Exposed: conflicts of interest among EFSA's experts on food additives

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Summary

The European Food Safety Authority (EFSA) is the European regulatory agency[1] responsible for providing scientific advice on the safety of substances like pesticides, genetically modified organisms (GMOs), and food additives to the EU institutions. In doing this, it is supposed to protect public health. However, EFSA has been the target of increasing criticism from MEPs and NGOs regarding its independence from industry. EFSA and the other EU agencies are currently being investigated by the European Court of Auditors over alleged conflicts of interest.

New research by Corporate Europe Observatory (CEO) has identified conflicts of interest among the members of the EFSA panel on food additives and nutrient sources in food (ANS panel) – as well as evidence of incomplete declarations of outside interests, which suggest further conflicts of interest may be being concealed.

The ANS panel is responsible for approving the public safety of food additives, including substances like flavour enhancers, sweeteners (aspartame) and colorants. CEO found that 11 out of the 20 experts on the panel have a conflict of interest, as defined by the Organisation for Economic Co-operation and Development (OECD).

Another EU agency, the European Medicines Agency (EMA), recently introduced new rules on conflicts of interest for scientific experts. 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.

If the new EMA rules had been previously in place at EFSA, two other panel members – Paul Tobback and Dominique Parent-Massin – would not have been appointed.

Four members of the ANS panel – John Christian Larsen (chair), Gerrit Speijers (rapporteur), Iona Pratt, and Jürgen König – have also failed to declare active collaborations with the food industry-funded think tank and lobby group, the International Life Sciences Institute (ILSI Europe). Under the current EFSA rules, failure to disclose "advice or services in a particular field falling within EFSA's remit" – even if unpaid – is considered as a "prima facie breach of trust towards EFSA" that could lead to these four experts' dismissal[2].

The ANS panel has been criticised in recent years for publishing controversial "scientific opinions" on certain food additives, including aspartame and artificial colorants. Several of these substances have been found to provoke allergies[3] or are suspected to be carcinogenic[4].

CEO's findings raise questions about the independence of EFSA's experts and about the reliance on studies carried out by industry, which has a vested interest in downplaying potential risks to consumers.

EFSA is currently recruiting new experts for its panels for 2012-2015, but so far has failed to adopt a proactive approach to ensure that experts recruited are genuinely independent.

CEO believes that new, stricter rules on conflicts of interest and fundamental changes in the way EFSA's advice is formed are urgently needed.

Introduction – the role of EFSA's panel experts

The European Food Safety Authority (EFSA) is the "risk assessment" agency for food and feed safety in the EU and is supposed to provide independent scientific advice to the EU institutions on the public health risks of substances including pesticides and food additives. While EFSA officially only provides advice and does not take decisions, it is recognised as the main risk assessment authority for food issues, and its influence is generally reflected in policy.

Advice is delivered by 10 scientific panels each responsible for a different set of products in the food chain[5]. Scientific experts from EU member states are recruited to sit on EFSA panels and working groups are formed from these panels to draw up advice, sometimes including external expertise.

Because EFSA is supposed to be independent, it is crucial that its management and the scientific experts involved do not have a vested interest in the issues EFSA is advising on (see box 1). However, EFSA's history is riddled with criticism of industry bias. In February, Corporate Europe Observatory (CEO) documented several examples of conflicts of interest on EFSA's management board[6]. Commissioner for Health and consumer policy John Dalli has recently pressed for better governance at the agency[7].

Box 1

What is a conflict of interest?

A conflict of interest is generally defined as a situation where an individual in a position of trust faces a conflict between their private interests and their official responsibilities[8].

According to the Organisation for Economic Co-operation and Development (OECD): "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"[9].

So the simple fact of being in such a position, even if no unethical or improper act results, represents a conflict of interest.

The conflict can be mitigated through disclosure, but it can be resolved only by removing the individual from the position[10].

Conflicts of interest can lead to prejudiced viewpoints and biased opinions – in this case on the safety of food. Following concerns raised about conflicts of interest, the European Court of Auditors is to investigate allegations of conflicts of interest at EU agencies including EFSA[11]. The investigation will look into the way the agencies' own rules on conflicts of interest are applied, and examine whether EU agency rules match with the OECD standards.

Remarkably, EFSA does not have any rules excluding anyone a priori from joining its panels, but instead makes decisions based on the individual case. Each member is required to make an annual declaration of interests and a "specific declaration of interests" for each panel or discussion they are involved in (see box 4). These declarations are screened by the head of unit supporting the panel, who takes the final decision on what should happen in each case.

Following recent criticism[12], the European Medicines Agency – the EU agency responsible for the scientific evaluation of the safety of medicines developed by pharmaceutical companies – introduced new rules on conflicts of interest for scientific experts[13]. These rules now include a "red list" that explicitly bans individuals with certain types of industry interests from becoming EMA experts. EFSA has never issued such a list.

Under EMA's new rules, 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[14]. These activities are considered as "direct interests" in industry. Chairs and vice-chairs are also not allowed to have acted as an "investigator within previous 5 years and at any time point during the term of the mandate" for any industry-funded study – an activity considered as an "indirect interest" in industry.

Rapporteurs and panel members cannot have any current employment, consultancy or strategic advisory role with industry at any time point during the term of their mandate.

The new rules introduced by the EMA however do present a major loophole, by not outlawing consultancy or advisory work for industry associations or think tanks. This is in clear contradiction with the OECD definition of a conflict of interest.

Conflicts on the ANS panel

The ANS panel is responsible for looking at the safety of food additives and nutrient sources in food. It is made up of 20 experts. CEO examined the scientific background of the experts on this panel. It also looked at how members of the panel would be assessed if EFSA introduced the kind of rules which are now in place at the EMA[15].

