, eel, and whitefish, higher concentrations can be found. In addition, fish caught in relatively polluted areas also have higher levels of dioxins and dioxin-like PCBs (SCOOP, 2000). Data from the USA (1998 and 1999) show concentrations of dioxins in crab, crawfish, lobster, pollack and scallops, varying from 0.033 - 0.53 pg WHO TEQ/g product. Canadian data show mean dioxin concentrations of 0.04 - 0.182 ng TEQ (dioxins)/g whole weight and 0.114 - 0.284 ng TEQ (non-ortho PCBs)/kg whole weight. In general, fish are more contaminated with PCBs than with dioxins, with a 2 tot 5-fold difference in general.
New Zealand collected data on fish fillets and deep fried fish, imported tinned fish and oysters and mussels. Dioxin content was highest in imported tinned fish (0.12 pg I-TEQ/g wet wt, ND=0.5LOD) and lowest in oysters and mussels (0.021 pg I-TEQ/g wet wt, ND=0.5LOD). PCB content was again highest in tinned fish (0.16 pg PCB-TEQ/g wet wt, ND=0.5LOD) and lowest in oysters and mussels (0.028 pg PCB-TEQ/g wet wt, ND=0.5LOD).

Meat

23. On average, poultry, beef and veal, and mutton contain dioxin levels in the range of 0.6 - 1 pg I-TEG/g, lipid basis (SCOOP 2000). For pork, most studies show levels below 0.4 pg I-TEQ/g, lipid basis, the estimated mean for pork meat being 0.3 pg I-TEQ/g, lipid basis. Game meat and liver present dioxin levels significantly higher than the other meat subgroups. No data on meat are available from the USA. Limited information on the occurrence of dioxin-like PCBs is available. The meat group taken as a whole yields confidence interval estimates of approximately 0.4-0.7 pg I-TEQ /g and 0.3-1.5 pg PCB-TEQ/g, both ranges expressed on a lipid basis. Canadian data on various kinds of meat show dioxin contents in the range of 0.023 (pork fresh) pg TEQ/g whole wt to 0.277 pg TEQ/g whole wt (beef ground). PCB contents (non-ortho's) vary between 0.004 pg TEQ/g whole wt and 0.058 pg TEQ/g whole wt (beef ground). New Zealand has collected data on various kinds meats and on processed meat products. The levels of dioxin and PCBs are generally lower than in European countries.

Milk and dairy products.

24. Recent surveys show national averages of 0.3-2.1 pg I-TEQ/g and 0.2-1.8 pg PCB-TEQ/g fat for dioxins and dioxin-like PCBs respectively (SCOOP 2000). The upper bound confidence limits are in the order of 1 pg I-TEQ/g, lipid basis, for dioxins and fall in the approximate range of 2-10 pg PCB-TEQ/g, lipid basis, for dioxin-like PCBs. The USA reported values of 0.32 pg WHO TEQ/g fat for cream and 0.56 pg WHO TEQ/g fat for cheese. New Zealand data on milk, cheese, butter and ice cream and yoghurt show contamination levels lower then mentioned above. Canada sampled various kinds of milk and other dairy products. The levels of dioxins and PCBs vary because the levels are expressed as pg TEQ/g whole weight.

Vegetables, fruits and cereals

25. The products of vegetable origin (fruit, vegetables and cereals with less than 2% fat,) exhibit very similar dioxin contamination levels, with mean concentrations in the order of 0.02-0.03 pg I-TEQ/g, whole food basis (SCOOP 2000).

26. Data from New Zealand show the following dioxin contents (ND=0.5LOD): potatoes and hot chips 0.016 pg I-TEQ/g wet wt, bread 0.0059 pg I-TEQ/g wet wt and cereals, cake, biscuits rice and spaghetti 0.0099 pg I-TEQ/g wet wt. The PCB contents are 0.0025 pg PCB-TEQ/g wet wt, 0.0040 pg PCB-TEQ/g wet wt and 0.0027 pg PCB-TEQ/g wet wt respectively.

