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TECHNICAL REPORT OF EFSA

Outcome of the public consultation on the draft Policy on Independence and Scientific Decision-Making Processes[1]

European Food Safety Authority[,]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

The European Food Safety Authority and its founding regulation attach a great importance to the independence of the Authority and of its scientific outputs and decision making processes.

On 17 June 2011, EFSA's Management Board endorsed a Draft Policy on Independence and Scientific Decision Making Processes.

Consequently, on 7 July 2011, the draft Policy was put out for consultation during summer. The public consultation closed on 16 September 2011. On 12 October, a Stakeholder Consultative Workshop was organised successfully by EFSA in Brussels with more than 140 participants. Overall, EFSA received more than 110 comments from 32 organisations and individuals.

This report outlines the comments received during the public consultation and at the Workshop and the way they are addressed in the forthcoming Policy.

KEY WORDS

(Independence, conflict of interest, bias, autonomy)

[1] On request from EFSA], issued on DD Month YYYY.

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BACKGROUND

The European Food Safety Authority and its founding regulation attach a great importance to the independence of the Authority and of its scientific decision making processes.

EFSA implemented the legal obligations related to independence already in 2004. This was further refined several times, and a new and comprehensive system was adopted by EFSA's Management Board in September 2007.

As part of the review of the Policy on Declarations of Interest, in March 2011, EFSA's Management Board discussed a reflection paper outlining outstanding issues and the respective policy options to address them in the context of a broader Policy on Independence.

In June 2011, EFSA's Management Board endorsed a Draft Policy on Independence and Scientific Decision Making Processes. The draft Policy describes the steps that have been taken by EFSA to ensure the implementation of those values and produces a comprehensive, overarching document that outlines the many, different facets of the measures that the Authority has progressively put in place to assure high-quality scientific outputs based on transparent, open and unbiased scientific decision-making processes. This draft Policy has been built through a process of extensive internal consultation with the Authority's Scientific Committee and Advisory Forum, taking account of more than three years of experience in the implementation of the 2007 Policy on Declarations of Interest, as well as the recommendations put forward by independent contractors and auditors delivering respectively a benchmarking report[2], an external review of the implementation[3] and audit reports.

Furthermore, the draft policy was put out for public consultation during summer for a duration of ten weeks. The public consultation closed on 16 September 2011.

On 12 October, a Stakeholder Consultative Workshop was organised by EFSA in Brussels with more than 140 participants. At the event, Commissioner Dalli expressed full support to EFSA's efforts on independence. Combining the outcome of the public consultation with the discussions held at the 12 October Stakeholder Consultative Workshop, overall EFSA received more than 110 comments from 32 organisations and individuals in total.

This report outlines the comments received during the public consultation and at the Workshop and the way they are addressed in the draft Policy. The draft Policy, amended accordingly, is submitted for discussion and possible adoption at the December 2011 meeting of EFSA's Management Board.

[2] Comparison between the tools ensuring EFSA's independent scientific advice and the instruments in use by organizations similar to EFSA, final report, February 2011.
[3] Independent report of factual findings in connection with the implementation of EFSA policy on Declarations of Interests in certain Scientific Panels.

1. Introduction

Combining the outcome of the public consultation held from 7 July to 16 September 2011 with the discussions held at the 12 October Stakeholder Consultative Workshop, where Commissioner Dalli expressed full support for EFSA's efforts, the Authority received in total more than 110 comments from 32 interested parties (individuals, nongovernmental organisations, industry sponsored organisations and trade associations, academia and national competent authorities) on its draft Policy on Independence and Scientific Decision Making Processes.

2. Screening and evaluation of the comments received

All submitted comments were compiled in a table with reference to the contributor and to the section of the draft Policy to which the comment referred (see Table 1 below). Comments submitted formally on behalf of an organisation appear with the name of the organisation. Comments submitted at the Consultative Worksop appear with the name of the person. All comments are addressed individually with a clear explanation of how they impacted on the revised text or of why they were rejected by EFSA.

Comments not related to the scope of the consultation are identified in the table as not relevant for this draft Policy. However, they were fed in the appropriate workflow and will be duly considered and addressed by the proper strategic document, such as EFSA's Science Strategy.

