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CC: Maroš Šefčovič, European Commission Vice-President in charge of Inter-Institutional Relations and Administration; Eoin O'Shea, European Court of Auditors

Brussels, 1st July 2011

Re: Your letter dated 24 June 2011 to Corporate Europe Observatory

Dear Ms Geslain-Lanéelle,

We have received your letter dated 24 June 2011. The letter's aim, you wrote, is to correct "factual mistakes" in our report on conflicts of interests in EFSA's scientific panel on food additives and nutrient sources added to food (ANS Panel).

These "factual mistakes", according to you, "misled EFSA's partners, stakeholders and the public about EFSA and its role in providing independent scientific advice to protect public health."

We find it quite disappointing that you use such categorical, if not aggressive language, when it turns out that you have not actually read our report carefully enough. As we demonstrate below, your attacks towards our report have no ground and the "factual mistakes" are indeed yours, not ours.

If we were to embrace the same style of communication, we would argue that it is your letter that misleads EFSA's partners, stakeholders and the public about our findings and analysis of EFSA's current policy on conflicts of interests.

1. <u>EFSA's definition of a 'conflict of interest' conflicts with the OECD's definition used in our report</u>

You wrote: "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)."

Corporate Europe Observatory (CEO)'s investigative report, "Exposed: conflicts of interest among EFSA's experts on food additives", does not compare at any moment EFSA's conflict of interest policy with that of the OECD. We have only used the most

recent OECD definition of a 'conflict of interest' to judge the level of conflicts of interest in the ANS panel.

This OECD definition, from 2007, is as follows[1]:

> Conflict of interest occurs when an individual or a corporation (either private or governmental) is in a position to exploit his or their own professional or official capacity in some way for personal or corporate benefit.

According to this definition, as we pointed in our report, the simple fact of being in a position to exploit one's official capacity at EFSA for personal or corporate benefit, even if no unethical or improper act results, represents a conflict of interest.

As you know, conflicts of interest can lead to prejudiced viewpoints and biased opinions. Even if some industry interests may seem unrelated to a specific agenda or mandate of a given EFSA expert, these interests clearly show a positive bias towards industry, and this bias may affect the decisions of that expert – even unconsciously. Much available evidence implies that commercial interests bias science in general[2] and regulatory science in particular[3].

But seemingly blind to this reality, EFSA continuously repeats its old mantra – "having an interest does not necessarily mean having a conflict of interest" – which clearly conflicts with the OECD definition we used.

2. EFSA rules on conflicts of interest do not have a "red list" and therefore are weaker than the new EMA rules

In our report, we do compare EFSA's rules with the new EMA rules on conflicts of interest (to enter into force in the autumn) that are demonstrably stronger than EFSA's. The EMA has set out a 'red list' of non-specific interests that an expert working for this agency cannot have. For instance, scientific committee chairs and vice-chairs are not allowed to have held any "employment, consultancy or strategic advisory role within previous 5 years and at any time point during the term of the mandate" with a pharmaceutical company[4].

If these rules were applied at EFSA, four of the experts on the ANS panel – Ivonne Rietjens (vice-chair), Gerrit Speijers (rapporteur), Jürgen König and Sandro Grilli – would be disqualified from sitting on the panel. We take note that you have not challenged this in your letter.

Contrary to the EMA, EFSA does not have a "red list" policy. Instead, you state: "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."

Elsewhere you express the same idea: "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." Then you add: "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."

We disagree with these statements and made this clear in our report. Regarding the first idea, we contend that a company's interests are not limited to one single substance (subject of a "concrete task" for a given EFSA expert). On the contrary, a company has a strong interest and a duty to its shareholders to promote an industry-friendly climate within regulatory and advisory bodies. Hiring EFSA experts as consultants or financing EFSA experts' labs are ways of fulfilling this role. As we

wrote, Danone and Nestlé are heavy users of aspartame. It can be beneficial for these food corporations to hire ANS panel members as advisors or fund their labs.

Regarding the second statement, considering whether the specific interests declared by an expert are compatible with the concrete tasks and roles to be assigned to him/her by EFSA is clearly not "fully in line" with the OECD's definition of conflicts of interest we use in our report.

3. The immediate update of four declarations of interest following the publication of our report confirms CEO claims

We note that the declarations of interest of panel experts John Christian Larsen (chair), Gerrit Speijers (rapporteur), Jürgen König, and Iona Pratt have been updated a few days after the publication of our investigative report "Exposed: conflicts of interest among EFSA's experts on food additives"[5].

