European Food Safety Authority

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PRESS RELEASE

EFSA provides risk assessment on mercury in fish: Precautionary advice given to vulnerable groups

The European Food Safety Authority's (EFSA) Scientific Panel on Contaminants in the Food Chain (CONTAM) published today an opinion regarding the possible risks to human health associated with the consumption of foods contaminated with mercury. Mercury is present as an environmental contaminant in foods, notably in fish and seafood principally in the form of methylmercury. While exposure to methylmercury varies by country, intake estimates for European consumers are close to internationally established safe intake limits. The Panel advises that further dietary studies be conducted among vulnerable population groups, including children and women of childbearing age, where specific intake data are lacking. Taking into account the important nutritional contribution that fish makes to the diet, EFSA recommends that vulnerable groups in particular select fish from a wide range of species without giving undue preference to large predatory fish likely to contain higher levels of methylmercury, such as swordfish and tuna. Additional guidance regarding the types of fish most suited to consumers' diets is provided by national food safety authorities in Member States.

Following a request from the European Commission, EFSA's Scientific Panel on Contaminants in the Food Chain (CONTAM) has evaluated the possible risks to human health from the consumption of foods contaminated with mercury, in particular methylmercury, based on intake estimates for Europe. In carrying out its risk assessment, the Panel focused on methylmercury, which is considerably more toxic than inorganic mercury in food. In doing so, the Panel considered the provisional tolerable weekly intake (PTWI) established recently for methylmercury by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) as well as the intake limits established by the U.S. National Research Council (US-NRC).

The main source of human exposure to methylmercury from food is fish and seafood products. Given that the average intake estimates of methylmercury for European consumers are below but at times rather close to the PTWI established by the JECFA (1.6 µg/kg body weight) and some intake estimates exceed the limit established by the US –NRC (0.7 µg/kg body weight per week), the CONTAM Panel recommends that a more complete evaluation of exposures be carried out in Europe.

Commenting on these conclusions, the Chair of the EFSA Panel, Dr. Josef Schlatter explained: "Above safe levels of intake, methylmercury is particularly toxic to the nervous system and developing brain. Exposure during pregnancy and early infancy is therefore of particular concern, and this is precisely where appropriate intake data are lacking. Consequently, the Panel advises that specific dietary intake studies be conducted among those more vulnerable population groups including children and women of childbearing age." Following on from this recommendation, EFSA has initiated and will pursue collection of data from Member States through the networks of its Advisory Forum.

In light of the conclusions of the CONTAM Panel, EFSA endorses the precautionary advice concerning fish consumption given by national food safety authorities in Member States in order to protect against the risks for the most susceptible life stages: the unborn child, breast-fed babies and young children. Taking into account the important nutritional contribution that fish makes to the diet, EFSA recommends that women of childbearing age (in particular, those intending to become pregnant), pregnant and breastfeeding women as well as young children select fish from a wide range of species, without giving undue preference to large predatory fish such as swordfish and tuna. Due to their place in the food chain, these fish are likely to contain higher levels of methylmercury than other fish species.

Fish is an important part of a healthy diet as it provides important nutrients. EFSA supports dietary advice given to consumers regarding the benefits of fish consumption. Indeed many national and international authorities advise that people should eat at least two portions of fish a week. Additional guidance regarding the types of fish most suited to consumers' diets is provided by national food safety authorities in Member States.

For additional information on the CONTAM Panel's risk assessment related to mercury and methylmercury in food, see the background note attached.

The opinion is available on the EFSA web site at:
http://www.efsa.eu.int//science/contam_panel/contam_opinions/catindex_en.html

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For more background information about the European Food Safety Authority, go to: http://www.efsa.eu.int

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Background note on EFSA risk assessment related to mercury and methylmercury in food (Request N° EFSA – Q- 2003-030)

1. Mercury and Health

Mercury is an environmental contaminant that exists in different chemical forms. Inorganic mercury in food is considerably less toxic than methylmercury which is mainly present in fish and seafood products. Due to the accumulation of mercury in the food chain, large predatory fish (such as swordfish and tuna) contain higher levels of methylmercury than other species of fish and represent significant sources of human exposure. Methylmercury is particularly toxic to the nervous system and developing brain; therefore, exposure during pregnancy is considered the most critical period for methylmercury toxicity. Population groups particularly concerned by exposure to mercury include: women of childbearing age and especially those intending to become pregnant; pregnant and breastfeeding women; and young children.

2. Exposure assessment

The exposure assessment carried out by EFSA's CONTAM Panel is based primarily on the scientific co-operation (SCOOP) task 3.2.11 report related to heavy metals (EC, 2003). Analysis of this data indicated that the average intake of mercury from fish and seafood products varied by country, depending on the amount and type of fish consumed. Although in most cases, the mean intakes were below the tolerable weekly intakes established by JECFA, occasionally the mean intakes were close to this level (1.6 µg/kg body weight). Moreover, when compared to the tolerable exposure levels of 0.7 µg/kg body weight per week established by the U.S.-NRC, some average intakes may exceed this limit. The Panel could not evaluate intake levels among pregnant women, as such specific intake data are not available.

3. Hazard characterisation

The hazard characterisation of methylmercury and in particular the assessment of tolerable methylmercury intake levels was based on epidemiological studies conducted in defined populations living in the Faroe Islands in the Atlantic and the Seychelles Islands in the Indian Ocean, populations with a high consumption of fishery products. In these studies, the differences in performance of children in specific tests were related to the mercury levels of their mothers (as determined by maternal hair concentration). Uncertainties such as the extrapolation of mercury levels found in hair to dietary intake estimations are subject to a number of conversions and assumptions, and consequently may result in slightly different tolerable intake levels.

