

Medlemmerne af Folketingets Europaudvalg
og deres stedfortrædere

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Til underretning for Folketingets Europaudvalg vedlægges Fødevareministeriets grundnotat om forslag til Kommissionens forordning om ændring af Kommissionens forordning (EF) 466/2001 af 8. marts 2001 om fastsættelse af grænseværdier for bestemte forurenende stoffer i levnedsmidler og udkast til Kommissionens henstilling til reduktion af indholdet af dioxiner i fødevarer, dokument SANCO/0384/01-rev2 og SANCO/0385/01-rev2.<>

Ministeriet for Fødevarer, Landbrug og Fiskeri

om forslag til Kommissionens forordning om ændring af Kommissionens forordning (EF) 466/2001 af 8. marts 2001 om fastsættelse af grænseværdier for bestemte forurenende stoffer i levnedsmidler og udkast til Kommissionens henstilling til reduktion af indholdet af dioxiner i fødevarer

Dokument SANCO/0384/01-rev2 og SANCO/0385/01-rev2.

Resumé

Forslaget vedrører fastsættelse af maksimalgrænseværdier i fødevarer samt en henstilling til fastsættelse af aktionsgrænser for dioxin med henblik på en reduktion af dioxiner og PCB i fødevarer. Forslaget er baseret på risikovurdering foretaget af Den Videnskabelige Komité for Levnedsmidler den 22. november 2000 af dioxin og dioxinlignende PCB i fødevarer.

Der kan ikke ud fra den begrænsede viden om indholdet af dioxin i fødevarer på det danske marked vurderes, om de foreslåede maksimalgrænseværdier øger beskyttelsesniveauet.

Baggrund

Kommissionen har den 27. juni 2001 fremsendt reviderede arbejdsdokumenter med forslag til Kommissionens forordning om ændring af Kommissionens forordning (EF) 466/2001 af 8. marts 2001 om fastsættelse af grænseværdier for bestemte forurenende stoffer i levnedsmidler samt udkast til Kommissionens henstilling til fastsættelse af aktionsgrænser for dioxin i fødevarer med henblik på reduktion af dioxiner og PCB i fødevarer.

Da forslagene foreligger som arbejdsdokumenter, må det forventes, at der kan ske ændringer i de omfattede produkter samt grænseværdiernes størrelse.

Forslaget til Kommissionens forordning er fremsat med hjemmel i Rådets forordning (EØF) nr. 315/93 af 8. februar 1993 om fastsættelse af fællesskabsprocedurer for forureninger i fødevarer, særligt artikel 2. Udkastet til Kommissionens henstilling om reduktion af dioxiner og PCB i

fødevarer har hjemmel i Traktatens artikel 211, hvorefter Kommissionen kan rette henstillinger og afgive udtalelser om de i traktatens omhandlede forhold.

Forslaget til forordning behandles i en III b-procedure i Den Stående Levnedsmiddelkomité. Hvis der er kvalificeret flertal, udsteder Kommissionen forordningen. Opnås der ikke kvalificeret flertal, forelægger Kommissionen sagen for Rådet, der kan forkaste forslaget med simpelt flertal eller kan vedtage forslaget uændret med kvalificeret flertal eller ændre det med enstemmighed. Handler Rådet ikke inden en frist på højst tre måneder, kan Kommissionen udstede forordningen. Henstillingen kan umiddelbart udstedes af Kommissionen, men det formodes, at den vil blive forelagt Den Stående Levnedsmiddelkomité.

Nærheds- og proportionalitetsprincippet

Der redegøres ikke for nærheds- og proportionalitetsprincippet, da der er tale om gennemførelsesbestemmelser til en allerede vedtaget retsakt.

Formål og indhold

Kommissionens forslag er baseret på Den videnskabelige Komité for Levnedsmidlers (SCF) risikovurdering fra 22. november 2000 af dioxin og dioxinlignende PCB i fødevarer.

På baggrund af en toksikologisk vurdering fastsatte SCF for dioxin og dioxinlignende PCB en midlertidig tolerabel daglig indtagelse (TDI) på 1 pg WHO-TEQ/kg legemsvægt/dag. Denne værdi er i maj 2001 revurderet af SCF til 2 pg WHO-TEQ/kg legemsvægt/dag.

SCF har ligeledes vurderet det gennemsnitlige indtag af dioxin og dioxinlignende PCB i EU-landene til mellem 1.2 og 3.0 pg WHO-TEQ/kg legemsvægt/dag. Det gennemsnitlige indtag i EU ligger for en del af befolkningen således noget over det tolerable indtag, og SCF anbefaler derfor en reduktion af indtaget.

Med den hensigt at reducere indholdet af dioxin og dioxinlignende PCB i fødevarer foreslår Kommissionen fastsat maksimalgrænseværdier for de mest anvendte animalske fødevarer herunder fisk. Kommissionen vurderer, at de foreslåede grænseværdier vil ulovliggøre de mest belastede fødevarer svarende til mellem 1 og 5 pct. af de varer, der findes på markedet i dag. På grund af begrænset viden om dioxinlignende PCB fastsættes grænseværdierne i første omgang kun for de egentlige dioxiner.

Maksimalgrænseværdierne vil træde i kraft 1. januar 2002. Grænseværdierne skal revideres første gang inden 31. december 2004 med henblik på inkludering af dioxin-lignende PCB i lyset af, at der forventes fremkommet nye data om tilstedeværelsen af dioxiner og dioxinlignende PCB. Grænseværdierne vil endnu engang blive gennemgået før 31. december 2006 med henblik på at reducere grænseværdierne på baggrund af en forventet reduktion af forureningen af miljøet.