This clearly confirms CEO claims that these four experts were in breach of EFSA rules by having failed to declare collaborations with the food industry-sponsored scientific think tank ILSI Europe.

ILSI Europe describes itself as a "a key partner for European industry" that "provides collective, cost-effective funding to timely build science in regulatory areas"[6]. Its members and funders include Nestlé, Unilever, Kraft Foods, Danone, Mars, Coca-Cola, Mc Donald's[7] – all food corporations that have a strong motivation to "build science" that serves their commercial interests in regulatory areas.

The fact that several EFSA experts collaborate in this masquerade casts serious doubts on the claim, in your letter, that "on a daily basis, with its scientific experts, staff and network of national food safety agencies, EFSA is committed to contributing to food safety".

Due to their ties and involvement with ILSI, and in line with the OECD definition of a conflict of interest, the four experts mentioned above are clearly in a position to exploit their official capacity at EFSA in some way for the benefit of ILSI and its members. They thus do have a conflict of interest according to the OECD.

Should we remind you that the chair of EFSA's management board, Diána Bánáti, stepped down from ILSI last year precisely because, in EFSA's own words, involvement with ILSI "may create a potential conflict of interests with EFSA activities"[8]?

4. EFSA should now start four internal procedures to establish whether the omissions of the four experts are a breach of trust vis-à-vis EFSA

According to the EFSA's Guidance document on declarations of interest that you signed on 8 September 2009, EFSA should start internal procedures regarding the cases of John Christian Larsen, Gerrit Speijers, Jürgen König, and Iona Pratt[9]:

> On the basis of the assessment of the updated DoI, EFSA shall start an internal procedure in order to establish whether the omission of the expert needs to be considered as a breach of trust vis-à-vis the Authority if it is found that:
>
> a. The information missing from the relevant DoIs is a declarable interest according to EFSA's Guidance; and
>
> b. The expert did not declare the missing information intentionally or through gross negligence or he/she failed otherwise to meet his obligations under EFSA's Policy on DoI.

Here, both conditions are clearly fulfilled: panel rapporteur Gerrit Speijers wrote Corporate Europe Observatory that "it was recently made clear by instruction from EFSA that [collaborations with ILSI] should be included in our declaration of interests"[10]. So we are in a situation of "gross negligence" at best, or of intentional concealing of information at worst.

Deliberations and detailed conclusions of these internal procedures should be made public so that EU citizens could understand the reasons why EFSA thinks or does not think that one of its experts has breached its trust.

5. <u>The benchmarking study commissioned by EFSA did not consider the OECD definition of a 'conflict of interest' used in our report</u>

You wrote: "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 (...)"

This benchmarking study examined 10 organisations similar to EFSA, not the OECD. It does not take into account the OECD definition of a conflict of interest we have used in our report.

Also, this study[11] was carried out by Milieu Environmental Consulting, the same firm that Ms Iona Pratt, one of the ANS panel members highlighted in the report, works for as consultant. EFSA would better have chosen a consultancy firm that has no expert working for EFSA, in order to avoid any conflict of interest.

It should be noted as well that this report does not just praise EFSA's conflict of interest policy. It also gives recommendations for improvement, including to give a more comprehensive definition of conflict of interest, to take lessons from the differentiated categories of acceptable risk of conflict of interest that the EMA has, and to give more clarity regarding the consequences if a conflict of interest is found.

Another recommendation however curiously proposes to *weaken* current EFSA rules:

> - **Shortening of the retrospective period.** (...) EFSA requires a 5-year period retrospectively for declaring an expert's interests. It was noted that this 5 year retrospective period could be overly limiting in terms of reducing the pool of experts and not necessary as a practical matter to capture those relationships which could truly create conflicts, and that a 3 year period might be more appropriate. (...).

6. <u>EFSA's stance that scientists need to have experience in industry to attain scientific recognition at international level is a myth</u>

In your letter you state: "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." And in a recent interview you said: "If we exclude everyone who receives money from industry, we won't have many experts left."[12]

First, we don't complain only about "prior experience" with industry but above all about blatant ongoing conflicts of interests like those of Ivonne Rietjens (Nestlé), Gerrit Speijers (Danone, PepsiCo), Jürgen König (Danone, Nöm, FIAA) or Paul Tobback (FEVIA).

Second, there is a difference when someone has gained scientific experience in a company developing pesticides with a view to sell as much of this as possible, or when this experience has been gained in a public institution with the aim to reduce pesticide use as much as possible. Experts with experience in the field with a view of

ensuring benefits for society at large (i.e. pesticide use reduction instead of profits from pesticides) should be prioritised to work on EFSA panels.