Fats and oils

27. Many different types of fats and oils of either vegetable or animal origin are used in the food industry in the manufacturing of different food products. A few studies have been reported by the Netherlands, Sweden and the UK, providing national average estimates of the dioxin content of these fats and oils below 1 pg I-TEQ and PCB-TEQ/g oil. Raw fish oil usually contains high levels of dioxins and dioxin-like PCBs. As the Food Industry is using industrial refined fish oil, the levels of dioxin in these fish oils are substantial decreased. A Dutch survey of refined fish oils revealed TEQ contributions of non-ortho PCBs comparable to those found for dioxins, i.e. around 1pg TEQ/g fish oil. A UK survey for dioxins and dioxin-like PCBs in fish oil dietary supplements shows that the concentrations of non-ortho PCBs are generally higher than those of dioxins, and that both are generally in excess of 1 pg TEQ/g fish oil. New Zealand data show a dioxin content of vegetable fats and oils of 0.041 pg I-TEQ/g fat (ND=0.5LOD) and a PCB content of 0.016 pg PCB-TEQ/g fat (ND=0.5LOD).

JECFA

28. JECFA has compiled the data from Western Europe, Japan, North America and New Zealand and calculated the weighted mean and derived median of concentrations of PCDDs, PCDFs and coplanar PCBs (in pg TEQ/g whole food). The data can be found in Table 4 of the JECFA report.

General

29. Levels in foods have been found to show seasonal (e.g. higher concentrations in winter than in summer) and geographical variations (elevated levels in foods - such as milk - collected near waste incineration sites). For the various types of foods, variations in the concentrations up to a factor of ten have been reported to occur.

30. A decreasing trend in the concentration of dioxins in foods has been reported for a few countries. This decline is most obvious for consumer milk and some types of meat. The decreasing trend is illustrated in Table II which contains data from the Netherlands.

Table II. Comparison of concentrations in pooled samples from 1991 (Liem et al., 1991) and 1999. Levels are all expressed as pg I-TEQ /g fat. TEF factors applicable in 1991 were used.

Food category	PCDDs and PCDFs (I-TEQ)			non-ortho PCBs (WHO-TEQ)		
	1991	1999	Remainder (%)	1991	1999	Remainder (%)
Milk	1.5	0.5	33	1.3	0.6	44
Beef	1.8	0.7	41	2.4	1.0	41
Pig	0.4	0.2	49	0.2	0.1	61
Butter	1.8	0.6	33	2.1	0.8	38
Egg	2.0	1.2	59	2.3	0.6	24
Cheese	1.4	0.6	42	2.1	0.7	35

Dietary Intake

31. In the following chapter, the available information on the intake of dioxins an dioxin-like PCBs is summed up. The total intake of the population is addressed as well as the relative contribution of the different food groups to this intake.

The European Union

32. The information from the SCOOP report can be summarised as follows:

- For the period after 1995, the average dietary intakes of dioxins ranged between 0.4-1.5 pg I-TEQ/kg bw/day. For surveys based on chemical analyses of foods collected in the 1970s and 1980s, intakes were estimated to be higher, ranging from 1.7-5.2 pg I-TEQ/kg bw/day). The 95-percentile (or 97.5-percentile) intake, based on data from the Netherlands and United Kingdom was 2-3 times the mean intake.
- For the TEQ contribution of dioxin-like PCBs, the average intakes were 0.8-1.8 pg PCB-TEQ/kg bw/day. In studies investigating both dietary intakes of PCDDs/PCDFs and PCBs, the TEQ contribution of dioxin-like PCBs was estimated to be almost equal (e.g. Finland, Netherlands, Sweden, United Kingdom) to approximately four times (Norway) the TEQ contribution of the dioxins.
- The main contributors to the average daily intake of dioxins (I-TEQ) in the participating countries are milk and dairy products (contributions ranged from 16-39%), meat and meat products (6-32%) and fish and fish products (11-63%). Other products, mainly of plant origin such as vegetables, cereals, contributed some 6-26% in those countries for which data were available.
- As to the above point, it should be noted that the relative contribution of the food groups to the total intake of I-TEQ differed from country to country. These differences may result from different food consumption habits in the participating countries. On the other hand, other factors may also be involved. These include factors related to the applied sampling strategy (e.g. differences in the coverage of products collected to represent the whole food group) and the large variations in concentrations of dioxin related substances in some of the food groups (e.g. vegetables and fruits, eggs and fish).
- In most countries, young children will have a higher intake per kg body weight than adults. This is especially true during the breast-feeding period as concentrations of dioxins in mother's milk are higher than in most foods. On a body weight basis, the intake of breast-fed infants has been estimated to be 1 to 2 orders of magnitude higher than the average adult intake. For young children exposed to dioxins via food the intake is about twice the intake of adults per kg bodyweight.

