

EXECUTIVE DIRECTOR

Parma, 24 June 2011  
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**Corporate Europe Observatory**  
Rue d'Édimbourg, 26  
1050 – Brussels  
Belgium

## To Whom It May Concern

**Re.: Your document dated 15 June 2011 entitled “Exposed: conflicts of interest among EFSA’s experts on food additives”**

Dear Sirs,

On 15 June 2011 you published a document entitled “*Exposed: conflicts of interest among EFSA’s experts on food additives*”. This letter aims at correcting factual mistakes reported therein which misled EFSA’s partners, stakeholders and the public about EFSA and its role in providing independent scientific advice to protect public health.

Firstly, I do not agree with your claim that EFSA’s rules are not compliant with, or are of a lower quality than, those of the Organisation for Economic Co-operation and Development (OECD) or the European Medicines Agency (EMA). In 2010, EFSA commissioned an external contractor to carry out a benchmarking study with the aim of comparing EFSA’s Policy on Declarations of Interests with equivalent policies in force with other national, European and international organisations, including EMA, the European Chemicals Agency (ECHA), the European Commission DG SANCO’s scientific committees, the Codex Alimentarius Commission (CODEX), the French Agency for Food, Environmental & Occupational Health Safety (ANSES), the German Federal Institute for Risk Assessment (BfR), the UK Food Standards Agency (FSA), the Canadian Health Products and Food Branch (HPFB), the US Food and Drug Administration (FDA) and the US National Academy of Sciences (NAS)<sup>1</sup>. The report was discussed publicly at EFSA’s Management Board session in March 2011 where it was concluded that EFSA’s Policy incorporated all the major features contained in the rules of the other bodies. According to this report, the Authority’s Policy stands out as a real international benchmark in terms of policies regulating conflicts of interest.

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<sup>1</sup> Milieu, *Comparison between the tools ensuring EFSA’s independent scientific advice and the instruments in use by organisations similar to EFSA*, revised final report, available on EFSA’s website at <http://www.efsa.europa.eu/en/mb110317/docs/mb110317-ax8b.pdf>.

In addition to the above, EFSA has been implementing its system since 2008 and has been audited with positive results on a number of occasions. As for the guidance of the OECD regarding conflicts of interest, please note that EFSA's Policy is fully in line with those guidelines and, as a matter of fact, implements them in as far as they are compatible with the particular characteristics of EFSA's governance and Founding Regulation.

EFSA's Declaration of Interests Policy is based on the principle that high-quality scientific expertise is by nature based on prior experience. This means that holding interests due to scientific activity is a natural and inevitable consequence of attaining scientific recognition at international level in a given field. Some of those interests may indeed conflict with EFSA's aim to deliver objective scientific advice. This is why EFSA assesses interests declared by scientific experts on a specific, case-by-case basis, assessing whether the interest in question represents a conflict in regard to the question being addressed. Some interests declared may *not* conflict with EFSA's mission or may have *nothing to do* with the task that those experts are requested to perform. In other words, interests do not necessarily generate a conflict of interests and specific activities should always be considered before concluding that a conflict exists.

In more detail, EFSA's Policy on Declaration of Interest foresees a three-step screening process of declarations of interest submitted by scientific experts: depending on the roles, functions and relevant groups of the persons concerned, they are required to complete and submit (i) an annual declaration of interests; and/or (ii) a specific declaration of interests linked to a specific subject matter (e.g. an application dossier) to be filled before each meeting; and (iii) an oral declaration of interests at the beginning of each meeting. Annual declarations of interest are posted by EFSA on its website, whereas specific declarations of interest and oral declarations of interest resulting in potential conflicts of interest are recorded in the minutes of the relevant meeting.

Conflicts can only be assessed by considering whether the specific interests declared by a person are compatible with the concrete tasks and roles to be assigned to him or her by EFSA. It should be highlighted that this is fully in line with OECD's definition of conflicts of interest, which requires that one or more interests of an individual creates a conflict with those of the relevant institution.

A transparent and traceable procedure for handling potential conflicts of interest has been implemented through a dedicated IT tool. In cases where a Panel member or other EFSA expert is found to have a potential conflict of interest with respect to certain activities, past or present, and that situation cannot otherwise be remedied, appropriate measures are taken to prevent a conflict of interest. These range from the exclusion of the expert from voting on a certain matter to the exclusion of the expert from some or all of EFSA's activities.