These independent experts exist and have at least the same level of scientific credentials as experts with food industry ties currently sitting on EFSA's panel. We have highlighted in our report why EFSA's non-proactive way of recruiting experts makes it easy for scientists with industry ties to put themselves forward for the panels.

You also write: "Regarding the other experts you mention in your document, the interests in question were already declared."

We wrote from the start that we drew our conclusions from the declarations of interests available online. We also want to stress that declaring publicly an interest does not make it disappear.

7. Factual mistakes, really?

You wrote that you have identified so-called "factual mistakes" in our report. Let's review your claims:

a) "Professor Ivonne Rietjens has not undertaken consultancy or privately funded research work on food additives"

Untrue. In her annual declaration of interests, Prof. Rietjens declared research funding from Nestlé since 2005 for "PhD projects on bioavailability of flavonoids". Flavonoids are food additives. This is the reason why Prof. Rietjens adds: "In case the respective flavonoids studied would be on the agenda of the Panel I would declare an interest."

b) "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"

This is exactly what our report explains page 15, quoting the minutes of the 22nd plenary meeting of the ANS panel: "Dominique Parent-Massin, professor of toxicology at the University of Western Brittany, France, worked (…) from 2005 to 2008 for Ajinomoto, the world's largest aspartame manufacturer. In March 2011 she declared 'financial links with Ajinomoto' that were considered a conflict of interest by EFSA. Since 2009, Parent-Massin has been removed from the ANS panel when aspartame and other sweeteners were on the agenda."

c) "Dr Jean-Charles Leblanc has never been an ILSI consultant but a member of a working group of that Institute"

We wrote on page 15: "Jean-Charles Leblanc from the French Agency for Food Safety (ANSES) was a member of an ILSI working group between 2006 and 2009". We also wrote on the same page that he is a "former ILSI consultant", because this is true according to EFSA rules. These rules, as you should know, define "Consultancy/Advice"[13]:

> as an activity in which the concerned person charges or does not charge a fee for providing advice or services in a particular field falling within EFSA's remit. Any contracts or collaborations with the EFSA falling outside the work of the Panel/Working Group/Scientific Committee as identified above should also be specified under this activity. [...]"

We contend that Jean-Charles Leblanc has provided advice and services to ILSI in spending "brain time" during more than three years in a ILSI working group on the

Margin of Exposure concept. ILSI's goal is to "timely build science in regulatory areas" in the food industry interest.

d) "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"

First, if EFSA uses a concept, which is a scientific tool, in a scientific opinion, then it means that EFSA endorses this concept. Second, contrary to what you wrote, the ANS panel did not use it only in one opinion. As mentioned in our report, the ANS panel used it in at least two opinions last year: on the safety of chromium picolinate[14] and on the safety of polyvinylpyrrolidone-vinyl acetate copolymer[15].

e) "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."

This conclusion is drawn from an ANS panel statement that criticised the Soffritti and Halldorsson studies. During its 21st Panel plenary meeting held on 1-3 February 2011 the ANS panel reviewed both studies and issued a "statement to advise EFSA on the need for further work"[16]. On the basis of this statement EFSA's ANS unit drew the only possible conclusion: that there is no need "to reconsider previous safety assessments of aspartame or of other sweeteners currently authorised in the European Union"[17]. EFSA acknowledges that it drew on the work of the ANS panel: "This EFSA statement follows the scientific statement adopted by the Food Additives and Nutrient Sources added to food Panel (ANS) on 3 February 2011".

f) "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."

Before the publication of our report Gerrit Speijers was listed on EFSA's website as "rapporteur" of the ANS panel on the panel page of the "Declarations of Interests database"[18]. Since the publication of our report his name has been removed from the list.

8. <u>Lowering an ADI is not evidence of independence from industry</u>

"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."

While laudable in itself, the fact that the ANS panel lowered some ADIs against the wish of industry does not provide any guarantee that the conflicts of interest raised in our report do not have damaging results. Lowering the ADI of a substance instead of banning is still not such a bad outcome for industry. We expect from EFSA the guarantee that *every* opinion and decision is taken based on independent science and by independent experts.

We trust that the above will help to further clarify our concerns, and we are looking forward to receiving the details of the announced stakeholder meeting in September.