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ＥＦＳＡ（Europian Food Safety Authority）プレスリリース（仮訳）

ＥＦＳＡは魚介類の水銀に関してリスクアセスメントを規定
影響を受けやすいグループに予防的アドバイスを提示

ＥＦＳＡに所属する食品流通上の汚染物質（CONTAM）に関する委員は、水銀に汚染された食品の摂食に関係して、健康上の予期されるリスクに関する意見を本日公表した。

水銀は、環境汚染物質として食品中に存在し、メチル水銀については、魚介類と水産食品に顕著に存在している。メチル水銀暴露は各国において様々であり、ヨーロッパ地域消費者の摂取概算は、世界的に確立された安全摂取上限に近いものであった。

委員は、更なる摂食調査により、子供と妊娠年齢の女性を含む影響を受けやすいグループに関して、特別摂食データが不足していることをアドバイスした。

魚介類が持つ重要な栄養学的効果を考慮して、ＥＦＳＡは、影響を受けやすいグループは、メカジキやマグロのような比較的高いメチル水銀を含有する大型補食魚のみを過剰に選択せず、広範囲の魚介類から選択するよう勧告した。加えて、消費者に最も適した魚種に関するガイドラインが、加盟国の国家食品安全庁により提供される。

ヨーロッパ委員会からの要請に基づき、ＥＦＳＡの CONTAM 委員は、ヨーロッパにおける摂食評価に基づき、水銀（特にメチル水銀）に汚染された食品の摂食に関して可能性のあるリスクについて評価を行った。

このリスクアセスメントにおいて、科学者はメチル水銀に注目した。そして、メチル水銀は食品中の無機水銀より毒性が高いと考察された。この中で、科学者は、近年、JECFA でメチル水銀に関して設定された暫定的耐容週間摂取量（PTWI）は、Ｕ．Ｓ．－National Research Council（US-NRC）で設定した摂取上限と同様であると判断した。

ヒトに対する食品を介したメチル水銀暴露の主要素は、魚介類と水産食品である。ヨーロッパ地域消費者のメチル水銀平均摂取概算は、ＪＥＣＦＡにより設定された PTWI（1.6 μ g/Kg BW）より低いものであったが、時々、PTWI に近い数値も見受けられた。そして、いくつかの摂取量概算では、US-NRC が設定した基準値（0.7 μ g/Kg BW/week）を超えていた。食品流通上の汚染物質に関する委員は、より完璧な暴露評価がヨーロッパ地域において実施されるべき旨を勧告した。

これらの結論に関するコメントとして、ＥＦＳＡ委員の議長である Dr.Josef Schlatter は以下の表明を行った。「より安全な摂取レベルに関して、メチル水銀は神経組織と発達中の脳に対して特に毒性があり、妊娠中と早期授乳時における暴露が特に関係がある。しかしながら、正確で適切な摂取データが不足している。従って、委員は、特別な摂取量調査が妊婦と子供を含むより影響を受けやすいグループについて実施されるべき旨を助言した。」この勧告に従い、ＥＦＳＡは行動を開始し、諮問委員会のネットワークを通じて加盟国からデータ収集を行うこととなった。

CONTAM 委員の結論の見地からすれば、ＥＦＳＡは、最も影響を受けやすいライフステージ（胎児、乳児そして幼児）のリスクに対する防御策として、加盟国の国家食品安全庁から提供される魚介類摂取に関する予防的アドバイスを保証する。魚介類が持つ重要な栄養学的効果を考慮して、ＥＦＳＡは、出産年齢の女性（特に妊娠を予定している女性）、妊婦、授乳婦、幼児は、メカジキやマグロのような比較的高いメチル水銀を含有する大型補食魚のみを過剰に選択せず、広範囲の魚介類から選択するよう勧告した。メカジキやマグロはその食物連鎖において高い場所に位置するため、たの魚種より高いメチル水銀を含有しがちである。

健康な食生活の重要な要素である魚介類は、大切な栄養素の提供源であり、ＥＦＳＡは魚介類摂取のメリットに関係した食生活のアドバイスを提供する。実際、多くの国家及び国際機関が、１週間当たり少なくとも２切れの魚を摂食すべきとアドバイスいる。加えて、消費者に最も適した魚種に関するガイドラインが、加盟国の国家食品安全庁により提供されるものである。

食品の水銀及びメチル水銀に関連する CONTAM 委員のリスクアセスメントの追加情報については、添付する Background Note を参照のこと。

以　上

Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to mercury and methylmercury in food

(Request N° EFSA-Q-2003-030)

(adopted on 24 February 2004)