Under the definition of "conflict of interest" given by the OECD, more than half of the members of the ANS panel (i.e. 11 members out of 20) face conflicts of interest in their work for the panel (see Appendix 1 for details):

- The chair of the panel, Danish scientist John Christian Larsen, did not report consultancies to controversial food industry-funded think tank and lobby group, the International Life Sciences Institute (ILSI Europe; see box 2), in his official declaration of interests to EFSA (see appendix 1 for details).

- The vice-chair of the panel, Dutch toxicologist Ivonne Rietjens has received funding for her lab from the food giant Nestlé since 2005 and from the International Organization of Flavor Industries (IOFI) since 2010. She also received funding from Polak Spices from 2007-2008. Besides, Rietjens has been a member of an expert group set up by the US Flavor and Extract Manufacturers Association (FEMA) – an industry lobby group driven by Coca-Cola and PepsiCo since 2006, and has been involved in ILSI work on redesigning risk assessment procedures for food and chemicals.

- Dutch toxicologist Gerrit Speijers, the rapporteur on the panel, is consultant to Danone (2007 onwards), PepsiCo (2010 onwards) and has collaborated extensively with ILSI Europe (2002 onwards).

- Austrian professor Jürgen König has been a consultant to both the French food giant Danone and Nöm since 2007. His lab was funded by the Austrian food industry lobby FIAA between 2007 and 2010.

- Belgian professor Paul Tobback has been a member of the scientific committee of FEVIA, the food industry lobby in Belgium, since 2001 and acted as a consultant for the supermarket chain Carrefour between 2003 and 2009.

- Irish consultant Iona Pratt has also had collaborations with ILSI, and is sometimes paid directly by companies whose products the Food Safety Authority of Ireland (FSAI) asks her to assess.

- The British businessman John Gilbert and French scientist Jean-Charles Leblanc both acted as advisors to ILSI until 2009 – and Gilbert has worked for ILSI for 15 years.

- French professor of toxicology Dominique Parent-Massin has worked as consultant for Coca-Cola in 2009, and acted as a consultant for Ajinomoto, the world's largest aspartame manufacturer, from 2005 to 2008. In March 2011 she declared "financial links with Ajinomoto" that were considered a conflict of interest by EFSA[16]. She also acts as a food consultant in a consultancy firm which does not disclose its clients.

- Italian professor of oncology Sandro Grilli has been a consultant for the supermarket chain Coop in Italy since 2004.

- Finally, the French scientist Fernando Aguilar has a conflict of interest because a "close family member" is employed by Nestlé.

Applying the EMA rules

If the EMA rules were applied to the EFSA ANS panel, four members of the panel would be required to stand down because of their current direct links to companies: König for his ties to French giant Danone and Austrian dairy product manufacturer Nöm, Rietjens for receiving research funding from Nestlé, Speijers for being a consultant to Danone and PepsiCo, and

Box 2

ILSI's industry-funded science

At least eight ANS panel experts have collaborated with the controversial scientific think tank and lobby group, the International Life Sciences Institute (ILSI)[17]. ILSI is a Washington DC-based body founded in 1978 with offices throughout the world, funded by food, chemical and pharmaceutical companies. ILSI Europe is based in Brussels, Belgium.

ILSI's mission is "to provide science that improves public health and well-being [...] by fostering collaboration among experts from academia, government, and industry on conducting, gathering, summarizing, and disseminating science. Its activities focus primarily on nutrition and health promotion, food safety, risk assessment, and the environment."[18]

But behind this façade hides an industry lobby organisation[19]. ILSI's main goal has proven to be redesigning risk assessment standards and procedures for food and chemicals to make them less rigorous and cheaper for industry.

In the late 1990s and early 2000s, ILSI worked with the tobacco industry to lobby the World Health Organisation (WHO) to limit tobacco control[20]. In 2006, the UN agency banned ILSI from taking part in WHO activities related to setting standards for food and water, because of its track record of putting the interests of its corporate members ahead of science and health concerns[21]. In 2007, ILSI was accused of having "demonstrably compromised the quality of the US Environmental Protection Agency's scientific inquiry"[22].

According to ILSI, its taskforce on GMOs had a significant impact on the EFSA guidelines for the risk assessment of genetically engineered plants, resulting in a less rigorous assessment[23]. The chair of EFSA's management board, Diána Bánáti, was a member of the ILSI board of directors, but stepped down from her position at ILSI after strong critique[24].

Grilli for being a consultant to supermarket chain Coop which sells food products under its distributor's brand name.

If these rules had been previously in place at EFSA, two other panel members would not have been appointed: Tobback for his recent links with Carrefour (which sells food products under its distributor's brand name), and Parent-Massin for her recent consultancy work for Ajinomoto and Coca-Cola (see appendix 1 for details on these six cases).

Other panel members would be prevented from taking any employment, consultancy, strategic advisory role, financial interests or patent ownership with industry at any time point during the term of their mandate under the new EMA rules.

Failing to declare collaborations with ILSI

Under the current EFSA rules, panel members are supposed to declare any outside interests, such as consultancy or advisory work to the food industry, even if unpaid[25]. Failure to disclose "advice or services in a particular field falling within EFSA's remit" is considered as a "prima facie breach of trust towards EFSA" that could lead to the experts' dismissal.

Four members of the ANS panel – John Christian Larsen (chair), Gerrit Speijers (rapporteur), Iona Pratt, and Jürgen König – have failed to declare collaborations with ILSI Europe (see box 3).

In October 2008 and February 2009, Larsen played a leading role in two ILSI workshops on food safety and drafted or reviewed the subsequent reports published by ILSI.

