



16 June 2015

World Health Organization
20 Avenue Appia
1211 Geneva 27, Switzerland

Food and Agriculture Organization of the United Nations
Viale delle Terme di Caracalla,
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Dr. Margaret Chan
Director-General
World Health Organization

And

The Secretariat of the Joint FAO/WHO Meeting on Pesticide Residues:

- Ms. Juliette Deweirdt, WHO JMPR Secretariat
- Dr. Philippe Verger, WHO JMPR Secretariat
- Ms. Yong Zhen Yang, FAO JMPR Secretariat

cc:

- Dr. Ian Smith, Executive Director of the Director-General's Office
- Gregory Hartl, WHO Media Officer

Dear Dr. Chan and the Joint JMPR Secretariats,

We are writing to support the scientific review and classification of the pesticides glyphosate, malathion, and diazinon as 'probably carcinogenic to humans' (Group 2A) by the International Agency for Research on Cancer earlier this year, and to raise concerns about the steps that are planned to be taken by the JMPR in response to the IARC classifications. IARC is a research arm of the World Health Organization (WHO). The role of the Joint FAO-WHO Meeting on Pesticide Residues (JMPR) is to conduct scientific evaluations of pesticide residues in food and provide advice on the acceptable levels of such residues. In fulfilling its role, JMPR should accept IARC's cancer classification as issued and proceed with the task of identifying acceptable levels based on that classification and not establish a process to second-guess the recent work of IARC. In addition, we have examined the make-up of the expert task force through

publicly available documents and have identified several members with actual or apparent conflicts of interest, including ties to glyphosate users and producers including Monsanto. Therefore we are very concerned about the ability of the expert task force as currently constituted to provide an impartial review of the risks, and make unbiased recommendations. We strongly urge WHO to ensure that the panel is free from conflicts and other biases that may unduly influence the work of the panel.

Info on the panel is here: http://www.who.int/foodsafety/areas_work/chemical-risks/jmpr/en/

List of experts is attached and: http://www.who.int/foodsafety/areas_work/chemical-risks/list_of_experts1.pdf

Our concerns are detailed below:

The IARC review of cancer hazards should be used by the WHO and the EU to set policies that protect human health and the environment

The International Agency for Research on Cancer ([IARC](#)) - the cancer evaluation arm of the World Health Organization - convened a meeting of 17 scientific experts from 11 countries to assess whether certain pesticides, including glyphosate, caused cancer in humans ([Meeting 112, March 2015](#)). The expert panel unanimously voted to classify glyphosate as genotoxic and “probably” carcinogenic in humans (IARC Group 2A). IARC’s reclassification of this pesticide is particularly concerning, as glyphosate is the most widely used pesticide in the world.¹

The IARC arrived at the consensus to increase glyphosate’s classification after reviewing hundreds of scientific studies, based on three primary lines of evidence:

- "sufficient" evidence of cancer in mice and rats that were fed glyphosate over several years (see reports by [EPA](#) 1991 and the [WHO](#) 2004);
- "strong" evidence from mechanistic or cellular studies that explain how glyphosate may cause cancer;
- "limited" evidence from epidemiologic studies of people, particularly pesticide applicators and farmworkers.

The details of the IARC decision are reported in the [Lancet Oncology](#) in summary, with the full length Monograph expected by early 2016.

JMPR should not attempt to re-do IARC’s work

The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) is not in a position to conduct a credible, independent review of whether or not glyphosate, or any other pesticide, is a risk for cancer. Instead, the JMPR is charged with conducting quantitative assessments of health risks posed by pesticide

¹ <http://www.transparencymarketresearch.com/glyphosate-market.html>

residues in food.² This should be done in light of the cancer evaluation done by IARC, and not by re-doing or undermining IARC's determination.

Unfortunately, with the current composition of the committee³, we have significant concerns that the committee will be unduly influenced by the overall pesticide industry and particularly Monsanto- the largest producer of glyphosate in the world (under the trade name Roundup®).