Canada

33. Using mean TEQs from 5 cities and food daily intakes, the mean intake of PCDDs, PCDFs and non-ortho PCBs was calculated. The mean intake of dioxins PCDDs and PCDFs was 0.8017 pg TEQ/kg bw/day, of the PCBs 0.2537 pg TEQ/kg bw/day, and the mean total TEQ intake was estimated to be 1.0554 pg/kg bw/day. Dairy products and meat were the main contributors to the total TEQ intake.

New Zealand

34. The Ministry for the Environment has estimated the dietary intake of PCDDs, PCDFs and dioxin-like PCBs in 1997 for two population groups:

- adult male: 80 kg, 10.8 MJ/day diet, median energy (50th percentile) intake
- adolescent male, 70 kg, 21.5 MJ/day diet, high energy (90th percentile) intake.

35. The dietary intake of PCDDs and PCDFs for an adult male was 0.18 pg I-TEQ/kg bw/day (ND = 0.5LOD) and for an adolescent male 0.44 pg I-TEQ/kg bw/day. For the PCBs (23 PCB congeners) the intake was estimated at 0.15 pg WHO TEQ/kg bw/day for an adult male and 0.32 pg WHO TEQ/kg bw/day for an adolescent male (ND = 0.5LOD).

36. For an adult male, the main contributor to the intake of PCDDs and PCDFs was meat (35%), followed by dairy (19%), fish (17%), other (13%), cereals (11%) and poultry (5%). For the adolescent male the contribution of the different food groups to dioxin intake follow the same pattern, except for the category 'other', which is the main contributor in this case (29%).

37. With respect to the intake of the dioxin-like PCBs the pattern of contributions of the different food groups to the total intake is similar to that of the intake of dioxins. Meat is the highest contributor (43%) followed by dairy (25%), fish (13%), cereals (8%), other (6%)and poultry (5%). For an adolescent young male, fish is a major contributor to the intake of dioxin-like PCBs (24%). Meat and dairy contribute both 28%.

The Netherlands

38. In the recent study carried out in the Netherlands RIVM and RIKILT estimated the median, average and 90th percentile of lifelong averaged intakes of dioxins and dioxin-like PCBs (Table III) in 1998/1999.

Table III. Estimated median, average and 90th percentile in the distribution of lifelong-averaged (1-70 yrs) intakes (pg WHO-TEQ/ kg bw/day) of dioxins (PCDDs and PCDFs) and dioxin-like PCBs.

Contaminant	Median (pg/kg bw/day)	Average (pg/kg bw/day)	90th percentile (pg/kg bw/day)
dioxins	0.65	0.69	1.0
non-ortho PCBs	0.43	0.47	0.70
mono-ortho PCBs	0.14	0.15	0.22
Σ PCBs	0.58	0.62	0.93
Σ dioxins, PCBs	1.2	1.3	1.9

39. Tables IV and V specify the contribution of the different food groups to the intake of dioxins and dioxin-like PCBs respectively for the period of 1991 and 1999.