Finally, EFSA is committed to continually strengthening its system, rules and procedures and is currently developing a new policy on independence and scientific decision making. The draft policy brings together all measures EFSA has put in place to ensure the independence of its scientific work. High-quality scientific outputs require transparent, open and unbiased scientific decision-making processes, all of which are critical in building further trust in EFSA's scientific advice. The independence of EFSA's advice is secured, amongst others, through procedures governing the processing of mandates and requests, information gathering, selection of experts, declaration of interests and collegial decision-making, as well as public

consultations and a comprehensive quality review programme. A draft of this policy has been endorsed for public consultation in June this year. Over the next few months, EFSA will carry out a public consultation on this draft policy and will welcome contributions from interested parties. I trust that you will actively participate in view of your strong interest in this subject.

Having addressed your concerns related to the overall quality of EFSA's Declaration of Interests Policy, let me now turn to the more specific allegations made in your publication regarding the alleged lack of independence of members of EFSA's Scientific Panel on Food Additives and Nutrient Sources Added to Food (ANS Panel).

In this respect, you raise multiple accusations regarding some members of the Panel. In line with EFSA's Declaration of Interests Policy, we carefully considered the interests you mentioned. Based on the updated declarations of interest of Jürgen König, John Christian Larsen, Iona Pratt and Gerrit Speijers, EFSA has analysed if the interests would have created a conflict or not.

In the case of Jürgen König, the new interest declared is outside of the remit of the ANS Panel and it was concluded that it did not generate a potential conflict of interest with regard to participation in the ANS Panel and its working groups.

In the case of John Christian Larsen, the new interests declared relate either to a subject that is outside of the remit of the ANS Panel or of a general scientific nature for which a scientific consensus has been established by an opinion of the Scientific Committee of EFSA adopted in 2005 related to a harmonised approach for risk assessment of substances which are both genotoxic and carcinogenic<sup>2</sup>. It was therefore concluded that these interests did not generate a potential conflict of interest with regard to participation in the ANS Panel and its working groups.

In the case of Iona Pratt, the new interest declared is of a general scientific nature and is covered by the above-mentioned opinion of the Scientific Committee of EFSA adopted in 2005. It was concluded that it did not generate a potential conflict of interest with regard to participation in the ANS Panel and its working groups.

In the case of Gerrit Speijers, the new interest declared is outside of the remit of the ANS Panel and it was concluded that it did not generate a potential conflict of interest with regard to participation in the ANS Panel and its working groups. Please note that Gerrit Speijers is not a panel member but attended part of the March 2010 plenary meeting of the ANS Panel as a hearing expert to present the activities of a working group.

The updated annual declarations of interest have been published on the EFSA website.

Regarding the other experts you mention in your document, the interests in question were already declared. Furthermore, please allow me to reiterate that interests should not be considered in an abstract and theoretical manner, as they have been done in your document, but with respect to the activities that the concerned experts are required to carry out at EFSA. Finally, I have identified *inter alia* the following factual mistakes in the representations depicted in your documents:

- Professor Ivonne Rietjens has not undertaken consultancy or privately funded research work on food additives;

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<sup>2</sup> Opinion of the Scientific Committee on a request from EFSA related to A Harmonised Approach for Risk Assessment of Substances Which are both Genotoxic and Carcinogenic , *The EFSA Journal* (2005) 282, 1-31

- Professor Parent-Massin has declared interests with Ajinomoto long before March 2011 and has been excluded from the respective discussions which were noted in minutes published on EFSA's website;
- Dr Jean-Charles Leblanc has never been an ILSI consultant but a member of a working group of that Institute;
- The ANS Panel has not endorsed the margin of exposure concept but only used it in one opinion and with reference to the 2005 opinion of EFSA's Scientific Committee on the margin of exposure;
- It is not the ANS Panel but EFSA scientific staff members who have concluded in February 2011 on the recent studies on aspartame and sweeteners.

As an additional reflection I would like to add that it is worth noting that the ANS Panel has issued several scientific outputs which concluded on the need to lower acceptable daily intakes (ADIs) of several food additives in order to provide maximum protection to European consumers.

I trust that the above will clarify and correct the content of your publication. Please also allow me to say that these mistakes could have been avoided easily had you contacted EFSA before going public with information that is factually incorrect and might erode public trust in organisations and regulations put in place in the EU to protect consumers from food-related risks. On a daily basis, with its scientific experts, staff and network of national food safety agencies, EFSA is committed to contributing to food safety.

Yours sincerely,

A handwritten signature in black ink, consisting of a stylized 'C' followed by a horizontal line and a small flourish at the end.

Catherine Geslain-Lanéelle