

Citation:

Verger P, Khalfi N, Roy C, Blanchemanche S, Marette S, Roosen J. Balancing the risk of dioxins and polychlorinated biphenyls (PCBs) and the benefit of long-chain polyunsaturated fatty acids of the n-3 variety for French fish consumers in western coastal areas. Food Addit Contam Part A Chem Anal Control Expo Risk Assess. 2008 Jun;25(6):765-71.

PubMed ID: [18484304](#)

Study Design:

Cross-sectional study

Class:

D - [Click here](#) for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

The objective of this study was to estimate the percentage of subjects below and above the toxicological thresholds for dioxins and PCBs and attainment of nutritional daily allowance for LC n-3 PUFA among a sample of the French adults (identified in the CORAI STUDY) who were fish eaters.

Inclusion Criteria:

A household was included if there was:

- a women of child-bearing age
- at least one child below 15 years of age and
- fish consumption

Exclusion Criteria:

Excluded if they did not meet inclusion criteria.

Description of Study Protocol:**Recruitment**

Recruitment was conducted in Nantes, France in May 2005.

A sample of 201 households based on the quota method to be representative of age groups and socio-economic status of the population of the city was recruited by telephone.

The experimental protocol was detailed previously:

Verger Ph, Blanchemanche S, Roosen J, Marette S. 2007. Impact of a risk–benefit advisory on fish consumption and dietary exposure to methylmercury in France. *Regulat Toxicol Pharmacol.* 48:259–269.

Design

Descriptive

Dietary Intake/Dietary Assessment Methodology (if applicable):

- Diet diary: The women in charge of food purchases recorded fish consumption during a month for her and the members of the household in a notebook.
- They were also asked to note the fish species. The notebook included a table with the name of 38 predefined categories of fish and the possibility to mention non-listed species as well as fish for which the subject did not know the name.
- They included details about the dish (as a filet, in a salad, etc.), and the place of the consumption (home or restaurant).

Blinding used (if applicable)

n/a

Intervention (if applicable)

n/a

Statistical Analysis

- Data were analysed separately for each member of the household, but for this study only the adults were considered.
- Frequency of consumption
 - The frequency of consumption for each subject was computed for 1 month.
 - For each fish species, the number of eating occasions recorded in the diary was transformed into frequency of consumption.
- Estimated dietary exposure
 - Subjects did not quantify the portions eaten.
 - An average portion size for each fish species was determined from a previous fish consumption study conducted in the same region.
 - The portion sizes were combined with the number of eating occasions.
 - The resulting amount of fish eaten was combined with the average concentration of polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzo-p-furans (PCDFs), polychlorinated biphenyls (PCBs), as well as long-chain polyunsaturated fatty acids n-3 (LC n-3 PUFA) in the various fish species in order to estimate exposure
 - The monthly exposure was divided by the respective body weight of subjects and standardized in daily or weekly exposure accordingly to health based guidance values.
- Data were presented as figures where two axes represented, respectively, the dietary exposure to dioxin compounds or NDL-PCBs contaminants and the intake of LC n-3 PUFA.
- This representation allowed a visualization of the number of subjects in each of the four categories:
 - Subjects not achieving the recommended amount of LC n-3 PUFA and exposed below the toxicological threshold for contaminants
 - Subjects not achieving the recommended amount of LC n-3 PUFA and exposed above

the toxicological threshold for contaminants

- Subjects achieving the recommended amount of LC n-3 PUFA and exposed below the toxicological threshold for contaminants
- Subjects achieving the recommended amount of LC n-3 PUFA and exposed above the toxicological threshold for contaminants
- Data were analyzed by sex and were presented as mean, SD, 95th percentile, median, minimum and maximum values

Data Collection Summary:

Timing of Measurements

- Interviewers visited each household at various dates yielding recording periods of about 1 month duration.
- The recorded consumption data were normalized to weekly consumption.

Dependent Variables

- Variable 1: Estimated dietary exposure to dioxins and PCBs
- Variable 2: Estimated intake of LC n-3 PUFA

To estimate exposure, the amount of fish eaten was combined with the average concentration in polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzo-p-furans (PCDFs), polychlorinated biphenyls (PCBs), and long-chain polyunsaturated fatty acids n-3 (LC n-3 PUFA) in the fish species reported in the diet diaries. Analytical values were collected by the French Ministry of Agriculture and Fisheries between 2002 and 2004 on fish and fish products on the French market. For NDL-PCBs, the analytical results are expressed as a sum of the six congeners, also called PCB indicators (PCBi).

Control Variables

- Sex

Description of Actual Data Sample:

Initial N: 8828 households were contacted by telephone. 5797 were excluded because they did not correspond to the criteria for inclusion (a household with a woman of child-bearing age and at least a child below 15 years of age and consuming fish)

Attrition (final N): A total of 401 subjects (206 women and 195 men from 206 households) were accepted for study.

Age: Household had to include at least one child below age 15. The final sample matches the quotas for socio-demographic characteristics in Nantes, France.