Table IV. Contribution of food groups to the total intake of dioxins (PCDDs and PCDFs) in the Dutch population in 1990/91 and 1999. The absolute average values are expressed per person (pg WHO-TEQ/day). The 1990/91 data were corrected for exclusion of vegetables.

Food group	Contribution to total intake (%)			
	1990/91		1998/99	
	pg /day	%	pg/day	%
Animal products	20	25	9.2	21
Dairy products	35	43	11	24
Fish	5.5	6.7	4.3	9.6
Eggs	3.5	4.4	2.2	4.9
Vegetable products	9.2	11	9.3	21
Industrial oils and fats	7.7	9.5	9.0	20
Total	81	100	45	100

Table V. Contribution of main food groups to the intake of non-ortho PCBs in the Dutch population in 1990/91 and 1998/99. The absolute average values are expressed per person (pg WHO-TEQ/day). The 1990/91 data were corrected for exclusion of vegetables.

Food group	Contribution to total intake (%)			
	1990/91		1998/99	
	pg/day	%	pg/day	%
Animal products	16	18	7.7	23
Dairy products	39	44	11	34
Fish	11	13	7.1	21
Eggs	3.6	4.1	0.6	1.9
Vegetable products	5.4	6.1	1.9	5.6
Industrial oils and fats	13	15	5.1	15
Total	88	100	34	100

JECFA

40. Using the GEMS/Food regional diets, JECFA concluded that the estimated intake of TEQ's for PCDDs and PCDFs is in the range of 7-68 pg/kg bw per month at the median, and 15-160 pg/kg bw per month a the 90th percentile of mean lifetime exposure. For co-planar PCBs these estimates are 7 -57 pg/kg bw per month at the median and 190-150 pg/kg bw per month at the 90th percentile of consumption. The intake estimates from national food consumption surveys were lower, namely 33-42 pg/kg per month at the median and 81-100 pg/kg bw per month at the 90th percentile for PCDDs and PCDFs. For the co-planar PCBs these intake estimates are 9-47 pg/kg bw per month and 25-130 pg/kg bw per month respectively. Estimates could not be made for the sum of PCDDs, PCDFs, and co-planar PCBs because data on concentrations were submitted separately by countries.

Trend

41. In some countries the intake of dioxins has decreased in the recent past (SCOOP 2000). The data from the Netherlands illustrate this (Table VI and V). The intake of dioxins and dioxin-like PCBs has decreased with roughly 50 % in the last decade of the 20th century.

TOLERABLE INTAKE AND COMPARISON OF THE DIETARY INTAKE WITH THE PTMI

Tolerable intake

42. In May 1998, a consultation convened by the WHO-ECEH and IPCS evaluated available information on the toxicology of dioxins and dioxin-like PCBs, and derived a tolerable daily intake (TDI) range of 1-4 pg TEQs/kg body weight for dioxins and dioxin-like PCBs. The TDI was based upon effects (LOAELs) in experimental animals, namely endometriosis, developmental neurobehavioural and developmental reproductive effects, and immunotoxicity.

43. The Scientific Committee on Food (SCF) of the European Commission has re-evaluated the toxicity of dioxins and dioxin-like PCBs in November 2000. Their evaluation was based on the WHO evaluation of 1998 and an expanded database containing studies published since then. For 2,3,7,8,-TCDD and related compounds, such as other dioxins and dioxin-like PCBs that have long half-lives in the human body, the SCF found it more appropriate to establish a temporary tolerable weekly intake (t-TWI) instead of a tolerable daily intake (TDI). The SCF established a group t-TWI of 7 pg WHO TEQ/kg bw for dioxins and the dioxin-like PCBs. On the basis of new scientific information the SCF updated the evaluation in May 2001. The SCF concluded that 14 pg WHO-TEQ/kg bw/week should be considered as the tolerable intake, based on a LOAEL for developmental effects in male rat offspring.