Nedenfor i tabellen angives Kommissionens forslag til maksimalgrænseværdier:

Produkter	Maksimalgrænseværdier for Dioxin (PCDD + PCDF) (pg WHO-PCDD/F-TEQ/g fedt eller ng WHO-PCDD/F-TEQ/kg produkt)
Kød og kødprodukter stammende fra	
Drøvtyggere (ko, får)	3 pg WHO-PCDD/F-TEQ/g fedt
Fjerkræ og opdrættet vildt	2 pg WHO-PCDD/F-TEQ/g fedt
Svin	1 pg WHO-PCDD/F-TEQ/g fedt
Lever og produkter heraf	6 pg WHO-PCDD/F-TEQ/g fedt
Fisk, fiskeprodukter og produkter heraf	4 pg WHO-PCDD/F-TEQ/g frisk vægt
Mælk og mælkeprodukter, inklusiv mælkefedt	3 pg WHO-PCDD/F-TEQ/g fedt
Hønsæg og ægprodukter	3 pg WHO-PCDD/F-TEQ/g fedt
- dog undtaget æg fra høns med adgang til udendørs arealer	
Olie og fedtstoffer	
Animalsk fedt, fra	
Drøvtyggere	3 pg WHO-PCDD/F-TEQ/g fedt
Fjerkræ og opdrættet vildt	2 pg WHO-PCDD/F-TEQ/g fedt

Svin	1 pg WHO-PCDD/F-TEQ/g fedt
Blandet animalsk fedt	2 pg WHO-PCDD/F-TEQ/g fedt
Vegetabilsk olie	0.75 pg WHO-PCDD/F-TEQ/g fedt
Fiskeolie	2 pg WHO-PCDD/F-TEQ/g fedt

Det er Kommissionens intension, at emissionen med dioxin og forureningen med dioxinlignende PCB skal reduceres ved kilden. For at kunne opspore kilderne til forurening af fødevarer foreslår Kommissionen i form af en henstilling, at der fastsættes såkaldte *aktions-* og *målgrænser*.

Aktionsgrænserne fastsættes på et niveau svarende til ca. 75 pct. af maksimalgrænseværdierne, og der fastsættes også aktionsgrænser for vegetabiliske produkter. Ifølge henstillingen skal myndighederne igangsætte en opsporing af kilderne til forurening med dioxin og dioxinlignende PCB, når nationale overvågnings- eller kontrolundersøgelser påviser et indhold, der overskrider aktionsgrænserne fastsat for dioxin. Myndighederne skal analysere disse prøver også for dioxinlignende PCB.

På denne måde må det forventes, at der kan udpeges specielt belastede fødevarer fra specielt belastede områder. Henstillingen lægger op til, at medlemslandene ved udpegning af sådanne hotspots skal følge op med henblik på at forhindre eller begrænse dioxinindholdet i de pågældende fødevarer gennem en indsats ved forureningskilden.

Endvidere skal aktionsgrænserne tilvejebringe et bedre datagrundlag til revurdering af maksimalgrænseværdierne og til inkludering af dioxinlignende PCB i maksimalgrænseværdierne.

Da forureningsgraden varierer fra medlemsland til medlemsland, kan der i de enkelte medlemslande fastsættes specielle aktionsgrænser for deres egne produkter, så myndighederne skal udrede forureningskilden til 5-10 pct. af de udtagne prøver i den offentlige kontrol. Aktionsgrænserne er derfor kun harmoniseret for produkter, der handles mellem medlemslandene.

Medlemsstaterne skal informere Kommissionen og de andre medlemsstater om deres fund og resultatet af deres undersøgelser samt de tiltag, der er gjort for at reducere eller fjerne kilden til forureningen.

Målgrænserne skal på længere sigt sikre befolkningen mod overskridelser af TDI. De er ikke fastsat endnu, men skal fastsættes inden 31. december 2004 på baggrund af den opnåede viden om reduktion af forureningsgraden i de forskellige fødevarer. Samtidig vil aktionsgrænserne blive revurderet for eventuelt at kunne medtage dioxinlignende PCB. Det er hensigten, at maksimalgrænseværdier og aktionsgrænser på sigt skal sænkes til målgrænse niveauet.

Udtalelser

Europa-Parlamentet skal ikke udtale sig.

Gældende dansk ret

Indholdet af dioxiner i fødevarer er i dag reguleret ved en individuel sundhedsmæssig vurdering efter fødevarerlovens § 7, stk 2, men der er ikke fastlagt maksimalgrænseværdier.

Konsekvenser

Forordningsforslaget kan få statsfinansielle konsekvenser. En endelig vurdering må dog afvente en eventuel fastlæggelse af de til grænseværdierne knyttede kontrolforanstaltninger, samt at der opnås et overblik over de nødvendige foranstaltninger i primærproduktionen til håndhævelse af maksimalgrænseværdierne. En høj kontrolfrekvens kan give finansielle konsekvenser grundet den høje analysepris. Kontrollen kan baseres på brugerbetaling eller på offentlig betaling.

Forordningen om maksimalgrænseværdier vil være umiddelbart gældende, henstillingen kan implementeres ved ændring af bekendtgørelse om forurenende stoffer i fødevarer samt gebyrbekendtgørelsen.