Yours faithfully,

Nina Holland
On behalf of Corporate Europe Observatory

Notes and references

[1] Conflict of interest, Glossary of statistical terms, OECD, 23 July 2007. http://stats.oecd.org/glossary/detail.asp?ID=7206

[2] Brennan TA, Rothman DJ, Blank L, et al. Health industry practices that create conflicts of interest: a policy proposal for academic medical centers. JAMA 2006;295:429-33. http://www2.kumc.edu/researchcompliance/doc/jama%20_1.25.06_health_industry_practices_that_create_coi.pdf ; Wazana A. Physicians and the pharmaceutical industry: is a gift ever just a gift? JAMA 2000;283:373-80. http://www.ncbi.nlm.nih.gov/pubmed/10647801

[3] "Prohibiting or 'managing' conflict of interest? A review of policies and procedures in three European drug regulation agencies [European Medicines Agency, Irish Medicines Board, the UK Medicines and Healthcare products Regulatory Agency]", J. Lexchin and O O'Donovan, Social Science & Medicine 70 (2010): 643-647. http://www.ncbi.nlm.nih.gov/m/pubmed/19782458/

[4] Overview of the Allowable Interests for the EMA Scientific Activities, European Medicines Agency, 13 October 2010. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/10/WC500097906.pdf

[5] Report available at: http://www.corporateeurope.org/lobbycracy/content/2011/06/conflicts-interest-among-efsa%E2%80%99s-experts-food-additives

[6] http://www.ilsi.org/Europe/Pages/Membership.aspx

[7] http://www.ilsi.org/Europe/Pages/currentmembers.aspx

[8] EFSA Management Board statement, 21 October 2010. http://www.efsa.europa.eu/en/press/news/corporate101021.htm

[9] Implementing act to the policy on declaration of interests - Guidance document on declarations of interest, EFSA, Catherine Geslain-Lanéelle, 8 September 2009. http://www.efsa.europa.eu/en/keydocs/docs/doiguidance.pdf

[10] E-mail from Gerrit Speijers to CEO, 10 June 2011. The full quote is : "In its statutes ILSI states that it is not a lobby organisation, therefore I did not consider my participation was a conflicting interest. Actually that is still my opinion, but it was recently made clear by instruction from EFSA that this should be included in our declaration of interests".

[11] http://www.efsa.europa.eu/en/mb110317/docs/mb110317-ax8b.pdf

[12] "Alle arbeiten mit der Industrie zusammen", Tageszeitung, 1 February 2011. http://www.taz.de/1/archiv/digitaz/artikel/?ressort=sw&dig=2011%2F02%2F01%2Fa0082&cHash=d47b0bbdbe ; http://www.gmo-safety.eu/news/1309.efsa-expert-independence.html

[13] Implementing act to the policy on declaration of interests - Guidance document on declarations of interest, EFSA, Catherine Geslain-Lanéelle, 8 September 2009, page 3. http://www.efsa.europa.eu/en/keydocs/docs/doiguidance.pdf

[14] "The Panel noted that specifications for chromium (III) picolinate should ensure that levels of chromium(VI) which is a genotoxic carcinogen are as low as possible and at least are such that they result in an adequate margin of exposure." Scientific Opinion on the safety of chromium picolinate as a source of chromium added for nutritional purposes to foodstuff for particular nutritional uses and to foods intended for the general population, EFSA Journal 2010;8(12):1883 [49 pp.]. doi:10.2903/j.efsa.2010.1883. http://www.efsa.europa.eu/en/efsajournal/pub/1883.htm

[15] "Taking the total combined exposure to VA at 0.12 µg/kg bw/day for adults and 0.08 µg/kg bw/day for children, this would lead to a Margin of Exposure (MoE) of respectively 3.7 x 106 for adults and 0.6 x 107 for children, and therefore the Panel concluded that the presence of VA at levels up to 5 mg/kg is unlikely to be of safety concern." Scientific Opinion on the safety of polyvinylpyrrolidone-vinyl acetate copolymer for the proposed uses as a food additive, EFSA Journal 2010;8(12):1948 [28 pp.]. doi:10.2903/j.efsa.2010.1948. http://www.efsa.europa.eu/en/scdocs/doc/1948.pdf

[16] Statement on two recent scientific articles on the safety of artificial sweeteners, ANS Panel, 2011. http://www.efsa.europa.eu/en/efsajournal/doc/1996.pdf

[17] Statement of EFSA on the scientific evaluation of two studies related to the safety of artificial sweeteners, 2011. http://www.efsa.europa.eu/en/efsajournal/doc/2089.pdf

[18] Declarations of Interests database, ANS Panel 2008-2011, EFSA. https://doi.efsa.europa.eu/doi/doiweb/doisearch/panel/ANS