44. In June 2001 the Joint FAO/WHO Expert Committee on Food Additives (JECFA) derived a Provisional Tolerable Monthly Intake (PTMI) of 70 pg WHO TEQ/kg for dioxins, and dioxin-like PCBs. It is based upon the lowest LOAEL and a NOAEL for developmental effects in male rat offspring.

45. The U.S. Environmental Protection Agency (EPA) released a draft review of health aspects of 2,3,7,8-tetrachlorodibenzodioxin (TCDD) in 1999. It was concluded that the margin of exposure between background levels in terms of TEQs, and levels where non-cancer effects are detectable in humans is small. With regard to carcinogenicity, the evaluation of cancer potency has resulted in a upper bound risk-specific dose estimate (risk of one additional cancer in one million exposed) of approximately 0.01 pg TEQ/kg body weight/day.

Dietary intake in relation to the PTMI

46. The median intakes estimated by JECFA using national food consumption surveys are 33 to 42 pg/kg/month for dioxins and furans, and 9 to 47 pg/kg/month for coplanar PCBs. The PTMI of 70 pg/kg/month derived by JECFA is based on total TEQ exposure, e.g. dioxins, furans and dioxin-like PCBs together. Therefore it is possible that in some countries or regions, the lifelong median intake will exceed the TDI. This certainly holds true for the consumers in the upper part of the intake distribution, since the 90th

percentile of the lifelong mean intake is estimated be 81 to 100 pg/kg/month for dioxins and furans, and 25 to 130 pg/kg/month for coplanar PCBs. Based on the uncertainties in the derivation of the TDI the JECFA meeting concluded that long term intake slightly above the PTMI will not necessarily result in adverse health effects but would erode the safety factor build in the PTMI.

47. Given the average dietary intakes of dioxins and dioxin-like PCBs in the European countries of 1.2 - 3 pg TEQ/kg bw/day, a proportion of the European population would still exceed the PTMI derived by JECFA or the PTWI derived by the SCF.

48. The Dutch intake study shows that the PTWI of 14 pg/kg bw per week established by the SCF is exceeded by 8% of the Dutch population. In New Zealand the estimated intake is below the 1 pg TEQ/kg bw/day for the majority of the general population.

PRESENT REGULATION IN CODEX MEMBER NATIONS

49. Present legislation ((provisional) legal standards, action limits or recommendations) in some Codex Member Nations is outlined in Table VI.

Table VI. (Provisional) Legal limits or action limits for dioxins in foods in various Codex Member Nations.

Country	Foodstuffs of animal origin
Austria	Provisional limits: Pork 2, milk 3, poultry and eggs 5 and beef 6 pg WHO-TEQ(dioxins)/g fat
Belgium	• Milk, bovine, poultry, animal fats and oils, eggs and derived products, if >2% fat: 5 pg WHO-TEQ (PCDD/PCDF)/g fat. • Pork and derived products, if >2% fat: 3 pg WHO-TEQ (PCDD/PCDF)/g fat.
France	Milk and dairy products : 5 pg/g fat
Germany	Recommendations for milk and dairy products in pg I-TEQ/g milk fat: • < 0.9 (desirable target) • >3.0 (identification of sources; measures to reduce input; recommendations for land use; recommendation to stop direct supply of milk products to consumers) • > 5.0 (ban on trade of contaminated milk products)
Luxembourg	Recommended: Pork 2, beef 6 poultry 5, milk 3 and eggs 5 pg (dioxins)/g fat
Spain	Levels > 5 pg (dioxins)/g fat are considered as non-acceptable in dairy products
The Netherlands	• Milk, bovine (excluding kidney and liver), poultry (excluding kidney and liver), animal fats and oils, eggs and derived products, if >2% fat: 5 pg WHO-TEQ (PCDD/PCDF)/g fat. • Pork and derived products, if >2% fat: 3 pg WHO-TEQ (PCDD/PCDF)/g fat. • Eel: 8 pg WHOTEQ (PCDD/PCDF)/g eel • Milk and derived products with < 2% fat: 120 pg TEQ (PCDD/PCDF)/kg foodstuff.
United Kingdom	Guideline for cows' milk: 0.66 ng WHO-TEQ/kg whole milk (16.6 ng WHO-TEQ/kg fat) (NB: for dioxins and dioxin-like PCBs together!)
Republic of Korea	Beef, pork, chicken meats and eggs: 5 pg WHO PCDD/F TEQ/g fat. (NB: Levels are applied on a temporary basis until reliable scientific evidence is obtained)