2.1. General comments

Several interested parties congratulated EFSA for its efforts in ensuring the independence of its scientific outputs, while some comments questioned the overall relevance and usefulness of the draft Policy albeit in rather general terms. When submitting specific criticism or suggestions, those comments were either incorporated in the revised text of the draft Policy or otherwise addressed.

There were also suggestions for editorial improvements and clarifications.

2.2. Specific comments

Although the full list of comments is only provided in Table 1 annexed hereto, a few of the most recurring themes deployed by several interested parties are summarised herein below.

- According to certain stakeholders, changes should be brought to the procedure of appointment and composition of members of EFSA's Management Board in order to involve interested parties in the process;
- Some interested parties recommended EFSA to implement mandatory cooling off periods, both for staff joining EFSA and for staff leaving the Authority;
- One contributor highlighted that EFSA should be more attentive in "outsourcing" scientific tasks to contractors, grant beneficiaries and external experts;
- Some stakeholders suggested that the rules and procedures regarding the selection of experts of Working Groups should be made more transparent and closer to those applicable to members of the Scientific Committee and Scientific Panels;
- Some contributors expressed their expectation that EFSA ensure the broadest base possible for documents and data supporting its scientific outputs;

- Some interested parties maintained that EFSA should perform constant and coherent reliability check of data gathered from Member States and interested parties;
- Some contributors argued that EFSA should ensure a closer involvement of nongovernmental organisations in its scientific activities, including their participation to plenaries of Panels and Scientific Committee or organisation of bilateral meetings between the Authority and applicants;

3. Incorporation of the relevant comments into the final text

EFSA's senior management with the specific support of its Legal and Regulatory Affairs Unit discussed the comments at several dedicated meetings. Many of the comments received were appropriate, of a high intellectual value and aimed at enhancing the quality and clarity of the document. These comments were taken into account and the draft Policy was revised where appropriate.

EFSA acknowledges the usefulness and quality of a large number of comments and would like to thank all interested parties for their efforts and contributions to its current and future work.

The way each comment has been addressed by EFSA is laid out in clear and concise terms in Table 1, below. The revised text of the draft Policy on Independence and Scientific Decision Making Processes is submitted to EFSA's Management Board for discussion and possible adoption at its December 2011 meeting.

Table 1: Table of public comments

1.CONTRIBUTOR	2. RELEVANT CHAPTER	3. CONTRIBUTION	4. EFSA's position
1. Introduction			
Corporate Europe Observatory	1. Introduction	Corporate Europe Observatory would like to submit some comments, without trying to be exhaustive, to the EFSA consultation on its draft "Policy on Independence and Scientific Decision Making Processes". As stressed in the introduction of this draft policy, "In fact, as shown in the Eurobarometer Survey Report on Science and Technology (2010)4 public concerns in relation to objectivity of scientific advice are widespread: 58% of Europeans have little confidence in scientists and scientific research because of the work they do with industry. Neither are regulators operating in the life sciences and food safety domains immune from criticism, most frequently in relation to genetically modified organisms (GMOs)." [21-25]. CEO however thinks this draft policy is fully inadequate to address these strong concerns, that are based on widely published information regarding EFSA experts with industry links, or the basic fact that most EFSA opinions are based on industry testing. It should therefore be fully revised.	This is a generic comment that questions in general terms the validity of the draft policy. Detailed comments submitted by CEO on specific points of the document are addressed below.
Testbiotech	1. Introduction	Final comments - conclusions (if necessary referenced to line 277-284): We strongly recommend this paper not be adopted. It is not based on a proper problem-solution approach nor can it be regarded as a consistent policy paper in itself; it reads for the most part like a paper for defending particular persons and current EFSA's standards and processes that have been criticised by various stakeholders. In conclusion it is not sufficient for giving guidance on how to safeguard EFSA's independence in future. We think a much more radical approach will be necessary to rebuild trust in EFSA. EFSA will need a restart first at the management level and secondly with its expert panels. EFSA has to face the fact that from the beginning there has been a lack of sufficient criteria and mechanisms for assuring its independence (from vested economic interests) and safeguarding its scientific standards. During the last few years, the management has not been able to successfully address significant weaknesses like the severe conflicts of interest within its expert panels. "Business as usual" is therefore not an option.	This is a generic comment that questions in general terms the validity of the draft Policy. Detailed comments submitted by Testbiotech on specific points of the documents are addressed below.