SUMMARY

The Panel has been asked to assess the possible risks to human health from the consumption of foods contaminated with mercury and methylmercury, based on intake estimates for Europe and the provisional tolerable weekly intake (PTWI) established recently by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Mercury is an environmental contaminant that is present in fish and seafood products largely as methylmercury. Food sources other than fish and seafood products may contain mercury, but mostly in the form of inorganic mercury. Based on the available data the contribution to methylmercury exposure from these foods is considered to be insignificant. Inorganic mercury in food is considerably less toxic than methylmercury. Methylmercury is highly toxic particularly to the nervous system, and the developing brain is thought to be the most sensitive target organ for methylmercury toxicity. The JECFA established a Provisional Tolerable Weekly Intake (PTWI) of 1.6 µg/kg body weight based on two epidemiological studies that investigated the relationship between maternal exposure to mercury and impaired neurodevelopment in their children. A previous evaluation by the (U.S.) National Research Council (NRC) established an intake limit of 0.7 µg/kg body weight per week. The estimated intakes of mercury in Europe varied by country, depending on the amount and the type of fish consumed. The mean intakes were in most cases below the JECFA PTWI but the average intake in some countries exceeded the U.S.-NRC limit. High intakes may also exceed the JECFA PTWI. A probabilistic analysis of the French data indicated that children are more likely to exceed the PTWI than adults. Intake data from a recent large survey in Norway indicate that the intakes derived from the analysis of the SCOOP data (*scientific co-operation on questions relating to food*) may overestimate the true intakes of methylmercury for some countries, when the type of fish consumed consists of species with a relatively low concentration of methylmercury. There may be population-groups in Europe with a frequent consumption of large predatory fish, which are at the top of the food chain (for instance swordfish and tuna) which often have a higher concentration of methylmercury. These population-groups may therefore have higher dietary intakes than those found in populations with a high intake of fish containing low levels of methylmercury. Because the intake estimates for high consumers are close to the PTWI established by the JECFA, and exceed the limit established by the U.S.-NRC, reliable intake data should be established from studies focused on women of childbearing age. Methylmercury toxicity has been demonstrated at low exposure levels, and exposure to this compound should therefore be minimized, while recognising that fish constitutes an important part of a balanced diet.

KEYWORDS

Methylmercury, fish, seafood products, developmental neurotoxicity.

BACKGROUND

Mercury, in particular methylmercury, poses a risk to public health, for example, it can affect the development of the brain of infants and can cause neurological changes in adults. However, the extent of the possible risks to the health of EU consumers from mercury in foods is unclear. At present there is no EU scientific opinion on mercury in food. However, legislation setting maximum levels for mercury in fishery products has been in place since 1993. Originally, maximum levels were set in veterinary legislation (Decision 93/351/EEC[1]). In 2001 these provisions were consolidated via Decision 2001/182/EC[2] into Regulation (EC) No 466/2001[3] setting maximum levels for certain contaminants in food, as amended by Regulation (EC) No 221/2002[4].

In June 2003, the FAO/ WHO Joint Expert Committee on Food Additives (JECFA) revised its Provisional Tolerable Weekly Intake (PTWI) for methylmercury to 1.6 µg/kg body weight, whereas it was previously 3.3 µg/kg body weight.

The Member States have gathered data on levels of mercury in foods and have made limited estimates on dietary exposure as part of the scientific co-operation (SCOOP) task 3.2.11 (Decision 2001/773/EC[5]). The results indicate that some consumers may exceed the JECFA PTWI.

The maximum levels set for total mercury in Commission Regulation 466/2001 are under review. At present a maximum level of 0.5 mg/kg applies to fishery products, with the exception of certain listed fish species for which 1 mg/kg applies. In addition to fishery products, the data from some Member States indicate that elevated levels of mercury can be found in other foods.

With reference to the risk assessment already performed by the JECFA, an assessment of the risks from dietary exposure to mercury in the EU is necessary. This assessment would be used to support the scientific basis for reviewing the legislative measures on mercury in food, aimed to help reduce possible risks to EU consumers

[1] OJ L 144 16.6.1993 p23-24
[2] OJ L 77 16.3.2001 p22-23
[3] OJ L 77 16.3.2001 p1-12
[4] OJ L 37 7.2.2002 p4-6
[5] OJ L 290 7.11.2001 p9-11

TERMS OF REFERENCE

The European Commission requests that the European Food Safety Authority issues a scientific opinion on the assessment of the risks to EU consumers from mercury, in particular methylmercury, in food. Assessment of the contribution of different foods towards the overall human exposure should be included. Considerations on the respective risks to vulnerable groups should be made, in particular regarding pregnant women, the unborn child and children.

Interpretation of the terms of reference by the Panel

Evaluation of the hazard database on methylmercury by the Panel would be a major undertaking that appears unnecessary given the background to the Commission request, and would be incompatible with the time-frame available. The risk characterization given below relates to comparisons of European intake estimates, based on the recent SCOOP report, with the PTWI derived by the JECFA and also the value calculated by the U.S.-NRC. The latter limit has been used previously in an EC position paper prepared by an independent expert group in connection with the EU´s Fourth Daughter Directive on Air Quality (Pirrone *et al.*, 2001). Different PTWI values for methylmercury were estimated by the JECFA and the U.S.-NRC, largely because of different interpretations of the main epidemiology studies, which reported different findings and conclusions. The methylmercury database is complex and raises a number of issues that will need to be considered generically by the Panel. These are described later under hazard characterisation.

The JECFA and the U.S.-NRC evaluations were based on the effects of methylmercury exposure in epidemiology studies, while the SCOOP report describes total mercury intakes. The major source of methylmercury intake is fish and seafood products and the opinion concentrates on these sources. Considering the lack of consistent data on conversion factor to allow the fraction of mercury present as methylmercury, the intake estimates for total mercury have been considered to represent methylmercury. Other possible sources of human intake, such as might arise from the consumption of meat and meat products of animals fed methylmercury containing fishmeal, have not been considered but would need to be taken into account in any comprehensive evaluation of methylmercury intake.