In 2002 Speijers reviewed an ILSI monograph on GM food. He was a member of an ILSI technical committee in 2005-2006 with employees from DuPont, Syngenta, Dow and Bayer.

Box 3

Even unpaid collaborations falling outside a panel's remit must be declared

The aim of the annual declaration of interests (ADoI) is "to concisely address all possible interests that might be considered relevant to assess independence, including interests that are inherent to the professional background of the individual", according to EFSA's guidance document on declarations of interest[26]. The members of the scientific panels and working groups are concerned, but also the members of the management board, advisory forum, scientific committee, as well as other EFSA experts and the executive director.

The following activities, current or past (last 5 years), must be declared in the ADoI: employment; research funding; membership of a managing body or equivalent structure; membership of a scientific advisory body; consultancy/advice; ownership or other investments, including shares; and intellectual property rights.

Consultancy/advice is to be interpreted as an activity in which the expert "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 [...] should also be specified under this activity."

Membership of a scientific advisory body is to be interpreted as meaning that the expert "is participating or has participated in the works of a Scientific Advisory Body operating in a domain falling within EFSA's remit with a right to vote on the outputs of that entity (e.g. voting on scientific output adopted by that entity)".

In October 2008 Pratt chaired a working group at an ILSI workshop and she worked on a scientific article commissioned by ILSI in 2009.

Jürgen König failed to declare work for ILSI in 2011 in his annual declaration of interests (see appendix 1 for details on these four cases).

EMA and EFSA – two contrasting approaches

The new EMA policy on the handling of conflicts of interest, while not perfect, is much stricter than EFSA's approach. The EMA has issued a "red list" completely excluding certain types of interests in industry, either in the form of current employment, or as a consultancy or strategic advisory role "regardless of contractual arrangements or any form of remuneration"[27] (see appendix 2).

The red list defines what is considered as unacceptable ties to industry, based on evidence that commercial interests bias regulatory science[28]. Even if some interests may seem unrelated to a specific agenda or the mandate of a given expert, they clearly show a positive bias towards industry, and this bias may affect the decisions of that expert – even unconsciously.

EFSA takes a completely different approach with the agency's executive director, Catherine Geslain- Lanéelle openly saying that she is "looking for people who have interests"[29]. She says EFSA needs people with expertise, wherever they had acquired it, and that "having an interest does not mean having a conflict of interest" – a position which contradicts the OECD definition of a conflict of interest. EFSA has not issued any "red list" of excluded interests (see appendix 3).

As mentioned, EFSA does not exclude any expert a priori from joining its panels but instead makes decisions based on the individual case, with each member required to make an annual declaration of interest and a "specific declaration of interests" for each panel or discussion they are involved in (see box 4). These are screened by the head of unit supporting the panel.

Box 4

EFSA: looking for independent expertise?

EFSA's scientific advice is provided by scientific panels. Each panel is made up of about 20 experts appointed by EFSA's management board following a "call for expressions of interest" for membership of the panels. EFSA is currently recruiting new experts to join its 10 panels and its scientific committee[30].

This system makes it easy for scientists with industry ties to put themselves forward for the panels. In contrast the new EMA rules insist on the necessary proactivity of the agency in looking for independent experts[31].

And because EFSA's panels draw heavily on unpublished industry-funded studies, the current system tends to exclude scientists who impose strict impartiality in their work. Many scientists would never agree to provide advice based on what are mainly unpublished studies provided and funded by industry.

Recent history has shown that industry studies cannot necessarily be trusted – tobacco companies for example manipulated the science on the effects of smoking and passive smoking[32].

Evidence also suggests that industry-sponsored studies are more likely to find favourable results for industry than non industry-funded studies. This has been demonstrated in the pharmaceutical[33], mobile phone[34], and chemical fields[35] as well as for climate change[36].

EFSA's approach relies on considerable subjective judgement – both from the expert, when making the declaration of interest, and from the head of unit. For instance, if the panel vice-chair Ivonne Rietjens, whose lab is funded by Nestlé, does not declare that Nestlé uses aspartame or any other substance under review in dozens of products, then the head of unit may not even consider that there is a conflict of interest. And if Jürgen König does not declare that Danone, where he is a consultant, is a major user of aspartame or of other food additives, no conflict may be revealed.

This leaves the work of the agency open to abuse from industry interests – and raises questions about the motivation behind EFSA's advice. Can the public be confident that EFSA's advice is issued in the public interest?

Doubts over EFSA advice

A number of questions have been raised over the independence of EFSA's advice, and in particular the independence of advice from EFSA's ANS panel. Some of its "scientific opinions" on certain food additives have attracted criticism, in particular the cases of aspartame[37] and caramel colours[38]. The panel's experts appear to rely primarily on industry studies, while independent studies which appear to suggest potential health risks seem to be sidelined.

In January 2011, the vice-chair of the European Parliament's committee on Environment, public health and food safety (ENVI), Corinne Lepage, backed by other MEPs, asked EFSA to reconsider its opinion on sweeteners in the light of new studies on the carcinogenic potential of aspartame and its negative impact on pregnant women[39]. Aspartame is the most widely used artificial sweetener in the world.

A few weeks later the ANS panel reviewed the new studies but announced that it did not find any reason "to reconsider previous safety assessments of aspartame or of other sweeteners currently authorised in the European Union"[40].

The European Commission however has not accepted this position and announced at the end of May that the panel must conduct a full re-evaluation of the substance by July 2012 – a review that originally was not scheduled until 2020.