I de nyeste estimater fra den danske dioxinhandlingsplan baseret på et begrænset datamateriale anslås den gennemsnitlige belastning af danske forbrugere således til 0.7 pg WHO-TEQ/kg legemsvægt/dag for dioxin og til 1.7 pg WHO-TEQ/kg legemsvægt/dag, når de dioxinlignende PCB medregnes. Det viser derfor, at en del af danskerne i dag har et indtag over TDI på 2 pg WHO-TEQ/kg legemsvægt/dag, hvor SCF anbefaler et indtag under TDI.

Der kan ikke ud fra den begrænsede viden om indholdet af dioxin i fødevarer på det danske marked vurderes, om de foreslåede maksimalgrænseværdier øger beskyttelsesniveauet i Danmark.

Landsudvalget for svin, Danske slagterier og Fødevarerindustrien finder det positivt, at der fastsættes maksimalgrænseværdier for fødevarer, idet de dog finder, at datagrundlaget er uklart. **Landsudvalget for svin** og **Danske slagterier** er tilfredse med konceptet med aktionsgrænser og arbejder hen imod en reduktion til målgrænserne, medens **Fødevarerindustrien** ønsker aktionsgrænser fjernet, da de mener at skabe flaskehalsproblemer med at få udført dioxinanalyser for virksomheder og myndigheder.

Danmarks fiskeriforening ønsker reduktion af udledning af dioxin til miljøet, og at der derfor skal være skrapere krav til forbrændingsanlæg m.m. Maksimalgrænseværdier vil ikke mindske dioxinindholdet i fiskene; dette kan kun opnås ved at hindre udledning, samtidig med at dioxin i økosystemet nedbrydes. Grænseværdier vil kun tilføre ekstra omkostninger. Foreningen vil gerne have nye data og målinger, inden der fastsættes grænseværdier, og har en række spørgsmål til analysefaciliteter og til, hvordan fødevaremyndighederne skal håndhæve grænseværdierne.

Den danske dyrlægeforening er enig i, at indsatsen mod forurening af foder og fødevarer med dioxin og PCB skal skærpes for at beskytte forbrugerne mod sundhedsrisici. Der bør snarest igangsættes forskning for flere data med henblik på permanente grænseværdier.

Dansk familielandbrug slutter op om intensionerne for at reducere dioxin i miljøet og om, at der fastsættes grænseværdier for dioxin i fødevarerne. De finder det positivt, at alle led i berøring med fødekæden skal tage medansvar for miljø og produktion.

Landsforeningen Økologisk Jordbrug, Økologisk Landscenter herunder bl.a. **Landsforeningen af Økologiske** og **Biodynamiske Mælkeproducenter** og **Ø-gruppen** bemærker i fællesskab, at de ser med alvor på problemerne med dioxinudledningen og den deraf følgende forurening af miljø og fødevarer, men har ifølge eget udsagn ikke noget kvalificeret indspil til arbejdet, idet man ser frem til at medvirke til en reduktion af fødevarernes indhold på et senere tidspunkt.

Landboforeningerne og **Landbrugsraadet** finder det vigtigt, at der fortsat sker reduktion i udledningen af dioxin til miljøet og positivt, at der fokuseres på både foder og fødevarer i henstillingen. Endvidere finder de det vigtigt, at der fastsættes realistiske maksimalgrænseværdier, som tager udgangspunkt i det "naturlige baggrundsindhold".

De samvirkende købmænd er tilfredse med, at der lægges fælles EU strategi for med tiden at reducere dioxinbelastningen. De vil ikke kommentere de foreslåede værdier og ønsker en analysemetode defineret inden ikrafttrædelsesdatoen for grænseværdierne.

FDB vil gerne vide, hvordan Fødevaredirektoratet vil gribe analysearbejdet an, når maksimalgrænseværdierne træder i kraft.

Den foreliggende udgave af dokumenterne har endvidere været i høring i det Rådgivende Fødevareudvalg.

Mejeriforeningen er enig i princippet om at dioxin skal bekæmpes ved kilden. Foreningen anser det fornuftigt at køre med en overvågningsgrænse/aktionsgrænse, som, hvis den overskrides, udløser, at man opsporer kilden til forureningen. Samtidigt finder foreningen det forkert at pålægge virksomhederne kontroludgiften under henvisning til, at dioxin er en miljøforurening, og som sådan et forhold virksomhederne ikke selv har kontrol med.

Danske Slagterier (DS) er principielt enig i, at problemer med forurening med dioxin og dioxinlignende stoffer skal løses ved kilden, men stiller spørgsmål ved det videnskabelige belæg for de foreslåede grænseværdier. **DS** finder det ikke videnskabeligt korrekt at sætte en grænseværdi baseret på en TEQ-værdi (toksicitetsækvivalenter) alene, hvilket kunne tale for, at mængden af dioxin på området er for sparsom til at berettige til lovgivning på området. **DS** finder, at det talmateriale, som er benyttet til fastsættelse af grænseværdierne, er meget sparsomt, hvorfor det anføres, at det er for tidligt at gå ud og opstille grænseværdier på et område, som er så dårligt belyst. **DS** finder, at en vejledende grænseværdi vil give mere mening og samtidigt kan finde anvendelse også som overvågnings/aktionsgrænse. Endelig påpeger **DS**, at analyser for dioxiner indtil videre er meget kostbare, og da problemet i stor udstrækning er et miljøproblem, som ikke kan styres af fødevarerindustrien, forventes det, at virksomhederne friholdes for disse udgifter.

Landbrugsraadet, Landboforeningerne og Dansk Familielandbrug henviser til høringssvar givet i forbindelse med Kommissionens arbejdsdokumenter om dioxin i foder.