ASSESSMENT

Intake Assessment

Mercury is widely distributed within food but methylmercury, its most toxic form, is found at significant levels only in fish and seafood products. Exposure to mercury from food sources other than fish and seafood products is not relevant in the present context because they contain inorganic mercury, and would not contribute to the exposure to methylmercury, which is the subject of the JECFA and the U.S.-NRC risk assessments.

The present exposure assessment is based mainly on the scientific co-operation (SCOOP) task 3.2.11 report related to heavy metals (EC, 2003) and in particular on the chapter entitled "Dietary Intake of Mercury". In the SCOOP report, all the results are expressed as "total mercury" for the various food categories considered, because mercury speciation is not performed routinely by national control laboratories. In order to provide an intake estimate for methylmercury, only the results related to fish, crustaceans, bivalves and molluscs were considered. The highest proportion of total mercury present as methylmercury in fish and seafood products can be estimated assuming conservatively that all the mercury is methylmercury.

Assessment of the mean international dietary exposure based on the results in the SCOOP report

The SCOOP data on fish and seafood product contamination by mercury consists of 14,912 samples aggregated by the Member States into 196 analytical results. In order to generate a distribution curve for methylmercury concentrations in fish and seafood products, it was necessary to combine those data from different sources, i.e. from both individual and aggregated results from different countries (FAO/WHO Workshop – 2000). The combination of these data permits a mean contamination level to be calculated, with weighting as a function of the number of samples. In practice, the data were "disaggregated" by weighting each result by the number of single samples of which it was composed; the resulting weighted mean was 109 µg/kg food of total mercury. In addition, based on the assumption that the distribution of contaminant data follows a lognormal distribution, a log transformation of the data can provide the standard deviation and a simulated distribution including high percentiles.

The weighted mean contamination, which was based on all data for the mercury concentration in fish and seafood products submitted by the Member States, was 109 ± 845 µg/kg; the high standard deviation reflects the wide variations in the analytical results.

Because of the biological half-life of methylmercury in the human body (about 1.5 to 2 month) and considering that the toxicological endpoints are related to long term exposure, the assessment should be based on chronic dietary exposure assessment. Considering the distribution of both food ingestion and food contamination, a realistic way of expressing the exposure consists of combining the distribution of consumption with the mean (or the median) value for the level of contamination. Such an approach means that even a high consumer is very unlikely to be exposed regularly to highly contaminated food but more realistically to food for which the contamination is randomly distributed.

The mean daily consumption for fish and seafood products provided by the Member States ranged between 10g (the Netherlands) and 80g (Norway) per person (70 to 560 g/week). A simple calculation based on these values and the overall international average concentration shows that the mean estimated dietary exposure would be between 7 and 61 µg/person per week of total mercury; for a 60 kg adult this corresponds to 0.1 to 1.0 µg/kg body weight per week. The SCOOP data show that for a food item like fish the variation of mean consumption in different countries across Europe is very high and the variation in food consumption could result in exposures that vary by a factor 10.

This analysis is consistent with the range estimated by the JECFA in 1999 of 0.3-1.1 µg/kg body weight per week based on GEMS regional diet and a mean contamination level of 200 µg/kg of food.

Assessment of the high international dietary exposure based on the results in the SCOOP report

To assess the exposure of high consumers, the high percentiles for fish consumption may be combined with the international average level of contamination. The highest figure from the SCOOP was reported by Norway with consumption (at the 95th percentile) equal to 275 g/day of fish and seafood products (Table 1). Consumption of such an amount on a regular basis would result in an exposure of 3.5 µg/kg body weight per week of total mercury for a 60 kg adult. This calculation assumes that the high consumer eats fish and seafood products of a composition corresponding to the European average.

Assessments of the national dietary exposures based on the results in the SCOOP report

The data available in the SCOOP report are not suitable for a probabilistic analysis. Based on the results in the SCOOP document, national average exposures to total mercury from fish and seafood products are between 1.3 (the Netherlands) and 97.3 µg/week (Portugal), corresponding to <0.1 to 1.6 µg/kg body weight per week (assuming a 60 kg body weight for adults) (Table 1). Based on the results from the same report, the range of high exposure in Member States is estimated to be between 0.4 µg/kg body weight per week (Ireland) and 2.2 µg/kg body weight per week (Greece) of total mercury.

Table 1. Summary of the data for fish- and seafood product consumption and dietary intake of methylmercury (MeHg) from such foods according to the SCOOP task 3.2.11 for countries showing high and low intakes

	The Netherlands	**Portugal**	**Ireland**	**Greece**	**France**	**Norway**
Food consumption	*(g/day)* *Mean (High)*	*(g/day)* *Mean (High)*	*(g/day)* *Mean (High)*	*(g/day)* *Mean (High)*	*(g/day)* *Mean (High)*	*(g/day)* *Mean (High)*
- Fish and seafood[1]	*10 (-)*	*50 (-)*	*20 (75)*	*41 (71)*	*35 (-)*	*80 (275)*
Intake of MeHg[2]						
SCOOP: **International dietary exposure**[3]	*µg MeHg/kg bw/week*	*µg MeHg/kg bw/week*	*µg MeHg/kg bw/week*	*µg MeHg/kg bw/week*	*µg MeHg/kg bw/week*	*µg MeHg/kg bw/week*
- Mean	0.1	0.6	0.3	0.5	0.4	1.0
- High[4]		-	1.0	0.9	-	3.5
SCOOP: **National dietary exposure**[5]						
- Mean	<0.1	1.6	<0.1	0.5	0.3	0.4
- High	-	-	0.4	2.2	-	1.8

