Unhappy meal

The European Food Safety Authority's independence problem

CEO
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"If it is dangerous to rely on scientists with financial conflicts of interest to interpret raw data, why should we depend on these scientists to provide advice to the regulatory agencies?"

David Michaels, *Doubt Is Their Product: How Industry's Assault on Science Threatens Your Health*, Oxford University Press, 2008.

One of the most important though least known institutions in the EU, the European Food Safety Authority (EFSA) is, according to its motto, “committed to ensuring that Europe's food is safe”. Everyone eating food in Europe is affected by its decisions. Following controversy over its close ties with industry, the agency has implemented a new policy designed to ensure the independence of its scientific panels. Yet serious conflicts of interest remain. Over half of the 209 scientists sitting on the agency's panels have direct or indirect ties with the industries they are meant to regulate. A much clearer and stricter independence policy needs to be set up and rigorously implemented to restore the Authority's reputation and integrity.

Disclaimer

The aim of this report is to review EFSA’s new independence policy and particularly its handling of conflicts of interests among its scientific panels members. It is therefore important to point out that what is being assessed here is EFSA's decision-making process in whether to accept or reject given experts on its panels for a public interest mission. Having a conflict of interest with the commercial sector does not mean that an expert is criticised for his/her ethics or intellectual honesty, but that he/she cannot be considered independent from industry's influence. Therefore, we think, the expert is not in a position to participate in the work of an agency whose workload consists primarily in assessing the safety of industrial products to be commercialised on the EU market.

All unreferenced interests mentioned in the report come from the experts' declarations of interests, downloaded from EFSA's website on 29 April 2013.

Summary

In recent years, the European Food Safety Authority (EFSA) has come under sustained criticism from the European Parliament, NGOs and the media over conflicts of interest of those sitting on its scientific panels. These experts play a crucial role in decisions key to the health and safety of Europe's food supply chain. Yet some were shown to have commercial ties with the industries whose profits depend on these products, undermining the credibility of the organisation's scientific output on issues such as food additives[1] and GMOs[2]. After an initial phase of denying there was a problem, EFSA has developed – in its own words – **"a new, comprehensive and sophisticated" policy on independence**[3]. The renewal of eight of its ten scientific panels in the course of Spring 2012 was the opportunity for the agency to start implementing its new policy to vet the participants for conflicts of interest – and regain credibility.

Having published a significant amount of research into industry's influence at the agency over the past few years[4], Corporate Europe Observatory (CEO) felt it important to assess this new policy, combining the experience we have acquired through previous investigations with a more systematic method of data analysis. Replicating EFSA's work and using only the information declared by the scientists themselves to EFSA – a conservative approach – we screened all interests of the scientific panel members as well as members of the Scientific Committee. As a result of its new independence policy, EFSA banned 85 experts from joining its panels, so there was room for optimism that some of the major problems had been fixed.

Unfortunately, that optimism is not borne out by our analysis. The results of our screening are dismaying. While we were still expecting to find conflicts of interest, we were surprised to find so many: 122 experts out of 209 (58.37%) have at least one conflict of interest with the commercial sector. **Experts with conflicts of interest dominate all panels but one.** All but two panel chairs and 14 vice-chairs among 21 have conflicts of interest. The "worst record" is held by EFSA's panel on Dietetic Products, Nutrition and Allergies (NDA), with 17 of its 20 members totalling 113 conflicts of interest between them. In all panels, ten experts have more than 10 conflicts of interests each. One member of the panel on Additives and Products or Substances used in Animal Feed (FEEDAP) has 24 on his own. Among 855 interests screened, CEO counted an overall sum of 460 conflicts of interest. On top of that, there is no visible difference in the proportion of conflicts of interests in the eight renewed panels compared to the two that are yet to be renewed, which poses further questions about the new policy's efficacy.

Why such terrible results? Complacency at EFSA? Excessive rigour on our part?

To repeat, our methodology for this screening was very conservative: we did not check for undeclared interests by experts, we did not add omitted interests that we found in the course of the research. Fortunately, lack of political will at EFSA seems to be less of an issue than in the past. **The agency now seems seriously concerned**, dedicating significant resources to the problem. Indeed, as soon as EFSA was informed of CEO's intention to scrutinize its new policy, we were invited to the agency's headquarters in Parma, Italy, in June 2013.

Thanks to this unprecedented gesture, we had the opportunity to converse with several high up officials from the Authority in the course of an intense full-day meeting, during which the agency's handling of conflicts of interests was extensively discussed. Showing dedication and good will was clearly part of the picture, but this exercise was also instructive for us in terms of what remains to be done at the agency: EFSA's independence policy has many flaws.

A first one has to do with the nature of the rules themselves, as they are insufficiently rigorous. Another important weakness is the reliance on experts to declare their own interests. But there is also a cultural issue, different in nature from problems of rule implementation, which we shall also examine.

Firstly, **EFSA's independence rules themselves are insufficient** in the sense that they are too narrow. The main criterion the agency uses to assess an expert's given interest is to consider whether it falls inside the thematic mandate of the panel the expert is applying to. In other words, any scientist with ties to the commercial sector can still be accepted as long as the interest is not related to the panel's topic. This is in our view the biggest loophole in the rules, and probably the one main factor explaining our results. We considered that the relevant criterion was not the panel's mandate but the remit of EFSA itself. Furthermore, this thematic specialisation forces the declarations of interest to be assessed individually – at a considerable expense of time and energy – by all the agency's heads of units.

As a consequence, some problematic interests are not considered as such. To cite only one example, a few ongoing collaborations with the industry think-tank International Life Sciences Institute (ILSI) are still tolerated whereas this particular organisation has been at the core of past controversies with EFSA. Moreover, there is no cooling-off period: recent activities with industry-affiliated bodies are not considered a problem by the agency insofar as they are terminated, meaning scientists can go straight from these to sit on an agency panel. As a result, more than 30 experts with a history – even in the very recent past – at ILSI are still members of EFSA's scientific panels[5].

Secondly, while EFSA as an institution should safeguard its independence by taking charge of the checks for conflicts of interest proactively, it relies instead on the experts' own self-assessments. Information recorded by the scientists themselves in their declarations of interests or CVs is the only source used by EFSA. Their accuracy is taken for granted, and not even a basic check on publicly available information, on the internet for example, is performed – almost an incentive for abuse. **The whole system will remain flawed as long as it only relies on experts' self-assessment**.

Many cases of conflicts of interest remain undetected by EFSA's current system because the rules are clearly insufficient. What is worse, there are problems of implementation of EFSA's already lenient existing rules: some conflicts of interests should have been detected according to EFSA's own rules but haven't been. Had EFSA thoroughly applied its new policy by the rulebook, we think, seven chairs and three vice-chairs of the scientific panels would not have been appointed.

Finally, and crucially, an insufficient understanding of what conflicts of interest entail in practice undermines the screning process performed

by EFSA's staff. **The agency's idea of a conflict of interest revolves around a dramatic picture of corruption and infiltration by industry "moles" with evil intent**. Even though this cannot be ruled out, the reality is usually more subtle. Industry influence tends to be exerted through long-term and structural processes of relationship-building within the scientific community itself, through culture, collective dynamics, accepted paradigms and group thinking – where it becomes natural to "think industry" – rather than through some kind of manipulation at the individual scientist level only. As we remind our readers in this report, science itself is nowadays an open battlefield for corporate interests. That should be cause for extra vigilance and scrupulousness when creating and implementing rules governing conflicts of interest. But EFSA seems unconcerned by this reality.

Based on our research, the numerous discussions we had and our previous knowledge of the field, we have come to a series of recommendations that can also be seen as a more general contribution to the EU's initiative to deal with conflicts of interest in the agencies in a more rigorous and informed manner. In the short term, **EFSA could upgrade its rules by banning commercial interests entirely** and improving its screening system. In the medium term, EFSA could outsource the screening of the declarations of interests from heads of units to specialised personnel, for instance magistrates from the European Court of Auditors. In the longer term, expertise could be in-sourced in order to give them all the means to do their work properly and be independent from the sectors they are regulating. Another long-term recommendation would consist of having the studies on regulated products conducted by independent/public laboratories on the basis of very strict rules including blinds (these could still be paid for by industry). Our recommendations are detailed at the end of this report.

It is important to keep the bigger picture in mind. While our recommendations for better rule implementation might improve the quality and credibility of EFSA expert panels, **there are also some larger structural issues** that are beyond the scope of this report to properly address. It is crucial to note that EFSA experts are unpaid (only expenses), for one. For another, there is a structural conflict of interest built into the system, as the experts only assess studies performed by the producers of the products at stake (they do not perform research themselves). Combine this with excessive workloads, and we can see that to do this job properly is a daunting task. Moreover, parts of these studies are usually kept secret for commercial confidentiality reasons, preventing their integration in the normal work of the scientific community. As a result, it seems that serving on an EFSA panel is neither beneficial nor attractive to build a scientific career, making it harder to find young and independent experts working disinterestedly for the public good. It is unacceptable that such a crucial task for public health is rendered so unrewarding.

