

EXECUTIVE DIRECTOR

Parma, 8 May 2012
Ref. CGL/AH/aa (2012) - out-6540277

Re: Discharge of EFSA Budget 2010

Dear Honourable Member of the European Parliament,

You have recently received a letter from a group of NGOs (CEO, Earth Open Source, Testbiotech, and Pesticide Action Network Europe) relating to alleged links of EFSA experts with the International Life Science Institute (ILSI) and arguing on the impact of such links on EFSA's independence. EFSA strongly refutes any allegation of undue influence on its work from any interest group, including ILSI.

EFSA is an organisation committed to openness, transparency and dialogue. While guaranteeing the impartiality of its scientific advice and as laid down in its Founding Regulation, EFSA interacts with a wide range of stakeholder groups with an interest in its work. These include consumer bodies, industry, primary producers and NGOs. Among the NGOs are Corporate Europe Observatory, Pesticide Action Network (Europe), Earth Open Source, Testbiotech and ILSI Europe, organisations that are privately funded, either wholly or in part, and represent those interests.

While in dialogue with these organisations, **EFSA's only interest is to protect public health.** EFSA has published more than 2500 scientific outputs to date which have supported risk managers in making decisions and defining policies to protect consumers. In 2011, at the height of the most serious food safety crisis encountered in the EU since BSE, EFSA led the EU-level scientific investigation – carried out in co-operation with national food safety agencies, the European Commission, the European Centre for Disease Prevention and Control (ECDC), WHO and FAO—to contain an outbreak of Shiga-toxin producing *Escherichia coli* (STEC). This work prevented the spread of a virulent pathogen which claimed over 50 lives and made over 3000 people sick.

In the past 10 years, EFSA's scientific advice has amongst others:

- helped cut by half the number of human salmonella cases in the EU;
- protected consumers from possible misleading information on the alleged health benefits of foods through its scientific evaluation of more than 3000 health claims made in food labelling and advertising;

- reduced the Acceptable Daily Intake (ADI) for a number of food colours and did not establish an ADI in other cases, leading to the suspension of use of one colour Red 2G (E128) following the identification of a safety concern;
- led to the reduction of active substances used in pesticides (of some 1000 active substances on the market in at least one Member State before 1993, only 26% have passed the harmonised EU safety assessment).

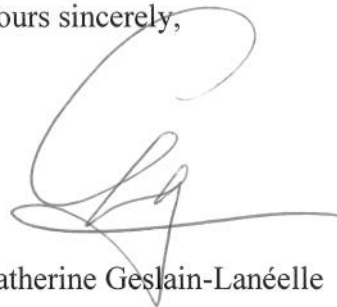
EFSA has full confidence in the impartiality of its scientific advice and integrity of the more than 1500 experts who, coming from public organisations such as national food safety agencies, research institutes and universities, dedicate their time and expertise to ensure that EFSA delivers scientific outputs of the highest quality to support EU policy makers and regulators in making timely and informed decisions.

To imply that the work of these public sector employees could be so easily biased in favour of private interests is an unwarranted and unacceptable attack on their integrity. In addition, EFSA has put in place a very robust system to guarantee the independence of its scientific work which is implemented in an open and transparent way to allow for full public scrutiny. As an open and listening organisation and building on its experience, EFSA will continue to transparently implement its policies and strengthen the rigorous procedures in place to ensure the independence of its scientific decision-making processes, thereby building further trust in the quality of its scientific advice.

For your information, I enclose correspondence from ILSI which I believe is illustrative of the firm position EFSA has adopted in relation to interests.

I trust this information will be helpful in your decision making with regard to EFSA's budgetary discharge and I remain at your disposal for any further information you may require.

Yours sincerely,

A handwritten signature in black ink, appearing to be 'Catherine Geslain-Lanéelle', written over a horizontal line.

