

SCIENTIFIC OPINION

Statement on the benefits of fish/seafood consumption compared to the risks of methylmercury in fish/seafood¹

EFSA Scientific Committee^{2, 3}

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ABSTRACT

Following a request from the European Commission to carry out a risk benefit analysis as regards the risks and benefits to human health of fish/seafood consumption related to methylmercury, the EFSA Scientific Committee used previous work performed by the EFSA Panel on Contaminants in the Food Chain and the EFSA Panel on Dietetic Products, Nutrition and Allergies to create scenarios based on typical fish consumption patterns of population groups at risk of exceeding the tolerable weekly intake (TWI) for methylmercury. The Scientific Committee then estimated how many servings of fish/seafood per week these population groups would need to reach the TWI for methylmercury and the dietary reference value (DRV) for n-3 (Long-Chain) Polyunsaturated Fatty Acid (LCPUFA). When consuming species with a high methylmercury content, only a few numbers of servings (<1-2) can be eaten before reaching the TWI, which may be attained before the DRV. To protect against inter alia neurodevelopmental toxicity of methylmercury and achieve the benefits of fish consumption (effect of fish/seafood consumption during pregnancy on functional outcomes of children's neurodevelopment and on cardiovascular diseases in adults), which are associated with 1-4 fish servings per week, fish/seafood species with a high content of mercury in the daily diet should be limited. Because a variety of fish species are consumed across Europe, it is not possible to make general recommendations on fish consumption. The Scientific Committee therefore recommends that each country needs to consider its own pattern of fish consumption, especially the species of fish consumed, and carefully assess the risk of exceeding the TWI of methylmercury while obtaining the health benefits from consumption of fish/seafood.

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KEY WORDS

Fish, risk-benefit, methylmercury, n-3 long chain fatty acids, servings, exposure, consumption

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SUMMARY

In December 2012, EFSA received a request from the European Commission to carry out a risk benefit analysis as regards the risks and benefits to human health of fish/seafood consumption related to methylmercury. As the EFSA Panel on Contaminants in the Food Chain (CONTAM) had adopted a scientific opinion on the risk for public health related to the presence of mercury and methylmercury in food (EFSA CONTAM Panel, 2012) the month before, the mandate was given to the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) who evaluated the beneficial effects of fish/seafood consumption in relation to health outcomes (effect of fish/seafood consumption during pregnancy on functional outcomes of children's neurodevelopment and the effects of fish/seafood consumption on cardiovascular diseases in adults) (EFSA NDA Panel, 2014). Having reviewed the conclusions of these two opinions during the 68th Plenary meeting of the Scientific Committee (8-9 July 2014), a decision was made that the Scientific Committee would produce a scientific statement, using the CONTAM and NDA Panels' work as a starting point, to answer the mandate received from the European Commission. As requested by the European Commission, this statement addresses the benefits of fish/seafood consumption, using n-3 long-chain polyunsaturated fatty acids (LCPUFA) as an example of related beneficial substance, compared to the risks of methylmercury in fish/seafood. Exposure to other possible contaminants (e.g. inorganic mercury and dioxin-like compounds) is not specifically addressed. In this respect, the Scientific Committee refers to the CONTAM opinion on the safety assessment of wild and farmed fish (EFSA CONTAM Panel, 2005). In that opinion the CONTAM Panel identified the following factors as having a major impact on both the nutrient and contaminant levels of fish: species, season, location, diet, life stage and age and, for some contaminants, regional differences.

In its opinion in 2012 on mercury, the CONTAM Panel assessed the data on mercury in food received from 20 European countries, of which about 22000 results were for the food group 'Fish and other seafood'. The mercury content varied widely among different fish species, and was highest in predatory fish. In order to assess dietary exposure to methylmercury it was assumed that the mercury was 100 % methylmercury in fish meat, fish products, fish offal and unspecified fish and seafood, and 80 % methylmercury in crustaceans, molluscs and amphibians, whereas other foods were assumed to contain inorganic mercury only. There is a wide variation in fish/seafood species consumed in different countries in the EU. Different fish/seafood species vary greatly in their content of n-3 LCPUFA as well as in their content of mercury. The fraction of fish consumers and the amount of fish/seafood consumed also vary substantially between countries.

Based on several epidemiological studies, the NDA Panel (EFSA, 2014) concluded that an intake of from 1–2 up to 3–4 servings per week of fish/seafood during pregnancy was associated with beneficial effects on functional neurodevelopment in children and on adults with coronary heart disease. This means that in the range of 1–4 servings per week, the benefits of fish consumption (as compared to no fish) outweigh the risks, whatever the respective contribution to this net effect of beneficial and harmful fish components may be. It is however noted that there are a number of uncertainties in these epidemiological studies about actual serving sizes and actual contents of the potentially active positive and negative components in fish/seafood consumed. In addition, fish and seafood provide many nutrients, in particular n-3 LCPUFA. Contrasting with the wealth of evidence reporting on the net beneficial balance of fish/seafood consumption, the availability of data allowing estimation/calculation of the net true effect of each fish component (especially n-3 LCPUFA and methylmercury) for each side of the balance is limited.

With regard to methylmercury the CONTAM Panel considered several adverse outcomes and established a tolerable weekly intake (TWI) of 1.3 μ g/kg bw/week for methylmercury based on prenatal neurodevelopmental toxicity.

The CONTAM Panel took account of the negative confounding effect of n-3 LCPUFA on the neurotoxicity of methylmercury. Conversely, one would expect methylmercury to negatively confound the positive impact of fish consumption on neurodevelopment and cardiovascular outcomes, but very few data are available on this issue.

Due to inadequate data, a full characterisation of the benefit of fish consumption was not performed. There is a large variation in the average amount of fish intake among the consumers of different age groups across Europe and not all consumers meet the recommended intake of fish of 1–2 servings (equivalent to 150–300 g) per week or the dietary reference value (DRV) for n-3 LCPUFA.

Estimated mean dietary exposures to methylmercury across age groups did not exceed the TWI, with the exception of toddlers and other children in some surveys. The medians of 95th percentile dietary exposures across surveys were close to or above the TWI for all age groups. Fish meat was the dominating contributor to methylmercury dietary exposure for all age classes, followed by fish products. In particular tuna, swordfish, cod, whiting and pike were major contributors to methylmercury dietary exposure in the adult age groups, while the same species, with the addition of hake, were the most important contributors in the child age groups. Dietary exposure in women of child-bearing age was not different from adults in general.

The methodology by which several of the dietary surveys available from 17 EU countries were conducted (i.e. 2-day dietary recalls or 3-day dietary records) overestimate the high ends of the distribution of fish/seafood intake and methylmercury exposure, particularly when transforming the intake data from daily to weekly intake. Therefore, scenarios were created to calculate, based on the composition of the main contributing fish/seafood species and serving sizes reported, the exposure to methylmercury and n-3 LCPUFA intake resulting from consumption of various fish/seafood items typical for different population groups. It was then estimated how many servings of fish/seafood per week a given population group would need to reach the TWI for methylmercury and the DRV for LCPUFA.

The age groups exceeding the TWI for methylmercury at the fewest number of servings per week were toddlers (1–<3 years) and other children (3–<10 years). In a few cases of other children, adolescents, women of childbearing age, adults and elderly, the TWI was reached after less than and around 1 serving per week. In most other cases for toddlers and other children the TWI was reached when the number of servings per week was between 2 and 3. In most cases the TWI for mercury was reached with between 2 and 4 servings per week. For the same groups the intake of n-3 LCPUFA met the DRV at higher than or equal to the number of servings per week that they reached the TWI for methylmercury.

Consuming species with a high content of methylmercury influences the number of servings that can be eaten before the TWI for methylmercury is reached. In the majority of cases the reported serving sizes were below 100g. For toddlers, children and women of childbearing age, the benefits of eating fish should be met by increasing the consumption of species low in mercury. In order to protect the foetus against adverse neurodevelopmental effects of methylmercury, women of childbearing age should not exceed the TWI. As the brain is developing also after birth, toddlers and children exposed to methylmercury above the TWI on a regular basis should also be considered at risk for neurotoxic effects of methylmercury. Besides limiting the intake of fish/seafood species with a high content of mercury in the daily diet to avoid regular exposure above the TWI, it is not possible to make general recommendations on fish consumption across Europe. The Scientific Committee therefore recommends that each country needs to consider its own pattern of fish consumption, especially the species of fish consumed, and carefully assess the risk of exceeding the TWI of methylmercury while obtaining the health benefits resulting from consumption of fish/seafood.



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1. Introduction

1.1. Background and Terms of Reference as provided by the European Commission

The Commission asked the Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) to issue a scientific opinion on the risk for public health related to the presence of mercury and methylmercury (MeHg) in food. The scientific opinion was published in 2012 (EFSA CONTAM Panel, 2012).