Testbiotech	1. Introduction	In the introduction much emphasis is placed on the "separation of science from policy". But this seems to be a misleading starting point for defining "a policy on independence" that aims at "rebuilding public confidence". First of all, the risk manager and risk assessor both contribute to the overall process of risk analysis. EFSA has to be seen as part of the overall process; it is an independent institution but cannot be seen as an isolated body. The risk manager has to deliver regulations concerning overall risk assessment policies, such as general standards for risk assessment, criteria for assuring independence, election of the management board and staff regulations. A sufficiently high quality in risk analysis and implementation of independence and transparency can only be achieved by strong cooperation between those two actors. But this EFSA paper more or less sets aside the role of the risk manager. Instead EFSA should have sorted out what the risk manager should do to support EFSA´s independence by defining appropriate regulations, processes and mechanisms. The current crisis in the credibility of EFSA is caused not only by the management of EFSA but also by the EU Commission not acting appropriately according to its responsibilities. Secondly, by giving so much emphasis to independence at the political level, the main crucial challenge is neglected - independence from economic interests that might impact the work of EFSA directly or indirectly. Indeed the issue of vested economic interests that can heavily impact any scientific decision-making process is not even explicitly mentioned in this paper. This major deficiency is likely to be a consequence of the lack of an adequate analysis of the problems involved in EFSA´s current situation. In general this paper lacks an analysis of strengths and weaknesses in EFSA's current work and the whole paper is not based on a problem-solution approach but simply aims at defending EFSA's current practice.	The founding regulation exactly aims at the separation between risk assessment and risk management and achieves it with the creation of an independent EFSA. EFSA's role is limited by law to providing scientific advice or scientific and technical assistance to EU Institutions or Member States. The draft policy does much more than defending current practices: it brings together in one comprehensive document all the policies already set in place and includes all the implementing rules concerning such issues as selection of experts, rules of procedure for the Scientific Committee and Scientific Panels staff procedures, the harmonisation of EFSA's assessment methodologies and risk assessment practices. It improves the Declarations of Interest pillar of the draft policy and goes further by proposing a few clarifications and improvements.
POT & PAN FOODSERVICE SA	1. Introduction	As there is no specific ISO standard for ensuring independence, I think that such one would contribute to further improvement. I also still believe that wider participation would add more value to the system.	EFSA is not aware of any ISO standards applicable for ensuring independence. However, it did take into account the 2007 OECD guidelines for managing on conflicts of interest in the public service.
Eurogroup for Animals	1. Introduction	Line 28 - Interested parties and the public do not need to be 'convinced', they need to be 'able to see for themselves' that decisions are sound.	EFSA will review the text accordingly.
Confederazione Nazionale Coldiretti	1. Introduction	Coldiretti welcomes the EFSA's initiative for a new policy on Independence and Scientific Decision Making Processes. In particular we appreciate the very honest and open starting point with reference made to the Eurobarometer survey and need to improve (perception of) independence and scientific decision making process. While agreeing with most parts of the documents, nonetheless we think a better focus could be required on: • the rationale, ie, exploring better what aspects could lead to 58% of EU citizens to mistrust the science-	EFSA will insert the additional references suggested and in 2012 will test the feasibility of opening up the Risk assessment process to observers from interested persons.

		industry governance of food safety. • the details of references made along the documents, which sometime seem left behind (quality system and procedures, measures to act independently, etc …) even if repealed. • additional EFSA's activities which could be covered by a new independence and transparency policy (including not only MB and Panels but also other critical moments of interplay with external factors, such as the SH fora etc.)	
7BEUC	1. Introduction	BEUC, the European consumer"s organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panellists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups are being given preferential treatment and could affect EFSA's work on ensuring transparency and independence.	In a 2010 benchmarking report commissioned by EFSA to assess the main features of other agencies' independence policies, EFSA's DoI Policy scores as the most comprehensive one. In an external audit commissioned in the same year, the contractor found a 1-2% of cases of inconsistent or wrong screening by EFSA staff. This does not mean that the screening of DoIs cannot be improved, but it shows that the scrutiny is already very strict. EFSA will clarify in the text the - so called - breach of trust procedure, which is triggered in case of omissions made by experts. EFSA commits to report annually on the implementation of its Policy on Independence as of 2012. EFSA is currently looking into the possibility of opening up the meetings of its Scientific Committee and Scientific Panels when horizontal matters are discussed. EFSA in 2012 will test the feasibility of opening up the Risk assessment process to observers from interested persons. The text will however be revised in order to clarify this aspect.