According to Lepage: "recent exchanges of letter between NGOs and the EFSA seem to indicate that the EFSA never took the time to look at the original evaluation, and that data have even been lost!"[41]

In a letter dated 24 May 2011, EFSA's head of unit responsible for the ANS panel, Hugues Kenigswald, wrote to the French NGO Réseau Environnement Santé: "EFSA does not have the authorisation application file for aspartame in Europe [...] the contacts we have had on this subject with our colleagues from the European Commission suggest that the European Commission no longer has this file"[42].

Questions have also been raised about the safety of some artificial colorants, including amaranth (E123) and erythrosine (E127) – considered to be "dubious", "allergenic", and "misleading/useless" by the food additives database of the Belgian consumers association Test-Achats[43].

Amaranth is the name of a dark red synthetic dye used as colouring for some aperitifs and in fish roe. US authorities consider it as a suspected carcinogen, and it was banned by the US Food and Drug Administration (FDA) in 1976[44].

Erythrosine, a cherry-pink food dye found in some sweets, ice pops and chewing-gum, is a known endocrine disruptor which alters the level of thyroid hormones to the extent that it can

cause thyroid tumours in animals[45]. It has been banned in Norway[46] and features on the list of the "11 most controversial food additives" published by a US health magazine[47]. In France, both amaranth and erythrosine are forbidden in confectionery for children.

Yet the ANS panel's recent "scientific opinions" on amaranth and erythrosine do not suggest any ban on these substances in food in the EU. The panel's working hypothesis is that manufacturers respect the maximum permitted levels (MPLs) for these substances – but no MPL has ever been approved for amaranth by the UN body responsible for setting MPLs at the global level[48]. French studies have repeatedly found that several artificial colorants – including erythrosine – were present in quantities above the permitted levels in confectionery[49].

The panel's opinion on erythrosine, published in February 2011, simply confirmed the admissible daily intake (ADI) established by the UN and EU bodies (SCF and JECFA) in 1989 and 1990, respectively[50].

Millions of EU citizens exposed to excessive doses of US-banned colorant E123

In its July 2010 opinion on amaranth, the ANS panel suggested lowering the ADI previously established in 1984[51]. Despite this new, stricter ADI, the ANS panel warned that the anticipated exposure of adults to amaranth "at the 97.5th percentile can be up to 6 times higher than the ADI" – an excess largely due to the consumption of certain alcoholic beverages[52]. In toxicological jargon it means that 2.5% of adults – or 9.4 million people in the EU[53] – are exposed daily to amaranth levels which are six times higher than what EFSA thinks is "admissible".

"What is the value for the consumer to authorise the use of a carcinogenic colorant at doses that result in exceeding the ADI?", Alfred Bernard, a toxicologist at the Catholic University of Louvain-la-Neuve, told CEO. "I think the FDA made a common sense decision at a time where we did not yet speak of the precautionary principle", he added.

What is more, the six-times-higher-than-the-ADI figure is based on unpublished data from the European non-alcoholic beverages association (UNESDA), an industry lobby group[54]. If these industry figures are under-estimates, exposure to amaranth could be much higher than EFSA assumes.

EFSA does not say what percentage of adults is exposed to levels four or five times higher than the ADI.

According to these opinions, none of the ANS panel members declared a conflict of interest over these discussions, although these food colours are widely used by a number of food companies which fund ILSI and which hire several ANS panel members as consultants. Nor did EFSA consider there to be conflicts of interest among these experts[55].

Conclusion

Given the critique from MEPs and environment and health groups, the European Court of Auditors investigation into allegations of conflicts of interest at EFSA[56], and Health Commissioner John Dalli recently pressing for better governance at the agency[57], there is increased pressure for change.

Stricter rules on conflicts of interest and fundamental changes in the way EFSA opinions are shaped are urgently needed. CEO believes that EFSA should adopt new rules on conflicts of interest that are more stringent than those recently endorsed by the European Medicines Agency (EMA). EFSA should avoid the major loophole in the new EMA rules that focus only

on experts' ties with individual companies. New, efficient EFSA rules on conflicts of interest should outlaw any consultancy and advisory work, paid or unpaid, not only for individual companies, but also for industry associations and think tanks predominantly funded by the food industry.

EFSA, which is currently recruiting new experts for its panels in 2012-2015, should not only publish a "call for expression of interests" but also set up a commission to proactively identify and recruit independent experts for its scientific committee and panels.

Finally, EFSA and its experts should remedy the most fundamental flaw in the way it operates: it should not rely on (unpublished) industry studies to judge the safety of products. Instead of the food industry paying for its own studies (commissioned from its own labs or from external labs), industry money should be collected at arm's length by a publicly-controlled institution which would commission independent studies from independent and publicly-funded laboratories in member states.

Appendix 1 – EFSA's ANS panel members and their conflicts of interest

Panel chair J. C. Larsen failed to declare consultancies to ILSI

The chair of the ANS panel John Christian Larsen was a member of the scientific board of the controversial food industry-funded think tank ILSI Europe from 2002 to 2008 advising on its scientific working programme, according to his signed declaration of interests[58].

Larsen left ILSI in August 2008 after he was elected chair of the ANS panel to comply with EFSA rules[59]. The rules state: "Once elected, and for the duration of the mandate, the Chair should endeavour not to engage in activities that may result in any potential conflict of interest. Any change of interest shall immediately be declared to EFSA[60]."

However, Larsen has kept strong ties with ILSI and failed to report them in all his subsequent annual declarations of interests. In October 2008 he chaired a 3-day ILSI workshop in Greece on the so-called 'margin of exposure approach' to substances both genotoxic and carcinogenic present in food. Larsen is also credited as the scientific reviewer of the report published several months after the workshop[61].