[1] *Including fish, crustaceans, bivalves and molluscs*

[2] *Assuming that all mercury is methylmercury*

[3] *Estimated intake = Consumption of fish- and seafood products x 109 µg/kg food.*

[4] *High percentile represents 95th or 97.5th percentile of the distribution depending of the country considered*

[5] *Estimated intake = Consumption of fish- and seafood products x national data for the concentration of mercury.*

The SCOOP data showed that, although the population in Norway had the highest total consumption of fish and seafood products, the estimated high intake of methylmercury from these foods was lower in Norway than, for instance, in Greece. The reason for this is probably that the type of fish consumed in Norway consists of species, such as cod and saithe, which contain relatively low levels of methylmercury. The consumption of large predatory fish, which are at the top of the food chain such as swordfish and tuna, which all contain higher levels of methylmercury, may be significantly greater in countries in southern Europe.

Refined intake assessment using national data

A probabilistic analysis of the likelihood of exceeding the PTWIs was carried out using the French contamination data as reported to SCOOP in combination with the distribution of fish and seafood product consumption in France (Table 2).

The probability for a population to reach an exposure over the JECFA-PTWI and the U.S.-NRC limit was calculated using an empirical method, in which the individual consumption of each consumer of seafood products is multiplied by the mean level of contamination. The empirical probability is calculated as the number of subjects with an intake greater than 1.6 µg/week divided by the total number of subjects in the survey.

Table 2. Exposure assessment and probability of overstepping the tolerable intakes based on the distribution of consumption and fish contamination in France (Tressou *et al.*, 2004).

Group	Number of subjects	Mean consumption (g/week)	Mean exposure	50th %ile	97.5th %ile	Empirical probability of exceeding the PTWI (µg/kg bw/week)	
			(µg/kg bw/week)			JECFA (1.6)	U.S.-NRC (0.7)
Children 3-6 years	293	178	0.83	0.61	3.0	11.3%	44%
Adults 25-34 years	248	282	0.38	0.28	1.28	1.2%	17%

Children in the 3 to 6 year age group consume a greater amount of fish and seafood products than adults, when the consumption is expressed on a body weight basis. The calculated probabilities of exceeding the methylmercury exposure limits are therefore much higher for small children, who may then constitute a group with increased exposure.

It should be noted that these calculations were performed for a country in which fish and seafood products are consumed in relatively small amounts. For example, the consumption of fish at the 97.5th percentile intake in France is about 880 g per week/person corresponding to 125 g/day which is about one-half the amount consumed in Norway.

In addition, since the SCOOP-data were submitted, the Norwegian Food Safety Authority has made a more detailed intake calculation of mercury based on individual consumption figures for fish and seafood products and self-reported body-weight. The intake calculations were based on data on food consumption and the mean concentration of mercury in foods that were submitted to the SCOOP task. Instead of using single point estimates for food consumption (mean and 95th percentile), which was the case when assessing the mean and high intake of mercury for the SCOOP task, the new intake estimate was based on the distribution of the consumption values. This means that the individual consumption estimate for each species of fish and seafood products was multiplied with the concentration value for this particular fish species and seafood products. Subsequently, the intake of mercury from each of the fish and seafood products was totalled for each individual. The resulting distribution of the total intakes of all the participants was used to derive the mean and 95th percentile intake of mercury. The self-reported body weight of each participant was used in order to calculate the intakes expressed on a body weight basis.

Based on the distribution of the intake of mercury among the consumers of fish and seafood products (n=5696) the estimated intake of mercury was 1.0 µg/kg body weight per week (at the 95th percentile). Female participants of childbearing age (n=1565) had an estimated high intake of mercury (95th percentile), equal to the intake among the rest of the participants.

These estimates show a considerably lower high-level intake from fish and seafood products than the high international estimated exposure of 3.5 µg/kg body weight/week for Norway. This is mainly due to a lower concentration in the fish most commonly eaten in Norway (i.e. <50 µg/kg fish) than the mean concentration of 109 µg mercury/kg fish used when estimating the international intakes of the substance. However, the estimates are also lower than the SCOOP high national intake for Norway (1.8 µg/kg body weight/week). This may be explained by the methods used for estimating the exposure. As mentioned before, the SCOOP estimates were based on single points estimates for consumption (95th percentile) combined with single point estimates for concentration, which generates higher high-level intakes than when the distribution of individual intake estimates are used to derive high-level intake.

Hazard Characterisation

Evaluations of methylmercury by the JECFA and by the U.S.-NRC

In 1999, the fifty-third meeting of the JECFA reviewed information that had become available since its previous evaluation, particularly the information available on neurobehavioral development in children in the Faroe Islands and Seychelles. Because of the absence of any clear indication of a consistent risk in the epidemiology studies available at that time, the fifty-third meeting recommended that methylmercury should be re-evaluated at a subsequent meeting, in order to consider the 96-month evaluation of the Seychelles cohort and other relevant data that may have become available. The provisional tolerable weekly intake (PTWI) for methylmercury was not reconsidered and was maintained at the value established previously (200 µg of methylmercury equivalent to 3.3 µg per kg of body weight). This value was originally based on adverse effects in adults exposed during a poisoning outbreak in Iraq, and did not allow for the fact that the foetus could be more susceptible than the mature organism.