France Nature Environment	1. Introduction	All public consultations are in English. This exclude from the consultation many people who don't speak this language, which is only one of the official languages in EU. I will speak about the GMO panel of EFSA which is the one I know. Transparency is essential, but it is not the case with EFSA. EFSA does not respond to questions from NGO and even to written questions from members of European Parliament. When a response is finally provided by EFSA, it doesn't constitute a proper answer, but unrelated comments. About "high quality science", it is not enough to claim that. In fact, it is not the case, as all GMO files are not scientifically correct, but they are validated by EFSA. For instance, it is very well known that the statistical conditions do not allow to any conclusion, but the EFSA experts do conclude without scientific basis. Why? About immunogenicity, EFSA refers to "the weight of evidence", which is very "heavy" for an expression which means in fact that there is no scientific data from which infer a conclusion. This is not serious. Again: why? line 162: divergent positions: from my knowledge, this has happened only ONCE (about resistance genes to antibiotics). This meens that experts are chosen to be very homogeneous. In none other case in science there are so few divergences. Therefore, it is obvious that the panel is profoundly biased.	EFSA's language regime is regulated by a decision of the Executive Director which recognises English as the scientific working language of the Authority. Contrary to what the contributor maintains, pursuant to its Code of Good Administrative Behaviour, EFSA replies to all the requests it receives within a two months timeline from the receipt. Comments related to the assessments performed by the GMO Panel should be fed into the public consultations regularly performed by that Panel. line 162: For, what concerns the point on minority opinions, while it is true that minority opinions occur rarely, this has happened seven times in the past.
ILSI Europe aisbl	1. Introduction	We welcome the opportunity to comment on this document. Overall, we found the document of high quality. Line 12-13: "…the Authority has to be a point of reference of risk assessment in the food chain by virtue of its independence, the scientific and technical quality of the outputs it issues…" In line with what is said in the preceding line 11, and as we believe that independence is required for and subject to quality, we would like to suggest to change into "…the Authority has to be a point of reference of risk assessment in the food chain by virtue of the scientific and technical quality of the outputs it issues, its independence…" Line 27-28: "no matter what seems to be the right decision for those involved in the advisory process, it is essential that interested parties and the public at large are themselves convinced that decisions are sound" While recognising the importance of public perception, we would nevertheless like to argue that the primary function of government is to protect its citizens against real risks, not perceived risks. Consequently, risk assessment resources should be focused on real risk, whereas perceived risks should be addressed by education and communication. Line 68: "or is likely to be perceived as such by the public." While recognising the importance of public perception, we would nevertheless like to argue that the primary function of government is to protect its citizens against real conflicts of interest, not perceived conflicts of interest.	Line 12-13: EFSA will review the text accordingly. Line 27-28: perception is considered as fundamental by EFSA's founding regulation so EFSA cannot ignore this requirement in assessing interests. Line 68: see above.