In February 2009 the Danish scientist participated to another ILSI workshop held in Brussels on the toxicity of 'fatty acid' esters found in foods. He was the 'rapporteur' for the meeting and subsequently authored a 20-page report published by ILSI in October 2009[62].

Larsen clearly failed to disclose these ILSI consultancies in his annual declaration of interests – a failure considered as a "prima facie breach of trust towards EFSA" that could lead to his dismissal, according to the agency rules[63].

When contacted for comment, John Christian Larsen sent Corporate Europe Observatory (CEO) the following reply: "The two meetings in which I participated were not related to the remits of the EFSA ANS panel: food additives and nutrient sources. Therefore I did not see the need to declare an interest. Moreover, the 3-MCPD meeting was also organised by the European Commission and by EFSA and the 'Margin of exposure (MoE)' meeting was a follow-up of a previous meeting on MoE jointly organised by EFSA, WHO and ILSI in 2005. I do not consider participation in scientific meetings and preparations of scientific reports as 'strong ties'."[64]

First, interests to be declared don't need to be strictly related to the remits of the ANS panel. EFSA rules state that the aim of the annual declaration of interests is to concisely "address all possible interests that might be considered relevant to assess independence, including interests that are inherent to the professional background of the individual"[65]. Any collaborative work for a food industry-funded body like ILSI clearly fall into that category.

Moreover EFSA recently gave instruction to declare all ILSI collaborations, according to the ANS panel rapporteur Gerrit Speijers[66]. In line with this instruction and EFSA rules, other ANS panel members have declared interests with ILSI even if they mentioned that their involvement has "no interference with EFSA work"[67] (Speijers), that they handle "only generic scientific issues"[68] (Gilbert) or that they do not "discuss issues on additives or nutrient sources which might fall under the remit of the ANS Panel"[69] (Rietjens).

But the rules are stricter for panel chairs: they should not engage in activities that may result in "any potential conflict of interest", and any change of interest must "immediately be declared to EFSA"[70].

It should also be stressed that the 'margin of exposure' (MoE) approach is a scientific tool that is directly used in two recent scientific opinions from the ANS panel co-authored by Larsen himself[71]. It is therefore no surprise that his fellow panel member Jean-Charles Leblanc has declared having been involved in ILSI's working group on margin of exposure (MoE)[72].

Finally, there is no point to argue that the MoE meeting in October 2008 was a "follow-up of a previous meeting" organised by ILSI, EFSA and WHO. The fact is that this 3-day ILSI workshop in Greece was exclusively organised and funded by ILSI, and thus should have been declared.

Vice-chair Rietjens's lab funded by Nestlé and flavour manufacturers

Ivonne Rietjens, professor of toxicology at the University of Wageningen, Netherlands, has received funding from Swiss food giant Nestlé since 2005 to carry out research on flavours and flavonoids (food additives)[73]. Flavonoids are used among other things to neutralise estragole, a flavour widely used in food products, perfumes, soaps and detergents that "has been demonstrated to be genotoxic and carcinogenic", according to the European Commission's Scientific Committee on Food[74]. Rietjens has co-authored several scientific articles with Nestlé employees on this topic[75].

Rietjens declared that flavours "[do] not fall under the remit of the ANS Panel" and that "in case the respective flavonoids studied would be on the agenda of the panel I would declare an interest". But Nestlé's interests are not limited to one single substance. Nestlé has a strong interest and a duty to its shareholders to promote an industry-friendly climate within regulatory and advice bodies and financing Rietjens's lab is a way to fulfil this role.

In 2010 Rietjens acted as a consultant to ingredient supplier, Unimills, on the daily intake of 3-MCPD, a suspected carcinogen found in some soy sauces[76]. According to Rietjens, this topic "does not fall under the remit of the ANS Panel"[77]. But Unimills is a major producer of raw materials for the food industry and several of these raw materials[78] and some of the ingredients they contain[79] fall directly under the remit of the ANS panel[80].

Rietjens was also a member of the board of trustees of the ILSI Health and Environmental Sciences Institute until December 2010[81], a body set up by the controversial industry-funded think tank ILSI to define and redesign risk assessment procedures for foods, pesticides and chemicals[82].

Since 2010 her lab has been funded by the global lobby of flavour manufacturers, the International Organization of Flavor Industries (IOFI)[83]. This federation seeks "global harmonization of flavor legislation" based on two pillars: the opinions of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) mainly based on unpublished studies funded by industry, and GRAS ("generally recognized as safe") exemptions[84], a concept developed in the United States that exempts some substances from the Federal Food, Drug, and Cosmetic Act (FDCA) tolerance requirements[85].

Ivonne Rietjens has been a member of an expert group set up by the US Flavor and Extract Manufacturers Association (FEMA) since 2006, which is driven by Coca-Cola and PepsiCo[86]. These experts determine whether a food additive is "generally recognized as safe". In 95% of the cases, their verdict is accepted by the Food and Drug Administration (FDA)[87].

Rietjens has also acted in 2007 as consultant to Nanotox, a company that helps businesses to market products containing controversial nanoparticles. That same year her lab has also been funded by the supplier of the confectionery industry Polak Spices.

Gerrit Speijers, consultant to PepsiCo, Danone and ILSI

Formerly at the Dutch Institute of Public Health and Environmental Protection (RIVM), the ANS panel rapporteur Gerrit Speijers has been a private consultant in toxicology with his one-man business, GETS since 2005. According to his declaration of interests he occasionally has consultancy roles which may interfere with his activities at EFSA but he declares these in a "specific declaration of interests" filled in for each specific agenda or mandate, according to EFSA rules[88].

In September 2010 he joined an advisory body for PepsiCo International. In his declaration of interests, he says that should he be involved in the evaluations of flavours or additives at PepsiCo, he would leave the meeting to not interfere in any case at EFSA[89].

