

To: Mrs Catherine Geslain-Lanéelle, EFSA Executive Director

CC: Mr Bernard Url, Director of Risk Assessment and Scientific Directorate  
Mrs. Julianne Kleiner, Head of Unit, Scientific Committee  
Mrs Diane Benford, CONTAM Panel chair  
Mrs. Claudia Heppner, Head of Unit for Food ingredients and packaging  
Mr. Janez Potočnik, Commissioner for the Environment  
Mr. Tonio Borg, Commissioner for Health and Consumers  
Mr. Karl Falkenberg, Director General for the Environment  
Mrs. Paola Testori Coggi, Director General for Health and Consumers  
Mr. Ladislav Miko, Deputy Director General for the Food chain  
Mrs. Almut Bitterhof (Pesticides Residues, DG SANCO)  
Mr. Frans Verstraete (Contaminants / Residues of veterinary medicinal products,  
DG SANCO)  
Mr. Pavlos Mouratidis (Industrial Emissions, Air Quality & Noise,  
DG Environment)

Brussels, 16 April 2013

Dear Mrs Catherine Geslain-Lanéelle,

Considering the EFSA recent revision of the Tolerable Weekly Intake (TWI) for methyl mercury from fish for the EU, we would like to draw your attention to two reports:

***ZMWG Report: “An overview of Epidemiological Evidence on the Effects of Methyl mercury on Brain Development, and A Rationale for a Lower definition of Tolerable Exposure” , December 2012***

***ZMWG Summary Report: “A New Global Picture Emerges”, December 2012***

The first report, ***“An overview of Epidemiological Evidence on the Effects of Methyl Mercury on Brain Development, and A Rationale for a Lower Definition of Tolerable Exposure”*** summarizes epidemiological research on the effects of methyl mercury on the developing brain, assessing severe pollution incidents in Japan that first documented methyl mercury’s effect and examining studies that found subtler but similar effects in island populations with high-fish diets. The report then reviews recent studies showing that methyl mercury has adverse effects even at exposures typical of ordinary fish consumption in most countries, suggesting that current health benchmarks for mercury levels in fish are outdated and inadequate.

The second report, ***“A New Global Picture Emerges”*** presents ZMWG’s recommendations on measures that governments and other stakeholders can take to reduce methyl mercury exposure risks to people all over the world based on this new health perspective.

We note that EFSA recently proposed lowering the TWI for methyl mercury from 1.6 µg/kg (established in 2003) to 1.3 µg/kg. While we support lowering the intake guideline, any new limit should be much lower than 1.3 µg/kg/week. As the enclosed report documents, seven recently published studies have associated adverse effects on brain development with methyl mercury doses **well below the PTWI of 1.6 µg/kg**. Several of those studies found adverse effects at or below the current US Reference Dose, which is 0.7 µg/kg on a weekly basis. By implication, to provide a margin of safety, we would consider that the TWI should be below 0.7 µg/kg.

EFSA's previous opinion on methyl mercury, issued in 2004<sup>ii</sup>, highlighted the need to minimize exposure to methyl mercury since its toxicity even at low doses has been demonstrated. This valid and significant point for risk management is lost in the recently delivered opinion, since the CONTAM Panel's mercury opinion states that because the benefits from fish consumption are generally larger than the risks from methylmercury, limits on methylmercury exposure more stringent than 1.3 µg/kg are not required. This position—that benefits justify accepting harm—is unprecedented in assessing risks to public health. Given the length of the Scientific opinion, what we convey here is a first reaction not based on a full in-depth examination of the entire opinion. However, we nonetheless feel it is important to state that the above-mentioned position appears to be problematic in three respects:

First, the scientific evidence upon which estimates of both benefits and risks are based is still subject to much uncertainty. The idea that benefit/risk ratios can be determined precisely enough to “titrate” risks against benefits in this manner is dubious.

Second, benefits and risks are distributed differently, and the ratio of benefit to risk differs widely for different individuals. For the majority who don't eat much fish or who eat only seafood varieties with low mercury content, the net effect is probably beneficial. But there is a substantial minority—people who eat far more than average amounts of fish in European countries, a larger share of the public in countries where fish is one of the primary protein source, and people who prefer to eat higher-mercury fish varieties—all of whom have above- average and potentially excessive methyl mercury exposure. Data gathered from a recent EU biomonitoring project found for one third of the people in 17 EU member states, levels of mercury were above the 0.58 µg/g hair level shown to be safe in the most recent scientific studies. This suggests that 1.8 million of the 5.4 million babies born in European countries each year may be affected by unsafe maternal mercury levels, safety being referenced to the 0.58 µg/g hair level<sup>iii</sup>. For these consumers, it seems probable that the harm is greater than the benefit, i.e. there is a net negative effect. To suggest that this risk need not be pro-actively managed because the majority benefits from fish consumption seems an unwarranted neglect of a sub-population. We are very concerned that EFSA's recent opinion appears to endorse this harm-blind, benefit-only approach to policy, and may be used by some governments as a reason to avoid managing mercury exposure.