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From EFSA with love

Parma, Italy. Keep going straight ahead after the Ponte delle Nazioni (Bridge of Nations). Walk past a minuscule traditional delicatessen shop exhibiting impressive Parmesan cheese wheels on the pavement and tempting hams hanging behind the counter. A little further on one comes across a Conad, an Italian supermarket chain. In-between them stand EFSA's brand-new headquarters. Even the coincidence of EFSA's geography, situated between these two vastly different food shops, seems to symbolise the paradoxes of this agency that has been entrusted with the ensuring the food that 500 million EU citizens eat is healthy and safe.

"Committed to ensuring that Europe's food is safe."

The official slogan printed in blue letters on the reception desk counter is a reminder of this: since its creation in 2002, EFSA has been "committed to ensuring that Europe's food is safe". Its mission is to provide independent scientific advice to the European institutions on food safety matters. Assessing the risks related to industry products represents about two thirds of its workload[6]. Upstream, when companies want to get new food products onto the market, these first have to be assessed by EFSA. Its advice is usually followed by the European Commission. Downstream, EFSA is also entitled to assess products that are already on the market. Because the overwhelming majority of the XXIst century food is made with processed ingredients, a large range of issues fall under EFSA's responsibility: additives such as sweeteners, preservatives or colouring agents, GMOs, pesticides and their residues, even meat inspection. EFSA is also in charge of substances that can enter into contact with food, such as plastic packaging materials: the assessment of bisphenol A, for example, is currently a hot potato on the agency's plate. Finally, EFSA also monitors issues around the processed feed and antibiotics and other medicines given to livestock[7].

For all these reasons, EFSA plays a crucial – although insufficiently widely known – role in public health, and has a direct affect on people's everyday life. At the same time, since its work involves enormous economic interests, it is an obvious strategic target for industry's lobbying. As a public agency, EFSA's role is to stand on the side of the protection of the public and the environment: to be a gatekeeper rather than an open door to market. However, much of its work consists in exchanging information with private companies over their products, creating a tension between these day to day relationships and the necessity of keeping industry interests at arm's length.

In the past few years, EFSA has come under harsh criticism for failing in its crucial mission as public protector. Civil society groups (CEO among them[8]), the European Parliament, other European institutions, some scientists and the media have accused EFSA of being far too indulgent towards industry. Particular criticism was levelled at the agency's poor management of its experts' conflicts of interest. One particularly symbolic case featured the chair of EFSA's management board, Diana Bánáti, who had failed to record that she was on the Board of Directors of the industry think-tank International Life Sciences Institute (ILSI) in her declaration of interest to EFSA[9]. Mrs Bánáti resigned from ILSI but stayed at EFSA until she finally took a position as Executive and Scientific Director of ILSI Europe

a few months later. In May 2012, these types of concerns over conflicts of interest caused the European Parliament's Committee on Budgetary Control to delay the discharge of the agency's 2010 accounts by six months[10].

"None of the selected agencies adequately managed the conflict of interest situations."

The EFSA's scientific opinions are not written by in-house scientists but by an army of around 1.200 external experts from all over Europe, sometimes beyond. They make up the ten scientific panels and their numerous working groups, and the Scientific Committee, which supports the work of the panels on matters of a horizontal nature, co-ordinates consistency in the scientific opinions they deliver, and provides advice to EFSA's Executive Director[11]. Making sure these experts are free from conflicts of interest with the activities they regulate is of paramount importance for EFSA's credibility.
A report by the European Court of Auditors "on the management of conflict of interest in four European agencies", published in October 2012, further increased the pressure. "None of the selected agencies adequately managed the conflict of interest situations", the report drily concluded[12].

In 2013, the members of the European Parliament granted the budget discharge without the delay of the previous year, but their concerns remained. They insisted that EFSA should conduct "a structured dialogue with civil society on matters relating to conflicts of interest and to invite those organisations concerned to openly discuss matters of common interest based on an agreed agenda"[13].

A word to the wise is enough. When we called EFSA to say we would perform a systematic assessment of the new independence policy, they asked us to come to pay a visit.

Meet the organisation

Alberto Spagnolli is a warm, casual man. In his capacity as Head of the Office of EFSA's Executive Director Catherine Geslain-Lanéelle[14], he decided to devote an entire day to explaining EFSA's independence policy to us. On 5 June 2013, at 9.15 AM sharp, he crosses the ultra-white lobby with a smile, accompanied by Lucia de Luca, the Stakeholder Relations Officer. On the eighth floor, the small conference room is quickly crowded with some of EFSA's key employees. Here are Dirk Detken, Head of Legal and Regulatory Services, and Hubert Deluyker, Scientific Adviser to the Executive Director. The latter just stepped down as Director of Science Strategy & Coordination and was replaced in March 2013 by Juliane Kleiner, who is also here. Claudia Heppner, Head of Food Ingredients and Packaging Unit, and Claudia Roncancio Pena, Head of Feed Unit, will briefly join us later. A significant section of the upper levels of the organisation[15] is sipping coffee in front of us: the topic is serious.

The conference room table is covered with papers and printed presentations. Amongst them lies a thick, grey binder nicknamed the "Bible", although EFSA's 54-page rule book on ethics has a typically convoluted official title: "Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests"[16]. This ethics "Bible" that we have gathered here to discuss was elaborated throughout the end of 2011 and the beginning of 2012. Eight of the ten EFSA scientific panels were to be completely renewed and to hold their first meetings on 1st July 2012, so the new policy entered into force on 21 February 2012. All the candidate-experts were submitted to a selection process in accordance with the new rules outlined in this grey binder. As a result, 85 of them could not join the panels because of conflicts of interest[17]: the system seems to work since it detected and eliminated these cases. But are the rules truly effective?

Capture, imagination and conflicts of interest

What does the EFSA "Bible" preach? The agency has endorsed and adapted a definition of conflict of interest based on guidelines developed by the Organisation for Economic Co-operation and Development (OECD) for the public sector [18]. A conflict of interest, EFSA says, is "a situation when an individual is in a position to exploit his or her own professional or official capacity in some way for personal or corporate benefit with regard to that person's function in the context of his or her cooperation with EFSA."

However, the EFSA's definition can lead to different interpretations. The agency seems to have focused on the aspect of conscious manipulation in its definition, stemming from the use of the word "exploitation". In the imagination of EFSA's officials, it seems, an expert with a conflict of interest is an industry mole on a secret mission, whose plans will be reduced to nothing by his or her twenty perspicacious panel colleagues. This is the magic of "collegiality". Collective discussions among peers will make sure individual vested interests do not influence the panel's opinion. EFSA, like most regulatory agencies, very often puts this argument as a line of defence: the collegial decision-making will neutralize individual interests. The "FAQ on common criticisms of EFSA", published

on the agency's website, states it: "*Collective decision-making* – Opinions adopted by EFSA Scientific Panels are always the outcome of collective deliberations and collective decisions. No expert, including the Chair, can unduly influence the decisions of the Panels"[19]. To EFSA's credit, such a sensational understanding of the problem also dominates in the media, which tend to report conflicts of interest through images of personal corruption. It also reflects a popular misconception about how power operates. According to this analysis, the core problem would be an individual's dubious ethics and intellectual dishonesty. But the way industry influences scientists and regulators goes beyond the individual level.

As a matter of fact, the way industry actually works to shape the decisions taken by public regulators contains far more subtle tools than day-to-day lobbying or, let's spell out the word: plain corruption, even though such cases exist. (Besides, it is not uncommon to see scientists work for industry organisations for free, just for prestige or other reasons.) The industry's strategy for influencing regulatory agencies is more often based on systematic partnerships: inviting regulatory experts to working sessions with industry scientists, signing consultancy contracts with the leading experts in a given field... What matters is to raise their awareness of and sympathy for industry's priorities. These various tactics have been called regulatory capture (see box 2), now a well-studied field in economics and political science over the past three decades[20]. However, in the small conference room, the EFSA officials almost jump on their seats and halt us in the middle of the sentence when we use the word "capture". It seems as though this understanding of how industry influence functions is a concept alien to them.

Box 1 | Conflicts of interest: a deeper definition

Another definition of conflicts of interest, developed by the World Health Organisation for its Roll Back Malaria Partnership (RBM)[21], can help us better understand what is at stake:

"*A conflict of interest can occur when a Partner's ability to exercise judgment in one role is impaired by his or her obligations in another role or by the existence of competing interests. Such situations create a risk of a tendency towards bias in favour of one interest over another or that the individual would not fulfil his or her duties impartially and in the best interest of the RBM Partnership. A conflict of interest may exist even if no unethical or improper act results from it. It can create an appearance of impropriety that can undermine confidence in the individual, his/her constituency or organization. Both actual and perceived conflicts of interest can undermine the reputation and work of the Partnership."*[22]

Three brief comments on this stimulating, rich definition. One, it does take into account that a conflict of interest is not always a conscious situation. Two, the very appearance of a conflict of interest is considered a problem. Three, the credibility of the output, and hence, of the institution, is seen as a crucial factor.

