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EFSA
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Dear Sir/Madam

Re EFSA Strategy 2020

EFSA's articulation and publication of its strategy is very much to be welcomed. The document contains many desirable features, but a few passages are problematic and it is on those that sections this document concentrates.

Paragraph I.i says that EFSA's vision is focussed on: "Protecting consumers by providing *independent* scientific advice on risks in the food chain." (emphasis added) Furthermore paragraph I.ii also invokes the term 'independent' and paragraph I.iv on EFSA's values lists 'independence' as the third of the Authority's values. In total the word 'independent' is used nine times in the Strategy document, but in every case it fails to engage with the fact that 'independent' is a relational term; the Strategy fails to clarify of what or whom EFSA and its advice is supposed to be independent. Obvious candidates include eg DG-SANTE and other parts of the European Commission, governments of Member States and the food industry. The Strategy document would be significantly strengthened if clarity on this point was provided.

It would, however, then be necessary to explain how EFSA can plausibly claim 'independence' given that it has people on its Board and its expert advisory panels who do or have worked in or with the food industry. The argument that I have heard to try to justify including such individuals on EFSA's Board and panels is that they provide invaluable expertise. My view is that their expertise can and should be contributed without them being included as member of panels and boards with responsibility for making risk assessment decisions or deciding which advice to give to DG-SANTE. The practice of requiring declarations on interests is not sufficient to ensure that conflicts of interest do not influence subsequent judgements. On occasions EFSA staff have claimed that not all commercial 'interests' constitute 'conflicts of interest' but those suggestions are entirely unconvincing. If EFSA is to be genuinely independent of commercial interests, and if it is seen to be genuinely independent of those interests, it will need to be seen transparently to

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keep commercial interests and political pressures from eg the European Commission and the governments of Member States at arm's length, and outside all its panels and off it Board.

In paragraph I.ii the text refers to EFSA having been: "…set up in 2002 as an impartial source of scientific advice and communication on risks associated with the food chain." 'Impartial' is also a relational term, but the Strategy fails to clarify between what and/or whom the advice is supposed to be impartial. This is important because in Para I.v the text states that: "EFSA is governed by a Management Board whose members are appointed to act *in the public interest* and do not represent any government, organisation or sector." (emphasis added) It is unclear how EFSA envisages reconciling the claim to impartiality with the obligation to 'act in the public interest', especially given that on almost all issues on EFSA's agenda the available scientific evidence is incomplete, equivocal and uncertain and consequently EFSA and its panels need to make judgements about how the benefit of the doubts are to be allocated. EFSA should always give the benefit of doubts in favour of the public interest, interpreted as the protection of consumers' interests and public health, but that implies something other than impartiality, which suggests indifference as between consumer and producer/commercial interests.

Paragraph I.iii says that EFSA's mission include providing: "…consistent advice to increase trust in the EU food safety system." That wording however fails to clarify that with which the advice is supposed to be 'consistent'. One cynical reading might interpret that as implying that EFSA is committed never to changing its mind on anything, but that is unlikely to be EFSA's intended meaning. It might be intended to mean that EFSA's advice will never contradict the judgements of eg ANSES - Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail, the ***Bundesinstitut für Risikobewertung***, the Food Standards Agency, the WHO/FAO's Joint Expert Committee on Food Additives and Joint Meeting on Pesticide Residues or even the International Agency for Research on Cancer, but that interpretation is also problematic because from time to time EFSA has issued statements that were inconsistent with judgements of some of those other bodies. A further possible interpretation might be that EFSA aspires to be consistent as between distinct cases, eg of different chemical agents, but then that would be in tension with EFSA's declared policy of making judgements on a 'case by case' basis. The meaning of the term 'consistent' is therefore in need of clarification, or else stakeholders will not know what EFSA's strategy is intended to convey.

Paragraph I.iv headed 'Our values' is seriously problematic because it muddles aspirations with achievements. For example the text asserts that: "EFSA provides accurate, up-to-date and timely scientific advice that helps risk managers to take decisions for the protection of consumer, animal, plant, and environmental health." As an aspiration that is unproblematic, but as a claim concerning what EFSA ready achieving it is seriously problematic. I am not alone in having provided evidence showing that that aspiration has not always been met. The section on EFSA's values needs to be re-worded to ensure that aspirations are not misrepresented as if they had all already been achieved, or else EFSA will rightly be criticised for complacency.

In the third paragraph of Section I.iv the discussion of 'Independence' refers to 'transparency'. EFSA's aspiration to achieving transparency is entirely welcome, as is its promise that its risk assessments will be 'reproducible'. (EFSA *Discussion Paper:*

Transformation to an "Open EFSA" Section 3.1 page 9) This is vital because several of the reports from EFSA panels have either not been reproducible, or only reproducible by adopting problematic assumptions that give the benefit of the doubts to commercial interests rather than the protection of public health.

EFSA's commitment to transparency and reproducibility are also hard to reconcile with a report of some remarks attributed to Bernard Url, EFSA's Executive Director. According to the commercial food industry news service *NutraIngredients.com,* in October 2015 Herr Url told one of their reporters that:

> "In a scientific process – which is what we call organised scepticism – the scientist must have the freedom to ask stupid questions that are out of the box, to challenge their peers, trial and error. …And there I'm not convinced we help the process of finding the nearest approximation of truth by putting every single question for the whole life of a scientist on Youtube….I think that science needs parts of the process in a closed room and then many steps of the process in an open atmosphere." But I think it also needs a protected room where they can speak completely freely, openly and challenge each other. That's also science."