Finally, it is possible both to maximize the benefits of seafood consumption and to minimize the risks from methyl mercury exposure by offering consumers clear guidance to choose primarily low-mercury fish<sup>iv</sup>. We believe policy should promote that dual goal, and we find the absence of this perspective from the recent EFSA opinion quite unsettling.

To that end we recommend that the recent mercury opinion be put on hold until these issues can be addressed, and until the approach it seems to endorse can be reviewed within EFSA and in the European Commission in terms of the mandate (2011/269) originally given from the EC to EFSA for this scientific opinion. A relevant note should be posted on the website to alert potential readers. We note that a new mandate (2013/0001) has now been given to EFSA to address risk and benefits of fish/seafood consumption as regards methylmercury. Nevertheless, we are very

concerned with the approach taken so far, and would therefore call for a full revision of the 2985 Scientific Opinion and that the new opinion considers our comments and reports. In addition, considering the widespread exposure risk from mercury, we would consider that stakeholder consultation should take place before finalisation of any such relevant scientific opinion.

Thank you in advance for considering our reports and addressing our concerns.

Yours sincerely,

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Michael Bender (MPP)  
ZMWG  
International coordinators

Jeremy Wates  
EEB  
Secretary General

Genon Jensen  
HEAL  
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<sup>i</sup> The **Zero Mercury Working Group (ZMWG)**, is an international coalition of more than 95 public interest non-governmental organizations from over 50 countries from around the world formed in 2005 by the European Environmental Bureau and the Mercury Policy Project/Ban Mercury Working Group. The aim of the group is to reach 'Zero' emissions, demand and supply of mercury, from all sources we can control, towards eliminating mercury in the environment at EU level and globally." [www.zeromercury.org](http://www.zeromercury.org)

The **European Environmental Bureau (EEB)**, is a federation of more than 140 environmental citizens' organisations based in all EU Member States and most Accession Countries, as well as in a few neighbouring countries. These organisations range from local and national, to European and international. The aim of the EEB is to protect and improve the environment of Europe and to enable the citizens of Europe to play their part in achieving that goal. [www.eeb.org](http://www.eeb.org)

The **Health and Environment Alliance (HEAL)** is a leading European not-for-profit organisation addressing how the environment affects health in the European Union. We demonstrate how policy changes can help protect health and enhance people's quality of life. With the support of more than 65 member organisations, representing health professionals, not-for-profit health insurers, patients, citizens, women, youth and environmental experts, HEAL brings independent expertise and evidence from the health community to different decision-making processes. Members include international and Europe-wide organisations, as well as national and local groups. [www.env-health.org](http://www.env-health.org)

<sup>ii</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/34.htm>

<sup>iii</sup> Economic benefits of methylmercury exposure control in Europe: Monetary value of neurotoxicity prevention, Martine Bellanger, Céline Pichery, Dominique Aerts, Marika Berglund, Argelia Castaño, Mája Čejchanová, Pierre Crettaz, Fred Davidson, Marta Esteban, Marc E. Fischer, Anca Elena Gurzau, Katarina Halzlova, Andromachi Katsonouri, Lisbeth E. Knudsen, Marike Kolossa-Gehring, Gudrun Koppen, Danuta Ligocka, Ana Miklavčič, M. Fátima Reis, Peter Rudnai, Janja Snoj Tratnik, Pál Weihe, Esben Budtz-Jørgensen, Philippe Grandjean, **Environmental Health**, a BioMed Central open access journal. See also Commentary by Elsie M Sunderland and Noelle E Selin, *Environmental Health*. Articles available on [journal website](http://www.environmentalhealthjournal.org) from Monday, 7 January 2013.

<sup>iv</sup> See " Patterns of Global Seafood Mercury Concentrations and their relationship with Human Health", Biodiversity Research Institute, December 2012. This report was published at the same time as the two reports enclosed. <http://www.briloon.org/uploads/documents/hgcenter/seafood/PatternsofGlobalSeafood.pdf>