Ethnicity: See above

Other relevant demographics: See above

Anthropometrics: Not specified. See above

Location: Nantes, France

Summary of Results:

Key Findings:

Toxin Exposure:

- Within the population of consumers of fish, about 20–30% respectively, of men and women are exposed above the provisional tolerable weekly intake (PTWI) of 14 pg kg^{-1} body weight from fish.
- For all levels of exposure, about 25% of toxic equivalent factors are from PCDD/F and about 75% are from DL PCBs
- Regarding NDL-PCBs, the results confirmed that the median dietary exposure for PCB_i is around 10 ng kg^{-1} body weight day⁻¹ (8.3 ng kg^{-1} body weight⁻¹ for all subjects from fish only) when the 95th percentile of the distribution is about 20 ng kg^{-1} body weight day⁻¹.

Estimated intake of LC n-3 PUFA:

- Consumption of LC n-3 PUFA from fish ranges from 14 to 2300 mg day⁻¹ in men and from 43 to 2500 mg day⁻¹ in women.
- About 50% of the studied population reaches the daily allowance for LC n-3 PUFA with a median intake of 563 and 612 mg day⁻¹ for men and women, respectively.

Exposure categories:

- 64% of women in the study reached the recommended intake of LC n-3 PUFA, within that group of women:
 - 39% of the women were exposed below the PTWI for dioxin compounds, and
 - 25% exceeded the PTWI for dioxin compounds.
- Within the 36% of women not reaching the recommended intake for LC n-3 PUFA:
 - 33% were exposed below the PTWI for dioxin compounds and
 - 3% were exposed above it.
- 57% of men in the study reached the recommended intake for LC n-3 PUFA, within them:
 - 44% were exposed below the PTWI for dioxin compounds and
 - 13% exceeded it.
- 43% of men failed to reach the recommended intake for LC n-3 PUFA but are exposed below the PTWI for dioxin compounds.

Summary Findings:

- Results show that recommended intakes of omega-3 PUFA can be met and even exceeded through eating seafood without going beyond POP's upper tolerable intake limits.
- 41% of the subjects had an optimal balance between the risk and benefit of eating fish, because 19% were meeting the nutritional recommendation but exceeding the toxicological threshold, whereas 38% were exposed below the toxicological threshold but failed to reach the recommended intake of LC n-3 PUFA.
- Results showed that meeting the nutritional requirements of 0.5 milligram per day of LC n-3 PUFA is compatible with respect to toxicological thresholds, while an intake higher than 1.5 gram per day is likely to lead to a dietary exposure above the provisional tolerable weekly intake for dioxins.

Author Conclusion:

- Overall measures for this group of adult subjects indicate that 60% are achieving the nutritional recommendation for LC n-3 PUFA and 79% are exposed to total dioxins below the toxicological threshold of 14 pg kg/body weight /week.
- Dietary exposure to dioxins is strongly correlated to the ingestion of LC n-3 PUFA and that there is an optimal area of the distribution of consumers that is maximizing the benefit of eating fatty fish without exceeding the PTWI of dioxins.
- A benefit/risk calculation resulted in a recommendation of a maximum intake of about 1500 mg/day for LC n-3 PUFA. That would correspond to a maximum daily consumption of about 150 g of various fishes (considering an average concentration of LC n-3 PUFA of 1000 mg/100 g).

Reviewer Comments:

The authors mentioned some drawbacks in the data analysis.

- *They did not include in estimations the dietary exposure to pollutants other than dioxins and PCBs, such as methylmercury.*
- *In addition, they stated that uncertainty remains about the possible combined effects of fish contaminants when the exposure from each of them remains below the threshold for safety concern.*

Abbreviations used in evidence worksheet and article:

- *Polychlorinated biphenyls (PCBs)*
- *Polychlorinated dibenzo-p-dioxins (PCDDs)*
- *Polychlorinated dibenzo-p-furans (PCDFs)*
- *Nondioxin-like PCBs (NDL-PCBs) (for NDL-PCBs, the analytical results are expressed as a sum of the six congeners, also called PCB indicators (PCBi))*
- *Dioxin-like PCBs (DL-PCBs)*
- *Analytical results for PCBs were also expressed as a sum of the six congeners, called PCB indicators (PCBi)*
- *Long-chain polyunsaturated fatty acids n-3 (LC n-3 PUFA)*
- *Provisional tolerable weekly intake (PTWI)*
- *pg = picogram*
- *I-TEQ = International Toxicity Equivalent*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)

Yes

2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	Was the research question clearly stated?	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	Was the selection of study subjects/patients free from bias?	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	Were study groups comparable?	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A

3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method of handling withdrawals described?	???
4.1.	Were follow-up methods described and the same for all groups?	???
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	???
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	???
4.4.	Were reasons for withdrawals similar across groups?	???
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	???
5.	Was blinding used to prevent introduction of bias?	N/A
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	N/A
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes

6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outcomes clearly defined and the measurements valid and reliable?	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	Was the statistical analysis appropriate for the study design and type of outcome indicators?	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	No
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	N/A
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	Are conclusions supported by results with biases and limitations taken into consideration?	N/A
9.1.	Is there a discussion of findings?	Yes

9.2.	Are biases and study limitations identified and discussed?	Yes
10.	Is bias due to study's funding or sponsorship unlikely?	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes