European Food Safety Authority

18 MARCH 2004

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.

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.