

Independence at the European Food Safety Authority: what is the problem ?

Discussing EFSA's 2012 implementing rules of its Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoI), June 5 2014

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Independence at EFSA : the situation, its causes and what could be done about it

1. State of play : numerous COIs/potential COIs involving food industry interests among members of scientific panels, and the situation persists today – and why is it important
2. Main weaknesses in EFSA's independence policy and tools
3. Fixing the policy: can it be done ? Do EFSA and the European Commission want to to fix it ?

conflict of interest : definitions

1. EFSA : "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;"
2. European Court of Auditors : "A conflict of interest is considered to be a conflict between the public duty and private interests of a public official, in which the public official has private-capacity interests which could improperly influence the performance of his official duties and responsibilities."
3. WHO : "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. [...] A conflict of interest may exist even if no unethical or improper act results from it."

COI : a concrete situation but not necessarily conscious, whose very appearance is a problem for a public institution's credibility.

Brief (and non-exhaustive) recap of COI scandals at EFSA before the new independence policy

- 29 September 2010 : EFSA's Management Board's [chair](#) (Banati) [found](#) by MEP Bové to have a COI with industry (ILSI Europe).
- 23 February 2011 : four members of the Management Board (Kovac, Horst, Ruprich, Vanthemsche) are [found](#) to have links with industry by CEO.
- 7 April 2011 : 3 members of the PPR panel (Moretto, Boobis, Brock) are [found](#) to have COIs with the pesticide industry by Earth Open Source.
- 15 June 2011 : 11 out of the 20 members of the ANS panel [have](#) COIs with industry, report by CEO. Four also did not declare links with ILSI Europe.
- 17 octobere 2011 : NDA panel chair (Flynn) has COI with industry, [report](#) by SüdDeutsche Zeitung
- November 2011 : 12 out of 21 members of the GMO panel [have](#) COIs with industry, notably the panel's chair (Kuiper) – CEO report.
- December 2011 : 10 out of 13 members of EFSA's working group on TTC have COIs with industry, [report](#) by PAN Europe

Brief (and non-exhaustive) recap of COI scandals at EFSA before the new independence policy - 2

An investigation by the European Court of Auditors [found](#) EFSA's management of conflicts of interest situations "inadequate" and called for reform (October 2012).

But EFSA's Management Board had already revised the agency's independence policy (November 2011), and EFSA's Director decided on this policy's implementing rules (February 2012) : CEO assessed this new policy in the report "Unhappy Meal" published in October 2013.

Main problems since the new independence policy is in place

Main findings from the "[Unhappy Meal](#)" report (S. Horel & CEO, Oct 2013), the first ever systematic assessment of EFSA's independence :

- **122 experts out of 209 (58.37%)** have at least one conflict of interest with the commercial sector.
- Experts with COIs dominate **all panels but one**.
- All but two panel chairs and 14 vice-chairs among 21 have conflicts of interest. **Seven chairs and vice-chairs should not have been appointed according to EFSA's own rules.**
- Among 855 interests screened, CEO counted an overall sum of 460 conflicts of interest.
- **No visible difference** in the proportion of conflicts of interests in the eight renewed panels compared to the two that were yet to be renewed.

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	20
Employment for an FSO (IV.A)	0	0	0	0	0	0	0	1	0	0	0	1
Employment by commercial 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	0	0	0	1	3	1	1	9
Consultancies (V)	7	5	10	0	5	32	10	12	5	9	7	102
Research funding (VI)	18	8	11	0	46	44	6	33	7	10	5	188
Direct Industry funding	12		5	0	32	15	6	17	1	2	0	90
Industry funding or co-funding through the expert's project	2	6	2	0	5	19	0	9	5	4	1	53
Involvement in EU-funded projects including substantial commercial sector interests or coordinated by persons or organisms linked to commercial sector interests	4	2	4	0	9	10	0	7	1	4	4	45
Intellectual Property Rights (VII)	1	0	0	0	1	2	1	1	0	0	1	7
Responsibilities in industry-sponsored scientific societies, journals or professional associations	4	2	2	2	2	10	2	5	0	5	1	35
Member of an industry-captured associations or journal	2	13	6	0	4	3	1	3	2	0	1	35
TOTAL PER PANEL	37	37	45	3	60	113	31	63	20	30	21	460

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
Experts with no COI	4	7	5	13	7	3	4	7	3	8	6	3	64
Experts not assessed (insufficient declared information)	4	2	0	6	2	0	3	0	5	0		0	22
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
Chair with COI (according to CEO)	1	1	1	0	1	1	1	1	1	0	1	1	9
Vice-chairs with COI (according to EFSA)	0	0	0	1	0	1	0	0	1	0	0	0	3
Vice-chairs with COI (according to CEO)	1	1	2	1	1	2	2	1	2	1	0	0	14
Case by case assessments by EFSA	52	36	26	19	15	66	26	28	4	20	65	9	301
Interests not assessed (insufficient declared information)	21	15	15	6	9	26	9	8	11	11	9	0	131
Misrecorded interests belonging to the "Consultancy" (V), "Management Body" (II), or "Scientific Advisory Body" (III) categories	0	2	1	0	0	22	4	12	2	0	12	1	44