50. The European Council has recently adopted a strategy to reduce the presence of dioxins and PCBs in environment, food and feed. As part of this strategy, maximum levels for dioxins in food and feed have been adopted (Table VII). The MLs for food will come into effect on July 1st 2002, and will be reviewed in 2004 in light of new data on the presence of dioxins and dioxin-like PCBs in food. Dioxin-like PCBs will then be included in the levels to be set. The MLs will again be reviewed by 31 December 2006 with the aim of significantly reducing the MLs. The MLs are not applicable for food products containing <1 %fat.
As of January 1st, 2002 MLs for dioxins in feedingstuffs (Table VIII) have to be implemented in the legislation of the EU Member States.

Table VII. Maximum levels in food in the EU which will apply as of July 1st 2002.

Product	Maximum level[1]
Meat and meat products originating from:	
- ruminants (bovine animals,sheep)	3 pg WHO-PCDD/F-TEQ/g fat
- poultry and farmed game	2 pg WHO-PCDD/F-TEQ/g fat
- pigs	1 pg WHO-PCDD/F-TEQ/g fat
Liver and derived products	6 pg WHO-PCDD/F-TEQ/g fat
Muscle meat of fish and fishery products and products thereof	4 pg WHO-PCDD/F-TEQ/g fresh weight
Milk and milk products, including butter fat	3 pg WHO-PCDD/F-TEQ/g fat
Hen eggs and egg products[2]	3 pg WHO-PCDD/F-TEQ/g fat
Oils and fats:	
Animal fat from:	
- ruminants	3 pg WHO-PCDD/F-TEQ/g fat
- poultry and farmed game	2 pg WHO-PCDD/F-TEQ/g fat
- pigs	1 pg WHO-PCDD/F-TEQ/g fat
- mixed animal fat	2 pg WHO-PCDD/F-TEQ/g fat
Vegetable oil	0.75 pg WHO-PCDD/F-TEQ/g fat
Fish oil intended for human consumption	2 pg WHO-PCDD/F-TEQ/g fat

[1]Upperbound concentrations: upperbound concentrations are calculated assuming that all values of the different congeners less than the limit of determination are equal to the limit of determination.
[2] Free-range or semi-intensive eggs must comply with the maximum level laid down as from 1 January 2004.

Table VIII. Maximum levels in feed in the EU.

Product	Maximum level[1]
All feed materials of plant origin including vegetable oils and by-products	0.75 ng WHO-PCDD/F-TEQ//kg
Minerals	1.0 ng WHO-PCDD/F-TEQ//kg
Animal fat, including milk fat and egg fat	2.0 ng WHO-PCDD/F-TEQ//kg
Other land animal products including milk and milk products and eggs and egg products.	0.75 ng WHO-PCDD/F-TEQ//kg
Fish oil	6 ng WHO-PCDD/F-TEQ//kg
Fish, other aquatic animals, their products and by-products with the exception of fish oil	1.25 ng WHO-PCDD/F-TEQ//kg
Compound feedingstuffs, with the exception of feedingstuffs for fur animals and feedingstuff for fish.	0.75 ng WHO-PCDD/F-TEQ//kg
Feedingstuffs for fish	2.25 ng WHO-PCDD/F-TEQ//kg

[1]Upperbound concentrations: upperbound concentrations are calculated assuming that all values of the different congeners less than the limit of determination are equal to the limit of determination.

METHODS OF ANALYSIS

51. The European Commission is preparing a document laying down the sampling methods and methods of analysis for the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs. The basis of this document is to define performance criteria, rather then prescribe mandatory tests.

GC/MS analysis

52. The analytical method for dioxins and planar PCBs is based on an extensive clean up followed by the use of a high-resolution mass spectrometer. Following isolation of fat, the dioxins are purified by combinations of gel permeation chromatography, acid/base silica, aluminium oxide or activated carbon. Labelled standards are added to compensate for recovery losses and quantification (isotope dilution).

53. High resolution gas chromatography in combination with high-resolution mass spectrometry is used for the separation and identification of the 17 dioxin and 4 non-ortho PCB congeners. Mono-ortho PCBs can be analysed on a low resolution mass-spectrometer. Several international ring-trials have been performed for the dioxin analysis. The results have demonstrated that the variations of the chemical analysis of dioxins do not deviate from the analysis of most other chemical compounds.

54. For dibenzo-(p)-dioxins and -furans, and dioxin-like PCBs in foodstuffs detectable quantities have to be in the picogram (10^{-12} g) range.

55. It is advised by the European Commission to report the analytical results of the various congeners individually, in addition to the total concentration in TEQs. The total dioxin content is calculated by multiplication of the levels of individual congeners with their corresponding TEF values, and summarisation to yield a total TEQ-level. According to the European Commission, for non quantified congeners both the concept of "upperbound ", "mediumbound", and "lowerbound" levels should be used to calculate the total of TEQs, as this provides information about the uncertainty of the data due to the different detection limits of the various congeners.

Alternative methods for dioxin analysis

56. Because of the relatively high costs and low sample throughput of the GC/MS analysis, several alternative methods have been developed.

57. Immunoassays have been developed for this purpose, but at present their limited sensitivity does not allow their use for food samples. More promising is the use of bioassays, which are based on the detection of dioxin (-like) compounds by the effects that underlay their toxicity. As a result, the tests detect total TEQ rather than individual congeners. Since some other non dioxin-like compounds are capable of binding to the Ah-receptor, a clean-up procedure (e.g. acid silica) is required to increase the specificity. These bioassays can be used as a rapid screening-method. Positive samples may then require confirmation by the GC/MS reference method.

58. Within the European Union different alternative screenings-methods are being validated at the moment. Inter-laboratory comparison studies should be conducted.

59. The CALUX bioassay is validated for the analysis of dioxins and dioxin-like PCBs in feed and food. A negligible chance of false negative samples has been demonstrated for feed, in comparison with results of the GC/MS analysis. For food data available data indicate less than 1 % false negative samples. The percentage false positives varies, as different non dioxin related compounds are known to interact with the CALUX assay.

POINTS FOR DISCUSSION AND RECOMMENDATIONS

60. Dioxins and dioxin-like PCBs are persistent environmental contaminants. The major sources are industrial activities, like incinerating processes. The residues in the environment accumulate in the food chain, and humans and animals are exposed to these residues via foods and animal feed.

61. In this position paper analytical data and dietary intakes of dioxins and dioxin-like PCBs in food products and feedstuff of various Codex Member Nations are summarised. Data from many countries are still not available. Especially for developing countries such data are hard to obtain, due to the high costs and technical difficulties. Nevertheless, the available data show that in many countries, a proportion of the population still exceeds the PTMI of 70 pg TEQ/kg bw/month derived by JECFA. If CCFAC decides that the intake of dioxins should be reduced, it should decide on the measures to be taken to reduce the intake sufficiently.

62. Several risk management options have been discussed previously at CCFAC meetings. The need for source directed measures was generally acknowledged at the last CCFAC meeting. Source directed measures like control of incinerating processes can be an effective means to decrease the emissions of dioxins into the environment, as already has been demonstrated in different countries. However, the decision on implementing this kind of source directed measures lies outside the scope of the CCFAC. With respect to the reduction of the dioxin contamination of food, a position paper will be presented at the present CCFAC meeting.

63. Part of the dioxin incidents in the past have been the consequence of contamination of animal feed. Therefore, setting maximum limits for animal feed is an effective way to control unwanted human exposure.

64. Another risk management tool is the setting of maximum limits (MLs) for foodstuffs, which has been the subject of debate at the CCFAC meetings in the recent past. The following arguments have been used against and for the setting of MLs:

Arguments against the setting of MLs:

1. Setting of MLs does not lead to a significant reduction of intake, unless the levels are set on the basis of maximally acceptable exposure levels.
2. The enforcement of the limits requires reliable monitoring and controlling programs. The initiation and implementation of these programs are costly and time consuming. Furthermore, the required technical expertise is not available in all Codex Member Nations.
3. Following from 1. and 2. is the discussion on risk-benefit analysis: Does the cost of the enforcement of MLs outweigh the benefits of the setting of MLs?
4. The lack of sufficient data on which to base the limits, especially concerning dioxin-like PCBs.
5. If maximum limits are set by the CCFAC, it can be expected that certain food products from certain countries will not comply with the MLs, and therefore should be rejected. This might have serious economical consequences.

Arguments for the setting of MLs:

1. MLs can protect consumers from acute high exposures through consumption of contaminated foodstuffs. Unacceptably high exposures of individuals to dioxins can occur from the consumption of highly contaminated food items from different sources, like the contamination of milk fat in the vicinity of incinerators, and the contamination of milk, bovine and poultry meat through contaminated feed. The number of exposed individuals and the extension of contamination depends on the magnitude of the contamination, the distribution and the trade of the contaminated products. Maximum limits are a useful tool to prevent such high exposure of consumers and to prevent the distribution of contaminated products.
2. MLs in food (and feed) will stimulate and support all involved parties (feed- and food industry, environmental authorities, incinerators and other emission sources) to take steps or continue efforts towards a decrease of emissions of dioxins into the environment, and to control the levels of dioxins in feed and food. In this way, MLs will contribute to the reduction of intake in the long term.
3. MLs are a legal instrument to exclude heavily contaminated foodstuffs from the market, in this way creating transparency for the consumer and industry. Food Safety and Consumer concern about contaminants is in many countries an important issue. Consumers need to have confidence in the safety of their

food and need transparent information. Setting maximum limits is a legal instrument for creating this transparency. The competent authorities and the industry can assure the consumers and other competent authorities that their food products are safe, i.e., comply with the maximum limits.

4. Maximum limits and results of analysis, which indicate that the maximum level is not exceeded, can serve to prevent trade barriers and extra superfluous costs at the beginning and during the course of incidents with dioxins. Experiences with the dioxin contamination of Belgian poultry in 1999 showed that many countries over the whole world closed their borders for Belgian and Dutch products. This was due to a lack of confidence and transparency in the manner in which the Belgian and Dutch authorities and industry handled the problem and a lack of confidence in the measures taken in the absence of maximum levels. The existence of maximum levels could have prevented these problems, since the authorities could have shown in an early stage of the incident, which food products were safe and which should be withdrawn from the market.
5. MLs may contribute to the reduction of the long-term intake of frequent consumers of products containing potentially high levels of dioxins.

Recommendations to CCFAC

65. In conclusion, the Dutch delegation proposes to the CCFAC the following:

1. That CCFAC decides whether or not the present intake is acceptable in terms of health risk, or if the intake should be reduced to below the PTMI.
2. If CCFAC decides that a reduction of exposure is necessary, that CCFAC then discusses what the goals are for the long term, in terms of reduction of exposure of the general population to PCDDs, PCDFs and PCBs through foodstuffs.
3. That CCFAC, as a next step, develops a strategy on how these goals can be reached (source directed measures, ML's in food and feed, action levels, target levels, etc).
4. That CCFAC, as part of this strategy, seriously considers the setting of ML's for foodstuffs, preferably for dioxins and dioxin-like PCBs but at least for dioxins.
5. That CCFAC discusses the feasibility of setting up a monitoring system, in order to obtain the necessary information needed for the implementation and/or evaluation of the risk management measures.

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