The sixty-first meeting of the JECFA in 2003 (JECFA, 2003) reviewed new data and analyses from the Seychelles Islands cohort and concluded that no adverse effects of prenatal methylmercury exposure had been detected in this cohort, in which intake occurs mainly from high levels of fish consumption. In contrast, neuropsychological deficits that correlated with the extent of methylmercury exposure have been detected consistently in a cohort of children in the Faroe Islands, in which intake occurs mainly from the consumption of whale meat. Stratifying analyses of the data from the Faroe Islands were used to allow for any confounding by possible neurotoxic effects of PCBs which are contaminants in whale blubber. The results from the two cohorts were combined in the JECFA evaluation, and the JECFA concluded that both were consistent with the absence of appreciable adverse effects in children born to mothers with hair concentrations of 14 µg mercury/g maternal hair. However, the Panel noted that this hair level was not a NOAEL in the data from the Faroe Islands. Information from other studies, including data from exposed cohorts in Iraq and New Zealand, were not incorporated quantitatively in the combined exposure-response assessment because these data were derived from smaller cohorts or differed substantially in study design.

The maternal hair concentration of 14 µg mercury/g was converted by the JECFA to a blood concentration using the average hair:blood ratio from a number of studies of Caucasian and Oriental subjects; the resulting maternal blood concentration (0.056 mg/L) was converted to a daily intake (1.5 µg/kg body weight) using an equation which incorporated the rate of elimination. Uncertainty factors were applied to allow for interindividual variability in the hair:blood ratio (2-fold) and in the rate of elimination ($10^{0.5}$ or 3.16-fold). Uncertainty factors for interindividual variability in (toxicodynamic) vulnerability or for incompleteness of the database were considered not to be necessary. Thus the PTWI was estimated as 1.6 µg/kg body weight/week ([1.5/6.32] µg/kg body weight/day). The JECFA considered that the available data for other effects, such as cardiotoxicity, were not conclusive and could not be used as a basis for estimating the PTWI.

As directed by the U.S. Congress, the U.S. Environmental Protection Agency (EPA) asked the U.S.-NAS to perform an evaluation of the toxicological effects of methylmercury and to prepare recommendations on the establishment of a scientifically appropriate methylmercury exposure reference dose (RfD) (NRC, 2000). The U.S.-NRC used benchmark dose level from the Faroes study (12 µg mercury/g maternal hair) and used a composite uncertainty factor of 10, to take into account interindividual variability and incompleteness of the data base, to derive an exposure limit of 0.1 µg/kg body weight per day or 0.7 µg/kg body weight per week. Further probabilistic modelling including the results of the three prospective studies (Faroe Islands, New Zealand, and Seychelles Islands) led basically to the same outcome. This limit agreed with the limit calculated previously by the U.S.-EPA on the basis of marked adverse effects in children prenatally exposed to methylmercury during a poisoning incident in Iraq, but the U.S.-NRC suggested that the justification should be based on the more recent epidemiological evidence on children exposed prenatally.

These risk assessments are based on studies of internal dose, as reflected by mercury concentrations in blood or hair. They have then been translated to average daily intake levels that can be compared with intake assessment included in the present opinion.

Evaluation of methylmercury by the Scientific Panel on Contaminants in the Food Chain

The Panel agrees with the JECFA and the U.S.-NRC evaluations that the developing brain should be considered the most sensitive target organ for methylmercury toxicity. The Panel also agrees with the JECFA that human risk assessment is possible on the basis of the prospective epidemiological studies on childhood development. However, an increasing body of data is now indicating that raised methylmercury exposure may augment the risk of cardiovascular morbidity and mortality (JECFA, 2003), but the complexity of the information available precludes a conclusion at this time.

There is a very large toxicity database from animal and epidemiology studies, and substantial complexity involved in assessing dose-response relationships from the available epidemiological data. In addition, the mathematical conversion of the exposure biomarker in the different cohorts into intake estimates depends on several assumptions, each associated with some degree of uncertainty. The Panel has noted that different approaches and uncertainty factors have been used in recent evaluations (e.g. the JECFA and the U.S.-NRC).

In interpreting the JECFA evaluation, several aspects should be kept in mind, which might lead to a lower exposure limit, such as the one determined by the U.S.-NRC. First, the benchmark dose level is a statistically defined point of deviation, and whether in the case of methylmercury it is consistent with a negligible adverse effect, as was concluded by the JECFA, will require careful and detailed consideration. Second, exposure assessment in epidemiological studies is always imprecise, since the exposure is not controlled *a priori*. In the case of methylmercury, calculation of the intake is complex because it is based on the conversion of biomarker data such as hair levels into daily intake. Imprecision in intake estimates may lead to underestimation of the true mercury effect and to an overestimation of the benchmark dose level. Third, epidemiology studies are associated with uncertainty because the effect of a single factor is ascertained in a situation where many covariates may affect the outcome. There are a large number of potential confounders in the main epidemiology studies on methylmercury, such as the source and pattern of methylmercury exposure, the nature of the populations, the influence of nutrition, and the presence of other pollutants such as PCBs, which make comparison of the studies and interpretation of the data difficult. Factors of potential relevance to the performance of children in neuropsychological tests, and that were not considered in the study reports include the possibility of an uneven distribution of parental consanguinity in isolated island populations which has been reported for the Faroe Islands and which could result in a depression of the performance of the children, and a number of other social, nutritional and environmental factors. All of these complexities need to be taken into account in evaluating the dose-response relationships and in assessing the adequacy of the uncertainty factors used in the recent evaluations.