Transparency and conflict of interest among the JMPR expert taskforce

Three committee members that we know of, Drs. Alan Boobis, Angelo Moretto, and Vicki Dellarco, have close ties with the global food and chemical industry trade group International Life Sciences Institute (ILSI) and its scientific arm, Health and Environmental Sciences Institute (HESI). In its 2014 Annual Report, ILSI stated that financial support for its North American programs is primarily funded by its industry membership, which includes glyphosate producers such as Monsanto Company and DuPont.⁴

The WHO has had a tumultuous too-cozy relationship with ILSI/HESI that in the past has attracted public concern. In 2006, after pressure from an NRDC-led coalition, the WHO barred ILSI from future participation in "setting microbiological or chemical standards for food and water" due to its close ties to major multinational corporations.⁵ Prior to that, the WHO was publicly shamed for its cozy relationship with ILSI, whose membership included tobacco companies:

*Similar complaints voiced in the 1990s were followed by a 2001 report by the WHO Tobacco-Free Initiative on how member tobacco companies had used ILSI to muster seemingly unbiased scientific opinions aimed at quashing WHO tobacco control efforts. ILSI vehemently denied these allegations and, Anderson says, worked with the WHO to provide assurances of transparency about how ILSI operates. Derek Yach, now head of the Rockefeller Foundation's Program on Global Health, led that WHO initiative and closely watched ILSI's response. "Part of the problem lies with the UN agencies themselves, or in this case the WHO," he concludes, noting that these bodies have yet to take many of the protective measures recommended by the report. "You can blame the corporations," he says, "but you also need to place blame on not having very clear, very transparent review of conflict-of-interest procedures internally."*⁶

² JMPR Terms of Reference: http://www.who.int/foodsafety/areas_work/chemical-risks/termofreference.pdf?ua=1

³ http://www.who.int/foodsafety/areas_work/chemical-risks/list_of_experts1.pdf?ua=1

⁴ <https://www.ilsixtra.org/AnnualReport/ILSINA/index.html#p=33>; http://earthopensource.org/wp-content/uploads/Eu_pesticidefoodsafety.pdf; <http://www.ilsa.org/NorthAmerica/Documents/MEMBERSHIP/2015%20Fact%20Sheets/ILSI%20North%20America%202015%20Membership%20Fact%20Sheet.pdf>; Transparency Market Research

⁵ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1570087/>

⁶ Loughheed T. WHO/ILSI affiliation sustained. Environ Health Perspect. 2006 Sep;114(9):A521. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1570087/>

The conflict between WHO and ILSI led to reports in the Lancet and in the popular press.⁷ For example:

WHO to Rely Less on U.S. Research

By JOHN HEILPRIN, Associated Press

Friday, January 27, 2006

WASHINGTON -- A U.S.-based research foundation is being barred by the World Health Organization from helping set global standards for protecting food and water supplies because of its funding sources. However, the nonprofit International Life Sciences Institute, which is funded by hundreds of chemical, food and drug companies, will remain as one of nearly 200 "non-governmental organizations" that WHO views as working partners... The institute's member companies include Bayer AG, Coca-Cola, Dow Agrosciences/Dow Chemical, DuPont, ExxonMobil, General Mills, Hershey Foods, Kellogg, Kraft, McDonald's, Merck & Co., Monsanto, Nestle, Novartis, PepsiCo, Pfizer and Proctor & Gamble.

Although the public does not trust the chemical and pesticide industry to regulate itself, the WHO seems to have allowed itself to be compromised. Despite the ban, ILSI has maintained its close relationship with the WHO International Programme on Chemical Safety (IPCS) and the JMPR, which is tasked to review the safety of pesticide residues in food -- the very same pesticides manufactured by ILSI members. We believe that this is a violation of WHO guidelines governing its relationship with NGOs. One of the criteria for admission into official relations with the WHO is for the NGO to "be free from concerns which are primarily of a commercial or profit-making nature."⁸ ILSI does not meet that standard.

We wish to emphasize that our following comments are not intended in any way to challenge the scientific and technical expertise or to impugn the personal integrity of these panel members. However, given the significance of this panel's decision, it is critical that the WHO carefully evaluates the information provided in the following comments and act as needed to avoid selecting panel members that have potential financial conflicts of interest. Doing so will help the WHO maintain public confidence in the peer review process and avoid any potential appearances of a lack of impartiality.

Alan Boobis is currently Vice-President of ILSI Europe and a former chair of the ILSI Health and Environmental Sciences Institute.⁹ In addition to being an extremely active member of ILSI over the past 20 years, he has also acted as a consultant for companies such as Endura, Sumitomo Chemical, and Proctor & Gamble, the latter of which are members of ILSI HESI.¹⁰

Angelo Moretto has been involved in projects with ILSI. Dr. Moretto is a member of the steering team of the ILSI RISK21 project on cumulative risk (the risk posed by multiple chemical exposures). RISK21 is