Catherine Geslain-Lanéelle

Enclosure: Correspondence from ILSI, 7 May 2012



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7 May 2012

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Re: Characterization of the International Life Sciences Institute (ILSI) and its Branches and Affiliated Entities

Dear Madame and Sir:

On behalf of the International Life Sciences Institute (ILSI), we write to express our concern with the characterization of ILSI in the Decision of the European Food Safety Authority (EFSA) Executive Director implementing EFSA's Policy on Independence and Scientific Decision Making Processes regarding Declarations of Interests (Executive Director's Decision). We believe that the characterization of ILSI and EFSA's newly imposed practice of excluding almost all scientists who work with ILSI from membership of EFSA panels and its scientific committee is based on incomplete and/or erroneous information. **We would like to take this opportunity to provide clarifying facts about ILSI and its branches and request that you reconsider these decisions based upon this information.**

We have been made aware that there is a document posted on the EFSA website entitled, "Frequently Asked Questions on the Implementing Rules for EFSA's Policy on Independence and Scientific Decision-Making" (the "FAQ Document"). The FAQ Document declares that "a member of a Scientific Advisory Body for a non-FSO, such as the International Life Sciences Institute ... cannot be considered for the role of chair or vice-chair of any of EFSA's scientific groups, nor can [s/he] become a member of a single mandate Working Group in a scientific area for which [s/he] ha[s] current experience at ILSI." We are unclear as to the rationales for both a) designating ILSI as a non-FSO and b) singling out ILSI, by name, as an example of an organization with whom EFSA participants should not affiliate.

After careful review of the available EFSA documentation to define a Food Safety Organization (FSO), it seems clear that ILSI does indeed fully meet EFSA's own definition. Specifically, ILSI (1) carries out tasks within EFSA's mission; (2) pursues public interest objectives; and (3) has in place governance mechanisms that ensure the performance of its tasks with independence and integrity. We would be happy to provide further clarification and evidence on any of these points as there is strong data to support all of these qualifiers.

EFSA recommends that involvement with ILSI scientific activities, such as those of its various project and technical committees, should be classified as v) Ad hoc or occasional consultancy in the Declaration of Interest by experts. We strongly contest this characterization of the scientific activities of ILSI and would respectfully ask that if this designation is to be maintained, EFSA provide a reasoned case for this decision.

We would like to take this opportunity to resolutely affirm our commitment to the quality, rigor, and integrity of ILSI's scientific programs and the scientists with whom it engages. Since 1978, ILSI has contributed to the improvement of public and environmental health as a global, not-for-profit, multi-stakeholder, scientific organization. To ensure that no single constituency dominates its operations, ILSI requires the governance bodies of its branches to have at least as many members from public institutions as from industry. In addition, ILSI's Code of Ethics and Standards of Corporate Conduct (<http://www.ilsa.org/Documents/ILSICodeofEthicsSofC2009.pdf>), which applies to all ILSI branches and affiliated entities, provides that, "All ILSI projects must have a primary public purpose and benefit, and must address issues of broad public health interest." These standards also prohibit ILSI from conducting lobbying activities.

ILSI and its branches conduct novel research, convene expert forums, provide training, and hold scientific workshops led by scientists from academia, government, nonprofit organizations, and industry. Each year the scientific programs of ILSI publish dozens of manuscripts in the scientific, peer-reviewed literature in an array of technical fields including food safety, nutrition, pharmacology, toxicology, risk assessment, and ecotoxicology among others. ILSI scientific research is routinely presented and made open for technical critique at international scientific meetings such as Experimental Biology, Society of Toxicology, Federation of European Nutrition Societies and International Association for Food Protection. A commitment to scientific quality and contribution to public health are foremost principles for the organization. Again, we would gladly provide further details, citations, or references as needed if this would be of interest.

We understand that EFSA faces many pressures and has a broad range of stakeholders. However, as a public entity, we urge EFSA to ensure that its process in characterizing ILSI has been equitable and fully vetted. Already, the outcome of these new policies has been the loss of well-respected scientific participation in both EFSA and in ILSI. In today's challenging economic climate, all international scientific bodies rely heavily upon the voluntary contribution of time and perspective from respected experts. The potential for this action to halt or discredit such inputs would be a loss to public health decision-making and the scientific community at large.

We would appreciate the opportunity for any further clarifying discussions and are committed to working with you to identify viable mechanisms for ILSI scientific programs to engage with EFSA staff, its scientific experts, and vice-versa.

Please don't hesitate to contact us to discuss potential next steps.

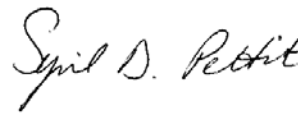
Respectfully,



Suzanne S. Harris, Ph.D.
Executive **Director**
ILSI



Laura Contor
Acting Executive Director
ILSI Europe



Cyril Pettit
Executive Director
ILSI Health and Environmental
Sciences Institute