Fish consumption is known to have beneficial effects on human health due to its nutrients, e.g. long chain n-3 polyunsaturated fatty acids that have beneficial effects on the neurodevelopment of children. On the other hand, fish contains methylmercury, the most toxic form of mercury which is known to have adverse effects on children's neurodevelopment. It is therefore important that fish consumption is such that benefits are maximised while risks are minimised.

As a follow up and second step to the question on mercury and methylmercury in food, the Commission therefore asked EFSA to carry out a risk benefit analysis as regards the risks and benefits analysis to human health of fish/seafood consumption related to methylmercury. The risk benefit analysis should fully take into account the information and conclusions drawn in the scientific opinion on mercury and methylmercury in food as well as the conclusions of the Joint FAO/WHO Expert consultation on the risks and benefits from fish consumption on 25–29 January 2010. This will enable the Commission and the Member States to take appropriate risk management action, e.g. to give dietary advice to consumers of fish

In accordance with Article 29 (1) (a) of Regulation (EC) No 178/2002 the European Commission asks the European Food Safety Authority for a scientific opinion on the risks and benefits of fish/seafood consumption to human health related to methylmercury.

In particular, the opinion should

- address risks and benefits as regards fish/seafood consumption related to relevant beneficial substances (e.g. nutrients such as long-chain n-3 polyunsaturated fatty acids) and the contaminant methylmercury
- address risks and benefits for relevant sub groups of the population (e.g. maternal fish consumption during pregnancy and breastfeeding, infants, children, general adult population, etc.)

The opinion should fully take into account all the findings and conclusions of the EFSA opinion on the risks for public health related to the presence of mercury and methylmercury in food as well as the dietetic benefits of eating fish. The conclusion of the Joint FAO/WHO Expert consultation on the risks and benefits from fish consumption should also be taken into account.

1.2. Interpretation of the Terms of Reference

The Scientific Committee noted that the mandate had been partially addressed by two opinions from the EFSA Panel on Contaminants in the Food Chain (CONTAM) and the Panel on Dietetic Products, Nutrition and Allergies (NDA). The first opinion addressed the risk for public health related to the presence of mercury and methylmercury in food (EFSA CONTAM Panel, 2012). The second opinion assessed the health benefits of seafood (fish and shellfish) consumption in relation to health risks associated with exposure to methylmercury (EFSA NDA Panel, 2014). The Scientific Committee reviewed the conclusions of these two opinions during its 68th Plenary meeting (8–9 July 2014) and considered which further steps are possible to further address the question received from the European Commission. A decision was made that the Scientific Committee would produce a scientific statement, using the CONTAM and NDA Panels' work as a starting point to answer the mandate received from the European Commission.



As requested, this statement focuses on the benefits of fish/seafood consumption compared to the risks of methylmercury in fish/seafood. Exposure to other possible contaminants (e.g. inorganic mercury and dioxin-like compounds) is not specifically addressed. In this respect, the Scientific Committee refers to the CONTAM opinion on the safety assessment of wild and farmed fish (EFSA CONTAM Panel, 2005).

1.3. Additional information

Mercury is released into the environment by both natural and anthropogenic sources, and exists as elemental or metallic mercury, inorganic mercury and organic mercury. Methylmercury is by far the most common form of organic mercury in the food chain. In the aquatic environment, mercury is methylated by microbial and abiotic processes mainly in sediments in fresh and ocean water but also in the water columns. Total mercury concentrations in foods, except for fish and other seafood, generally do not exceed 50 μ g/kg. Higher concentrations are observed in fish and other seafood, which therefore provide the major source of dietary exposure to methylmercury in consumers. The contribution of methylmercury to total mercury is typically 80–100 % in fish and 50–80 % in seafood other than fish. In other foods, mercury is presumed to be present as inorganic mercury. The amount of mercury in fish is related to the age of the fish and the position of the fish species within the food chain, predatory fish and older fish having higher concentrations than others. Unlike some persistent contaminants (e.g. dioxins and PCBs), mercury content is not related to the fat content of the fish and therefore is not considered specifically associated with oily fish (EFSA CONTAM Panel, 2012).

Some fish species that usually have higher concentrations of mercury include shark, swordfish and marlin. Examples of fish with low concentrations of mercury include herring, salmon and trout. Tables 6 and A9 of the EFSA CONTAM Panel opinion (2012) provide a detailed statistical description of the concentrations of mercury in different types of fish.

There are maximum levels set for mercury in fish feed (Directive (EC) 2002/32) but because the types of fish that generally contain higher levels of mercury are wild, not farmed, it is not possible to reduce the levels by controls on feed. It is noted though that there has been a 50 % reduction in the mercury content of Norwegian farmed salmon in the period from 2006 to 2014; the current concentration (14 μ g/kg fillet) is very low in comparison with wild fish species contributing to mercury exposure from fish (VKM, 2014). The only prospects for reducing mercury levels in wild fish are by reducing emissions of mercury to the environment. This needs to occur throughout the world because of the long-range transmission of mercury in the environment. Considerable reduction in production, use and industrial discharge of mercury has occurred during the last decades, but this has been countered by an increase in emissions of mercury from coal burning and artisanal gold mining (Bjerregaard et al., 2014). Recently, an international treaty, the Minamata Convention, was developed under the auspices of the United Nations Environment Program (UNEP), and was ratified by delegates from 140 countries on January 19, 2013. It aims to reduce the release of mercury to the immediate environment resulting from human activities⁴.

2. Data and Methodologies

2.1. Data

The Scientific Committee used the opinion of the EFSA CONTAM Panel on the risk for public health related to the presence of mercury and methylmercury in food (EFSA CONTAM Panel, 2012) and the EFSA NDA Panel opinion on the health benefits of seafood (fish and shellfish) consumption in relation to health risks associated with exposure to methylmercury (EFSA NDA Panel, 2014) as the main source of data for the hazard / positive health effect characterisation of its risk benefit assessment. The Scientific Committee also considered previous work of the CONTAM panel for the hazard characterisation of methylmercury for human health, as well as the NDA opinion on Dietary Reference Values (DRVs) for fats, including saturated fatty acids, polyunsaturated fatty acids,

⁴ http://www.mercuryconvention.org/Home/tabid/3360/Default.aspx



monounsaturated fatty acids, *trans* fatty acids, and cholesterol (EFSA NDA Panel, 2010) to retrieve the adequate n-3 LCPUFA intake values for various population groups. A summary of this information is provided in the following sections.

2.1.1. Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to mercury and methylmercury in food (EFSA CONTAM Panel, 2004)

In 2004, the CONTAM Panel issued a scientific opinion in relation to a request on the assessment of the risks to EU consumers from mercury, in particular methylmercury, in food. At that time the CONTAM Panel did not review the toxicological or epidemiological data on methylmercury, but referred to the health-based guidance values that had been established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the U.S. National Research Council (U.S.-NRC), i.e. 1.6 and 0.7 μ g/kg body weight (bw)/week, respectively. The exposure assessment was based mainly on the scientific co-operation (SCOOP) task 3.2.11 report related to heavy metals (EC, 2004). All the results were 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 exposure estimate for methylmercury, only the results related to fish, crustaceans, bivalves and molluscs were considered, with the assumption that all the mercury was methylmercury.

The weighted mean mercury concentration, based on all data for fish and seafood products submitted by the Member States, was $109 \pm 845 \ \mu g/kg$, the high standard deviation reflecting the wide variation in the analytical results. 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). Based on these values and the mean concentration, the mean estimated dietary exposure would be between 7 and 61 μ g/person per week of total mercury, corresponding to 0.1 to 1.0 μ g/kg bw/week for a 60 kg adult. For high consumers, the highest consumption of 275 g/day of fish and seafood products, the 95th percentile reported by Norway, indicated an exposure of 3.5 μ g/kg bw/week of total mercury for a 60 kg adult if the high consumer eats fish and seafood products of a composition corresponding to the European average. However, the types of fish consumed in different countries vary in a manner that means such a calculation is not necessarily appropriate. Based on national data for fish consumption and the concentrations of mercury in fish, estimated mean exposure ranged from <0.1 (the Netherlands) to 1.6 μ g/kg (Portugal) bw/week (assuming a 60 kg bw for adults). The range of high exposure was estimated to be between 0.4 μ g/kg bw/week (Ireland) and 2.2 μ g/kg bw/week (Greece) of total mercury.

The CONTAM Panel concluded that data from the SCOOP report indicated that the average intake of fish and seafood products in some countries may be close to the JECFA provisional tolerable weekly intake (PTWI) and some may exceed the U.S.-NRC value. Specific intake data for pregnant women were not available.

2.1.2. Opinion of the Scientific Panel on Contaminants in the food chain on a request from the European Parliament related to the safety assessment of wild and farmed fish. (EFSA CONTAM Panel, 2005).

In 2004, EFSA was requested by the European Parliament to conduct a scientific assessment of the human health risks related to consumption of wild and farmed fish. The resulting opinion, published in 2005, concentrated on some of the most popular fish species (farmed, wild, marine, freshwater, lean, and oily) marketed in the European Union, and therefore those most likely to be consumed more frequently. These were salmon, herring, anchovies, tuna, mackerel, pilchards, rainbow trout and carp. Furthermore, the assessment focused on those chemicals generally considered most relevant in the context of health risks of fish consumption and for which substantial analytical data exist. The CONTAM opinion summarises the toxicity of metals, selective organochlorine compounds, brominated flame retardants, and organotin compounds. Also, the nutritional composition of wild and farmed fish was considered as well as the beneficial effects associated with fish consumption.

The following factors were identified by the CONTAM Panel as having a major impact on both the nutrient and contaminant levels of fish: species, season, location, diet, life stage and age. The levels were found to vary broadly within species and between species in both wild and farmed fish. The limited data available indicated that there are no consistent differences between wild and farmed fish. However, regional differences exist, e.g. with increased contaminant concentrations in wild fish from the Baltic Sea.

Fish can contribute significantly to the dietary exposure to some contaminants, such as methylmercury, persistent organochlorine compounds (particularly polychlorinated dioxins and furans (PCDD/F), dioxin-like polychlorinated biphenyls (DL-PCBs)), brominated flame retardants and organotin compounds. The CONTAM Panel concluded that the most important of these are methylmercury and the dioxin-like compounds, for which high level consumers of certain fish may exceed the provisional tolerable weekly intake (PTWI) even without taking into account other sources of dietary exposure. Such exceedance is undesirable and may represent a risk to human health if repeated frequently.

The CONTAM Panel further concluded that, out of all the fish that are most commonly consumed in the EU, the highest levels of methylmercury are found in tuna, which is mostly caught in the wild.

The CONTAM Panel noted that contaminant levels in wild fish can only be reduced by long-term control of emissions of pollutants to the environment and advice on fish consumption needs to take into account total dietary exposure of relevant contaminants, based on national consumption patterns including relevant fish species. As mentioned above, the levels of chemicals in fish were found to vary broadly within species and between species. Therefore, any consideration of fish consumption in Europe has to take account of the international nature of fish production and trading, since fish is one of the most widely traded commodities.

2.1.3. Scientific opinion on the risks to human health related to the presence of inorganic mercury and methylmercury in food (EFSA CONTAM Panel, 2012).

The CONTAM Panel was asked to consider new developments regarding the toxicity of inorganic mercury and methylmercury since its last opinion (EFSA CONTAM Panel, 2004) and to evaluate whether the PTWIs established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) of 1.6 μ g/kg bw for methylmercury and of 4 μ g/kg bw for inorganic mercury were considered appropriate. The CONTAM Panel was also asked to assess human dietary exposure, taking into account specific sensitive groups and to consider the non-dietary sources of exposure to mercury. The opinion focused only on the risks related to dietary inorganic mercury and methylmercury exposure and did not assess the nutritional benefits linked to certain foods (e.g. fish and other seafood).

The CONTAM Panel assessed the data on mercury in food (approximately 60,000 results, mainly from 2004–2011 and mostly reported as total mercury) received from 20 European countries, of which 36.8 % were for the food group 'Fish and other seafood'. The mercury content varied widely among different fish species, and was highest in predatory fish. In order to assess dietary exposure to methylmercury it was assumed that the mercury was 100 % methylmercury in fish meat, fish products, fish offal and unspecified fish and seafood, and 80 % methylmercury in crustaceans, molluscs and amphibians, whereas other foods were assumed to contain inorganic mercury only.

In order to estimate dietary exposure, the mean methylmercury concentration for each specific fish species at the most detailed level possible was multiplied by the corresponding individual consumption amount per body weight separately for each individual within the dietary surveys, resulting in a distribution of individual exposures, from which the mean and 95th percentile were identified for each survey and age class.



The mean middle bound (MB) methylmercury dietary exposure across surveys and countries varied from the lowest minimum of 0.06 μ g/kg bw/week seen in elderly and very elderly to the highest maximum of 1.57 μ g/kg bw/week in toddlers. The 95th percentile MB dietary exposure across surveys and countries ranged from the lowest minimum of 0.14 μ g/kg bw/week in very elderly to the highest maximum of 5.05 μ g/kg bw/week in adolescents.

Fish meat was the dominating contributor to methylmercury dietary exposure for all age classes, followed by fish products. In particular tuna, swordfish, cod, whiting and pike were major contributors to methylmercury dietary exposure in the adult age groups, while the same species, with the addition of hake, were the most important contributors in the child age groups. Dietary exposure in women of child-bearing age was not different from adults in general. The dietary exposure estimations in high and frequent consumers of fish meat (95th percentile exposure, consumers only) was in general approximately two-fold higher in comparison to the total population and varied from a minimum MB of $0.54 \mu g/kg$ bw/week in the elderly to a maximum MB of $7.48 \mu g/kg$ bw/week in children.

The CONTAM Panel also reviewed the information related to toxicokinetics and adverse effects of methylmercury. After carefully considering endpoints other than neurodevelopmental outcomes, particularly cardiovascular disease, the CONTAM Panel concluded that associations between methylmercury exposure and neurodevelopmental outcomes after prenatal exposure still formed the best basis for derivation of a health-based guidance value for methylmercury. Reassessments of the results of studies conducted in the Seychelles, which included adjustment for prenatal maternal blood n-3 long-chain polyunsaturated fatty acids (n-3 LCPUFA), led to identification of an apparent no-observed-effect level (NOEL) at a mercury level of approximately 11 mg/kg maternal hair, which was lower than the previously assumed NOEL for this cohort. Taking this reanalysis into account, the CONTAM Panel established a tolerable weekly intake (TWI) for methylmercury of 1.3 μ g/kg bw expressed as mercury.

The estimated mean dietary exposures across age groups did not exceed the TWI for methylmercury, with the exception of toddlers and other children in some surveys. The medians of 95th percentile dietary exposures across surveys were close to or above the TWI for all age groups. Similarly, biomonitoring data on blood and hair concentrations indicated that in the general European population, methylmercury exposure is generally below the TWI. However, higher concentrations in blood and hair were also observed, confirming higher dietary exposure in some population groups. The CONTAM Panel concluded that high consumers of fish meat may exceed the TWI by up to approximately six-fold and that exposure to methylmercury above the TWI is of concern, but if measures to reduce methylmercury exposure are considered, the potential beneficial effects of fish consumption should also be taken into account.

2.1.4. Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol (EFSA NDA Panel, 2010)

The NDA Panel was asked to deliver a scientific opinion on Reference Intakes for fat for the European Population. Dietary fats or lipids are a major energy source for the body. Fatty acids are also involved in many other vital processes in the body (e.g. structural components of cell membranes, precursors for bioactive molecules, regulators of enzyme activities, regulation of gene expression).

Fatty acids can be classified according to their number of double bonds; polyunsaturated fatty acids (PUFA) have two or more double bonds, and are frequently subdivided into n-6 polyunsaturated fatty acids, n-3 polyunsaturated fatty acids, and n-3 long-chain polyunsaturated fatty acids (n-3 LCPUFA). This latter class of fatty acids has 20 or more carbon atoms.

The quantitatively most important n-3 LCPUFA in the diet are alpha-linolenic acid (ALA – C18:3), eicosapentaenoic acid (EPA – C20:5), docosapentaenoic acid (DPA – C22:5) and docosahexaenoic acid (DHA – C22:6).

ALA is essential in human nutrition as a precursor for the n-3 LCPUFA. EPA, DPA and to a lesser degree DHA are synthesised from ALA. ALA cannot be synthesised by the human body but is required to maintain "metabolic integrity"; it is therefore considered an Essential Fatty Acid. ALA is found in some vegetable foods, e.g. linseeds, rapeseed oil and walnuts, while fish is a unique rich source of n-3 LCPUFA (EPA and DHA).

Intervention studies have demonstrated beneficial effects of preformed n-3 LCPUFA on recognised cardiovascular risk factors, such as a reduction of plasma triacylglycerol concentrations, platelet aggregation, and blood pressure. These effects were mainly observed at intakes \geq 1g per day. In infants, DHA intakes at levels of 50 to 100 mg per day have been found effective for visual function during the complementary feeding period.

The NDA Panel set the following adequate intakes (AIs):

- 250 mg/day of EPA+DHA for adults, based on considerations of cardiovascular health
- 100 mg of DHA for infants/toddlers between 6 and 24 months
- No adequate intake is proposed for children aged 2 to 18 years but the dietary advice should be consistent with the advice for the adult population (which is 1 to 2 fatty fish meals per week or ~250 mg of EPA + DHA per day)
- 250 mg/day of EPA+DHA plus 100 to 200 mg preformed DHA for women during pregnancy or lactation.

2.1.5. Scientific Opinion on health benefits of seafood (fish and shellfish) consumption in relation to health risks associated with exposure to methylmercury (EFSA NDA Panel, 2014)

The NDA Panel was asked to address the risks and benefits as regards fish/seafood consumption related to relevant beneficial substances (e.g. nutrients such as n-3 long-chain polyunsaturated fatty acids (n-3 LCPUFA)) and the contaminant methylmercury.

The NDA Panel a) reviewed the role of seafood in European diets; b) evaluated the beneficial effects of seafood consumption in relation to health outcomes and population subgroups previously identified by the FAO/WHO Joint Expert Consultation on the Risks and Benefits of Fish Consumption and/or by the CONTAM Panel as relevant for the assessment. These include the effects of seafood consumption during pregnancy on functional outcomes of children's neurodevelopment, and the effects of seafood consumption on cardiovascular disease risk in adults; c) addressed which nutrients in seafood may contribute to the beneficial effects of seafood consumption in relation to the above-mentioned outcomes; and d) considered whether the beneficial effects of seafood consumption in relation to the above-mentioned outcomes could be quantified. The Panel focused on seafood consumption since in most of the epidemiological studies, dietary intake of n-3 LCPUFA is generally deduced from fish intake; in addition, available evidence indicates that the relationship between seafood intake and the very diverse biochemical markers of n-3 LCPUFA used in some studies is complex and confused by many other dietary and non-dietary factors.

On the basis of the data available, the Panel concluded that:

a) Seafood is a source of energy and protein with high biological value, and contributes to the intake of essential nutrients, such as iodine, selenium, calcium, and vitamins A and D, with well-established health benefits. Seafood also provides n-3 LCPUFA, and is a component of dietary patterns associated with good health. Most European Food-Based Dietary Guidelines recommend (a minimum of) two servings (of about 150 g each) of fish per week for older children, adolescents, and adults to ensure the provision of key nutrients, especially n-3 LCPUFA, but also vitamin D, iodine and selenium. Recommendations for children and pregnant women refer to the type of fish and are also based on safety considerations, i.e.

presence of contaminants. Available data suggest a large variation in the amount of fish and other seafood consumed across European countries and age groups, as well as in the type of seafood and species eaten, although data from European surveys are difficult to compare, the type of seafood consumed is largely unknown in some countries, and data are particularly scarce for infants. Seafood provides the recommended amounts of n-3 LCPUFA in most of the European countries considered and contributes to the needs for other essential nutrients, such as vitamin D, iodine or selenium, in some countries.

b) Consumption of about 1–2 servings of seafood per week and up to 3–4 servings per week during pregnancy has been associated with better functional outcomes of neurodevelopment in children compared to no seafood. Two large prospective cohort studies conducted in Europe (UK and Denmark) reported significant positive associations between fish/seafood consumption during pregnancy and functional outcomes of children's neurodevelopment, one of which included objective measures of intelligence quotient, and that similar findings were reported in two smaller studies with comparable seafood intakes (UK and US). The Panel also noted that these associations were observed for fish/seafood intakes of about 1–2 servings per week or lower and up to 3–4 servings per week compared to no fish/seafood intakes, and that no additional benefit might be expected at higher intakes, as suggested by the lack of association between seafood intakes during pregnancy and children's neurodevelopmental outcomes in two studies where habitual seafood consumption was much higher than current intakes (and recommendations) in the majority of European countries

Considering published meta-analyses of observational prospective cohort studies in adult populations without pre-existing coronary heart disease (CHD) that aimed at quantifying the relationship between seafood (or n-3 LCPUFA from seafood) consumption and risk of CHD mortality, the consumption from about 1–2 servings and up to 3–4 servings per week has also been associated with a lower risk of CHD mortality in adults and are compatible with current intakes and recommendations in most of the European countries considered. These associations refer to seafood per se and include beneficial and adverse effects of nutrients and non-nutrients (i.e. including contaminants such as methylmercury) contained in seafood. No additional benefits on neurodevelopmental outcomes and no benefit on CHD mortality risk can be expected at higher intakes.

- c) The observed health benefits of seafood consumption during pregnancy may depend on the maternal status with respect to nutrients with an established role in the development of the central nervous system of the foetus (e.g. DHA and iodine) and on the contribution of seafood (relative to other food sources) to meet the requirements of such nutrients during pregnancy. No effect of these nutrients on functional outcomes of children's neurodevelopment is expected when maternal requirements are met. The health benefits of seafood consumption in reducing the risk of CHD mortality are probably due to the content of n-3 LCPUFA in seafood.
- d) Quantitative benefit analyses of seafood consumption during pregnancy and children's neurodevelopmental outcomes, and of seafood consumption in adulthood and risk of CHD mortality, have been conducted, but are generally hampered by the heterogeneity of the studies which have investigated such relationships. Indeed, the comparability of results from the individual studies pooled in quantitative benefit analyses may be hampered by the use of different tools to estimate seafood consumption, ascertain the cause of death, and the adjustment for different confounders. An attempt to fit intrinsic differences among studies into a dose-response model did not allow the benefit of seafood consumption on CHD mortality to be quantified with sufficient certainty. Quantitative benefit analyses using n-3 LCPUFA intakes from seafood introduce an additional level of uncertainty in the benefit estimate.



2.1.6. Data sources used for the exposure assessment

For the methylmercury occurrence data in fish and seafood, and the methylmercury exposure levels of the various population groups considered in this statement, the Scientific Committee used the data reported in the EFSA CONTAM opinion (2012).

For the n-3 LCPUFA contents of the various fish and seafood items considered in this statement, except for swordfish and whitefish, the Scientific Committee used the data collected by the NDA Panel for their opinion (2014). The n-3 LCPUFA content for swordfish was calculated using the data from the report of the EU-funded project CALIPSO (Leblanc, 2006); the same formula as the one used by the NDA Panel for calculating the n-3 LCPUFA content was used, i.e. the sum of the C20:5 (n-3) and C22:6(n-3) contents for swordfish. For whitefish, the Scientific Committee used the n-3 LCPUFA level reported in the Finnish food composition database (Fineli⁵): 750 mg/100g.

For the fish and seafood consumption data the Scientific Committee used the dietary surveys included in the EFSA Comprehensive European Food Consumption Database; See section 4.1.1 of the EFSA CONTAM opinion (2012) and section 5.1 of the EFSA NDA opinion (2014) for further details on the database and the information it contains. Within the dietary surveys, subjects were classified in different age groups, as defined in Appendix A.

2.2. Methodologies

In the opinion of the Scientific Committee on risk benefit assessment (EFSA Scientific Committee, 2010), risk is defined as "the probability of an adverse effect in an organism, system, or (sub)population in reaction to exposure to an agent"; mirroring the definition of risk, the benefit has been defined as "the probability of a positive health effect and/or the probability of a reduction of an adverse health effect in an organism, system, or (sub)population, in reaction to exposure to an agent". Therefore, "in the risk-benefit assessment, the probability of an adverse health effect or harm (both incidence and severity) as a consequence of exposure can be weighed against the probability of benefit, if both are known to be possible." The agent to be considered in this opinion, as specified in the Terms of Reference, is "fish/seafood [...] related to relevant beneficial substances (e.g. nutrients such as long-chain n-3 polyunsaturated fatty acids) and the contaminant methylmercury".

The Scientific Committee used the EFSA Comprehensive Food Consumption Database to identify the population groups that exceed the TWI for Methylmercury. Only population groups composed of at least 20 individuals were considered for this evaluation; the data for Spanish toddlers, based on 17 individuals were therefore not taken into account. The surveys in the EFSA Food Consumption Database from which data were extracted and used for this statement are listed in Appendix B. The population groups identified to exceed the TWI for methylmercury, their exposure levels to methylmercury, the fish/seafood items mainly contributing to this exposure with their respective percentage of contribution and the average serving sizes for the various food items and population groups are presented in Appendix E.

The methodology by which several of the dietary surveys were conducted (i.e. 2-day 24 hours dietary recalls or 3-day dietary records) have the potential for overestimating the high ends of the distribution of fish/seafood consumption and methylmercury exposure, particularly when transforming the consumption data from daily to weekly. Moreover, because exposure to methylmercury is expressed in µg per kg bw <u>per week</u>, there is a need for fish/seafood consumption data to be expressed per week. Fish/seafood consumption data available in the EFSA Comprehensive database are reported <u>per day</u> and a simple multiplication of consumption amounts by seven would have led to a large overestimation of consumption. The Scientific Committee therefore decided to perform a scenario-based exposure assessment and estimate the number of servings of fish/seafood per week that a given population group would need to reach the TWI for methylmercury. In these scenarios, exposure to methylmercury and n-3 LCPUFA intake resulting from consumption of various fish/seafood items

⁵ See http://www.fineli.fi/food.php?foodid=815&lang=en

typical for that population group were calculated; it was then estimated how many servings of fish/seafood per week a given population group would need to reach the TWI for methylmercury and the DRV for n-3 LCPUFA. Fish consumption data of women of childbearing age (18–45 years old) were used for women in the year preceding pregnancy and during pregnancy.

The dietary reference values (DRV) for n-3 LCPUFA (EPA+DHA) set by the NDA panel were used (see section 2.1.4). A DRV of 250 mg per day was considered for adults. For practical reasons, in the absence of specific data for DHA in fish, the Scientific Committee decided to use 125 mg and 350 mg (EPA+DHA) as adequate intakes for toddlers and women of child-bearing age, respectively. In the absence of a DRV for older children and adolescents and as their serving sizes of fish are close to those of adults, the DRV for adults was used for these groups. This is consistent with the dietary advice on fish for this age group.

The example of the population group "other children" in Belgium is used throughout this section to illustrate the calculations made.

Fish/seafood consumption for the various contributors was calculated by multiplying the average serving sizes by their respective percentage of contribution to the exposure to methylmercury.

Main contributor	%	Average serving sizes (g)	Mean fish consumption (g)
Fish meat	0.37	105.6	39.1
Cod/Whiting	0.28	78.3	21.9
Fish products	0.14	84.9	11.9
Salmon/trout	0.07	62.2	4.4

Note: only food items contributing for at least 5 % of the total exposure to methylmercury were considered for the exposure assessment. Because of this decision, the sum of the various contributors is often less than 100 % (86 % in this case) and needs to be corrected when calculating what would be the serving size of fish/seafood for a population group:

1 serving size = $\sum_{\text{contributors}} (\% \text{ contribution} \times \text{serving sizes}) / \sum (\% \text{contribution})$

The fish/seafood serving for the population group "other children" in Belgium is therefore 89.8 g $(0.37 \times 105.6 + 0.28 \times 78.3 + 0.14 \times 84.9 + 0.07 \times 62.2)/(0.37 + 0.28 + 0.14 + 0.07)$

The exposure to methylmercury and the n-3 LCPUFA intake resulting from the consumption of a fish/seafood item were calculated by multiplying the fish consumption amount for the food item with the respective methylmercury concentration or n-3 LCPUFA content level in the food item considered (Appendix C).

Main contributor	%	Average serving sizes (g)	Mean fish consumption (g)	MeHg exposure (µg/week)	n-3 LCPUFA intake (mg/day)
Fish meat	0.37	105.6	39.1	6.5	381
Cod/Whiting	0.28	78.3	21.9	2.1	54
Fish products	0.14	84.9	11.9	0.5	36
Salmon/trout	0.07	62.2	4.4	0.1	79

Because the methylmercury exposure is expressed in μg per person per week in the above table, the respective value needs to be divided by the average bodyweight value of the population group considered (e.g. 17.88 kg for Belgian other children) so that it can be compared with the TWI for methylmercury.



Because n-3 LCPUFA intake resulting from the consumption of 1 serving of fish/seafood is expressed in mg per day in the above table, the respective value needs to be divided by 7 to obtain the average n-3 LCPUFA intake that the consumption of 1 serving per week of fish/seafood would provide and to compare it with the DRV for n-3 LCPUFA.

Belgian "other children" eating one serving of fish/seafood per week will get 91.3 mg of n-3 LCPUFA $[(381+54+36+79)/(0.86\times7)]$ and will be exposed to 0.6 µg/kg bw/week of methylmercury $[(6.48+2.05+0.45+0.14)/(0.86\times17.88)]$. The TWI for methylmercury (1.3 µg/kg bw/week) will therefore be reached with 2.2 servings of fish/seafood per week, while 2.7 servings would be required to get the dietary reference value of n-3 LCPUFA.

3. Assessment

3.1. General considerations

Long term follow-up of a large number of subjects in prospective cohort studies allows the assessment of well-defined clinical outcomes such as morbidity and mortality for cardiovascular diseases with limited uncertainty or to assess physiological functions using validated tools for neurological and cognitive development in children. Cardiovascular diseases in adults, as well as neurological and cognitive development in children have been recognized as the most relevant health outcomes for risk and benefit analysis of fish consumption in the previous EFSA opinions summarized above. These outcomes represent the result of complex positive and negative interactions of many factors on human health, such as genetic background, diet, lifestyle and environment. Unravelling the causal contribution of each of these factors to the final outcome is difficult and numerous statistical adjustments for potential confounders that are possible in large cohort studies are needed. However, the consistency of the results from many different cohort studies around the world, considered together with the results obtained in more simple experimental models, provide confidence there is causality between eating fish and the above-mentioned health effects.

In the epidemiological studies reviewed by the EFSA CONTAM and NDA Panels, the use of validated tools for dietary surveys provide information on broad food categories, but detailed information on fish species and other fish characteristics that can affect the content of nutrient and contaminants (such as season, location, diet, life stage and age) are systematically lacking; this leads to considerably larger uncertainties when translating fish consumption into intakes of nutrients and contaminants, since these contents vary broadly both within and between fish species.

As reported in the NDA opinion, there is a general scientific agreement on a net benefit of fish consumption for the two major outcomes considered (i.e. cardiovascular diseases in adults and neurological and cognitive development in children), starting from 1–2 servings per week and up to 3–4 servings per week, as compared to no fish consumption. This means that in the range of 1–4 servings per week, the benefits of fish consumption (as compared to no fish) outweigh the risks, whatever the respective contribution to this net effect of beneficial and harmful fish components may be. The limited number of high and very high fish consumers in these epidemiological studies does not allow for drawing firm conclusions about the actual balance of risk and benefit at these high intakes. On this basis and considering uncertainties about actual serving sizes and actual contents of the potentially active positive and negative components, considering the established toxicity of methylmercury and the presence of other potentially harmful contaminants, most of the health authorities of European countries recommend the consumption of at least two servings of fish per week; sometimes, more detailed recommendations are made on the explicit basis of meeting the requirement of key nutrients, especially n-3 LCPUFA, and limiting intake of methylmercury.

Contrasting with the wealth of evidence reporting on the net beneficial balance of fish/seafood consumption, the availability of data for estimating/calculating the net true effect of each fish component (especially n-3 LCPUFA and methylmercury) for each side of the balance is limited. In the CONTAM Panel opinion, an adjustment on prenatal blood DHA level was needed for the detection of an apparent NOAEL for the mercury level of maternal hair. This negative confounding of n-3

LCPUFA on neurotoxicity of methylmercury was also observed in a recent study from the Faroe Islands (Choi et al, 2014). Conversely, one would expect methylmercury to negatively confound the positive impact of fish consumption on neurodevelopment and cardiovascular outcomes, but very few data are available on this issue; this has been suggested by the study of Wennberg et al, (2012), where blood concentration of PUFA and hair concentration of methylmercury were considered in a group of subjects participating in a Swedish or a Finnish cohort and having experienced myocardial infarction who were compared to a control group without myocardial infarction. However, considering the difficulty to relate a blood marker to fish/seafood intake (especially in the case of n-3 LCPUFA where there are regulatory mechanisms and interferences with many other nutrients), the results obtained with blood markers cannot be translated back for drawing quantitative conclusions on fish/seafood intake.

The impact of negative confounding for assessing benefit and risk would vary depending on health outcome, and also of the nutritional status of a given population (Stern and Korn, 2011). An example of the importance of nutritional status mentioned in the NDA opinion (EFSA NDA Panel, 2014) concerns British pregnant women showing mild to moderate iodine deficiency and negative impact on neurodevelopment (Bath et al, 2013); fish is an important iodine source, and as such fish intake would likely have a different impact compared to situations of adequate iodine status where fish consumption would not be needed for meeting iodine requirements.

3.2. Assessment of benefits and risks

For the risk-benefit assessment of fish/seafood consumption at the level of the European population and contrary to epidemiological cohort studies, there is no representative longitudinal follow-up that could have provided simultaneously good quality data on fish/seafood consumption and clinical/physiological endpoints. Data that have been compiled by EFSA are obtained from crosssectional national dietary surveys that include fish consumption but no information on health outcomes. According to the EFSA guidance on risk-benefit assessment of food (EFSA Scientific Committee, 2010) a tiered approach should be followed and the elements responsible for risks and benefits should be characterised separately before they can be weighed against each other.

Due to inadequate data, a full characterisation of the benefit of fish consumption could not be performed. It is noted though that according to the numbers given in the NDA opinion (EFSA NDA Panel, 2014), there is a large variation between European countries in the fraction of fish/seafood consumers in the whole population (from 10 to 70%), in the fraction of consumers between age groups, and in the amount of fish consumed per week. Not all consumers meet the recommended intake of fish of 1–2 servings (equivalent to 150–300 g) per week or the DRV for n-3 LCPUFA. Obviously, only those who consume fish will benefit from fish intake and also be at risk for exposure to methylmercury.