Landbrugsraadet, Landboforeningerne og Dansk Familielandbrug støtter således forslaget om, at der skal ses på indholdet af dioxin både i foder og i fødevarer, således at indholdet af dioxin i fødekæden reduceres. Med hensyn til fastsættelse af grænseværdierne lægges vægt på, at de er realistiske og tager udgangspunkt i, at der er et "naturligt baggrundsindhold", og samtidig, at der sikres mod direkte forureninger, der medfører sundhedsproblemer. **Landbrugsraadet, Landboforeningerne og Dansk Familielandbrug** peger på, at et givet dioxinindhold kan bero på udefra kommende forhold, hvorfor det er afgørende, at myndighederne håndterer denne situation uden at straffe landmanden, men i stedet sætter ind over for den direkte årsag til forureningen. Organisationerne ønsker endelig at blive inddraget i den nationale implementering af forslaget.

Forbrugerrådet kan grundlæggende tilslutte sig princippet i forslaget om fastsættelse af maksimalgrænseværdier samt aktions- og målgrænser. Umiddelbart vurderes det, at grænseværdien for specielt fisk er meget høj set i forhold til det anbefalede daglige indtag af fisk og i forhold til værdien for det tolerable daglige indtag (TDI) samt i betragtning af, at værdien kun gælder for dioxin. **Forbrugerrådet** anmoder derfor om at maksimalgrænseværdien revurderes, ikke bare for fisk, men også for fx kød og mælkefedt, der indtages i større mængder end fisk.

Tidligere forelæggelse for Folketingets Europaudvalg

Forslaget har ikke tidligere været forelagt Folketingets Europaudvalg.

EN

COMMISSION OF THE EUROPEAN COMMUNITIES



WORKING DOCUMENT – DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION SERVICES

Draft

COMMISSION REGULATION (EC) No .../..

REPRESENT THE VIEWS OF THE COMMISSION SERVICES

of [...]

F THE COMMISSION SERVICES

amending Commission Regulation (EC) N° 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food, and in particular Article 2(3) thereof,

Whereas:

1. The term "dioxins" covers a group of 75 polychlorinated dibenzo-p-dioxin (PCDD) and 135 polychlorinated dibenzofuran (PCDF) congeners, of which 17 are of toxicological concern. The most toxic congener is 2,3,7,8-tetrachlordibenzo-p-dioxin (TCDD), classified by the International Agency for Research on Cancer (IARC) and other reputable international organisations as a known human carcinogen. The Scientific Committee for Food (SCF), in line with the World Health Organisation (WHO), concluded that the carcinogenic effect of dioxins does not occur at levels below a certain threshold. Other adverse effects, such as endometriosis, neurobehavioural and immunosuppressive effects occur at much lower levels and are therefore considered relevant for determining a tolerable intake.
2. Polychlorinated biphenyls (PCBs) are a group of 209 different congeners which can be divided into two groups according to their toxicological properties: 12 congeners exhibit toxicological properties similar to dioxins and are therefore often termed "dioxin-like PCBs". The other PCBs do not exhibit dioxin-like toxicity but have a different toxicological profile.
- 3.
4. Each congener of dioxins or dioxin-like PCBs exhibits a different level of toxicity. In order to be able to sum up the toxicity of these different congeners, the concept of toxic equivalency factors (TEFs) has been introduced to facilitate risk assessment and regulatory control. This means that the analytical results relating to all 17 individual dioxin congeners and to the 12 dioxin-like PCB congeners are expressed in terms of a single quantifiable unit: "TCDD toxic equivalent concentration" (TEQ).
5. Dioxins and PCBs are extremely resistant to chemical and biological degradation and therefore persist in the environment and accumulate in the feed and food chain.
6. More than 90% of human dioxin exposure derives from foodstuffs. Foodstuffs of animal origin normally contribute to approximately 80% of overall exposure. The dioxin burden in animals derives mainly from feedingstuffs. Therefore feedingstuffs, and in some cases soil, raise concerns as potential sources of dioxins.
7. The European Scientific Committee on Food (SCF) adopted an opinion on the Risk Assessment of Dioxins and Dioxin-like PCBs in Food on 30 May 2001; this is an update based on new scientific information which has become available since the adoption of the SCF opinion on this matter on 22 November 2000. The Committee fixed a tolerable weekly intake (TWI) for dioxins and dioxin-like PCBs of 14 pg WHO-TEQ/kg body weight. Exposure estimates indicate that a considerable proportion of the European population has a dietary intake in excess of the tolerable intake. Certain population groups in some countries could be at higher risk due to particular dietary habits.
8. The reduction of human exposure to dioxins through food consumption is therefore important and necessary to ensure consumer protection. Foodstuffs of animal origin are a predominant source of consumer exposure to dioxins. Particularly high levels have been observed in certain food groups. As food contamination is directly related to feed contamination, an integrated approach must be adopted to reduce dioxin incidence throughout the food chain, i.e. from feed materials through food-producing animals to humans.
9. The Scientific Committee has recommended that continuing efforts should be made to limit environmental releases of dioxins and related compounds to the lowest levels feasible. This is the most effective and efficient way to reduce the presence of dioxins and similar substances in the food chain and to ensure continued reduction of the human body burden. The Committee has noted that recent investigations on human milk and blood seem to indicate that dioxin levels are no longer decreasing.
10. Measures based solely on establishing maximum levels for dioxins and dioxin-like PCBs in foodstuffs would not be sufficiently effective in reducing human exposure to dioxins unless levels were set so low that a large part of the food supply would have to be declared unfit for human consumption. However, maximum levels are an appropriate tool to prevent unacceptably high exposure of the human population and to prevent the distribution of feedingstuffs with an unacceptably high level of contamination. Furthermore, the setting of maximum levels is indispensable for the implementation of a regulatory control system and to ensure uniform application.