Those remarks are problematic and inconsistent with EFSA's commitment to genuine transparency and reproducibility. No-one is talking about putting anyone's ***entire*** life on Youtube, but in this context the issue relates to the transparency of specific activities of expert advisors when providing scientific judgements and advice to EFSA. I take the view that anyone who is not willing to be fully accountable for their judgements in respect of EFSA's food safety risk assessments is not appropriately qualified to serve on any of EFSA panels. What counts as a **stupid** question may often be an issue about which people can legitimately disagree, but I am concerned to ensure that members of EFSA panels are consistently asking **wise** and thoughtful questions that challenge the claims put before them.

In order for those outside the panels, both professional scientists and concerned citizens to have confidence in the judgements of EFSA's panels it will be essential for the entire process to be transparent; organised scepticism cannot be confined just to panel members. If some deliberations and discussions take place in 'closed rooms' EFSA's aspiration to genuine transparency will be betrayed, and the 'trust' that EFSA and DG-Sante understandably value so highly will be imperilled.

Paragraph III.i refers to "…safeguarding the independence of scientific assessments." If those assessments are to be, and to be seen to be, genuinely independent of commercial and/or political interests that are antithetical to the protection of consumer interests and public and environmental health, then the deliberations of EFSA panels will need to be fully transparent. If they are not fully transparent then trust will inevitably be forfeited.

Since April 2002 when the UK-based Food Standards Agency issued its report on scientific advisory committees, all those committees have held their meetings in open public sessions, but that has not inhibited the Agency or its advisory committees from conducting their deliberations or providing their reports. Partial transparency is not genuine transparency.

Section II.iii refers to the growing need and importance for: "…EFSA and the wider risk assessment community to partner with research bodies, risk managers and funding bodies to identify and prioritise research funding for the generation of data for its on-going work." Those comments are welcome, but they deserve to be clarified. On page 14, under Strategic Objective 3 we are told that EFSA aspires to: "Establish clusters with other EU Agencies to identify research priorities and establish close collaboration with DGs JRC, R&I and Agri for the funding of key research projects and the monitoring of their early results." What are required are specific mechanisms by which EFSA can contribute to setting research priorities and agendas for Framework Programmes and the successors to Horizon 2020. The wording of EFSA's Strategy suggests that no such mechanism is yet in place. Why such a mechanism has not already been established remains unexplained.

Section III.v acknowledged the financial pressures under which EFSA's is operating. If resources are becoming scarcer and demands are increasing, it might be appropriate for EFSA's strategy to make it abundantly clear that it will be unrealistic to expect EFSA to fulfil its remit. There are bound to be limits to what can be accomplished by introducing greater efficiencies. Furthermore, transparency cannot be achievable at zero cost. There may be scope for greater collaboration with EFSA's counterparts in the EU Member States, but sub-contracting tasks to those national organisations will undermine EFSA's claim to be *the first among equals*. EFSA's strategy document should provide some indication of how it would prioritise its various activities, to make clear the consequences of a declining resource base, so that the European Commission, the European Parliament and the governments and parliaments of EU Member States fully appreciate the likely consequences of failing to provide EFSA with the resources needed properly to meet all of its responsibilities.

Section IV sets out EFSA's **Strategic Objectives** in a helpful manner, the first of which is to "Prioritise public engagement in the process of scientific assessment". A commitment to prioritising public engagement is very welcome, but the objective needs further clarification because it fails to make clear which constituent parts of the process of scientific assessment will be the main focus for public engagement. I have argued in several places[1] that it is equally important in relation to selecting the criteria by reference to which decisions are made as to which different types of evidence are included or excluded, as well as the criteria by which the evidence is interpreted. For example, should EFSA panels take greater care to try to identify and discount potential false negatives or potential false positives or both equally? In relation to all of those types of issues, the judgements that are made are invariably normative; they cannot be settled solely by reference to scientific considerations. The EFSA Strategy document could usefully be elaborated to include those types of judgements on the set of issues for which public engagement is appropriate and indeed required.
On page 11, in Section IV.1, Operational Objective 2, we are told that EFSA should:

[1] See eg E Millstone, 'Can food safety policy-making be both scientifically and democratically legitimated? If so, how?', *Journal of Agricultural and Environmental Ethic*s, 2007, Vol. 20, pp. 483-508; E Millstone 'Science, risk and governance: radical rhetorics and the realities of reform', *Research Policy*, Vol 38, No 4, May 2009, pp 624-636; and with P van Zwanenberg & E Millstone, *BSE: risk, science and governance*, Oxford University Press, 2005

"Provide access to non-confidential data/information and methods used in the risk assessment process." But we are not told which types of data should be deemed confidential and which not confidential. I maintain that in respect of food products, and the ingredients from which they are made, the only type of information that can legitimately be kept confidential are characteristics of processes of production that have no consequences whatsoever for public or environmental health but may be relevant to commercial cost structures; all other data relevant to the characteristics of the products should be in the public domain. Having an 'Open Data approach' is entirely desirable, but that should imply, not just having a data warehouse, but ensuring that the data are publically available in searchable electronic forms.

I am grateful to EFSA for providing outsiders to comment on its Strategy 2020, and look forward to receiving a set of carefully considered responses to these comments and those of all other contributors.

Yours sincerely

Erik Millstone