Other important findings of the "Unhappy Meal" report

- EFSA ill-equipped to defend its independence :
 - low budget (experts are not paid...)
 - structural COI: heads of unit in charge of screening DOIs whereas they also have to deliver opinions within tight deadlines
 - no proactive policy to identify COIs beyond individuals' self-assessment
 - improper understanding of regulatory capture and its consequences: an independence policy shouldn't be about trying to regulate individuals' honesty but about defending a public agency's scientific integrity
- **But** : no will to publicly acknowledge problems
 - => consequence : the scandals continue !

Most recent COIs scandals at EFSA

- December 2013 : investigative TV report (Envoyé Spécial, France 2) [finds](#) "more than half" of EFSA's experts have COIs – shocking images of EFSA in denial of an obvious case (D. Parent-Massin, ANS panel)
- February 2014 : 52 % of scientists working on pesticides mixtures in food for EFSA have ties with industry, [report](#) by PAN
- April-May 2014 : specific case of Ivonne Rietjens, member of CONTAM panel and former chair of ANS panel, failed to declare 50,000€ income from food company Royal Wessanen, "resigned" after investigation by EU Food Policy (but "Unhappy Meal" report already showed she had COIs with food industry).
- no action was taken after the "Unhappy Meal" report, so all conflicts of interest documented then remain valid.

How long will this series of scandals continue before EFSA actually does something meaningful?

Why is independence important ?

- EFSA scientists' conflicts of interest with industry ruin the reputation of a public agency meant to work in the public interest and whose workload consists at least for 60 % in assessing industry products. All the more important that EFSA's opinions are hotly debated in several controversial areas : BPA, TTC, GMO risk assessment methodologies, health claims, additives...
- assessing the content of a given scientific opinion is difficult for non-specialists, but conflicts of interest situations are easier to understand : EFSA's claims of scientific excellence are thus worthless in all cases where its scientific opinions' authors have COIs.
- conflicts of interest are a well-documented source of scientific bias (cf. abundant literature on how conflicts of interest influence scientific conclusions), and financial COIs are qualitatively different from the others : because they are concrete and measurable, they can be assessed and regulated. Again, EFSA is not credible when pretending to scientific excellence while ignoring scientific literature on regulatory capture.

So, if independence is so important for scientific credibility, how is it possible that there are so many COIs at EFSA still today ????????

EFSA's independence policy does not respect EFSA's Founding Regulation

EFSA's Founding Regulation (178/2002) insists a lot on the necessary independence of the Authority. **Independence is foreseen in the regulation as the first criteria for the agency's trustworthiness**, see for instance alinea 7 of the Regulation's Article 22 ("Mission of the Authority") :

*"7. The Authority shall carry out its tasks in conditions which enable it to serve as **a point of reference by virtue of its independence**, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it. [...]"*

EFSA's independence policy does not respect EFSA's Founding Regulation

Independence is also the only imperative characteristic foreseen for the experts composing the Scientific Panels, see alinea 4 of the Regulation's Article 28 ("Scientific Committee and Scientific Panels") :

"The Scientific Panels shall be composed of independent scientific experts. [...]"

The Regulation's Article 37, "Independence", defines clearly what this implies : Members of the Management Board, members of the Advisory Forum and the Executive Director are required to *"act independently in the public interest"*, while, crucially, **members of the Scientific Panels are required to *"act independently of any external influence."***

EFSA's independence policy does not respect EFSA's Founding Regulation

BUT: EFSA's Management Board watered down this principle when it defined its rules for the selection of experts in its late 2011 independence policy. See section 6.1, "Selection of Experts", paragraph 2:

"Public-private partnerships are an established feature of research in the EU and worldwide.[...] Therefore, during the selection process, all relevant interests declared by the applicants, such as financial ones, are screened with a view to **preventing the appointment of candidates with evident and general conflicts of interest**. In other words, a candidate is not considered for membership of the Scientific Committee or Scientific Panels when EFSA identifies a potential conflict of interest of **such a magnitude that would prevent his or her active participation in the majority of the meetings of that Committee or Panel.**"

EFSA's independence policy does not respect EFSA's Founding Regulation

In other words, **EFSA's Management Board transformed EFSA's independence rules from "no external influence allowed"**

into

"conflicts of interest allowed as long as they do not impact more than half of the panel meetings"

During our discussions with EFSA's management in June 2013, we learned that EFSA was now applying a threshold of about 33 %, not 50 %. **This still goes completely against both the text and the spirit of EFSA's Founding Regulation that stipulates that EFSA scientists should be free of any external influence.**

EFSA's implementing rules therefore implement a flawed policy

- the main loophole in EFSA's [implementing rules](#) is **article 9-c** : interests to be assessed according to the tasks/functions assigned to the person and the mandate of the group. This allows heads of unit to assess experts' interests as narrowly as they want/need to, and to let experts with ties to numerous companies on EFSA's panels as long as they don't work on exactly the same topic.