M. Groenleer, Delft University of Technology	1. Introduction	On the assumed relationship between the separation of science from politics and rebuilding public confidence: Strengthening food safety through the separation of science from politics does not necessarily lead to increased public confidence. Instead of mutually reinforcing, they may sometimes even be conflicting or contradictory, which is also reflected in the continuing tension between risk assessment and risk management. The example of GMOs shows that, while on paper risk assessment and risk management may be clearly separated, in practice there is often no sharp distinction between science and politics. Science is not completely objective: when assessing risks scientists for instance take decisions on the use of particular methodologies and techniques, which potentially affect their conclusions. And even if science would be completely objective, politicians and the general public are not always willing to accept conclusions that only take into account purely scientific factors. So too much emphasis on the separation of science and politics might even be counterproductive from the agency's point of view, as it allows the Commission and the member states to distance themselves from EFSA and use it as a scapegoat. This, in turn, negatively affects the agency's reputation for independence and thus comes at the expense of public confidence in the agency in specific and the EU's food safety regime in general. Hence, the agency is now also answering, more broadly, concerns raised by national authorities and NGOs, if I have understood correctly. Rather than repeating the official rhetoric used upon the creation of EFSA, my suggestion would therefore be to acknowledge that science and politics cannot always be separated, and that this is often not desirable either, for the very reason that it sometimes comes at the expense of public confidence. Independent from whom? It would be useful to make a distinction in the draft policy between independence (or rather autonomy) from politics and from industry, or at least whenever referring to independence also make clear in respect of whom exactly. My point is that initiatives to safeguard the agency's independence from politics are likely to be different from those to safeguard the agency's independence from industry. The draft policy now primarily focuses on independence from one type of actor in the agency's environment, ie industry. What about the agency's independence from political actors, such as the Commission and the member states including the national authorities? See also my other comments.	The founding regulation aims at the separation between risk assessment and risk management and achieves it with the creation of an independent EFSA. EFSA's role is limited by law to providing scientific advice or scientific and technical assistance to EU Institutions or Member States. On the other hand, the concept of autonomy differs from that of independence, which has been identified by the Founding Regulation as one of the core values that the Authority should live up to.

M Groenleer, Delft University of Technology	1. Introduction	I very much support EFSA's efforts to come up with a policy on independence and am generally satisfied with what is already in the draft. My comments – which tend to be more general and thus often relate to more than one section of the draft policy - therefore focus on what in my perspective, which is an academic one, is missing. Of course, the proof of the policy is in its implementation and I am curious to learn more about how exactly implementation is going to be ensured. On the difference between independence and autonomy: A general remark to start off with. I prefer to use the term 'autonomy' instead of 'independence'. The terms 'autonomy' and 'independence' are often used interchangeably, as synonyms for the same concept. The term independence stresses the condition of being (politically) free. In contrast, the term autonomy emphasizes the capacity to manage one's own affairs. An agency is said to be fully autonomous when it is able to act independently of some or all of the groups that may constrain it. Fully autonomous (or independent) agencies can decide for themselves what to do instead of doing what others tell them to do. In reality, fully autonomous agencies of course do not exist. Agencies can never do exactly what they want. An autonomous agency is granted a level of autonomy by other actors or will attempt to ascertain a degree of control over its own affairs, but this does not mean that it is enjoying complete freedom, not subject to any external control, without constraints and restrictions, that it is, in fact, independent. Instead of referring to agencies as being fully autonomous or not at all, it is therefore more useful to describe them as more or less autonomous. Autonomy, in other words, is a matter of degree, varying across agencies and over time. Furthermore, whether agencies are considered autonomous highly depends on the environment in which they operate. Autonomy has different meanings within different socio-cultural settings and historical contexts; no objective criteria exist to qualify an agency as autonomous. Moreover, agencies are not autonomous by themselves. They are autonomous in relation to other actors in their environments. Agencies can be autonomous from a wide range of groups, both governmental and private or non-governmental. Autonomy thus is not only a continuous and a situational concept, it is also a relational concept. In that sense, the concept is highly suitable to apply to the case of (EU regulatory) agencies.	EFSA is bound by the legal framework applicable to it and to the concepts foreseen therein.