11.

12. It is generally recognised that, in order to actively reduce the presence of dioxins in foodstuffs, maximum levels should be accompanied by measures stimulating a proactive approach, including action levels and target levels for foodstuffs in combination with measures to limit emissions. Target levels indicate the levels to be achieved in order to ultimately bring human exposure for the majority of the population down to the TWI set by the Scientific Committee. Action levels are a tool for competent authorities and operators to highlight those cases where it is appropriate to identify a source of contamination and to take measures for its reduction or elimination not only in the event of non-compliance with the provisions of this Regulation, but also where significant levels of dioxins above the normal background levels are found in foodstuffs. This approach will result in a gradual reduction of dioxin levels in foodstuffs, and the target levels will ultimately be achieved. A Recommendation from the Commission on this issue is therefore being addressed to the Member States.
13. Although, from a toxicological point of view, any level should apply to dioxins and dioxin-like PCBs, for the time being the maximum levels are set only for dioxins and furans and not for dioxin-like PCBs, given the very limited data available on the prevalence of the latter. In the meantime, the above-mentioned investigations to be carried out if the action level is exceeded should also include analysis of dioxin-like PCBs, in order to establish a reliable database on their presence in foodstuffs within a relatively short period. This will enable a review of maximum levels to take account of dioxin-like PCBs. The same will apply to action levels and target levels.
14. For the time being, the unacceptable levels of dioxin in foodstuffs must be assessed in the light of the current background levels of contamination, which differ from one foodstuff to another. The maximum level should be fixed, taking account of background contamination, at a strict but feasible level. It is appropriate that foodstuffs which contain unacceptably high levels are not used for human consumption. This could apply to foodstuffs produced in/originating from certain highly contaminated locations/regions.
15. In order to ensure that all operators in the food and feed chain continue to make all possible efforts and to do all that is necessary to limit the presence of dioxins in feed and food, the maximum levels applicable will be reviewed within a defined period with a view to setting lower maximum levels. An overall reduction of at least 25% in human exposure to dioxins should be achieved by 2006. The gradual decrease in the maximum levels, as a consequence of the continuing efforts of operators to decrease the presence of dioxins in feed and food, the downward trend in the level of dioxins in the environment as a result of environmental measures and the proactive to reducing dioxins in foodstuffs, as recommended by the Commission in its Recommendation .../2001, will ultimately result in the target level being achieved.
- least 25% in human exposure to dioxins should be achieved by 2006. The gradual decrease in the maximum levels, as a consequence of the continuing efforts of operators
- 16.
17. Maximum levels are stipulated mainly for foodstuffs of animal origin. None currently apply to products such as horsemeat, goat meat, rabbit meat and eggs from ducks, geese and quail. Only limited data are available on the prevalence of dioxins in these foodstuffs. Moreover, as they are of limited significance from an intake point of view, no maximum level has been laid down for the time being. Nor does any maximum level currently apply to cereals, fruits and vegetables, as these food items have generally low levels of contamination and are therefore only a minor contributory factor in overall human exposure to dioxins. However, it is appropriate that the levels of dioxins and dioxin-like PCBs in these foodstuffs are monitored regularly.
18. Vegetable oils normally do not contain significant levels of dioxins or dioxin-like PCBs. As vegetable oils can be introduced onto the market mixed with animal fats for use as ingredients in foodstuffs, it is appropriate to establish a maximum level for vegetable oils for monitoring purposes.
19. The data currently available do not allow maximum levels to be laid down for different categories of fish and fishery products. The maximum permitted level of dioxins in feedingstuffs for fish means that farmed fish have significantly lower dioxin levels. It may in future be appropriate to lay down different levels for the various categories of fish and fishery products.
20. Monitoring data indicate that free-range or semi-intensive eggs contain higher levels of dioxins than battery eggs. Measures may be taken to ensure that the dioxin levels in these eggs are reduced. It is therefore appropriate to provide for a transition period before the maximum levels apply to free range or semi-intensive eggs.
21. In view of the disparities between Member States and the consequent risk of distortion of competition, Community measures are required in order to protect public health and ensure market unity while adhering to the principle of proportionality.
22. Consequently, amendments should be made to Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs.
23. The Scientific Committee on Food has been consulted, in accordance with Article 3 of Regulation (EEC) No 315/93, on the provisions liable to affect public health.
24. The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS REGULATION:

Article 1

Commission Regulation (EC) No 466/2001 is amended as follows:

1. The following Article 5a is inserted:

"Article 5a

1. With regard to dioxins in products mentioned in section 5 of the Annex, it is prohibited

- to mix products complying with the maximum levels with products exceeding these levels

- to use products which do not comply with the maximum levels as ingredients for the manufacture of other foodstuffs.

2. The provisions in section 5 of the Annex shall be reviewed for the first time by 31 December 2004 at the latest in the light of new data on the presence of dioxins and dioxin-like PCBs, in particular with a view to the inclusion of dioxin-like PCBs in the levels to be set. In addition, the possible establishment of maximum levels for other foodstuffs will be considered.

"These provisions shall be further reviewed by 31 December 2006 at the latest with a view to significantly reducing the maximum levels and possibly laying down maximum levels for other foodstuffs"

2. The Annex is amended in accordance with the Annex hereto.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities*. It shall apply from 1 January 2002.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, [...]

r States.