Box 2 | Crash course on regulatory capture

Regulatory capture is a theory developed by George Stigler, Nobel laureate economist of the Chicago School of Economics, who developed it in a 1971 seminal article. “The state – the machinery and power of the state – is a potential resource or threat to every industry in the society”, he wrote. “A central thesis of this paper is that, as a rule, regulation is acquired by the industry and is designed and operated primarily for its benefit.”[23]

The reasoning behind this argument is that regulators need very specific information retained exclusively by the sector's players themselves. This places them in an information dependence vis-à-vis the regulated. Industries ending up controlling regulation by feeding regulators with information they base their work on. Hence, the challenge for regulators to escape this trap consists in maintaining and developing independent sources of expertise.

Regulatory agencies are typical targets for industry's influence tactics. By issuing scientific opinions or sometimes decisions on industry products, they have a major impact on business. Getting to the regulators is therefore essential for industry. But, although corruption and other forms of brutal interference in the decision-making process exist, industry's influence tactics are rather about building long-term, smooth personal and professional links that will lead the officials or the experts to “think industry”. How to resist daily politeness, useful partnership proposals or appealing future career opportunities forever if there is no institutional control on these practices? The inconvenient truth is that regulators and experts are only human beings... An instructive book called “*The regulation game: strategic use of the administrative process*”, published in 1978 and quoted in Ben Goldacre's important book *Bad Pharma: How drug companies mislead doctors and harm patients* (2012), provides useful insights:

“The experts themselves must not recognise that they have lost their objectivity and freedom of action.”

“*Of course, there are also important tactical elements of lobbying. This is most effectively done by identifying the leading experts in each relevant field and hiring them as consultants or advisors, or giving them research grants and the like. This activity requires a modicum of finesse; it must not be too blatant, for the experts themselves must not recognise that they have lost their objectivity and freedom of action. At a minimum, a programme of this kind reduces the threat that the leading experts will be available to testify or write against the interests of the regulated firms.*”[24]

One of the most convenient ways to succeed in capturing regulatory agencies is to trap experts and officials in a situation of double loyalty, where they owe allegiance to both the industry and the regulator. While conflicts of interest are usually seen as an unfortunate side effect, they could also be a direct result of calculated corporate strategies.

Allan M. Brandt, a Professor of the History of Science in Harvard, who has dedicated a significant part of his career to study tobacco industry tactics, has reached this conclusion. It is now an established and documented fact that Big Tobacco has dedicated huge sums of money in order to prevent public health measures against the harms of smoking since the 1950s. Part of the programme was to get independent scientists into generously funded tobacco-friendly research. “The goal was to disrupt the normative processes of knowledge production in medicine, science, and public health”, wrote Allan M. Brandt. “I make the somewhat provocative claim that the industry invented the modern conflicts of interest that now are the subject of such intensive contention in the world of science and medicine as well as media, politics, law, and policy.”

As he noticed the same pattern in other areas of science, he therefore recommends that “[a]ny systematic investigation of the modern relationship of medicine and science to industry must consider what has become the epiphenomenal case of the tobacco industry as it confronted new medical knowledge about the risk of cigarette smoking in the mid-20th century”[25].

In that sense, the think-tank International Life Sciences Institute (ILSI) is an almost perfect embodiment of a regulatory capture tool. Although it claims to be seeking “a balanced approach to solving problems of common concern for the well being of the general public”, ILSI, co-founded by Coca-Cola, Heinz, Kraft, General Foods and Procter & Gamble, is financed by food, chemical, pesticides, biotechnology and pharmaceutical multinational corporations and, between 1983 and 1998, “provided assistance to the tobacco industry in its attempts to subvert many attempts at legislative control over the industry's activities”[26]. ILSI systematically organises work streams replicating EFSA's as well as other regulatory agencies’. While “bring[ing] together scientists from academia, government, industry, and the public sector” in a “partnership” spirit[27], ILSI invites all key agency experts to help blur the borders between public and private interests[28]. CEO published ample evidence of the EFSA-ILSI connections in 2012[29].

Their visible ignorance of industry strategy fundamentals is a turning point for us. Although we do come from very different perspectives, we can now see the situation from their point of view. What it reveals, though, is just how fundamental the differences are. Where their perception of conflicts of interest centre around ideas of corruption and morality, we take into account the institutional dimension of the issue.

Contrary to EFSA, our own understanding of the OECD definition does not limit itself to the individual “exploitation” of a position. It embraces the mere existence of such a position.
This does not just take into account the unquestioned assumptions an institution can immerse itself in. It also acknowledges what is known as the “double loyalty” problem. For example, a scientist can be genuinely convinced that his integrity is not compromised by a consultancy contract, but evidence suggests otherwise. Recent studies have documented the impact of the broader research environment on scientists' integrity[30] and particularly the link between funding sources and conclusions[31]. Otherwise said: financial ties can cloud judgment without this becoming necessarily conscious. But to what extent?

Measuring the influence of a conflict of interest on any one individual – as the current EFSA rules appear to attempt – is not only a methodological dead end, but also extremely dangerous politically. It should not be within the remit of a public agency in a democracy to try to guess at individuals' private morals or intellectual honesty. This is why we think that interests should be assessed at the institutional level, according to the remit of the agency itself which is to guarantee that products consumed every day by millions of EU citizens are safe. This in turn means that the commercial interests behind these products should not have a say in their assessment. Unlike intellectual bias, these interests are measurable. They can be listed. Declarations of interests are made for this.

Banning entirely conflicts of interest between EFSA and the sector it is meant to regulate has therefore been our approach for screening interests. We tried to produce an assessment designed to protect a public agency's scientific integrity, not to repel hypothetical industry moles.

Conflicts of interest at EFSA: the bill, please

Altogether there are 209 experts in EFSA's ten scientific panels and in the Scientific Committee. On average, 20 scientists sit on each panel. All experts being *de facto* members of the panels, it can be assumed that EFSA has judged they had no conflict of interest. Yet we did not come to the same conclusion. In the course of a four-month-long painstaking screening exercise, we reviewed all 209 declarations of interests, looking at 855 different interests one by one. The detailed results of this work can be consulted in annex 6. See overview tables pages 16 and 17.

First observation: we consider that EFSA has not respected its own rules on ten occasions, all involving chairs and co-chairs of the panels as well as the chair of the Scientific Committee. More precisely: these experts should not have been allowed to take the position had the agency rigorously implemented its own rules. The interests at stake range from very problematic (links to a lobby group of the food industry) to lighter (membership of a public organisation not recognised by EFSA as granting the right to be a chair or vice-chair) to even insignificant (EFSA's rules would normally see a conflict of interest where we would not). (See annex 4).

But EFSA's failure to comply with its own rules, though serious at times, is not the main problem. Despite the new policy, we found that a significant number of blatant conflicts of interest remain in the scientific panels and Scientific Committee. We considered that ties to the commercial sector regulated by EFSA constituted conflicts of interest, since the agency's role is to regulate that sector (see our methodology in annex 1). EFSA, for its part, adopted an approach both considerably narrower and more lenient.

A few key figures. According to our screening, experts with conflicts of interest dominate all but one panel (Plant Health - PLH). 122 of the 209 experts have conflicts of interests, more than half the total. Note that 22 experts were not included in this statistic because we considered the available information was insufficient to assess their interests.

The worst results were found in the panel on Dietetic Products, Nutrition and Allergies (NDA) – a core strategic panel. There, out of 20 members, 17 experts have conflicts of interest, chair and vice-chairs included, totalling 113 problematic interests. In all EFSA's panels, 10 experts have more than 10 each. One member of the panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Alex Bach, has 24 on his own (he sees that as a guarantee of his independence: see box 3). As the icing on the cake, all but two panel chairs and 14 of the 21 vice-chairs have conflicts of interest. (See annex 1 and 5).

All panels have more than half their members with interests linked to the commercial sector. The Plant Health panel (PLH) – where just two experts have problematic interests – is the only clear exception. This very high proportion undermines EFSA's collegiality line of defence: if one single individual cannot impose his views on an entire panel, the situation is obviously different when more than half of the members are susceptible to bias towards industry.

Another important finding: there is no noticeable difference between the eight panels that were renewed according to the new policy and the two panels whose composition was determined according to EFSA's previous independence policy (ANS and CEF panels). The proportion

of conflicts of interest is pretty much the same. The only area where there could be a difference is the category "membership of an advisory body": these two panels have the highest numbers of conflicting interests (but this last finding is probably not statistically significant).

Our table "conflicting interests by panels and categories" provides some useful insights (see page 17). The largest sources for conflicts of interest are research funding and industry consultancies, followed by responsibilities in industry-sponsored journals and scientific societies as well as industry-captured scientific societies and journals. On the other hand, the categories "employment" and "intellectual property rights" only provide a handful of cases. These findings clearly illustrate both the regulatory capture strategy and the current evolution of the EU's research policies that tend to systematically encourage cooperation between the public research sector and industry.

Our screening revealed an overall sum of 460 conflicts of interest.