2. Why a policy on independence and scientific decision making processes?			
Corporate Europe Observatory	2. Why a policy on independence and scientific decision-making processes?	It should be noted that while EFSA says to be an independent body delivering scientific excellence, it is the EU institutions that give EFSA its mandates and finance their work. The EU institutions also deliver regulations concerning the overall risk assessment policies, general standards for risk assessment, criteria for assuring independence, election of the management board and staff regulations. New members of the Management Board are even selected from a short list drawn up by the European Commission; the EC itself is also represented on the Management Board. Therefore, it is also to an important extent the responsibility of the EU institutions to ensure radical change in EFSA's ways of working in order to guarantee food safety. The main goal of this policy should have been to make sure EFSA is independent from economical interests that might impact the work of EFSA directly or indirectly. This is what is at the root of much public concern as well. This is not at all addressed by this draft policy which we therefore find fully inadequate and should not be adopted.	EFSA's role is limited by law to providing scientific advice or scientific and technical assistance to EU Institutions or Member States. EFSA does not have the power to review its founding regulation.
Testbiotech	2. Why a policy on independence and scientific decision-making processes?	What is mostly missing under the heading of "Why a policy on independence and scientific decision-making processes? " is a proper "swot analysis" explicitly discussing the risks of vested economic interests" impact on EFSA's scientific decision-making process. In lacking a proper analysis of the recent crisis in EFSA´s credibility, the purpose of this paper becomes evident as being simply a tool to defend EFSA's position (and very likely also Mrs Banati herself and her close affiliations with the International Life Sciences Institute, ILSI, closely cooperating with industry). Without a proper analysis of the problems involved, the whole process of initiating the dialogue with stakeholders about EFSA's independence is in danger of becoming irrelevant. Issues that should be considered in this analysis are, for example, the several reports recently published clearly showing deficiencies in the independence of EFSA and its scientific decision-making process. Some examples: The move of Suzy Renckens from being head of EFSA´s GMO unit to biotech industry (http://www.testbiotech.org/en/node/316), the affiliation of the head of Management board Mrs Banati with ILSI (http://www.gmwatch.org/latest-listing/1-news-items/12527-efsa-chair-in-conflict-of-interest-scandal), and the affiliation of the chair of the GMO panel with ILSI (http://www.testbiotech.org/en/node/431). Further criticism was voiced concerning further conflict of interests within other EFSA units and panels. These publications lead to several discussions within the European Parliament, were picked up by media and are still an unsettled issue, contributing to the current crisis of EFSA´s credibility. So EFSA would indeed need a new policy to safeguard its independence, but this necessary process is counteracted by EFSA's attempt to defend its position and neglect the real problems and challenges within this draft policy paper.	EFSA's independence is not just about economic interests. Re. the proposal to have a SWOT analysis, the draft policy is the result of a large body of critical assessment, which has included a number of reviews undertaken by EFSA, internal and external audits, together with the experience gained in the implementation of our rules and procedures. The Comment regarding individual cases was addressed over the last two years in bilateral correspondence with Testbiotech. However, for what concerns comments submitted with reference to the Management Board, in accordance with a procedure foreseen in EFSA's Founding regulation Management Board members are appointed by the Council after consultation with the Parliament on the basis of a short list drawn up by the European Commission. EFSA plays no role. Management Board members act in the public interest and in accordance with EFSA's rules on DoIs, declarations of members of the Management Board are screened. In addition, members have voluntarily committed to a Code of conduct, which

			upholds core principles and values such as integrity, objectivity and serving in the public interest while providing guidance on standards expected by EU institutions and the general public. In September 2011, the Board adopted a revised version of its rules of procedure, which clarifies and strengthens even further the process for the screening of its members' DoIs. For what concerns criticism related to former EFSA staff, EFSA is implementing the rules of the Staff Regulations. Further, after having learnt some lessons from past cases, EFSA has adopted a strengthened framework decision for staff who leave EFSA, which better details the process and the steps that are to be followed. This has already been successfully implemented in one case, where EFSA imposed certain limitations to a staff member leaving EFSA. In addition, the DoI screening system similar to that adopted for experts has been extended also to staff members (ADs, CA FG IV and SNEs). This allows the Appointing authority to have at any time a complete picture of the interests of its staff, with a view to preventing the occurrence of a CoI.
Eurogroup for Animals	2. Why a policy on independence and scientific decision-making processes?	Line 39 - An 'unbiased' scientific decision is not possible if gaps in the scientific data are identified. This happened with food products from cloned animals and their offspring, when a scientific decision was made based upon available and therefore potentially 'biased' data. When this happens it needs to be acknowledged so the audience is clear if enough data is available for an unbiased decision to be made based upon scientific data or if assumptions have been made, and/or a decision is based upon available data. If a decision relies on available data then a process needs to be established for managing/reviewing decisions made on this basis.	Following good risk assessment practices, EFSA ensures it includes a statement about uncertainties in its opinions. Each of its opinions includes information about the data included and when necessary highlights limitations and the possible need for future research. This will be better reflected in the document and is thoroughly addressed in the EFSA draft Science Strategy.