The reduction of the PTWI for methylmercury by the JECFA at its latest meeting is justified because the new PTWI is based on the most susceptible lifestage, i.e. the developing foetus and intake during pregnancy, rather than on the general adult population, which was the basis for their previous evaluation. The recent evaluations by the JECFA and the U.S.-NRC considered several sources of uncertainties. The health based guidance values differed by a factor of two, and arose largely because of the different uncertainty factors used. Any refinement of the hazard characterisation for methylmercury will be dependent on resolution of a number of generic issues that have been raised above. The Panel recognises that this will require the establishment of working groups by the EFSA Scientific Committee.

Risk characterisation

Exposure evaluation based on the SCOOP data can be compared to the new PTWI of the JECFA. Comparison with the lower U.S.-NRC limit may offer additional guidance.

Fish and seafood products are important sources of energy, protein, and a variety of essential nutrients, such as vitamins, trace elements, and fatty acids. The nutrient contents vary between species, and dietary advice should seek to optimize the contribution of fish and seafood products to a healthy diet, while at the same time minimizing the exposure to contaminants, such as methylmercury.

Simplistic analyses of the data in the SCOOP report indicated that the international mean intake of methylmercury was below the PTWI established by the JECFA in 2003. Population-groups who frequently consume large predatory fish, such as swordfish, tuna, and halibut, may have a considerably higher intake of methylmercury and exceed the PTWI. Based on national data the highest average intake estimates were just at the PTWI and exceeded the U.S.-NRC exposure limit.

Analyses were done on national data sets in order to assess the probability of intakes above the PTWI established by the JECFA in 2003. The limited data available indicate that proportions of young children may exceed the PTWI when expressing exposure on a body weight basis. In addition, a percentage of adult populations with higher fish consumption would be predicted to have intakes above the PTWI. Nevertheless, the quality of data at European level is not sufficient to assess the size of these population groups.

Conclusions and Recommendations

The major source of methylmercury intake in humans is fish and seafood products. Specifically, large predatory fish which are at the top of the food chain, such as swordfish and tuna, which all contain higher levels of methylmercury, are significant sources of human exposure to methylmercury. Food sources other than fish and seafood products may also contribute mercury exposure, but mainly in the form of inorganic mercury that would not affect the current opinion on methylmercury.

The developing brain is the most sensitive target organ for methylmercury toxicity; *in utero* exposure is believed to be the critical period for methylmercury neurodevelopmental toxicity, although the duration of increased susceptibility may extent into postnatal development. To derive a PTWI, the JECFA used the data from two major epidemiological studies of foetal neurotoxicity performed in the Faroe Islands and the Seychelles Islands thereby basing its evaluation on the most sensitive population. The data from the SCOOP report indicate that the average intake of fish and seafood products in some countries may be close to the JECFA PTWI and, when compared to the previously established U.S.-NRC limit, some average intake levels may exceed this limit. Specific intake data for pregnant women are not available.

The data available in the SCOOP report do not allow reliable estimations of the intakes by high consumers in different populations. Because in some cases the estimated intakes based on the SCOOP report are close to or exceed the PTWI, specific intake studies, especially for women and children, should be performed on methylmercury. A more complete evaluation of exposures in Europe that includes data on internal dose levels would allow direct comparison of exposure with the dose-effect relationships, which are the basis for the hazard characterisation.

Mercury compounds serve no biological purpose in the human body. Methylmercury toxicity has been demonstrated at low exposure levels, and exposure to this compound should therefore be minimized, while recognizing that fish represents an important part of a balanced nutrition.

Documentation provided to EFSA

EC (European Commission), 2003. Draft Report from Task 3.2.11: Assessment of the dietary exposure to arsenic, cadmium, lead and mercury of the population of the EU Member States. European Commission, Directorate-General Health and Consumer Protection, Reports on tasks for scientific co-operation, Final draft, 5 December 2003.

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Reports on tasks
for scientific cooperation

Report of experts participating in Task 3.2.11

March 2004

Assessment of the dietary exposure
to arsenic, cadmium, lead and mercury
of the population of the EU Member States

Directorate-General Health and Consumer Protection

CONTENT **PAGE**

1. FOREWORD

According to Council Directive 93/5/EEC "on the assistance to the Commission and cooperation by the Member States in the scientific examination of questions relating to food" Member States of the European Union can cooperate on problems facing the Commission in the area of food. Directive 93/5/EEC also indicates that an inventory of Tasks to be undertaken has to be published as a Commission Decision at least every six months. For each Task, the participating Member States, the Member State which provides coordination and time limit for completion will be indicated. The rationale for each Task is to provide harmonised and reliable information to be used by the Commission for the management of problems related to food. With this aim the Competent Authorities responsible for Scientific Cooperation in the Member States nominate experts in the specific field of interest that will provide the Coordinator with the information necessary to prepare a final report. In principle the final report should contain factual information, but it should be underlined that gathering and presenting scientific data, especially deriving from sources of different origin, can require a degree of interpretation by experts and by the Coordinators. It is therefore important to stress that the interpretation and views in the present report are not necessarily those of the participating Member States or those of the European Commission.

1.1 Summary

Data on occurrence, consumption and intake calculations for the mean adult population were submitted by BE, DK, FI, FR, DE, HE, IR, IT, NL, NO, PT, SE and UK. Several factors have an impact on the validity of the intake estimation. The most important is probably the limited amount of occurrence data, which in many countries left several food groups empty. DK and UK had sufficient data for a complete intake assessment. Other confounding factors are differences in analytical quality and different choices of age groups for the intake estimations. The results therefore have to be viewed with caution.