Overview table

	AHAW	BIOHAZ	CONTAM	PLH	FEEDAP	NDA	ANS	CEF	GMO	PPR	SCOM*	TOTAL*	%
Members	21	21	20	21	20	20	19	21	19	21	23 / 6	209	
Experts with COI	13	12	15	2	11	17	12	13	11	13	17 / 3	122	58,37%
Experts with no COI	4	7	5	13	7	3	4	7	3	8	6 / 3	64	30,62%
Experts not assessed (insufficient declared information)	4	2	0	6	2	0	3	0	5	0	0	22	10,53%
Interests screened	99	79	73	46	92	164	58	89	50	77	128 /28	855	
COIs	37	37	45	3	60	113	31	63	20	30	73 / 21	460	
Chair with COI (according to EFSA)	0	0	1	0	1	1	0	1	1	1	1 / 1	7	70%
Chair with COI (according to CEO)	1	1	1	0	1	1	1	1	1	0	1 / 1	9	90%
Vice-chairs with COI (according to EFSA)	0	0	0	1	0	1	0	0	1	0	0 / 0	3	15%
Vice-chairs with COI (according to CEO)	1	1	2	1	1	2	2	1	2	1	0 / 0	14	70%
Case by case assessments by EFSA	52	36	26	19	15	66	26	28	4	20	65 / 9	301	35,20%
Interests not assessed (insufficient declared information)	21	15	15	6	9	26	9	8	11	11	9 / 0	131	15,32%
Misrecorded interests belonging to the "Consultancy" (V), "Management Body" (II), or "Scientific Advisory Body" (III) categories	0	2	1	0	0	24	4	12	2	0	12 / 1	44	5,38%

AHAW – Animal Health and Welfare
BIOHAZ – Biological Hazards
CONTAM – Contaminants in the Food Chain
PLH – Plant Health
FEEDAP – Additives and Products or Substances used in Animal Feed
NDA – Dietetic Products, Nutrition and Allergies
ANS – Food Additives and Nutrient Sources added to Food
CEF – Food Contact Materials, Enzymes, Flavourings and Processing Aids
GMO – Genetically Modified Organisms
PPR – Plant Protection Products and their Residues
SCOM – Scientific Committee
COI / COIs – conflict of interest / conflicts of interest
FSO – Food Safety Organisation

* The Scientific Committee (SCOM) is composed of the chairs of the Panels and six other experts who do not belong to any of the Panels. In the SCOM column, the first figure concerns all the members, while the second only concerns the 6 other experts. To avoid a double count, the "TOTAL" column includes only the 6 experts

Conflicting Interests by panels and categories

	AHAW	BIOHAZ	CONTAM	PLH	FEEDAP	NDA	ANS	CEF	GMO	PPR	SCOM	TOTAL*
Economic interest (I)	1	1	0	0	0	1	0	0	0	0	0	**3**
Member of a management body or equivalent, of an FSO (II.A)	0	0	0	0	0	0	0	0	0	2	0	**2**
Member of a management body or equivalent, other than FSO (II.B)	0	4	2	0	1	5	1	0	0	0	3	**16**
Member of a scientific advisory body (III) managed by a FSO (III.A)	0	0	0	0	0	0	0	0	0	0	0	**0**
Member of an other scientific advisory body (III.B)	1	3	12	1	1	14	7	6	3	2	2	**52**
Employment (IV)	3	1	2	0	0	2	3	3	3	2	1	**21**
Employment for a FSO (IV.A)	0	0	0	0	0	0	0	1	0	0	0	**1**
Employment by private sector	1	1	1	0	0	2	3	1	0	1	0	**10**
Employment for an institution with substantial ties to industry	2	0	1	0	1	0	0	1	3	1	1	**10**
Consultancies (V)	7	5	10	0	7	32	10	12	5	9	7	**104**
Research funding (VI)	18	8	11	0	44	44	6	33	7	10	5	**186**
Direct industry funding	12	0	5	0	27	15	6	17	1	2	0	**85**
Industry funding or co-funding through the expert's project	2	6	2	0	8	19	0	9	5	4	1	**56**
Involvment in EU-funded projects including substantial private sector interests or coordinated by persons or organisms linked to private sector interests	4	2	4	0	9	10	0	7	1	4	4	**45**
Intellectual property rights (VII)	1	0	0	0	0	2	1	1	0	0	1	**6**
Responsibilities in industry-sponsored scientific societies, journals or professional associations	4	2	2	2	1	10	2	5	0	5	1	**34**
Member of an industry-captured associations or journal	2	13	6	0	5	3	1	3	2	0	1	**36**
TOTAL PER PANEL	37	37	45	3	60	113	31	63	20	30	21	**460**

Box 3 | Scrutinising the FEEDAP Panel

To its credit, EFSA has had a notable recent success in eliminating a conflict of interest incident[32]. In January 2013, Josep Gasa Gasó, an expert at the FEEDAP panel (responsible for animal feed) routinely submitted his declaration of interests when he joined an EFSA working group. But this time, EFSA asked him to provide more details of his work as a Scientific Coordinator of the University of Barcelona's SNIBA Institute. It turned out that SNIBA was carrying out research on feed additives for private companies. "EFSA understood in more detail" the scope of his work, they explained, and "decided this activity was incompatible with his role as a member of the FEEDAP Panel"[33].

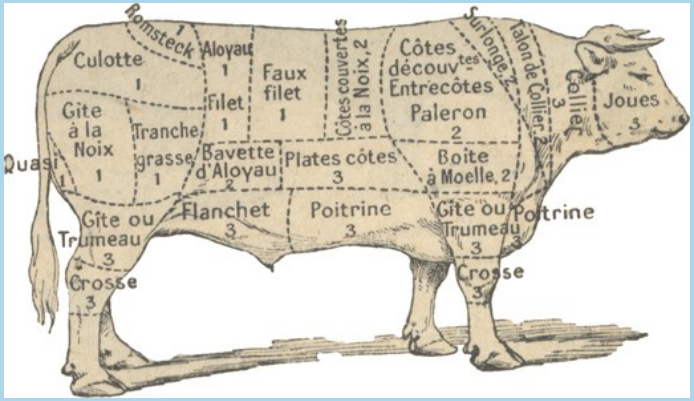
Curiously, the information had been available in Mr Gasó's declaration of interests since 5 May 2012, which reads: "In the last five years, SNIBA (UAB) has had research contracts with some companies in the area of animal nutrition: Alltech, CHR Hansen, Itpsa, Indukern, Rubinum, Roche, Bioiberica, Abenzymes. The research subject is related with aminoacids, probiotics, enzimes (sic), …" Rather than give up his professional activities with SNIBA, Dr Gasó chose to resign from EFSA on 20 March 2013.

Then on 26 June 2013, in the same panel on animal feed, Alex Bach, who holds EFSA's record for 24 conflicts of interest, updated his declaration and added new, upcoming research contracts. He already had five current research fundings from animal feed companies. EFSA "identified that the new activities declared were not compatible with his participation" in the plenary meetings of the panel and of its working groups. EFSA informed Alex Bach of their evaluation, and he resigned on 15 July 2013[34].

In a phone conversation, Mr Bach characterised EFSA's percentage criteria for research funding (less than 25% from industry) as a "silly policy". When a multi-million-euro EU-funded project comes to an end, he said, "all of a sudden your income on research from industry becomes 80%".

"If we have no industry, we have no public."

While he did not contest at all EFSA's decision to ask him to leave, Mr Bach believes he is "totally objective". "You have a conflict of interest if you work only with one company. You then may be in favour of helping this company." But working with several companies prevents from favouring one in particular, according to him. He simply did not think there was any opposition or difference in interests between public and private. "Being in favour of public interest is being in favour of industry. If we have no industry, we have no public"[35].



EFSA's complicated independence mechanism

Our marathon discussion continues at the basement level over the cafeteria trays. Alberto Spagnolli and Juliane Kleiner genuinely strive to understand the outsiders' point of view. The Scientific Adviser to the Executive Director, Hubert Deluyker, leans over a pizza-soda lunch, while everyone else has manifestly tried to assemble a more diverse meal. We still have three hours left to disentangle EFSA's reasoning on independence. By the way, the food is not bad there.

The "annual declarations of interests" forms filled by experts every year are the cornerstone of EFSA's new independence policy. They were used for the entire selection process of the experts for the renewal of eight of the ten scientific panels in 2012. The complex selection process itself took one whole year, they tell us (see box 4).

Once the forms were filled in by the candidates, the declarations of interests needed to be assessed. This herculean task was passed onto the nine heads of units, EFSA employees who have a scientific university background. They relied on the independence policy's reference table listing of acceptable and non-acceptable interests. Here, the experts' interests are sorted by numbered categories: economic interest (I), member of a management body (II) or of a scientific advisory body (III), employment (IV), consultancy (V), research funding (VI), etc. For each of them, the table lists what is allowed and what is not (see annex 3). The rules are stricter for chairs and vice-chairs. At first sight, it seems straightforward. But it is not.

The system permits many problematic collaborations on a case by case basis. A panel member can engage in many activities unless s/he "has a potential conflict of interest of a general nature that would regularly lead to [his/her] exclusion […] from the meetings of the scientific group". This vague notion is left to the subjective interpretation of the head of unit assessing the application. The same case by case judgment applies for the interests declared in categories VIII and IX ("Other membership or affiliation or other relevant interest"), catch-all categories that are sometimes (mis)used to record consultancy activities. Figures speak for themselves: out of a total of 855 interests that we screened, 301 were assessed on a case by case basis by EFSA.

The very fact that EFSA's process system relies on a case by case assessment for almost a third of the interests makes it un-transparent: an outsider would be unable to understand on which criteria the judgment was made. And what is a conflict of interest "of a general nature", by the way?

Well, at EFSA, it depends. "Having an interest is neutral. It turns into a conflict of interest in a particular context", says Dirk Detken, Head of Legal Affairs. In the conference room, someone presses the space bar on the laptop and EFSA's "screening triangle" appears on the screen: "Interest declared / Mandate of the panel / Role in the panel". What EFSA's reviewers look at in the first place is the scope (or the "remit") of the panel, i.e. the themes it deals with. When an interest falls into the panel's scope, EFSA assesses how often it could conflict with the discussions' topics. A "recurrent" interest becomes problematic when it appears in 30-35% of the meeting agendas, according to EFSA's rough calculation. A conflict of interest occurs when it goes over this ceiling, explains Juliane Kleiner, the newly appointed Director of Science

Strategy & Coordination. Incidentally, Mrs Kleiner's CV contains a curious section: she served as a senior scientist for ILSI from 1996 until she was hired at EFSA Contaminants Unit in March 2004[36].
Alberto Spagnolli even makes a preventative joke about it. Just in case we had already picked up on it, perhaps (we had)[37].

Panels are appointed for three years. During this period, a second screening tool is used: the "specific declaration of interest" (or "sDOI", which is not made public). EFSA is proud of this tool: "we invented it", says Dirk Detken. The sDOI is designed to detect "conflicts of interest on science", i.e. intellectual bias. The experts check the future agenda of the panel themselves and declare whether they see a problem. The rule is that they cannot review their own work for five years, one of the three situations where "cooling-off" periods (a given period of time after which a specific interest prevents participation to the panel's activities) are used by EFSA (the two others only apply to chairs and vice-chairs).
Apart from these instances, experts do not have to observe a cooling-off period after their interest is terminated, a serious limitation to the policy. In other words, they can sit in the scientific advisory board of an industry-funded organisation until the day they attend the panel's first meeting.

Finally, at the third stage of the complicated sorting process, the experts are also required to make an "oral declaration of interest" (oDOI) at the very beginning of each meeting. If they believe the scope of the discussion will cover an area worth mentioning as a potential conflict of interest, their statement is recorded in the minutes (these are public documents).

Box 4 | The candidate-experts' selection

After EFSA's adoption of their new ethics "Bible", the renewed selection procedure for eight of the ten scientific panels in 2012 consisted of first selecting the 447 "highest ranked candidates". After their "annual declarations of interests" (aDOIs) were screened by the agency, 66 were eliminated. More precisely: 7 withdrew their application, "27 were excluded due to a potential conflict of interest, and the 32 remaining candidates were excluded for not replying to requests to update their aDOI". Of the 381 candidates left on the shortlist, only 169 survived the elimination process of the Advisory Forum, a meeting point for the representatives of all 28 EU Member States's national food safety authorities, plus Iceland, Norway and Switzerland (candidate Countries and the European Commission also attend as observers)[38]. A further 211 candidates were then "proposed for inclusion in the reserve list".

On 15 March 2012, EFSA's Management Board adopted the two lists, after which EFSA went back to the candidates to ensure that they "had acquired no new interests in the interim period". "During these final checks, whenever any new potential conflict of interest was identified the candidate was approached in order to evaluate his willingness to resign from such current potentially conflicting interest.[39]" Eleven experts agreed to resign from problematic activities. Eight experts refused and were asked to voluntarily withdraw or were "de-nominated" by the Management Board.

According to EFSA, a total of 85 conflicts of interest were avoided during the whole process.

The Fast Food Panel

Prior to our visit to Parma, we had submitted five examples to EFSA in order to compare our assessment with the agency's. These were not whole declarations of interests but isolated interests raising specific questions. Intrigued by the way they were handled, we thought a crash test on the efficiency of EFSA's sophisticated filters in real life conditions could be enlightening. It was.

The first case involved Alex Bach, a member of the panel on Additives and Products or Substances used in Animal Feed (FEEDAP)[40], and also EFSA's record holder of 24 conflicts of interest. But we had only asked about Mr Bach's consulting activity for the American Soybean Association to "provide nutritional advice for ruminants in countries such as Morocco, Turkey, and Poland" since September 2006, as specified in his declaration of interest. A puzzling occupation for a public health scientist given that this association is the lobby organisation for American soybean farmers[41]. Not to mention that soy is the main ingredient in industrial farms' feed.

Claudia Roncancio Pena seems a little tense. As the Head of the Feed Unit, she gave him the green light to enrol as a panel member in 2012. "Soybean is out of the scope of the panel: it is a raw material", she says. The American Soybean Association "is a soy lobby but the panel does not deal with soy" itself, only with the additives that are mixed with it, she asserts. We goggle at her in astonishment, while she puts forward one final perplexing argument: "Any animal nutrition advice given by the expert is not linked to a particular additive, but rather to a complete diet composition for the benefit of the animal's health and welfare".

From a purely technical point of view, these arguments are true. Soy additives are not the same thing as soy. And dietary advice is broader than just a discussion of soy additives. However, not only is it highly unlikely that the American Soybean Association does not have any interest in soy additives, but such an interest creates a potential bias for factory farming, an industry-friendly (but not animal welfare or public health-friendly) approach to meat production. But, indeed, such notions do not fall "into the panel's remit".

Juliane Kleiner takes the floor for a second case. Peter Farmer, member of the panel on Contaminants in the Food Chain (CONTAM), collaborated with ILSI's Health and Environmental Sciences Institute (HESI). His declaration of interest mentions: "Member of the Biomonitoring Technical Committee (non remunerated).
Provided advice on this subject. Publications may be prepared by ILSI/HESI committees. 12/2004 - 09/2012."

Tricky one. Mrs Kleiner explains: "The mission of the Technical Committee was to integrate biomonitoring exposure data into the risk assessment process. This type of wide scope is within the remit of [EFSA's Scientific Committee] and not within the remit of the CONTAM Panel. CONTAM only describes and uses biomonitoring data if such data are available, which is rarely the case. Thus the HESI-ILSI mandate does not overlap with the mandate of CONTAM.
No [conflict of interest] identified and the expert is eligible as a member of the CONTAM Panel."

Hearing this, we had another of those moments, where we entered into a completely different way of seeing the world. Unfortunately it was to discover a sort of tunnel vision on the issue at stake. EFSA only uses the list of declared interests to detect topic/intellectual conflicts of interest. This narrow approach is what leads EFSA to have this almost absurd reasoning: an expert can work for any industry organisation as long as the topic of this activity does not "fall into the panel's remit".

Let's look at how this tunnel vision reasoning might work. Imagine for a minute that EFSA sets up a Fast Food panel (the FAFO panel). An expert called Mr Bean applies. Mr Bean heads the Department of Obesity Research at the University of West-Syldavia. He declares he is a consultant on carbohydrates intakes for the major fast-food chain FastBig in his annual declaration of interests. Chances that the panel will deal with carbohydrates in general are probably below 30-35%: they are not in the FAFO panel's remit, which is more about processes and products specific to the fast-food industry. So Mr Bean has no conflict of interest "of a general nature". He is therefore appointed as a full member of the panel. Some time later, sodas are placed at the agenda of an upcoming meeting. Mr Bean fills in his *specific*

declaration of interests. Assessment by EFSA's Head of FAFO unit: 1– He has a carbohydrates interest. 2– The topic is soda. Verdict: no conflict of interest. Mr Bean can participate and vote in the meeting even though he sells consultancy services to a major fast food chain selling soda every day. Congratulations, Mr Bean!

The rules' design fault

In the experts' defence, the declaration of interests forms themselves are ill conceived. The categories of interests are sometimes vague and incomplete. First, some types of professional activities, although extremely common for scientists, do not even have a dedicated box. For example, attendance or presentations in conferences, workshops etc. – are completely missing. As a result, some were declared either in the "Consultancy", or "Other", and sometimes the "Employment" categories. The relatively small number of conferences listed might lead to suspect that many have not been declared because they had no dedicated space. Yet a vast majority of these meetings are sponsored by corporations, sometimes heavily (see box 6).

Second, there is the "Employment" category (IV). No differentiation is made between working in publicly funded institutes and public structures that perform contract work for the private sector.
For example, two experts work at the Fraunhofer Institute, a German research body with a €1.9 billion annual research budget. "Of this sum, €1.6 billion is generated through contract research. More than 70 percent of the Fraunhofer-Gesellschaft's contract research revenue is derived from contracts with industry and from publicly financed

research projects", details the Institute's website[42]. This dependence link clearly poses a problem that should be taken into account in the assessment. Yet, the list of "food safety organisations" (FSOs) – that are regarded as non-problematic by EFSA[43] – includes such institutions (see box 5).

"The research (co-)funding I received from the private sector in the latest full budget year, and for the areas covered by the Panels, does not exceed 25% of the total annual research budget that is managed by me."