The CONTAM Panel in its opinion (2012) noted that the estimated mean dietary exposures to methylmercury across age groups did not exceed the TWI, with the exception of toddlers and other children in some surveys. The medians of 95th percentile dietary exposures across surveys were close to or above the TWI for all age groups. The CONTAM Panel concluded that high consumers of fish meat may exceed the TWI by up to approximately six-fold and that exposure to methylmercury above the TWI is of concern. There is a large variation in the concentration of mercury in different fish species (see Table 6 of EFSA CONTAM Panel, 2012). Fish meat was the dominating contributor to methylmercury dietary exposure for all age classes, followed by fish products. In particular tuna, swordfish, cod, whiting and pike were major contributors to methylmercury dietary exposure in the adult age groups, while the same species, with the addition of hake, were the most important contributors in the child age groups. Dietary exposure to women of child-bearing age was not different from adults in general.



The Scientific Committee decided to create intake scenarios for the different groups reported by the European Member States (see section 2.2) and to examine the relationship between the number of servings per week, the methylmercury exposure in relation to the TWI, and the intake of n-3 LCPUFA in relation to the DRV for the population groups identified to be at risk for exceeding the TWI for methylmercury (Figure 1 and Appendix D).





Figure 1: Number of servings per week needed for a given population group to reach the TWI for methylmercury and the DRV for n-3 LCPUFA. Groups above the dotted line reach the TWI for methylmercury at a lower number of servings per week than needed to attain the DRV.

Serving sizes for the food group "fish and other seafood" reported by the European Member States differ for various age/population groups, ranging from 23 to 135 g. The lowest ones were for toddlers (varying from 23 to 100 g) and other children (varying from 38 to 82 g). Each serving was composed of the relative amounts of the major contributing fish species reported for that group (see section 2.2 and Appendix E). It should be underlined that in some cases, these contributing amounts are quite uncertain because they are based on a limited number of eating events (see section 3.3).

The number of servings needed to meet the DRV for n-3 LCPUFA and to reach the TWI for methylmercury is displayed in Figure 1 and Appendix D. The age groups exceeding the TWI for methylmercury at the fewest number of servings per week were toddlers (1–<3 years) and other children (3–<10 years). In a few cases of other children, adolescents, women of childbearing age, adults and elderly the TWI was reached after less than or around 1 serving per week. In most other cases, for toddlers and other children, the TWI was reached with a number of servings per week. There were a few groups of adolescents, adults, women of childbearing age and very elderly that reached the TWI above 4 servings per week.

Intake of n-3 LCPUFA was also calculated for the same groups. It turned out, when relating this to the DRV for n-3 LCPUFA, that some of the groups reached the TWI for methylmercury at a lower number of servings per week than needed to achieve the DRV (groups above the dotted line in Figure 1). Several groups reached the TWI and the DRV at approximately the same number of servings per week (Figure 1).

In creating the scenarios, the Scientific Committee took account of the differences in consumption pattern of different fish species across Europe. It is also noted that there are some differences in the way DRVs are set and how a TWI is established. The TWI for methylmercury includes an uncertainty factor of 6.4 to account for uncertainties (variability) in the extrapolation from mercury in hair to mercury intake, while no such uncertainty factor was used for establishing the DRV for n-3 LCPUFA.

Although the scenarios described above were based on the major contributing species to diets and reported serving sizes of the groups at risk for exceeding the TWI for methylmercury, it should be noted that the outcomes described above represent scenarios and not necessarily the actual dietary intakes.

The results clearly show that consuming diets containing fish species with a high content of methylmercury strongly influences the number of servings that can be eaten before exceeding the TWI for methylmercury. In the majority of cases the reported serving sizes used were below 100 g. In order to protect the foetus against adverse neurodevelopmental effects of methylmercury, women of childbearing age should not exceed the TWI. As the brain is developing also after birth, toddlers and children exposed to methylmercury above the TWI on a regular basis should also be considered at risk for neurotoxic effects of methylmercury.

For toddlers, children, and women of childbearing age in particular, but also for other population groups, the benefits of eating fish could be met by increasing the consumption of species low in methylmercury. Hence, given the diversity in fish consumption in different countries in the EU, it is not possible to make general recommendations on fish consumption across Europe. In achieving and optimizing the benefits of fish and seafood consumption, each country needs to consider its own pattern of fish consumption and carefully assess the exposure to and the risk of exceeding the TWI of methylmercury and at the same time to obtain the health benefits. This specifically applies to countries in which fish/seafood species with a high content of mercury are frequently consumed. In addition to assessing methylmercury exposure via fish intake, the use of biomarkers of methylmercury exposure, e.g. mercury in blood and hair (EFSA CONTAM Panel, 2012), may help to assess the exposure in different population groups.



3.3. Uncertainties

Uncertainties related to the establishment of the TWI for methylmercury and exposures of various population groups to methylmercury have been described in the CONTAM Opinion on mercury (EFSA CONTAM Panel, 2012). Similarly, the limitations in the data mentioned for epidemiological studies concerning benefits of fish/seafood consumption and n-3 LCPUFA as well as fish/seafood intakes compiled from the Member-states and available in the EFSA databases have been described in the NDA Opinion on the benefits of fish/seafood consumption (EFSA NDA Panel, 2014).

The contents of methylmercury used for the various fish/seafood items considered in this statement are the same as those used for the exposure calculations in the CONTAM Opinion on mercury (EFSA CONTAM Panel, 2012). Some of the fish/seafood commodities consumed and reported in the surveys that populate the EFSA Comprehensive European Food Consumption Database were not very well characterised and assumptions have been made as to their content of methylmercury.

The 2014 NDA opinion concludes on a net benefit of eating fish, but stresses the large uncertainty to attribute the beneficial effect to individual components such as n-3 LCPUFA, selenium, iodine, vitamin D etc. or to avoiding contaminants / less beneficial nutrients present in other foods by the fact of eating fish. It should be underlined that, as requested by the European Commission, the current statement addresses methylmercury and used n-3 LCPUFA intake as a marker of the beneficial effect of eating fish. The presence of other contaminants / beneficial compounds in fish and seafood has not been addressed in this statement; further details on the beneficial components can be found in the 2014 NDA opinion.

The Scientific Committee used scenarios based on the percentage of contribution of various fish/seafood items to calculate an average serving of fish/seafood for various age groups and member states; the results do not necessarily represent the actual dietary intake of n-3 LCPUFA and exposure to methylmercury of these various population groups.

Some of the serving sizes have been calculated based on a limited number of eating events and are therefore highly uncertain. Serving sizes based on a number of eating events lower than 10 have been highlighted in red in Appendix E. The uncertainty is symmetric, i.e. actual serving sizes highlighted in red may have been over- or under-estimated.

The Scientific Committee had no information on the n3-LCPUFA content for the category "Redfish". Several fish species have been reported by various European Member States under this name but the closest and most plausible one is "Ocean Perch". Therefore the n-3 LCPUFA content for "Perch" was also used for the category "Redfish". It is not possible to clarify whether using the n3-LCPUFA content in "Perch" for "Redfish" leads to an over- or under-estimation of the real level of n3-LCPUFA in redfish.

Several fish categories (i.e. Pike, Swordfish and Redfish) are not referenced in the FoodEx classification used in the EFSA Comprehensive Database and had to be created ad-hoc for the EFSA CONTAM Panel opinion on methylmercury (2012), based on the original food description. As a consequence, it was not possible to retrieve European Member States' specific average serving sizes for these fish items. The values reported in Appendix E for these specific fish items have been calculated by averaging the individual eating events where these particular fish items were mentioned. As European Member States differ in their fish consumption pattern, it is not possible to say whether the pike/swordfish/redfish consumption for a given Member State is over- or under- estimated compared to the European average consumption value.

Spain reported "Norway Lobster" as one of the contributors to methylmercury exposure, while n-3 LCPUFA content level from the NDA opinion (2014) refers to "Lobster (Homarus vulgaris)". The Scientific Committee applied the latter n-3 LCPUFA content level also to "Norway Lobster". It is not possible to say whether this extrapolation results in an over- or under- estimation of the "real" n-3 LCPUFA content of Norway Lobster.

4. Conclusions

In its 2012 opinion, the EFSA CONTAM Panel considered several adverse outcomes of methylmercury and, based on prenatal neurodevelopmental toxicity, set a TWI of 1.3 μ g/kg bw/week for methylmercury. Estimated mean dietary exposures to methylmercury across age groups did not exceed the TWI, with the exception of toddlers and other children in some surveys. The medians of 95th percentile dietary exposures across surveys were close to or above the TWI for all age groups. As the brain is developing also after birth it is undesirable that toddlers and children are exposed to methylmercury above the TWI on a regular basis. Fish meat and fish products, tuna, swordfish, cod, whiting, pike and hake were major contributors to methylmercury dietary exposure.