We think that this article could be revised according to Article 3, which stipulates that **all interests falling within EFSA's remit should be declared** : if the relevant perimeter for declaring interests is EFSA's remit, why not using the same scope for their assessment ?

Another important loophole is the list of Food Safety Organisations (FSOs) whose members/employees are granted larger rights in the EFSA system : some organisations on the list should not be on it (OPERA...).

The European Parliament on the same line

The European Parliament is on the same line and has [called](#) EFSA to apply "*a two-year cooling-off period to all material interests related to the commercial agrifood sector*". We think 5 years would be better but the principle is there : keep industry away from the assessment of its products.

The EP also called for the list of Food Safety Organisations (FSOs) to be revised after a [report](#) we published showed how a lobby group of the pesticides industry had managed to find its way on the list (OPERA).

However, EFSA's Director said to stakeholders in March that he did not want to tighten independence rules, only transparency. But why would more transparency on existing problems bring trust ?
Strange reasoning.

EFSA's implementing rules

General points about Declarations of Interest (DOIs) for more consistent rules

- Indicate whether the interest was remunerated or not.
- If remunerated, indicate if the payment went to the expert or his/her 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. The practice of some experts to anonymise organisations paying them/they belong to should not be accepted.

EFSA's implementing rules

Suggestions of additional categories to the Declarations of Interest (DOIs) to better take into account existing mechanisms of regulatory capture

- 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.

EFSA's implementing rules

Article 10 – 1 : Heads of unit not in a good position to assess experts' independence : they are under strong operational constraints.

10 – 1 – a : "potential conflict of interest of a general nature" : very vague, lots of room for arbitrary assessment (policy says >50 %, practice meant to be >33 %...).

10 – 1 – a – ii : report found 16 conflicting interests in IIB category and **102** in category V (consultancy – V.A&V.B merged)

10 – 1 – a – iv : 19 conflicting interests found in the IV.B category

10 – 1 – 1 – v : categories I & VII : 10 conflicting interests in total

EFSA's implementing rules

10 – 1 – 1 – vi : research funding from private sector limited at 25 % of annual budget. **Why 25 %? Arbitrary figure.** No financial ties to a private company within EFSA's remit should be allowed.

10 – 1 – b (rules for chairs) : we found that 7 chairs and 3 vice-chairs should not have been appointed under EFSA's existing rules. No action seems to have taken.

Article 13 (Committee on Conflicts of Interest) : composition partly inadequate (3 science directors + legal services director) because members also under operational constraints : create specialised function, or, better, outsource to independent body ?

Article 14 : very important ! EFSA doesn't perform any pro-active checks beyond looking at the CVs experts send, indefensible policy to only count on external observers (journalists, NGOs...) to diagnose problems. EFSA must check pro-actively, using all sources available, that DOIs are as complete and accurate as possible. The Commission did it for candidates to EFSA's Management Board, why couldn't EFSA do it for its experts?

EFSA's implementing rules

Article 15 : assessment of consequences, good a process is in place but probably very difficult (collegial decision). Was a published scientific opinion ever amended/withdrawn following such a process ?

Article 18 : also very important : hearing experts are the way for EFSA to access any expertise it wants without compromising its integrity. Existing rules are clear.

Article 19 : "Observers shall not in any way take part in the discussion", already cases of breaches... webcasting much preferable.

Article 23 : DOIs of the entire EFSA staff should be made public, not only those of EFSA's management.

Article 27-7 : DOIs are kept, but 5 years a bit short. Besides, DOIs of past experts should be kept public (not the case today, only on demand).

Can the system be fixed ?

Today, EFSA's COIs screening system is very heavy and costly but does not guarantee the authority's independence. This is because of loopholes introduced in it to sacrifice independence to, we believe, operational considerations. The general policy is to "manage" conflicts of interest, which is illusory : how can you manage people's opinions and biases ? The only credible option in our opinion is to ban conflicts of interest, not manage them, and it is just not fair to appoint experts with COIs and let them take the blame afterwards. The idea of "personal capacity" in practice is nothing more than a legal fiction.

As a conclusion, the existing system, while very limited, could be largely improved by :

- using more specific criteria and demanding complete transparency on financial aspects
- assessing interests at the relevant scope : the agency's remit.
- having interests assessed by specialised staff independent from EFSA's management
- aiming at banning COIs with commercial interests, not managing them.
- have EFSA and the European Commission depart from their denial attitude and commit to actual reform. Wishful thinking ?