Then there is the "Research funding from the private sector" (VI). EFSA's rule is: if less than 25% of the expert's total current research budget comes from the private sector, it is not a conflict of interest. Above that figure, it might become a conflict of interest… but this is only judged on a case by case basis. How does EFSA know that it is more or less than 25%? Well, the expert does the maths him/herself and writes the following template sentence on the form: "The research (co-)funding I received from the private sector in the latest full budget year, and for the areas covered by the Panels, does not exceed 25% of the total annual research budget that is managed by me". But some experts do not even bother to write it: we were not able to understand on which basis EFSA made its assessment for 38 interests.

When the funding amount does exceed 25%, the criterion for exclusion is merely, and again, whether the *topic* the panel deals with is something the expert is privately funded to research. The third case we submitted to EFSA is that of Marina Heinonen, a member of the panel on Dietetic Products, Nutrition and Allergies (NDA). She declared four private funding sources for her research on polyphenols (from Kiantama, Valio, Mildola and Raisio, all food companies).
As the funding amounted to less than 25% of the total, no conflict of interest was detected by EFSA. Had it been more than 25%, she would probably have been excluded from certain panel meetings, explains Juliane Kleiner. As a result of this shoehorn system, the afore-mentioned Alex Bach (FEEDAP panel) can quietly declare his heavily industry-financed work: 20 research funds from a diverse portfolio of food, animal feed, ingredient and veterinary pharmaceutical companies over the past five years (Alex Bach resigned from EFSA in July 2013. See box 3). One could finally ask: why 25%? And not 10%? Or 0%? That is a mystery. The figure seems arbitrary. But can conflict of interest management be otherwise?

Box 5 | The 'public' food safety organisations loophole

EFSA's independence policy makes an important distinction between so-called "food safety organisations" (FSOs) and non-FSOs. A FSO is an organisation that is considered "to carry out tasks within EFSA's mission, that pursues public interest objectives and whose governance ensures the performance of its tasks with independence and integrity. Examples include universities or public research institutes"[44].

Because these organisations are seen as independent and acting in the public interest, stronger links are allowed than with other organisations. However, EFSA's list of FSOs features institutes that are for instance privatised parts of a university, doing work for (undisclosed) private parties. One example is Plant Research International (PRI), part of Wageningen Agricultural University (Netherlands). PRI has had Syngenta and Bayer as their clients in the past[45] but this is not evident from their website.

Another example is the Italian private university Università Cattolica del Sacro Cuore. This university hosts a research centre called OPERA that defines itself as a "young, growing independent research centre and think tank providing simple pragmatic solutions to support EU and national decision making. We bridge science and policy through a transparent platform to debate the right approaches for sustainable, intensive agriculture"[46]. OPERA also has a Brussels office with five staff and has registered with the EU lobbying transparency register[47]. OPERA's director is Ettore Capri, member of EFSA's panel on Plant Protection Products and their Residues (PPR).

In 2011, OPERA published a report with annual updates entitled "Bee health in Europe"[48]. The report seeks to shift the focus from neonicotinoid pesticides – that many studies have shown to be an important factor in bees' colony collapse disorder – by pinning the blame for dwindling bee numbers on a "wide range of factors". The report was prepared with the help of Bayer, Syngenta, Dow and BASF, with the two first companies manufacturing the pesticides implicated. Contacted by journalist David Cronin[49], EFSA denied that Mr Capri was involved in a conflict of interest and declared that OPERA was viewed by the authority as a "food safety organisation" as it pursues "public interest objectives".

Clearly, EFSA's list of "independent" organisations provides major loopholes in its independence policy.

The categories' hide-and-seek game

At the end of EFSA's forms, the "miscellanea" categories VIII ("Other membership or affiliation") and IX ("Other relevant interest") are vague enough to welcome… well, you name it. These categories are the perfect places to keep a low-profile on certain activities which, had they been declared elsewhere, could have led the expert not to be appointed in the first place. This is where most of the orphaned presentations at industry and industry-sponsored conferences ended up, but also and most notably, participations in ILSI activities. A total of 18 ILSI festivities were conveniently tucked away in this section.

In curt phrases, Claudia Heppner, Head of Food Ingredients and Packaging unit, defends a thorny fourth case. Roland Franz, member of the panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), declared three ILSI collaborations in the "miscellanea" category. Mrs Heppner, who screened his case, explains: Mr Franz is currently a reviewer for an ILSI Europe report entitled "Multilayer packaging for food and beverages". "A review of a report is not a consultancy", judges Claudia Heppner. "So the category IX is correct. And it is not a conflict of interest". Second one: Mr Franz was "temporarily" member of the Scientific Committee of a 2012 ILSI Europe symposium on food packaging. Analysis: "He was 'just' giving advice on the scientific programme". Third one: Mr Franz gave an oral presentation on the results of a European-funded project he participated in at the very same symposium. Explanation: "He was 'just' presenting results from the European project". Hubert Deluyker says soberly that Mr Franz fills in a specific declaration of interest when Polyethylene terephthalate (PET), a sort of plastics in his area of research, is on the meetings agenda. "Here you see the system is working", he assures us. That is: Mr Franz is "just" allowed to work with an industry think-tank – ILSI – notorious for seeking to influence EFSA (see box 2) and to sit in an EFSA panel, provided it is not on the topic he is working on.

However, it must be said that ILSI's role in attracting criticism for EFSA has caused the agency to try to severe its links with it. According to the dates recorded in the 209 forms, one can diagnose an ILSI resignation epidemic that struck down 10 experts around April 2012, i.e. when EFSA was drawing its short-list for the panels' renewal. As a matter of fact, EFSA approached these experts and asked them to chose between ILSI and EFSA. Hubert Deluyker confides: "It was a shock for them". An interview with one of them confirms it was.

"I felt they would have to find somebody else."

"Some of us felt – I wasn't alone – really puzzled", said Alan Boobis, a former member of the CONTAM panel (2009-2012). "Because we felt that what we had been trying to do was to put at the service of society our scientific expertise and training.[50]" In 2012, Mr Boobis applied to EFSA's Scientific Committee. "I was informed that I had some interests which were considered unacceptable to be on the Scientific Committee because of the impending new declaration of interests policy", he explained. He subsequently resigned from ILSI Europe's Board of Directors, ILSI's Board of Trustees and from RISK 21, a HESI/ILSI programme on risk assessment he used to co-chair. But still, EFSA "had some reservations" about his membership of some

ILSI working groups. Mr Boobis then “felt they would have to find somebody else”. Although “it didn’t seem fair” to him, he understood “EFSA was put in a very difficult position”: “no hard feelings”, he said. “Fortunately”, he was accepted back to the ILSI boards when he asked to be re-appointed.

Incidentally, for those who chose the public side and left ILSI, resignation was good enough for EFSA. No cooling-off period was requested for the ILSI-reformed. A few experts still declare on-going collaborations with ILSI.

Finally, the “miscellanea” categories harbour affiliations that are considered insignificant: namely scientific societies and, to a lesser extent, journals. Yet, even very modest scientific societies often owe their survival to private sponsors, and those are rarely the local plumbers. In general, their main activities consist of organising annual conferences or congresses – the ones that do not belong to any dedicated box in EFSA’s forms – and sometimes publishing journals.

“Platinum” (more than 12.000€), “Gold” (8.000€), “Silver” (4.000€), “Bronze” (minimum 1.000€).

For a scientist, networking with colleagues matters. Being member of a scientific society multiplies the chances to be invited to make presentations at conferences, a necessary step in a scientist’s work, and this is even more true for attending conferences. These events are often corporate sponsored. The annual conference of all European societies of Toxicology, EUROTOX is, for example, an important event that would be most unfortunate to miss for a toxicologist. However, last September, the 2013 edition of the conference was sponsored by numerous major corporations and lobby organisations[51] following a generosity scale: “Platinum” (more than 12.000€), “Gold” (8.000€), “Silver” (4.000€), “Bronze” (minimum 1.000€)[52].

A scientist who would not attend such conferences would most certainly damage his/her career, especially at its outset. Therefore we drew a line between mere membership, even if the scientific society was heavily industry-sponsored, which was not considered a conflict of interest; and responsibilities in the society, which was considered a conflict of interest, because closeness with the corporate members or contacts with the sponsors could expose the expert to a risk of double loyalty. Also, a handful of scientific societies look more like industry front groups than academic gatherings (see box 6). It is most unfortunate that a substantial number of the experts’ connections with the private sector went unrecorded because of EFSA’s lack of scrutiny of these activities.

Box 6 | The scientific societies' secrets

All scientific societies have a website, but almost none display their funding sources or the logos of their sponsors on their homepage. An example: the benefactors of the German Society for Experimental and Clinical Pharmacology and Toxicology (Deutsche Gesellschaft für experimentelle und klinische Pharmakologie und Toxikologie - DGPT) – if any – are not disclosed[53].
The British Toxicology Society, on the other hand, is openly "grateful for donations" from GlaxoSmithKline, AstraZeneca, Roche, pharmaceutical companies; Johnson Matthey, a chemical company; Unilever, a food company; and Syngenta, a pesticides and biotech company[54]. The Hellenic Veterinary Medical Society welcomes the visitors to its website with an advertisement for a Bayer product[55]. But more often, one only finds out about a society's funding sources by looking at the logos on their conferences programmes.
The website of the European Society for Veterinary Virologist (ESVV) is discrete over its funding sources[56], but Pfizer and Merial (a Sanofi subsidiary) feature as sponsors of its 2012 annual congress[57].