The NDA Panel concluded in its 2014 opinion that an intake of from 1–2 up to 3–4 servings per week of fish/seafood during pregnancy was associated with beneficial effects on functional neurodevelopment in children and coronary heart disease in adults, compared to no fish intake. In addition fish/seafood provides many nutrients, in particular n-3 LCPUFA. There is a large variation in the fraction of the population consuming fish, in the fish/seafood species consumed in different countries (different fish/seafood species vary greatly in their content of mercury as well as in their content of n-3 LCPUFA) and in the average amount of fish intake among the consumers of different age groups across Europe. As a consequence, not all the consumers meet the recommended intake of fish of 1–2 servings (equivalent to 150–300 g) per week or the DRV for n-3 LCPUFA.

The Scientific Committee used in the current statement previous work by EFSA as well as the consumption surveys submitted by 17 EU countries to the EFSA Comprehensive European Food Consumption Database to try and refine the fish and seafood consumption of European population groups and to evaluate their exposure to methylmercury and intake of n-3 LCPUFA.

As the methodology by which several of the surveys were conducted (i.e. 2-day 24 hour dietary recalls or 3-day dietary records) has the potential to overestimate the high ends of the distribution of fish/seafood intake and methylmercury exposure, particularly when transforming the intake data from daily to weekly intake, the Scientific Committee decided to create scenarios for population groups at risk of exceeding the TWI for methylmercury. The composition of the main contributing fish/seafood species and reported serving sizes for a given population group were used to calculate the number of servings needed per week for that group to reach the TWI for methylmercury and the DRV for n-3 LCPUFA.

The age groups exceeding the TWI for methylmercury at the fewest number of servings per week are toddlers (1–<3 years) and other children (3–<10 years). In a few cases of other children, adolescents, women of childbearing age, adults and elderly, the TWI was reached after less than around 1 serving per week. In most other cases for toddlers and other children the TWI was reached when the number of servings per week was between 2 and 3. In most cases the TWI for mercury was reached between 2 and 4 servings per week. For some groups the intake of n-3 LCPUFA met the DRV at a higher or equal number of servings per week than they reached the TWI for methylmercury.

Consuming species with a high content of methylmercury influences the number of servings that can be eaten before the TWI for methylmercury is reached. For toddlers, children and women of childbearing age, the benefits of eating fish should be met by increasing the consumption of species low in methylmercury.

5. Recommendations

Besides limiting the intake of fish/seafood species with a high content of mercury in the daily diet in order to avoid regular exposure above the TWI, it is not possible to make general recommendations on fish consumption across Europe. Each country needs to consider its own pattern of fish consumption and carefully assess the risk of exceeding the TWI of methylmercury while obtaining the health benefits resulting from consumption of fish/seafood. In addition to assessing exposure via fish intake,



the use of biomarkers of methylmercury exposure may help to assess the exposure to methylmercury in different population groups.

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APPENDICES

Appendix A.	Age	classes	considered	in	the	EFSA	Comprehensive	European	Food
	Cons	umption	Database.						

Age class	Age range
Infants	0–11 months
Toddlers	12–35 months
Other children	36 months-9 years
Adolescents	10-17 years
Adults	18-64 years
Elderly	65-74 years
Very elderly	75 years and above
Women in child-bearing age	18-45 years



Appendix B.	Surveys included in the EFSA Comprehensive European Food Consumption
	Database for calculating "chronic" dietary intakes.

Country	Survey	n(a)	Method	Days	Age	Year
Belgium	Regional Flanders	661	Dietary record	3	2–6	2003
Belgium	Diet National 2004	3 245	24-h dietary recall	2	15-105	2004
Bulgaria	NUTRICHILD	1 723	24-h dietary recall	2	0.1–5	2007
Cyprus	Childhealth	303	Dietary record	3	11-18	2003
Czech Republic	SISP04	1 751	24-h dietary recall	2	4–64	2004
Germany	DONALD 2006	303	Dietary record	3	1-10	2006
Germany	DONALD 2007	311	Dietary record	3	1-10	2007
Germany	DONALD 2008	307	Dietary record	3	1-10	2008
Germany	National Nutrition Survey II	13 926	24-h dietary recall	2	14-80	2006
Spain	enKid	382	24-h dietary recall	2	1-14	2000
Spain	NUT INK05	760	24-h dietary recall	2	4-18	2005
Spain	AESAN	418	24-h dietary recall	2	18–60	2009
Spain	AESAN FIAB	1 068	Dietary record	3	17-60	2001
Finland	DIPP	1 448	Dietary record	3	1–6	2005
Finland	STRIP	250	Dietary record	4	7–8	2000
Finland	FINDIET 2007	2 038	48-h dietary recall	2	25-74	2007
France	INCA2	4 079	Dietary record	7	3–79	2006
Italy	INRAN SCAI 2005/06	3 323	Dietary record	3	0.1–98	2006
Latvia	EFSA TEST	2 070	24-h dietary recall	2	7–66	2008
Sweden	NFA	2 495	24-h dietary recall	4	3–18	2003



	Occurrence MeHg (µg/kg)	Occurrence n-3 LCPUFA (mg/100g)
Bass	202	467
Bream	225	467
Carp	55	296
Cod/Whiting	94	245
Fish meat	166	974
Fish products	38	304
Hake	136	679
Herring	36	2482
Lophiiformes	195	261
Lobster	302	515
Mackerel	107	2504
Perch	165	175
Pike	394	229
Plaice	64	403
Redfish	189	175
Salmon/trout	33	1815
Sole	76	226
Squid	46	350
Swordfish	1212	3015
Tuna	290	2806
Whitefish	85	750

Appendix C. Methylmercury concentration and n-3 LCPUFA content levels in fish and seafood



Appendix D. Number of servings needed for a given population group to reach the TWI for methylmercury and the DRV for n-3 LCPUFA

Country	Population group	Servings to reach the TWI for MeHg ^a	Servings to reach the DRV for n-3 LCPUFA ^b
Belgium	Other Children	2.2	2.7
	Adults	6.0	1.5
	Very Elderly	5.5	1.5
Bulgaria	Toddlers	1.7	1.0
	Other Children	3.1	1.9
Cyprus	Adolescents	3.4	1.1
Czech	Other Children	2.7	2.3
Republic	Adolescents	2.9	1.4
	Adults	4.1	1.2
	Women Child-bearing age	3.7	1.8
Finland	Toddlers	1.7	4.3
	Other Children DIPP	3.1	3.8
	Other Children STRIP	3.0	2.8
	Adults	3.6	2.3
	Elderly	2.7	3.1
	Women Child-bearing age	4.4	3.1
France	Other Children	3.2	2.8
Germany	Toddler 2006	2.0	2.7
	Toddlers 2008	2.0	2.8
	Other Children	3.5	3.5
	Very Elderly	4.1	1.7
Italy	Toddlers	1.4	2.4
	Other Children	0.5	1.0
	Adolescents	0.7	0.7
	Adults	0.8	0.6
	Elderly	1.1	0.7
	Women Child-bearing age	0.7	0.9
Latvia	Other Children	2.8	3.1
Spain	Other Children	0.8	1.2
	Adolescent Nut-Ink05	5.2	2.1
	Adolescents Aesan-Fiab	6.6	2.9
	Adolescents enKid	1.2	0.9
	Adults Aesan-Fiab	1.6	1.0
	Adults Aesan	2.5	1.1
	Women Child-bearing age Aesan-Fiab	1.3	1.3
	Women Child-bearing age Aesan	1.9	1.5
Sweden	Other Children	3.8	3.0

(a): 1.3 µg/kg bw/week

(b): Toddlers: 125 mg/day, other children/adolescents/adults/elderly/very elderly: 250 mg/day, women in child-bearing age: 350 mg/day



Appendix E. Fish/seafood consumption and methylmercury exposure data extracted from the EFSA Comprehensive European Food Consumption Database

Age group	Exposure level	MeHg exposure (µg/kg bw/week) (Middle bound)	Main contributors	% (x≥5 %)	Average serving sizes (g)
Other children	P95	1.60	Fish meat	37	105.6
			Cod/Whiting	28	78.3
			Fish products	14	84.9
			Salmon/Trout	7	62.2
Adults	P95	1.35	Tuna	31	50.6
			Fish meat	26	126.4
			Cod/Whiting	11	113.5
			Salmon/Trout	5	65.9
Very elderly	P95	1.41	Fish meat	27	119
			Cod/Whiting	18	120.1
			Tuna	15	76.4
			Salmon/Trout	5	77.8

Belgium



Bulgaria

Age group	Exposure level	MeHg exposure (µg/kg bw/week) (Middle bound)	Main contributors	% (x≥5 %)	Average serving sizes (g)
Toddlers	P95	1.53	Hake	45	105.8
			Mackerel	20	40.3
		Whitefish	20	72.9	
			Salmon/Trout	8	108.4
Other	P95	1.43	Whitefish	28	95.4
children		Hake	25	74.9	
			Mackerel	25	53.6
			Salmon/Trout	12	110.7
			Carp	10	34.2

Cyprus

Age group	Exposure level	MeHg exposure (µg/kg bw/week) (Middle bound)	Main contributors	% (x≥5 %)	Average serving sizes (g)
Adolescents	P95	1.83	Fish meat	46	123.3
			Tuna	43	77.0
			Squid	5	106.6