Speijers has also been a consultant to Numico, the specialist baby food and clinical nutrition subsidiary of Danone, since 2007. “In general there is no overlap with my activities in EFSA”, he wrote in his declaration of interests to EFSA. Speijers coordinated a Danone-sponsored study assessing the safety of some carbohydrates, published in 2010[90].

According to his declaration of interests, in July 2010 he joined the food industry-funded think tank ILSI Europe’s task force on process-related compounds and natural toxins[91], an activity which he says has “no interference with EFSA work”.

In October he co-authored a 50-page report for this ILSI task force[92].

CEO has found that Speijers’ ties with ILSI are in fact much older and that he failed to declare them to EFSA. In 2002 he was a scientific reviewer of an ILSI monograph on genetically-modified food[93]. In 2005-2006, Speijers was a member of the Agricultural chemical safety assessment (ACSA) technical committee of the ILSI Health and Environmental Sciences Institute (HESI). In 2006 he co-authored an article with fellow members of this committee, including employees from DuPont, Syngenta, Dow and Bayer, proposing a new approach to assessing the safety of crop protection chemicals[94].

This 2005-2006 collaboration with ILSI should have been declared, as EFSA rules state that activities “that have been completed in the five years preceding the filling in of the declaration of interests” must be declared[95].

When contacted for comment, Dr Speijers stressed that ILSI expert groups are generally composed equally of representatives from industry, universities and governments, and that all ILSI publications are available in the public domain[96]. “These publications are brought forward to national and international authorities, such as JECFA and EFSA, where they can be discussed and discarded if needed”, he added.

“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”, Speijers wrote to Corporate Europe Observatory.

So Dr Speijers confirms that he should have declared his 2005-2006 collaboration with ILSI as it falls in the 5-year period EFSA takes into account.

Jürgen König, a Danone consultant and ILSI collaborator whose lab is on the payroll of the Austrian food industry lobby

Jürgen König, professor of nutrigenomics at the University of Vienna[97], has been a consultant to the French food giant Danone and the Austrian dairy products manufacturer Nöm since 2007[98]. König’s lab also received funding from the Food Industries Association of Austria (FIAA), a lobby group representing some 400 companies[99], from January 2007 to December 2010. In his 2010 annual declaration of interests König described this powerful industry lobby group as a “public” organisation.

König is also involved with the controversial food industry-funded think tank International Life Sciences Institute (ILSI Europe). As a “collaborator” of ILSI Europe’s “Functional foods task force”[100] he is currently organising an international symposium on “Health benefits of foods” with employees from Nestlé, Danone, Coca-Cola, Red Bull, and Tate & Lyle[101].

König failed to report this collaboration with ILSI in his 2011 annual declaration of interests signed on 31 May 2011. According to EFSA rules, failure to file an annual declaration of interests “in a timely and complete manner” is considered as a “prima facie breach of trust towards EFSA”[102].

Paul Tobback, a consultant to the Belgian food industry lobby

Professor emeritus at the Catholic University of Leuven, Belgium, Paul Tobback has been a high profile member of the ANS panel since it was set up in 2003. From 1997 till 2003 he was a member of the European Commission's Scientific Committee on Food (SCF) – the forerunner to EFSA's Food Additives, Flavorings and Food Contact Materials (AFC panel), renamed the ANS panel in 2008[103].

Since 2001 Tobback has also been a member of the scientific committee of FEVIA, the Belgian food industry lobby group[104]. Little is known about this committee's activities[105].

From 2003 to 2009, Tobback was a member of the Scientific Committee of the supermarket group Carrefour which sells hundreds of food products with food additives under its distributor's brand name.

From 1997 to 2009 he was a consultant for European Advisory Services (EAS), a lobbying and consulting firm which delivers "strategic advice on nutritional products" to food companies[106]. Its core business is to "assist and support companies through our legal and policy advice for the licensing and marketing of their products in Europe". EAS is also "closely involved in monitoring EFSA", particularly on health claims[107].

EAS | Strategic advice on nutritional products

La branche européenne d'EAS est spécialisée dans la législation européenne et internationale, concernant l'alimentation et les produits nutritionnels. Nous accompagnons et soutenons les entreprises par nos conseils juridiques et stratégiques, pour l'autorisation et la mise sur le marché de leurs produits, en Europe.

"The European branch of EAS specializes in European and international legislation concerning food and nutritional products. We support companies through our legal and policy advice for the licensing and marketing of their products in Europe". Source :EAS website (http://www.eas.eu/UserFiles/SERVICES%20FR.pdf).

Paul Tobback has not declared – or been asked to declare – which companies he represented during those 12 years.

Iona Pratt's undisclosed collaborations to ILSI and direct payments from industry

Dr Iona Pratt is an Irish toxicologist who worked four years as an employee for the Food Safety Authority of Ireland (FSAI). She still works today as a "consultant" for the FSAI because Irish law prohibits her working as staff member after retirement age.

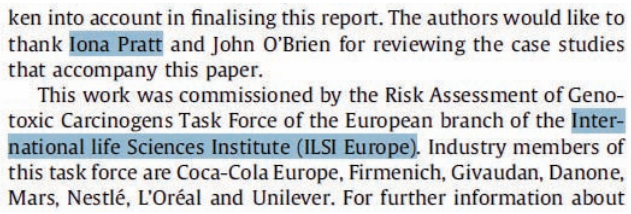
Corporate Europe Observatory (CEO) has found that Dr Pratt failed to report at least two active collaborations with the International Life Sciences Institute (ILSI Europe) in her annual declarations of interests.