For the Commission

David BYRNE

Member of the Commission

ANNEX

In the Annex, the following section 5 is added :

"Section 5: Dioxin (sum of polychlorinated dibenzo-*para*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO –TEFs (toxic equivalency factors, 1997)

Products	Maximum levels for Dioxins (PCDD + PCDF) ⁽¹⁾ (pg WHO-PCDD/F-TEQ/g fat or ng WHO-PCDD/F-TEQ /kg product)	Performance criteria for sampling	Performance criteria for the methods of analysis
5.1.1 Meat and meat products ⁽⁴⁾ originating from - Ruminants (bovine animals, sheep) - Poultry and farmed game - Pigs	3 pg WHO-PCDD/F-TEQ /g fat ^(2,3) 2 pg WHO-PCDD/F-TEQ /g fat ^(2,3) 1 pg WHO-PCDD/F-TEQ /g fat ^(2,3)	Directive 2001/././EC Directive 2001/././EC Directive 2001/././EC	Directive 2001/././EC Directive 2001/././EC Directive 2001/././EC
5.1.2 Liver and derived products	6 pg WHO-PCDD/F-TEQ /g fat ^(2,3)	Directive 2001/././EC	Directive 2001/././EC
5.2. Muscle meat of fish and fishery products ⁽⁵⁾ and products thereof	4 pg WHO-PCDD/F-TEQ /g fresh weight ⁽²⁾	Directive 2001/././EC	Directive 2001/././EC
5.3. Milk ⁽⁶⁾ and milk products, including butter fat	3 pg WHO-PCDD/F-TEQ /g fat ^(2,3)	Directive 2001/././EC	Directive 2001/././EC

5.4 Hen eggs and egg products ^(7,8)	3 pg WHO-PCDD/F-TEQ /g fat ^(2,3)	Directive 2001/./EC	Directive 2001/./EC
5.5.Oils and fats - Animal fat - from ruminants - from poultry and farmed game - from pigs - mixed animal fat - Vegetable oil - fish oil intended for human consumption	3 pg WHO-PCDD/F-TEQ /g fat ⁽²⁾ 2 pg WHO-PCDD/F-TEQ /g fat ⁽²⁾ 1 pg WHO-PCDD/F-TEQ /g fat ⁽²⁾ 2 pg WHO-PCDD/F-TEQ /g fat ⁽²⁾ 0.75 pg WHO-PCDD/F-TEQ /g fat ⁽²⁾ 2 pg WHO-PCDD/F-TEQ /g fat ⁽²⁾	Directive 2001/./EC Directive 2001/./EC Directive 2001/./EC Directive 2001/./EC Directive 2001/./EC Directive 2001/./EC	Directive 2001/./EC Directive 2001/./EC Directive 2001/./EC Directive 2001/./EC Directive 2001/./EC Directive 2001/./EC

⁽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⁾ These maximum levels shall be reviewed for the first time by 31 December 2004 at the latest in the light of new data on the presence of dioxins and dioxin-like PCBs, in particular with a view to the inclusion of dioxin-like PCBs in the levels to be set, and will be further reviewed by 31 December 2006 at the latest with the aim of significantly reducing the maximum levels.

⁽³⁾ The maximum levels are not applicable to food products containing < 1% fat.

⁽⁴⁾ Meat of bovine animals, sheep, pig, poultry and farmed game as defined in Article 2(a) of Council Directive 64/433/EEC (OJ 121 29.7.1964, p. 2012), as last amended by Directive 95/23/EC (OJ L 243, 11.10.1995, p.7) and Article 2(1) of Council Directive 71/118/EEC (OJ L55, 8.3.1971, p. 23), as last amended by Directive 97/79/EC (OJ L24, 30.1.1998, p.31) and Article 2(2) of Council Directive 91/495/EC (OJ 268, 24.09.1991, p.41) as last amended by Directive 94/65/EC (OJ L 368, 31.12.1994, p.10), excluding edible offal as defined in Article 2 (e) of Directive 64/433/EEC and Article 2(5) of Directive 71/118/EEC.

⁽⁵⁾ Muscle meat of fish and fishery products as defined in categories (a), (b), (c), (e) and (f) of the list in Article 1 of Council Regulation (EC) No 104/2000 (OJ L 17, 21.1.2000, p.22). The maximum level applies to crustaceans, excluding the brown meat of crab, and to cephalopods without viscera.

⁽⁶⁾ Milk (raw milk, milk for the manufacture of milk-based products and heat-treated milk as defined in Council Directive 92/46/EEC (OJ L 268, 14.9.1992, p.1) as last amended by Council Directive 94/71/EC (OJ L368, 31.12.1994, p.33).

⁽⁷⁾ Hen eggs and egg products as defined in Article 2 of Council Directive 89/437/EEC (OJ L 212, 22.07.1989, p.87).

⁽⁸⁾ Free-range or semi-intensive eggs as defined in Article 18 of Commission Regulation (EEC) No 1274/91 (OJ L121, 16.5.1991, p.1) must comply with the maximum level laid down as from 1 January 2004.

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COMMISSION OF THE EUROPEAN COMMUNITIES



Brussels, 21.6.2001

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COMMISSION RECOMMENDATION

of [...]