Czech Republic

Age group	Exposure level	MeHg exposure (µg/kg bw/week) (Middle bound)	Main contributors	% (x≥5 %)	Average serving sizes (g)
Other children	P95	3.35	Fish meat	90	77.1
Adolescents	P95	2.49	Fish meat	85	125.5
Adults	P95	1.52	Fish meat	79	145.3
			Tuna	7	77.0
Women P95 Child-bearing age	P95	1.67	Fish meat	83	137.1
			Tuna	5	70.0



Finland

Age group	Exposure level	MeHg exposure (µg/kg bw/week) (Middle bound)	Main contributors	% (x≥5 %)	Average serving sizes (g)
Toddlers	P95	2.72	Fish meat	39	27.6
			Pike	37	33.7
			Salmon/Trout	10	22.3
Other	P95	2.36	Fish meat	52	40.9
children (Dipp)			Tuna	19	22.0
× •••			Salmon/Trout	10	46.6
			Pike	10	55.3
Other	P95	1.38	Fish meat	59	66.6
children (Strip)			Pike	12	55.3
			Tuna	9	48.3
			Perch	8	64.4
			Salmon/Trout	7	54.6
Adults	P95	2.03	Pike	46	112.7
			Tuna	24	44.0
			Fish meat	15	94.3
			Salmon/Trout	9	91.9
Women –	P95	1.78	Tuna	40	44.1
child-bearing age			Pike	34	95.2
-			Fish meat	16	70.8
			Salmon/Trout	7	72.8
Elderly	P95	2.49	Pike	58	124.0
			Fish meat	17	111.1
			Salmon/Trout	9	88.0
			Perch	5	181.2



France

Age group	Exposure level	MeHg exposure (µg/kg bw/week) (Middle bound)	Main contributors	% (x≥5 %)	Average serving sizes (g)
Other P95 children	P95	1.97	Fish meat	40	69.2
			Tuna	20	32.9
			Fish products	12	78.7
			Cod/Whiting	6	74.0

Germany

Age group	Exposure level	MeHg exposure (µg/kg bw/week) (Middle bound)	Main contributors	% (x≥5 %)	Average serving sizes (g)
Toddlers06	P95	2.13	Fish meat	49	47.5
			Pike	13	33.7
			Fish products	9	60.8
			Redfish	9	35.7
			Tuna	7	23.1
			Cod/Whiting	7	32.2
Toddlers08	P95	1.65	Fish meat	39	47.5
			Redfish	21	35.7
			Perch	13	72
			Fish products	12	60.8
			Tuna	11	23.1
Other	Other P95 children	1.53	Fish meat	43	71.8
children			Fish products	17	89.4
			Redfish	16	57.2
			Tuna	9	27.1
			Perch	6	46.2
			Salmon/Trout	6	44.4
Very elderly	P95	1.42	Fish meat	46	116.2
			Perch	10	163.6
			Cod/Whiting	9	151.3
			Herring	8	96.9
			Pike	5	285.0



Italy (1/2)

Age group	Exposure level	MeHg exposure (µg/kg bw/week) (Middle bound)	Main contributors	% (x≥5 %)	Average serving sizes (g)
Toddlers	Mean	1.57	Cod/Whiting	41	123.5
			Sole	33	133.9
			Tuna	8	27.7
			Bass	7	129.4
Other	Mean	1.49	Sword fish	29	130.3
children			Tuna	15	34.2
			Cod/Whiting	14	122.9
		4.96	Bream	10	148.3
	P95		Bass	6	136.0
			Fish products	6	121.9
			Sole	5	131.0
Adolescents	P95	5.05	Sword fish	43	129.0
			Tuna	16	41.1
			Cod/Whiting	8	142.9
			Bream	7	157.5
			Bass	6	164.0
Adults	P95	3.04	Sword fish	39	161.5
			Tuna	17	42.7
			Bream	9	168.1
			Cod/Whiting	8	149.5
			Bass	6	168.8
Women –	P95	5.03	Swordfish	41	163.5
child-bearing age			Tuna	17	43.1
č			Bream	9	164.5
			Cod/Whiting	7	143.9
			Bass	6	157.8



Italy (2/2)

Age group	Exposure level	MeHg exposure (µg/kg bw/week) (Middle bound)	Main contributors	% (x≥5 %)	Average serving sizes (g)
Elderly	erly P95	1.73	Sword fish	26	196.8
		Tuna	17	44.8	
		Cod/Whiting	15	140.0	
		Bream	8	166.2	
		Bass	6	145.3	
		Sole	6	160.5	
		Fish meat	6	178.1	

Latvia

Age group	Exposure level	MeHg exposure (µg/kg bw/week) (Middle bound)	Main contributors	% (x≥5 %)	Average serving sizes (g)
Other children	P95	1.63	Fish meat	65 17	74.1 55 3
			Pike	7	55.5 120



Spain (1/2)

Age group	Exposure level	MeHg exposure (µg/kg bw/week) (Middle bound)	Main contributors	% (x≥5 %)	Average serving sizes (g)
Other	P95	4.69	Hake	34	99.8
children (enKid)			Tuna	21	45.7
			Sword fish	15	130.3
			Fish meat	6	115
			Lophiiformes	6	75
Adolescents	P95	2.80	Hake	31	120.6
(Nut-Ink05)			Tuna	25	35.3
			Fish meat	17	86.9
			Cod/Whiting	6	117
Adolescents	P95	1.60	Hake	26	111.7
(Aesan-Fiab)			Tuna	20	31.4
			Norway lobster	9	28.3
			Cod/Whiting	8	118.8
			Lophiiformes	8	118.1
			Fish meat	5	81.8
			Squid	5	47.2
Adolescents	P95	3.45	Tuna	26	52.9
(enKid)			Sword fish	24	129
			Hake	23	147.6
			Fish meat	5	127.3
			Sole	5	164
Adults	P95	2.86	Hake	21	130
(Aesan-Fiab)			Sword fish	18	161.5
			Tuna	17	39.6
			Cod/Whiting	9	109.3
			Fish meat	9	113.2
			Lophiiformes	6	110.6



Age group	Exposure level	MeHg exposure (µg/kg bw/week) (Middle bound)	Main contributors	% (x≥5 %)	Average serving sizes (g)
Adults	P95	2.98	Tuna	38	48.2
(Aesan)			Hake	14	130.7
			Fish meat	10	125.4
			Sword fish	9	161.5
			Cod/Whiting	5	113.7
Women –	P95	3.08	Swordfish	19	163.5
child-bearing age			Tuna	19	41.4
(Aesan-Fiab)			Hake	19	124.6
			Cod/Whiting	8	108.3
			Fish meat	7	120.1
			Lophiiformes	6	114.7
Women –	P95	3.05	Tuna	39	44.6
child-bearing age	child-bearing age		Hake	14	133.7
(Aesan)			Swordfish	12	163.5
			Fish meat	7	97.8
		Cod/Whiting	5	118.5	

Spain (2/2)

Sweden

Age group	Exposure level	MeHg exposure (µg/kg bw/w) (Middle bound)	Main contributors	% (x≥ 5%)	Average serving sizes (g)
Other children	P95	1.31	Fish meat Fish products	32 22	85.7 82.9
			Cod/Whiting	22	81.4
			Salmon/Trout	5	86.6
			Plaice	5	95.3
			Tuna	5	49.2



AI:	Adequate Intake
ALA:	Alpha-linolenic acid
BE:	Belgium
BG:	Bulgaria
BW:	Body weight
CHD:	Coronary Heart Disease
CONTAM:	EFSA Scientific Panel on Contaminants in the Food Chain
CY:	Cyprus
CZ:	Czech Republic
DE:	Germany
DHA:	Docosahexaenoic acid
DL-PCBs:	Dioxin-Like Polychlorinated Biphenyls
DRV:	Dietary Reference Value
EC:	European Commission
EPA:	Eicosapentaenoic acid
EU:	European Union
FAO:	Food and Agriculture Organisation
FI:	Finland
FR:	France
IT:	Italy
JECFA:	Joint FAO/WHO Expert Committee on Food Additives
LCPUFA:	Long-Chain Polyunsaturated Fatty Acid
LV:	Latvia
MB:	Middle Bound
MeHg:	Methylmercury
NDA:	EFSA Scientific Panel on Dietetic Products, Nutrition and Allergies.
NOEL:	No-Observed-Effect-Level
PCBs:	Polychlorinated Biphenyls
PTWI:	Provisional Tolerable Weekly Intake
PUFA:	Polyunsaturated Fatty Acid
SC:	EFSA Scientific Committee
SCOOP:	Scientific Co-Operation
SE:	Sweden
SP:	Spain
TWI:	Tolerable Weekly Intake
UNEP:	United Nations Environment Program

ABBREVIATIONS AND ACRONYMS



US NRC: US National Research Council

WHO: World Health Organization