In October 2008 she chaired a working group during a three-day ILSI Europe workshop in Rhodes, Greece, on the 'margin of exposure approach' to substances both genotoxic and carcinogenic in food[108]. She had thus an active role in this ILSI workshop where she was not a simple member of the audience.

In 2009 Pratt reviewed case studies for a scientific article commissioned by ILSI Europe "to follow up the recommendations" of that workshop[109].

According to EFSA rules, failure to disclose "advice or services in a particular field falling within EFSA's remit" – even if unpaid – is considered as a "prima facie breach of trust" towards the agency and it could lead to her dismissal .

Yet Pratt denies any wrongdoing: “I participated by invitation at the Rhodes workshop as a member of the Irish national food safety agency FSAI”, she wrote in an e-mail to CEO , without justifying her active role as chair of a working group.



ken into account in finalising this report. The authors would like to thank Iona Pratt and John O'Brien for reviewing the case studies that accompany this paper.

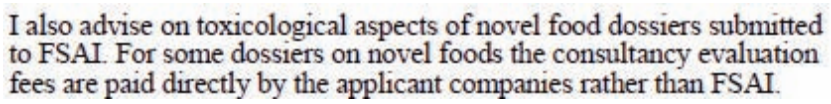
This work was commissioned by the Risk Assessment of Genotoxic Carcinogens Task Force of the European branch of the International life Sciences Institute (ILSI Europe). Industry members of this task force are Coca-Cola Europe, Firmenich, Givaudan, Danone, Mars, Nestlé, L'Oréal and Unilever. For further information about

Source: Application of the Margin of Exposure (MOE) approach to substances in food that are genotoxic and carcinogenic, Diane Benford et al., Food and Chemical Toxicology 48 (2010) S2–S24.

Regarding the case studies she reviewed for the ILSI-driven article, she says it was “a gesture to support the scientific publication that was being produced”.

Yet, these collaborations correspond to services in a field falling within EFSA’s remit and should have been declared according to EFSA rules.

Besides, her work as consultant for the FSAI is also subject to discussion. According to her declaration of interests, she is sometimes paid directly by companies whose products the FSAI asks her to assess[110].



I also advise on toxicological aspects of novel food dossiers submitted to FSAI. For some dossiers on novel foods the consultancy evaluation fees are paid directly by the applicant companies rather than FSAI.

Source: Annual declaration of interests, Iona Pratt, EFSA, 11 February 2011.

Contacted for clarification, Iona Pratt denies that this situation could lead to conflicts of interest: “I do not act contractually as an independent consultant to any of the companies submitting novel food dossiers to the FSAI. I act as consultant to the FSAI, as assessor of the toxicological aspects of the novel food dossier. I prepare a report for the FSAI who as national competent authority has responsibility for this work and personally I have no direct contact with the companies involved”, she wrote to CEO.

Pratt has not been asked by EFSA to reveal the names of these companies that pay her directly. And she did not mention them in her declaration of interests “because these companies are not my clients”, she wrote. “In the last 2 years, FSAI has received novel food dossiers from Giuliani SpA (Italy), Wacker Chemie GmbH (Germany), and Biothera, Inc. (USA). The payments were made to remunerate me for the work I carried out for the FSAI and not in any way for the company itself”, she added.

In these specific cases where industry bypasses the FSAI and pays her directly, there is a direct financial link with food companies that may pose problem. Dr Pratt is not at arm’s length from industry while she works for a public institution. These direct financial links could generate conflicts of interest if, for instance, extra payments to her were made by companies – a scenario that would be much more unlikely if industry would pay the FSAI which would then in turn pay Pratt.

Dr Pratt is also a consultant for the Brussels-based law firm Milieu Environmental Law and Policy, for contracts whose clients, she says, are the European Parliament or the Commission[111]. This law firm is not registered in the European Commission’s register of interest representatives.

John Gilbert's undisclosed clients

John Gilbert is currently a director of FoodLife International Ltd, providing services for "instrument and test manufacturers and contract laboratories undertaking analytical work in food safety"[112]. Are there any labs that depend on the food industry among these clients, creating a conflict of interest? Gilbert has not disclosed his clients. John Gilbert also chaired a Packaging Task Force set up by ILSI Europe between 1995 and 2009.

Jean-Charles Leblanc, former ILSI consultant

Jean-Charles Leblanc from the French Agency for Food Safety (ANSES) was a member of an ILSI working group between 2006 and 2009[113] which developed the concept of "margin of exposure" (MoE) for the assessment of risks posed by substances with genotoxic and carcinogenic properties[114]. This concept has been endorsed by EFSA and the ANS panel in recent scientific opinions.

Dominique Parent-Massin, advising Coca-Cola and aspartame giant Ajinomoto

Dominique Parent-Massin, professor of toxicology at the University of Western Brittany, France, worked for Coca-Cola in 2009, and from 2005 to 2008 for Ajinomoto, the world's largest aspartame manufacturer[115]. In March 2011 she declared "financial links with Ajinomoto" that were considered a conflict of interest by EFSA[116]. Since 2009, Parent-Massin has been removed from the ANS panel when aspartame and other sweeteners were on the agenda[117].

Parent-Massin has been a food consultant to consultancy firm Orchidee since 2009, giving lectures, writing articles and advising on flavourings, new foods, enzymes and dietary supplements. In her declaration of interests, she does not disclose who Orchidee's clients are, which could conceal conflicts of interest.

In 2003, her lab received funding from Panzani and Lustucru via the Union of industrial manufacturers of pasta in France (SIFPAF).