⁷ http://switchboard.nrdc.org/blogs/jsass/ilsi_the_international_life_sc.html

⁸ www.who.int/civilsociety/relations/principles/en/

⁹ http://www.ilsi.org/Documents/election_news_release_vFinal.pdf

¹⁰ http://earthopensource.org/wp-content/uploads/Eu_pesticidefoodsafety.pdf

directly financed by pesticide companies BASF, Bayer, Dow, DuPont, and Monsanto.¹¹ He was also involved in ILSI/HESI's Agricultural Chemical Safety Assessment (ACSA). Of greater concern was his resignation from chair of the European Food Safety Authority's Plant Protection Products and their Residues (PPR) Panel in 2011 after his industry connections came to light.¹² (Note: Dr. Boobis also sat on the panel). Dr. Moretto failed to reveal his position as an advisor for Melete Srl, which helps companies comply with the EU's REACH, nor the fact that he owns 17% of the company's shares. Additional industrial ties include Dow and Syngenta, two pesticide manufacturers and ILSI members that have paid Dr. Moretto for his consultancy services to in the past.¹³

Vicki Dellarco retired from her position as Science Advisor to the Director of the Office of Pesticide Programs in 2013 and is now an independent consultant for organizations that include ILSI/HESI. Her involvement with ILSI began much earlier in her career, such as serving on the Risk21 Integrated Evaluation Strategy Subteam alongside Drs Moretto and Boobis.¹⁴ While on the HESI Agricultural Committee on Safety Assessment Technical Committee between 2000 and 2006, Dr. Dellarco also participated in the 2004 JMPR working group that reviewed glyphosate to determine the Acceptable Daily Intake (ADI) for humans.¹⁵

Dr. Dellarco has participated in several ILSI-hosted workshops with the topic of dissociating the evidence of cancer from animal studies with predictions of cancer risk in humans. For example:

Dellarco, V., Fenner-Crisp, P., Meek, M.E., Olin, S. and Patton, D. (2006) Evaluating the Human Relevance of Animal Modes of Action, ILSI Research Foundation Society for Risk Analysis Continuing Education Course, Baltimore, December 3rd

Dellarco, V., Fenner-Crisp, P., Meek, M.E., Olin, S. and Patton, D. (2007) Evaluating the Human Relevance of Animal Modes of Action, ILSI Research Foundation Workshop Course, ILSI, Washington, April 16th.

This effort to undermine confidence in use of animal models to predict human cancer risk is propagated by ILSI and its collaborators, including Dr. Dellarco. For example, in 2008, Dr. Dellarco gave a presentation on the subject as an employee of the EPA Office of Pesticide Programs which chronicles the origin as the WHO-IPCS and ILSI (slide 6), and reveals that both sources link to documents produced by ILSI authors including Dr. Boobis (slide 20).¹⁶

¹¹ http://docs.nrdc.org/health/files/hea_11021801a.pdf

¹² <http://earthopensource.org/earth-open-source-reports/europes-pesticide-and-food-safety-regulators-who-do-they-work-for/>

¹³ <http://earthopensource.org/earth-open-source-reports/europes-pesticide-and-food-safety-regulators-who-do-they-work-for/>

¹⁴ <http://www.hesiglobal.org/files/Updated%202014%20RISK21%20Technical%20Committee%20Members.pdf>

¹⁵ <http://www.inchem.org/documents/jmpr/jmpmono/v2004pr01.pdf>

¹⁶ http://ec.europa.eu/health/ph_risk/documents/ev_20081113_co17_en.pdf

Drs. Boobis, Moretto and Dellarco have co-authored multiple papers and have worked together on multiple occasions for industry trade associations.

More recently, HESI sponsored Dr. Dellarco's recent participation at XXXII Argentine Conference on Interdisciplinary Toxicology and Iberoamerican Congress of Toxicology (September 2014). She presented on the "use of experimental evidence in the risk analysis and risk management of crop protection products."¹⁷

Roland Solecki, while not directly affiliated with ILSI, raises concerns due to his position as the head of the Pesticides Safety Department at the Federal Institute for Risk Assessment (BfR). Germany, acting as the European Union rapporteur member state (RMS), has been charged with conducting a safety review of glyphosate for the European Union, *but three of the panelists on the scientific panel are employees of BASF and Bayer* according to a recent report by Corporate European Observatory (April 2015) that raised significant doubts about the neutrality and independence that Germany brings to its pesticide review.¹⁸ Both BASF and Bayer are major global pesticide producers. Reports indicate that Bfr itself was overwhelmed with the task of assessing glyphosate, and heavily relied on information provided by the Glyphosate Task Force (GTF).¹⁹ GTF is a consortium of pesticide manufacturers across Europe, including ILSI members Arysta Lifesciences SAS, Dow, and Syngenta, and Monsanto, with the goal of joining "resources and efforts in order to renew the European glyphosate approval."²⁰ Bfr was heavily criticized for relying solely on information provided by industry.²¹