F THE COMMISSION SERVICES

on the reduction of the presence of dioxins and PCBs in foodstuffs

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Article 211 thereof,

1. For the time being, the unacceptable levels of dioxin in foodstuffs must be assessed in the light of current background levels. The maximum levels, established by Commission Regulation .../..., are fixed at a strict but feasible level, while taking account of background contamination. These maximum levels will prevent unacceptably high exposure levels among the human population and the distribution of foodstuffs with an unacceptably high level of contamination. Measures based on establishing maximum levels for dioxins and dioxin-like PCBs in foodstuffs will not be sufficiently effective in reducing the level of contamination in foodstuffs unless levels are set so low that a large part of the food supply is declared unfit for human consumption.
2. The European Scientific Committee on Food (SCF) adopted an opinion on the Risk Assessment of Dioxins and Dioxin-like PCBs in Food on 30 May 2001; this is an update based on new scientific information which has become available since the adoption of the SCF opinion on this matter on 22 November 2000. The Committee fixed a tolerable weekly intake (TWI) for dioxins and dioxin-like PCBs of 14 pg WHO-TEQ/kg body weight. From exposure estimates, it is evident that a considerable proportion of the European population has a dietary intake in excess of the tolerable intake. Certain population groups in some countries could be at a higher risk due to particular dietary habits.
3. The reduction of human exposure to dioxins through food consumption is therefore important and necessary to ensure consumer protection. More than 90% of human dioxin exposure derives from food. Food of animal origin normally contributes about 80% of overall exposure.
4. Measures should be implemented with the aim of reducing the presence of dioxins and their release into the environment in order to limit the impact of environmental pollution on the contamination of foodstuffs. Moreover, in the case of contamination by dioxins, it is absolutely necessary to make every effort to further reduce their presence in the food chain, thereby reducing human exposure to dioxins.
5. It is generally recognised that, in order to actively reduce the presence of dioxins in foodstuffs, maximum levels should be accompanied by measures stimulating a proactive approach, including the setting of action levels and target levels for food in combination with measures to limit emissions. Target levels indicate the contamination levels to be achieved in order to ultimately bring human exposure for the majority of the population down to the TWI set by the SCF. Action levels are a tool for competent authorities and operators to highlight those cases where it is appropriate to identify a source of contamination and to take measures for its reduction or elimination not only in the event of non-compliance with the provisions of this Regulation but also where significant levels of dioxins above normal background levels are found in foodstuffs. This approach will result in a gradual reduction of dioxin levels in foodstuffs, and the target levels will ultimately be achieved.
6. For the time being, no maximum levels for dioxins have yet been laid down for cereals, fruits and vegetables as these food items have generally low levels of contamination and are therefore only a minor contributory factor in overall human exposure to dioxins. However, it is appropriate that the levels of dioxins and dioxin-like PCBs in these foodstuffs are monitored regularly. It is therefore appropriate to set action levels for these foodstuffs for reference purposes in order to help the competent authorities and operators identify those cases where significant levels of dioxins are present, and which then require further investigation to identify and reduce or eliminate the sources.
7. The target levels must be such that it may be reasonably assumed that the exposure of a large majority of the European population will be within the tolerable weekly intake (TWI) for dioxins and dioxin-like PCBs laid down by the SCF, once these levels are achieved. Since it is for the time being difficult to foresee accurately the impact of the environmental measures on the levels in different feed materials, and thus also in the different foodstuffs of animal origin, no target levels have yet been set.
8. Although, from a toxicological point of view, any level should apply to dioxins and dioxin-like PCBs, the maximum levels established in Commission Regulation .../... are for the time being set only for dioxins and furans and not for dioxin-like PCBs, given the very limited data available on the prevalence of the latter. It is therefore necessary, in accordance with the recommendation of the SCF, to generate reliable data on the presence of dioxin-like PCBs in the widest possible foodstuffs in order to establish a reliable database within a relatively short period. This will allow a review of maximum levels established by Commission Regulation .../... and also of the action levels laid down in this Recommendation, with a view to the inclusion of dioxin-like PCBs in the levels to be set and the establishment of numerical target levels.
, in accordance with the recommendation of the SCF, to generate reliable data on the presence of dioxin-like PCBs in the widest possible
- 9.
10. Alongside the review for the purpose of including dioxin-like PCBs, the action levels will have to be periodically adjusted in line with the downward trend in dioxin levels and the active approach pursued to gradually reduce their presence in foodstuffs and ultimately achieve the target level. Target levels will have to be set in the light of more detailed information on the impact of environmental measures in reducing the levels of dioxins and dioxin-like PCBs in various foodstuffs, and on data concerning occurrence etc., in order to achieve the objective of bringing the exposure of a large majority of the European population within the tolerable weekly intake (TWI) for dioxins and dioxin-like PCBs set by the SCF,

HEREBY RECOMMENDS:

That Member States, in co-operation with operators, initiate investigations to identify the source of contamination, check for the presence of dioxin-like PCBs and take measures to reduce or eliminate the source of contamination in cases of non-compliance with the provisions of Commission Regulation 2001/466/EC of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs, as amended by Commission Regulation 2001/., and in cases where increased levels of dioxins close to the maximum level are found, in order to reduce the presence of dioxins in the food chain to the extent feasible; and that Member States inform the Commission and the other Member States of their findings, the results of their investigations and the measures taken to reduce or eliminate the source of contamination. This information shall be transmitted by 31 December of each year, except where the information is of immediate relevance for the other Member States, in which case it should be transmitted immediately.

in order to assist Member States and ensure a uniform approach, action levels triggering the above-mentioned investigations are laid down as guidance in the Annex to this Recommendation.

In order to take into account their national background contamination levels, Member States may set national action levels for their domestic production of foodstuffs. These should be set so that in 5-10 % of cases, an investigation is undertaken to identify the source of contamination.