Confederazione Nazionale Coldiretti	2. Why a policy on independence and scientific decision-making processes?	With regard to the scope (Paragraph 2, ll. 34-39, Par. 3), even if EFSA's foundations inside the Reg. 178 seems useful, it should be stated clearly if the present Policy (Guidance Document) stems from an initiative of the Management Board or from the Executive Directors. It could help to address the kind of reflections and thinking behind and the rationale. Also recovering a broader (time)frame of the discussion on the policy of independence and transparency may be helpful, including past sessions of the MB inside which dialogue on EFSA's policy took place and the main issues at stake; or particularly meaningful events which have been informative for organizational learning, including -allegations and conflicts with third parties media resonance of episodes interpreted as "lack of independence". A step by step analysis of the most salient of them could help supporting the major changes proposed inside the documents, and assess the relevance and pertinence of them with an eye on the "problem solving"capability of the action proposed via a virtual simulation "what if" ("what would have happened if this kind of policy/measures had been in place?"). Also a framework of EFSA step-wise improvements could be useful. Inside the SH platform was produced a Guidance for Public Consultation, which now allows for public scrutiny and motivation from EFSA in case of acceptance/rejection of the comments submitted from third parties.	Comment is unclear.
BEUC	2. Why a policy on independence and scientific decision-making processes?	BEUC, the European consumer's organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panellists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups are being given preferential treatment and could affect EFSA's work on ensuring transparency and independence.	In a 2010 benchmarking report commissioned by EFSA to assess the main features of other agencies' independence policies, EFSA's DoI Policy scores as the most comprehensive one. In an external audit commissioned in the same year, the contractor found a 1-2% of cases of inconsistent or wrong screening by EFSA staff. This does not mean that the screening of DoIs cannot be improved, but it shows that the scrutiny is already very strict. EFSA will clarify in the text the - so called - breach of trust procedure, which is triggered in case of omissions made by experts. EFSA commits to report annually on the implementation of its Policy on Independence as of 2012. EFSA is currently looking into the possibility of opening up the meetings of its Scientific Committee and scientific Panels when horizontal matters are discussed. In 2012, EFSA will test the feasibility of opening up the Risk assessment process to observers from interested persons. The text will be revised in order to clarify this aspect.

Food Standards Agency	2. Why a policy on independence and scientific decision-making processes?	Please note that our response to this consultation is a coordinated response and brings together comments from colleagues in the FSA and other UK government departments who work in areas of EFSA's remit, and from scientific advisory committees which advise the FSA. Overall we welcome this policy document which brings together current practice and operating procedures of EFSA in one document. In general, we feel the document sets out a sensible framework for independent scientific advice and emphasises the importance of science-based decision making, which we fully support. It would at the outset be useful to describe the breadth of science input to EFSA's work - in particular to refer to the importance of the social, as well as the natural and physical sciences, to informing EFSA's role in undertaking effective risk assessment and risk communication and ultimate aim of engendering consumer trust.	EFSA thanks the FSA and the other UK government departments who work in areas of EFSA's remit for their support to the policy.
one of the societies	2. Why a policy on independence and scientific decision-making processes?	Madam,Mister, I just heard about your plans on the Draft Policy measures, and read them. My studies were on cellular biology, and the affect of them on each type of cells. I understand in your project that European Union will allow the Food Industry to create some new chemistry and add them to our food without a single scientific opinion of an independent laboratory. I just want to remind what happened bout lot of chemical additives that used to be on the food market several years ago: 1:the growth hormon was such a dangerous product million of people had diseases with that! 2:DEHP is used for plastics, but it is forbidden to contamine food with it: we just had an example in China few days ago. There is much of this kind of examples, you should know them much as anybody. 3:aspartam seems to be the most enormous mistake governments made. This product is dangerous and no one turned back on its resolution [Does] anyone want to make this mistake go on and on? Your purpose is just the open gate to this kind of tragedy. Do you consider that Food industrialists are such trustworthy we can allow them to manage our health with their develop[ment]s? Which kind of public scandal haven't be[en] retained from all those diseases discovered and "accidentally" created in the XXth century? It seems like European people were some people with a good health, a large life expectancy. I consider that this kind of decision is dangerous for our children, for our parents, and even for the all society that made millenars to create. "Man is a wolf for man", your authority is here to protect man from himself. Be strong and represent the power people gave to you. Please reconsider your plans and help [E]uropean people to keep a good health, say no to plural food addi[t]tives, to "cocktail effects", to new products non available for eating. Thanks to take a real care about those words	These comments do not relate to the draft policy, which is the only subject to the public consultation.