Even before IARC made their decision public, Dr. Solecki co-authored a paper with fellow BfR employees (Niemann et al 2014) concluding that glyphosate exposure in people is so low as to be of "no health concern" from either dietary intake or occupational exposure, based on human urine sampling from seven studies in Europe and the US.²² The BfR Committee for Pesticides and their Residues, which reports to Germany's Federal Ministry of Food and Agriculture, has already come out with a statement against IARC's decision. Dr. Solecki has also been openly critical of the WHO's "incomprehensible conclusion."²³

Conclusion – a process lacking credibility is a violation of the public trust

¹⁷ <http://www.hesiglobal.org/files/Insights%20September%202014-final%20for%20website.pdf>

¹⁸ <http://corporateeurope.org/food-and-agriculture/2015/04/glyphosate-saga-independent-scientific-advice-according-germany-uk>

¹⁹ http://www.academia.edu/7595699/Glyphosate_re-assessment_in_Europe_is_corrupt_Toxicology

²⁰ <http://www.glyphosate.eu/legal-notice>

²¹ <http://www.corporateeurope.org/food-and-agriculture/2015/04/glyphosate-saga-independent-scientific-advice-according-germany-uk>

²² <http://rd.springer.com/article/10.1007/s00003-014-0927-3/fulltext.html>

²³ Translated from a German news report, March 2015. <http://www.sueddeutsche.de/gesundheit/glyphosat-hoehere-krebsgefahr-durch-weltweit-verwendetes-pestizid-1.2406147>

The information provided above was gathered through relevant searches of publicly available sources. We consider it more than sufficient to draw conclusions regarding potential conflict of interest and appearance of lack of impartiality with respect to these specific candidates. However, our searches are certainly not comprehensive, and the WHO staff should conduct additional, more thorough investigations.

The WHO is a highly respected organization and should not repeat past mistakes that could hurt its credibility and weaken public trust. As such, we strongly urge that the following steps are taken :

1. *WHO should conduct a thorough investigation of the proposed JMPR experts to ensure that there are no potential conflicts of interest, financial or otherwise.*
2. *WHO should remove any candidates with potential conflicts from serving as JMPR experts or advisors – including Drs. Boobis, Moretto Dellarco and Solecki.*
3. *WHO and JMPR should consider that their mission is not to challenge IARC's classification, but instead to use that information to set safety standards to protect human health.*

Thank you for your consideration of these comments.

Respectfully,

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APPENDIX: The IARC review of glyphosate cancer risk

The IARC Working Group of experts made an independent assessment of existing studies, including those sponsored by Monsanto, the glyphosate manufacturer. Monsanto representatives attended the 8-day meeting as observers and given the opportunity to speak, but did not vote on the classification of glyphosate or other pesticides being reviewed by the Working Group experts.

The IARC Working Group reviewed ten laboratory studies on rodents, five on mice and five on rats, culled from the public literature and reports of the [EPA](#) (1991) and the [WHO](#) (2004). One mouse study reported a positive trend for haemangiosarcoma (WHO report) and another mouse study reported a rare tumor called a renal tubular carcinoma (EPA study) associated with glyphosate in long-term feeding studies. In both cases, effects were stronger in the males than females. The IARC Working Group of experts also reviewed five studies in rats: two reported significant increases in pancreatic islet-cell adenomas in male rats (EPA report); two studies did not find significant cancer increases; one study did not last long enough to draw any conclusions about cancer risks. The Working Group determined that there was a statistically significant trend in the occurrence (incidence) of haemangiosarcoma in the male mice, but not the female mice. In accordance with the [pre-specified procedures and criteria](#) of IARC, the Working Group concluded that the studies provided evidence of carcinogenicity in experimental animals.

The IARC experts also reviewed cellular studies and determined that there was "strong" evidence from mechanistic studies showing that glyphosate caused damage to the cell's genetic information (genotoxicity), which can lead to abnormal cell function and ultimately a cancerous cell. Studies also showed that glyphosate also caused oxidative stress in cells, which can lead to cellular damage and elevate the risk of a cell becoming cancerous. This mechanistic evidence - both genotoxicity and

oxidative stress - provides a plausible explanation for how glyphosate may cause cancer, and therefore supports the evidence from the animal studies.

The IARC experts found that the evidence from epidemiologic studies provided some evidence of cancer, in particular elevated risk of non-Hodgkin lymphoma, but it was "limited" because the studies were either weakly positive or did not find a cancer risk at all.

Taken together, these three lines of evidence support the classification of glyphosate as a Group 2A chemical that "probably" causes cancer in exposed people, according to the [pre-specified procedures and criteria](#) of IARC.