The action levels in the Annex will be reviewed by 31 December 2004 at the latest with a view to including dioxin-like PCBs once data on their presence in foodstuffs become available.

The action levels will be further periodically reviewed and adjusted in line with the downward trend in dioxin levels and the active approach pursued to gradually reduce their presence in foodstuffs and ultimately achieve the target level.

The target levels indicate the contamination levels to be achieved in order to ultimately bring human exposure for the majority of the population down to the tolerable weekly intake (TWI) for dioxins and dioxin-like PCBs set by the SCF. They will be set by 31 December 2004 at the latest, when the action levels are first revised with a view to the inclusion of dioxin-like PCBs. The setting of target levels will also take into account the impact of the environmental measures on the presence of dioxins and dioxin-like PCBs in each foodstuff.

Done at Brussels, [...]

tely bring human exposure for the majority of the population down to the tolerable weekly intake (TWI) for dioxins and dioxin-like PCBs set by the SCF. They will be set by 31 December 2004 at the latest, when the action levels are first revised with a view to the inclusion of dioxin-like PCBs. The setting of target levels will also take into account the impact of the environmental measures on the presence

For the Commission

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Member of the Commission

ANNEX

Dioxin (sum of polychlorinated dibenzo-*para*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO –TEFs (toxic equivalency factors, 1997)

Product	ACTION LEVEL FOR DIOXINS (PCDD + PCDF) ⁽¹⁾ (pg WHO-PCDD/F-TEQ/g fat or ng WHO-PCDD/F-TEQ /kg product) ⁽¹⁾	TARGET LEVEL ⁽¹⁾
Meat and meat products ⁽⁴⁾ originating from - Ruminants (bovine animals, sheep) - Poultry and farmed game - Pigs	2 pg WHO-PCDD/F-TEQ/g fat ⁽³⁾ 1.5 pg WHO-PCDD/F-TEQ/g fat ⁽³⁾ 0.6 pg WHO-PCDD/F-TEQ/g fat ⁽³⁾	(2) (2) (2) (2)
Liver and derived products	4 pg WHO-PCDD/F-TEQ /g fat ⁽³⁾	
Muscle meat of fish and fishery products ⁽⁵⁾ and products thereof	3 pg WHO-PCDD/F-TEQ /g fresh weight	(2)
Milk ⁽⁶⁾ and milk products, including butter fat	2 pg WHO-PCDD/F-TEQ /g fat ⁽³⁾	(2)
Hen eggs and egg products ^(7,8)	2.0 pg WHO-PCDD/F-TEQ /g fat ⁽³⁾	(2)

Oils and fats	2 pg WHO-PCDD/F-TEQ /g fat	(2)
- Animal fat		(2)
- from ruminants	1.5 pg WHO-PCDD/F-TEQ/g fat	(2)
- from poultry and farmed game		(2)
- from pigs		(2)
- mixed animal fat	0.6 pg WHO-PCDD/F-TEQ/g fat	(2)
- Vegetable oil		(2)
- Fish oil intended for human consumption	1.5 pg WHO-PCDD/F-TEQ /g fat	(2)
	0.5 pg WHO-PCDD/F-TEQ /g fat	(2)
	1.5 pg WHO-PCDD/F-TEQ /g fat	(2)
Fruits	0.4 ng WHO-PCDD/F-TEQ /kg product	(2)
Vegetables		(2)
Cereals	0.4 ng WHO-PCDD/F-TEQ /kg product	(2)
	0.4 ng WHO-PCDD/F-TEQ /kg product	(2)

⁽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⁾ The target levels will be set by 31 December 2004 at the latest when the action levels are first revised with a view of the inclusion of dioxin-like PCBs.

⁽³⁾ The action levels are not applicable to food products containing < 1% fat.

⁽⁴⁾ Meat of bovine animals, sheep, pig, poultry and farmed game as defined in Article 2(a) of Council Directive 64/433/EEC (OJ 121 29.7.1964, p. 2012), as last amended by Directive 95/23/EC (OJ L 243, 11.10.1995, p.7) and Article 2(1) of Council Directive 71/118/EEC (OJ L55, 8.3.1971, p. 23), as last amended by Directive 97/79/EC (OJ L24, 30.1.1998, p.31) and Article 2(2) of Council Directive 91/495/EC (OJ L268, 24.09.1991, p.41) as last amended by Directive 94/65/EC (OJ L 368, 31.12.1994, p.10), excluding edible offal as defined in Article 2 (e) of Directive 64/433/EEC and Article 2(5) of Directive 71/118/EEC.

⁽⁵⁾ Muscle meat of fish and fishery products as defined in categories (a), (b), (c), (e) and (f) of the list in Article 1 of Council Regulation (EC) No 104/2000 (OJ L 17, 21.1.2000, p.22). The maximum level applies to crustaceans, excluding the brown meat of crab, and to cephalopods without viscera.

⁽⁶⁾ Milk (raw milk, milk for the manufacture of milk-based products and heat-treated milk as defined in Council Directive 92/46/EEC (OJ L 268, 14.9.1992, p.1) as last amended by Council Directive 94/71/EC (OJ L368, 31.12.1994, p.33)

⁽⁷⁾ Hen eggs and egg products as defined in Article 2 of Council Directive 89/437/EEC (OJ L 212, 22.07.1989, p.87). Free-range or semi-intensive eggs as defined in Article 18 of Commission Regulation (EEC) No 1274/91 (OJ L121, 16.5.1991, p.1)