Now, are membership to any of these scientific societies and attendance to sponsored conferences really a problem? In other words: are they conflicts of interest? The Ethics Committee of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) explored this tricky question. French law states that experts advising the agency need to record this kind of membership in the declarations of interests. According to the Committee, this provision implies that the non-profit statute of an organisation does not prevent conflict of interest. Even if the scientist is not remunerated, the Committee recommends that ANSES should carefully enquire about the object of the association, its leadership, and its funding sources. It judges that mere membership does not constitute a conflict of interest unless the expert has established close links with the managers of a company, whose business is related to the panel's topic; or unless he has received financial support from this company. The assessment is different, however, when an expert has a leadership position or scientific responsibilities inside the association. In this case the Committee unequivocally considers the risk of being influenced is high[58].
EFSA would do well to take note of the French agency's position.

"Advancing Food & Health Through Sound Science."

Some scientific societies are also notorious for being captured by industry. The International Society of Regulatory Toxicology & Pharmacology (ISRTP) has been announcing it will disclose its sponsors "soon" since 2009[59]. Previous disclosures, however, have left some traces in the depths of the Internet. Notably, over the course of the last decade ISRTP has been supported by the American Chemistry Council, Dow AgroScience, Merck, Coca-Cola, Monsanto, the product defence company The Weinberg Group, and the tobacco company R.J. Reynolds[60]. ISRTP owns the journal *Regulatory Toxicology and Pharmacology*, whose editor Gio Gori has a long history as a consultant for the tobacco industry[61]. Another example is the Institute of Food Technologists (IFT) and its long list of sponsored awards[62]. The current President, John Ruff, worked for 36 years for Kraft Foods, headed General Foods R&D for both International and North American wings, and is a former President of ILSI[63]. IFT also owns two publications: the *Journal of Food Science* and *Food Technology*, whose subtitle is "Advancing Food & Health Through Sound Science"[64]. "Sound science" is a red flag phrase: tobacco industry strategists invented it[65]. Three EFSA experts are affiliated with ISRTP and its journal, and two with IFT. For these experts, we feel the conflict of interest is clear.

The experts' oath

Being both judge and jury is always bad for creating conditions of impartiality. So how much worse is it to be one's own judge and jury? That would be almost to ensure bias. Asking someone to objectively judge their own behaviour – as EFSA experts do when they fill in their own declaration of interest forms – almost sets up the agency for problems. A whole body of scholarly literature on the pharmaceutical industry has documented how bad people are at judging their own behaviour. In one oft-cited study, the researchers asked about 100 interns at the University of California-San Francisco School of Medicine how they perceived the impact of small promotion gifts such as pens on their prescriptions habits. 84% of them thought it could influence their colleagues, but only 39% reckoned it could influence their own prescriptions[66]! Conflict of interest has perhaps less to do with individuals' sincerity than with human beings' inability to stay clear and objective when their own honesty is questioned.
Yet the entire EFSA system of declaration of interests relies on the experts' self-assessment.

The experts fill and update the declaration of interests forms online themselves. But no one at EFSA ever investigates basic facts such as, for example, the true nature of certain "non-profit" organisations, although this camouflage legal status, available in most countries, is favoured by industry for its lobby structures, think tanks and other front groups. ILSI and its Health and Environmental Sciences Institute (HESI) are registered as non-profits in the United States[67]. ILSI Europe is legally an "International non-profit association" (Association Internationale Sans But Lucratif – AISBL) in Brussels[68].
As ILSI is enjoying a certain notoriety, it is interesting that two experts still deemed it necessary to write "non-profit" next to their collaborations with this industry-funded think tank. The experts' declarations of interests include numerous other "non-profits" appearing under deceptive denominations such as the International Meat Secretariat[69] or the American Meat Science Association (AMSA)[70], actually both organisations for the powerful U.S. meat industry. There is also the Dairy Council for Northern Ireland, a dairy industry organisation[71]; or the Danish Agriculture & Food Council (Landbrug & Fødevarer), the lobby organisation for the Danish farming and food industry[72].

"I consider myself not to be in a potential conflict of interest."

The problem with self-declaration does not end there. At the bottom of the declaration of interests, the experts have to tick a box and confirm: "I consider myself to be in a potential [conflict of interest]" or "I consider myself not to be in a potential conflict of interest with respect to my activities at EFSA". And then swear "the above declaration is truthful and complete" (see annex 2). Is "complete" too drastic a request? We double-checked on a small sample of five experts. Ten minutes on the internet were enough to find that each one had omitted some noteworthy activities (see annex 5).

Head of Legal Affairs Dirk Detken is EFSA's "Ethics Adviser", a position that was created with the new rules and that he defines as a "help-desk for staff". He is also a member, with three science directors, of the "Committee on Conflict of interests". To justify this passive attitude vis-à-vis the declarations of interests, he invokes the law: "We don't have a mandate to question the experts' integrity", he says. That would indeed explain why EFSA does not perform any pro-active investigation. But in fact, what article 37 of EFSA's founding regulation states is:

"*The members of the Scientific Committee and the Scientific Panels shall […] make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence*.[73]"

Nowhere does this text say that EFSA should stand behind some kind of a "do not cross" yellow cordon that would prevent any inquiry. But as a result of this narrow interpretation of the law, there is not even a routine check of the information recorded in the experts' declarations of interests. Or if there is, it is only a minimalist one.

In the event that EFSA does pick up information that appears strikingly misleading or incorrect, the expert is politely requested to modify his or her declarations of interests. EFSA's staff cannot edit the information themselves: connection requires a personal login. In the course of year 2013, EFSA has scheduled "compliance and veracity checks" on a random sample of 15 declarations of interests[74]. But this expert's "second oath" – as Dirk Detken qualifies it – will only consist in asking him/her *once again* whether s/he is certain the information is correct. Maybe because of these repeated opportunities to set things right, sanctions are rare. Since 2002, the "breach of trust" procedure – whereby EFSA's Management Board dismissed the concerned experts from membership of the Scientific Committee and the scientific panels – has been initiated only six times[75].

The hunt for the elusive independent expert

All this might well lead one to ask: why are there so many intricate links between the business sector and the world of science in the first place? The main reason is that public money for research has been drastically reduced in numerous relevant sectors. Nowadays, scientists have to devote an increasing amount of their time to hunting for funds. In the name of the contribution of research to economic growth, EU and national research policies increasingly demand the inclusion of a private partner or private co-funding in order to benefit from public grants. In some instances, it is even a *sine qua non* condition.

More than half of the research and development activities carried out in the EU are now funded by industry[76]. While filling the void left by states, private money now has a say in a considerable part of public research and has created a generalised conflict of interest situation across the board.

Eventually, EFSA has to deal with a situation created by public policy-making.

This is particularly a problem with EU-funded research, in which many EFSA experts are involved. The successive "Framework Programmes" (funding programmes created by the EU in order to support research) play a significant role in global European research spending. The 7th Framework Programme (2007-2013) alone handed out no less than €50.5 billion. But a previous report by CEO has shown that about one quarter to one third of the projects' participants are private companies[77]. Aside from the general concern that the involvement of large corporations might divert research agendas from the interests of society, this forced intimacy has created many grey areas that were extremely difficult for us to assess in terms of our research. These are highlighted in the "grey zone" column of our tables (see annex 6), meaning that some form of subjective judgment was needed to decide whether there was a conflict of interest.

Each EU-funded project is unique in its design and organisation: all shades of grey available! Some involve only public universities and research institutes with 100% public funding. Some combine public bodies with small and medium-sized companies that perform sample analyses or supply equipment. Some mix public institutions and major corporations, and are partly financed with private money. And some are even coordinated by major corporations or lobby groups.
The EURRECA consortium ("Harmonising nutrient recommendations across Europe with special focus on vulnerable groups and consumer understanding"), for example, is entirely financed by the EU (€13.200.000), but is coordinated by ILSI[78]. EFSA did not rule out one expert participating in this project – Susan Fairweather-Tait (NDA panel), the fifth and last case we had submitted to EFSA – because, quote, ILSI "only" does the secretariat and logistics.

Finally, one could ask another series of basic, almost naive questions. Let's not forget that corporations carry out in-house research with their own employees. So why would they fund the work of scientists employed by public institutions and regulatory agencies? Why would they need to hire them as consultants? Why would they invite them to their advisory boards? Not to deprive themselves from their expertise and insight, they generally argue. But what if the goal was also the influence they obtain by working with these scientists? Shouldn't public institutions have a duty to provide safeguards against this phenomenon?