The occurrence levels of Cd, Pb and Hg in foodstuffs, for which maximum limits (ML) have been established in Commission Regulation 466/2001, are generally well below the MLs.

Arsenic. Nine Member States submitted occurrence and intake data for arsenic in fish, the main source of arsenic in the food, for the mean adult population. Very few data was provided on arsenic in other foodstuffs. An accurate estimation of the total intake is therefore not possible in most Member States. The results from DK and the UK, which cover all major food groups, indicate that fish and other seafood contribute more than 50% of the dietary arsenic. The mean daily intake of arsenic from fish and other seafood is below 0.35 mg. It is thus assumed that the total daily intake of arsenic by the mean adult population is below 1 mg. Consumers of fish and seafood may reach an intake of 1 mg/day from these foods alone.

Data from FR and DE indicate that children have a lower intake of arsenic than adults. The burden/kg bodyweight of children may, however, be larger than for adults due to their lower bodyweight.

The type of water in which the fish is caught, i.e. marine or fresh, is of major importance for the As-content, with the highest levels in marine species. No data was available on the inorganic arsenic-species, which are the most toxic species present in food. The ratio inorganic/total As in foodstuffs is thus largely unknown.

Cadmium. Thirteen Member States submitted occurrence and intake data for the mean adult population. DK, FI, FR, DE and the UK had the best data to make an accurate intake estimation. IR had data for only two food categories. The mean intake in the Member States is less than 30% of the PTWI, with the exception of the Netherlands with 38%. The PTWI is 0.49 mg for a person weighing 70 kg. In the UK the intake by mean consumers is 22% of the PTWI, whereas for high consumers is 37% of the PTWI. Cereals and vegetables are the main sources of cadmium in the diet, representing approximately 2/3 of the mean cadmium intake.

Data from FR and DE indicate that children have a lower intake of cadmium than adults. However, children have a larger burden/kg body weight, due to their lower body weight. The cadmium dietary intake of children 4-6 years old is estimated to 65% of the PTWI.

Lead. Twelve Member States submitted occurrence and intake data for the mean adult population. Only DK and the UK had sufficient data to make a complete intake estimation. All other Member States were lacking data from one or several food groups. The results indicate,

however, that in 11 Member States the average intake of lead via food by is less than 25% of the PTWI, which is 0.025 mg/kg bodyweight/week (equal to 1.75 mg for a person weighing 70 kg). In PT the intake was in the order of 50% of the PTWI. This high intake is due to certain food groups which were reported to contain unusually high lead levels. In PT these foods, e.g. potatoes, were analysed with methods with extremely high detection limits ($\leq$1 mg/kg). Since half of that limit is used as the occurrence level for the intake calculation, intake may erroneously appear to be very high. In e.g. IR the intake is underestimated (0.4% of the PTWI) since occurrence data were available only from a few food items.

The mean intake in the Member States is 14% of the PTWI. In the UK the intake by the mean population is 11% of the PTWI, whereas the intake by mean consumers is 24% and for high level consumers 43% .

Specific foodstuffs from some Member States were reported to contain very high lead levels (wine, game, fish and meat). If these high occurrence levels are confirmed, or the sampling found to be representative, consumers in these Member States may be at risk of exceeding the PTWI.

Data from FR and DE indicate that children have a lower intake of lead than adults. However, children have a larger burden/kg body weight, due to their lower body weight, and may reach 35 % of the PTWI.

Mercury. Thirteen Member States submitted occurrence and intake data for fish**.** DK, DE and the UK had the best data to make an accurate intake estimation. FI, IT and SE had data for only one food category. Fish is the main source of mercury in the food, for the mean adult population. In fish and shellfish, mercury is present mainly in the form of methylmercury, while its almost entirely inorganic mercury in other foodstuffs.Fruits and vegetables are the main source of mercury in FR, NL and DE. In FR and DE mushrooms is included in this category,which strongly affects the intake level. Dried fruit and vegetables also has an enhancing effect on the intake in DE.
The mean intake for the Member States is less than 30% of the PTWI for total mercury, corresponding to 0.35 mg for a person weighing 70 kg. In the UK the intake by mean consumers is 6% of the PTWI, whereas for high consumers is 13% of the PTWI.

The current PTWI (established 2003) for methylmercury is 1.6 µg/kg bodyweight, which corresponds to 0.112 mg/week for a person weighing 70 kg. Data were reported for total mercury, but as an overestimate assuming this was all methylmercury, the mean intake of methylmercury from fish and shellfish in the Member States would be less than 30% of the PTWI for methylmercury. In the UK the methylmercury intake by mean consumers would be 13% of the PTWI, whereas for high consumers it would be 41% of the PTWI for methylmercury. In NO the methylmercury intake by mean consumers would correspond to 78% of the PTWI for methylmercury, whereas for high consumers, the PTWI for methylmercury would be exceeded.

Data from FR and DE indicate that children have a lower intake of mercury than adults. However, children have a larger burden/kg body weight due to their lower body weight. Depending upon the proportions of methylmercury present in the foods tested for total mercury, it is possible that the intake could exceed the PTWI for methylmercury .

The results from the SCOOP task indicate that there is a risk that population-groups with a high consumption of fish and seafood may have intakes of methylmercury that are close or even exceed the PTWI for methylmercury of 1.6 µg/kg body weight/week. More information is needed on the relative proportions of methylmercury to total mercury in different foods.