Sandro Grilli, consultant to supermarket chain and food additives user Coop

Sandro Grilli is professor of oncology at the Bologna University Medical School. According to his declaration of interests, he has been a consultant to the Italian supermarket chain Coop since 2004[118]. He has delivered toxicological opinions on various compounds and products, including food additives. Coop sells dozens of food products using food additives under its distributor's brand name.

Fernando Aguilar, "close family member" at Nestlé

Fernando Aguilar, scientific coordinator at the French food safety agency (ANSES) since 2003, has a "close family member" who is a quality coordinator at Nestlé[119]. This situation may create conflicts of interest given Nestlé's use of food additives.

Appendix 2: European Medicines Agency (EMA)'s new policy on handling conflicts of interest

			CHMP Chair	CHMP Member	Rapp	WP Chair	WP	SAG	EW
Direct	Employee	Current	N	N	N	N	N	N	N
		0 to 2	N	Y(exclude 6)	Y (exclude 8)	Y(exclude 9)	Y(exclude 6)	Y(disc. only 7)	Y
		>2 to 5	N	Y(disc. only 7)	Y (exclude 8)	Y(exclude 9)	Y(disc. only 7)	Y	Y
	Consultant	Current	N	N	N	N	N	Y(disc. only 7)	Y
		0 to 2	N	Y(exclude 6)	Y (exclude 8)	Y(exclude 9)	Y(exclude 6)	Y(disc. only 7)	Y
		>2 to 5	N	Y(disc. only 7)	Y (exclude 8)	Y(exclude 9)	Y(disc. only 7)	Y	Y
	Advisor	Current	N	N	N	N	N	Y(disc. only 7)	Y
		0 to 2	N	Y(exclude 6)	Y (exclude 8)	Y(exclude 9)	Y(exclude 6)	Y(disc. only 7)	Y
		>2 to 5	N	Y(disc. only 7)	Y (exclude 8)	Y(exclude 9)	Y(disc. only 7)	Y	Y
	Financial	Current	N	N	N	N	N	N	Y
		0 to 2	Y	Y	Y	Y	Y	Y	Y
		>2 to 5	Y	Y	Y	Y	Y	Y	Y
	Patent	Current	N	N	N	N	N	N	Y
		0 to 2	Y	Y	Y	Y	Y	Y	Y
		>2 to 5	Y	Y	Y	Y	Y	Y	Y
Indirect	PI	Current	N	Y(exclude 6)	Y (exclude 8)	Y(exclude 9)	Y(exclude 6)	Y(disc. only 7)	Y
		0 to 2	N	Y(exclude 6)	Y (exclude 8)	Y(exclude 9)	Y(exclude 6)	Y	Y
		>2 to 5	N	Y(disc. only 7)	Y (exclude 8)	Y(exclude 9)	Y(disc. only 7)	Y	Y
	I	Current	N	Y(disc. only 7)	Y (exclude 8)	Y(exclude 9)	Y(disc. only 7)	Y	Y
		0 to 2	N	Y(disc. only 7)	Y (exclude 8)	Y(exclude 9)	Y(disc. only 7)	Y	Y
		>2 to 5	N	Y	Y	Y	Y	Y	Y
	Grant	Current	Y (exclude 10)	Y	Y	Y	Y	Y	Y
		0 to 2	Y (exclude 10)	Y	Y	Y	Y	Y	Y
		>2 to 5	Y (exclude 10)	Y	Y	Y	Y	Y	Y

6 No involvement with respect to procedures involving the medicinal product or a competitor product, i.e. no part in discussions, final deliberations and voting as appropriate as regards these medicinal products.
7 Involvement in discussions only with respect to procedures involving the medicinal product or a competitor product, i.e. no part in final deliberations and voting as appropriate as regards these medicinal products.
8 Individual can not act as (Co)-Rapporteur in relation to the medicinal product or a competitor product.
9 Chair to be replaced for the discussions, final deliberations and voting as appropriate in relation to the medicinal product or a competitor product.
10 Chair to be replaced for the discussions, final deliberations and voting as appropriate in relation to any medicinal product from the pharmaceutical company giving a grant or other funding to the institution

15 EMA Policy on the Handling of CoIs of Scientific Committee Members and Experts

Source: European Medicines Agency policy on the handling of conflicts of interest of Scientific Committee members and experts, European Medicines Agency, 13 October 2010.
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/10/WC500097905.pdf

Appendix 3: European Food Safety Authority (EFSA)'s policy on handling conflicts of interest

ANNEX 1
REFERENCE TABLE
(high quality of scientific expertise is by nature based on prior experience and that therefore having an interest does not necessarily mean having a conflict of interest)

Nature of Activities and subject matter		Interest Level based on Annual Declaration of Interest[8]		Indicative conflict of Interest Level based on the Specific agenda or mandate		
		Current activity	Previous activity	current	past	none
I	Ownership of other investments, including shares	Y/N		C		A
II	Member of a Managing Body or equivalent structure	Y/N	Y/N	C	B	A
III	Member of a Scientific Advisory Body	Y/N	Y/N	B	A	A
IV	Employment	Y/N	Y/N	C	B	A
V	Consultancy/Advice	Y/N	Y/N	C	B	A
VI	Research funding	Y/N	Y/N	B	A	A
VII	Intellectual property rights	Y/N	Y/N	B	A	A
VIII	Other membership or affiliation	Y/N	Y/N			
IX	Other	Y/N	Y/N			
	Interests of close family members should be listed as appropriate under category I to IX					

[8] Y (Yes), N (No)

11

Source: Implementing act to the policy on declaration of interests - Procedure for identifying and handling potential conflicts of interest, EFSA, Catherine Geslain-Lanéelle, 8 September 2009. http://www.efsa.europa.eu/en/keydocs/docs/doiconflicts.pdf

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