Being an expert for the public interest and being an expert for the private sector are two different jobs. Maybe scientists who volunteer to participate in the shaping of public decisions would be less receptive to all those generous industry offers if they had better

working conditions. Being an EFSA expert is not in itself financially rewarding. EFSA experts only get reimbursements of costs, while chairs and rapporteurs get a modest fee for their work[79]. On top of that, EFSA has to deliver scientific opinions within strict deadlines (typically 6 months), and the general feeling is that experts cannot cope with the workload in a satisfactory manner.
As Albert Deluyker puts it with humour as the meeting comes to its end: “It is 1– a lot of work 2– for free 3– you get criticized 4– and it is not useful for your career”. Indeed, expertise in a public agency counts for little in a scientist’s career, unlike publishing articles (with the caveat that belonging to EFSA panels enables scientists to network at the EU level, which helps accessing EU research funds). Public expertise is such a crucial task for public health that it should be much more rewarding.

“Independence is a guarantee of incompetence”: this blunt assertion was made by Deputy Vice-President of the French Association of Pharmaceutical Companies (LEEM) Bernard Lemoine during a hearing at the French Senate in 2006[80]. However disconcerting it might be, this idea is widespread in the regulatory ecosystem. EFSA itself grants a sort of waiver to industry interests when it says: “High quality of scientific expertise is by nature based on prior experience and knowledge acquired in the relevant domain. Interests are therefore a natural and inevitable consequence of attaining scientific recognition at international level in a given field”[81]. EFSA’s former Executive Director Catherine Geslain-Lanéelle seems to have accepted this as the status quo: “If we were to exclude all experts who had received money from industry at one time or another, we would not have many experts left”[82].

Yet, independent experts still exist. At EFSA, 64 of them, a third, do not seem to have any conflict of interest. Independent experts may be an endangered species, but they are not extinct yet. This mirrors the result of a recent survey conducted in the United States. The authors asked 3.080 academic life sciences researchers about their relationships with the industry and found that 52,8% of them had some – consulting, paid-speaking, research funding, or sitting on a scientific advisory board. What this implies is that 47,2% had no relationship *at all* with the industry. The authors concluded that “this finding supports the belief that it is difficult, but not impossible, to find academic scientists without industry relationships to serve in advisory roles for organizations such as the Food and Drug Administration, the NIH, or the Institute of Medicine”[83]. With thousands of public researchers working for Europe's best public universities, and an improvement in scientists' working conditions and recognition at EFSA, it is hard to believe that the agency wouldn't find the expertise it needs.

Conclusion | “Try again. Fail again. Fail better.” (Samuel Beckett)

Before he was appointed Head of the Occupational Safety and Health Administration (OSHA), the U.S. federal agency in charge of workplace safety and health, by the Obama administration in 2009, epidemiologist David Michaels wrote a remarkable, seminal book. “*Doubt is their Product. How Industry's Assault on Science Threatens your Health”* gives a fascinating though depressing account of how corporate influence has undermined several important public health decisions throughout the past decades, whether it was tobacco, lead, beryllium, chrome, or vinyl chloride. In the final pages, David Michaels offers his insight on how to stop this process and protect the independence of public agencies’ scientific panels:

“If it is dangerous to rely on scientists with financial conflicts of interest to interpret raw data, why should we depend on these scientists to provide advice to the regulatory agencies? It makes no sense, and the law reflects this view: scientists with financial conflicts of interest cannot now serve on advisory panels unless they receive a waiver. However, this stipulation has so little currency today that waivers are routinely granted, no matter how glaring the conflict. ‘Conflict of interest can be managed’ is the current mantra. Well-meaning administrators of these committees believe they desperately need the leading researchers in their fields, regardless of how conflicted they may be. […] I am convinced that conflict of interest cannot be “managed”. It must be eliminated. Too much is at stake. Data interpretation requires independent judgment; the public needs assurance that the opinions expressed in these settings are unbiased by commercial interest.[84]”

Moreover, managing conflict of interest requires a significant amount of public money – not to mention human resources and time. EFSA invested €1,59 million in developing the declaration of interests online IT tool[85]. In 2012, no less than 6.869 annual and specific declarations of interests were screened at EFSA, and 36.609 meeting agenda items were scrutinised[86]. The head of units devoted half of their working time in 2012 screening the experts’ declarations of interests for the panels’ renewal. But aside from these intensive periods, processing the forms still consumes one third of their working time. With what result? As Alberto Spagnolli puts it: “The screening of thousands of declarations of interest every year is a very demanding and burdensome exercise. It is a substantial constraint which has to be factored when estimating EFSA’s capacity to deliver on his core missions of scientific advice, yet necessary to ensure that such advice is independent and free from any undue influence”.
Yet despite all this expense of time and resources, EFSA still has a credibility problem in terms of conflict of interest.

More than half of EFSA’s experts have conflicts of interest, according to CEO’s review. “Being exposed for an expert is a disgrace”, says Hubert Deluyker. Yet, it is the EFSA who exposes the experts to criticism when it gives those who have conflicts of interest a seat on its panels.

Our own screening exercise has made it very clear that analysing a declaration of interest often relies on personal judgment, cultural background and political assessment – that is: also on subjectivity.

Only strict and clear rules can efficiently limit arbitrary assessments. EFSA is self-regulating, but does not do it properly. For two years now, EFSA has been building an absurdly complicated machine – the French call it “une usine à gaz” – that does not deliver. Now, what is “worse than fail” is to give “false reassurance that the problem has been fixed”, as Ben Goldacre wrote in his book “*Bad Pharma. How drug companies mislead doctors and harm patients*”[87]. EFSA needs a clearer, simpler and more effective policy. Managing conflicts of interest is a dead end. We think entirely banning them from EFSA should be an obvious policy decision if public health means anything to anybody.

Recommendations

A | Specific recommendations for the existing conflicts of interest (COI) screening system

Bearing in mind that only looking at the conflicts of interest of individual experts is insufficient to maintain EFSA's independence from the economic interests it is meant to regulate, these are recommendations we think could, if well implemented, more efficiently ban conflicts of interest at the agency.

♦ Conflict of interest rules

- A 5 years cooling-off period should be applied to all interests related to the commercial sector.

- The current 25% ceiling in place at EFSA for research funding from the commercial sector is not acceptable, as you cannot measure a COI (and any attempt to do so would be highly problematic from an individual privacy perspective). No research funding from the commercial sector therefore should be accepted.

- The list of “food safety organisations” (FSOs) used by EFSA to grant extended permissions to sit on panels contains organisations with close ties to industry. The list must be double-checked and updated.

♦ Declaration of interest forms

- Indicate whether the interest was remunerated or not. If remunerated, indicate if the payment went to the expert or to the institution.
- Specify the amounts.
- Indicate the country of origin of the expert at the top of the form.
- Indicate the names of the organisations at stake in English as well as in their original language so that they can be easily identified.
- Create new categories for:

    - Attending industry or industry-sponsored conferences. Indicate who paid the expenses and their nature.
    - Talks at industry or industry-sponsored conferences. Indicate who paid the expenses and their nature.
    - Membership or responsibilities in scientific societies: indicate the expert's tasks if relevant, the society's funding sources and their respective share in the society's total income.
    - Responsibilities in scientific journals: indicate the expert's tasks if relevant, the journal's funding sources and their respective share in the society's total income.

B | Broader recommendations

- **Short-term:**

  - Outsource the screening of the declarations of interests from heads of units to dedicated in-house personnel. Alternatively, this task could be entrusted to specialised magistrates from the European Court of Auditors.

  - In the present situation, EFSA can only rely on information recorded by experts in their declarations of interests and CVs, basing the entire system on these persons' self-assessment. Such a process is unreliable. A more efficient approach could be to improve the system with pro-active and random checks by the above-mentioned staff with extensive training on regulatory capture, based on publicly available information as well as complementary investigations when needed. Any conflict of interest found would cause the non-appointment or dismissal of the expert at stake. The officers in charge of the checks would therefore play the role of a permanent and dedicated integrity watchdog, something that is currently lacking.

  - Invite “hearing experts/expert witnesses” to ad hoc information sessions, that is to say scientists with conflicts of interests whose contribution would be seen as indispensable but without granting them any drafting or decision-making powers in the panel's work.

- **Long-term:**

  - In-source expertise: give experts the means (financial, human, institutional) to do their work properly and be independent from the sectors they are regulating. An idea for this would be to create a European school of independent expertise and a body of European experts with statuses and careers, a proposal put forward by FORMINDEP, an association at the forefront on the conflict of interest in French medicine[88], and endorsed by a information report of the French Senate after the Mediator Affair[89].

  - Exactly as with the pharma sector where lack of public access to clinical trials data is strongly criticised, food safety studies is another area where a whole body of data with crucial public health relevance escapes the kind of scrutiny that is expected and required in any other scientific process: peer review and replicability. One could imagine a system where studies would still be paid for by industry but be conducted by independent/public laboratories on the basis of very strict rules including blinds (to avoid bias and pressures on the labs by producers). EFSA could be a facilitator and have an integrity watchdog role before actually performing the risk assessment based on these studies and the general scientific literature.
    On top of enabling a genuinely scientific assessment of products being consumed every day by millions of EU citizens, this would also offer the scientists involved the

opportunity to actually publish their work in the scientific literature and obtain credentials for it. As this report indicates, making public expertise more attractive is not just a minor detail in tackling the wider context within which conflicts of interest problems occur! Such a system would probably require new legislation and would be fought tooth and nail by corporations and their lobby groups. It would not be in their interests – but it would be in the public's.

Disclosure statement

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