3. EFSA's core values			
Corporate Europe Observatory	3. EFSA's core values	EFSA's core values are said to include "scientific excellence, openness, transparency and independence" [43]. We find it hard to see how scientific excellence and independence can be guaranteed in the current situation, where EFSA opinions are based on industry testing and are formed by panels that comprise many experts with ties to the same industry. Food safety should be guaranteed by independent testing (the burden of which should be borne by the company) and research, and by assessments done by independent experts.	The pillar of Declarations of interests of EFSA's draft policy on independence aims exactly at avoiding conflicts of interests. EFSA's Policy on Declarations of Interests which is in force since 2007, which will form the backbone of the future Implementing act on declarations of interest of the forthcoming policy, has been recognised as an effective tool to prevent CoI. In a 2010 benchmarking report commissioned by EFSA to assess the main features of other agencies' independence policies, EFSA's DoI Policy scores as the most comprehensive one. In an external audit commissioned in the same year, the contractor found a 1-2% of cases of inconsistent or wrong screening by EFSA staff. This does not mean that the screening of DoIs cannot be improved, but it shows that the scrutiny is already very strict. Regarding the suggestion of having industry paying for "independent" testing, it should be borne in mind that EFSA's role is limited by law to providing scientific advice or scientific and technical assistance to EU Institutions or Member States.

Testbiotech	3. EFSA's core values	Again, safeguarding EFSA´s independence from vested economic interests is not even mentioned as a crucial challenge or core value.	Safeguarding EFSA from vested economic interests is already part of the broader and multifaceted concept of independence. However, the text will be reviewed to make this even clearer.
Confederazione Nazionale Coldiretti	3. EFSA's core values	ll.46 With regard to the details of the document, we think that there are often very promising parts left undeveloped and somehow black boxed with respect to the possibility to reassure external publics on the kind of quality procedures in place to achieve independence and transparency. For example, at line 46 we know that "The Authority' core values are implemented by EFSA through a number of rules and procedures put in place over time". To have examples here could help (if not an exhaustive list of them). EFSA's activities related to independence and transparency can also be better detailed. EFSA activities do not end up in Panels and Management Board. In fact the most critical aspects of independence, transparency and quality of the process may arise from events that even if peripheral to EFSA' core assessment, allow for a wider interplay with stakeholders and selected publics (ie, applicants). No mention in the document is made about those. It could be useful to include them.	The rules of procedure referred to in general terms as a matter of fact are developed in much more detail in the following paragraph of the text. We therefore believe it is not necessary to elaborate further on that point. The same holds true for transparency and openness, which are addressed in § 7 of the Policy. EFSA is currently looking into the possibility of opening up the meetings of its Scientific Committee and Scientific Panels when horizontal matters are discussed. In 2012, EFSA will test the feasibility of opening up the Risk assessment process to observers from interested persons. The text will however be revised in order to clarify this aspect.
BEUC	3. EFSA's core values	BEUC, the European consumer's organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panellists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups	In a 2010 benchmarking report commissioned by EFSA to assess the main features of other agencies' independence policies, EFSA's DoI Policy scores as the most comprehensive one. In an external audit commissioned in the same year, the contractor found a 1-2% of cases of inconsistent or wrong screening by EFSA staff. This does not mean that the screening of DoIs cannot be improved, but it shows that the scrutiny is already very strict. EFSA will clarify in the text the so called breach of trust procedure, which is triggered in case of omissions made by experts. EFSA commits to report annually on the implementation of its Policy on Independence as of 2012.

		are being given preferential treatment and could affect EFSA's work on ensuring transparency and independence.	EFSA is currently looking into the possibility of opening up the meetings of its Scientific Committee and Scientific Panels when horizontal matters are discussed. In 2012, EFSA will test the feasibility of opening up the Risk assessment process to observers from interested persons. The text will however be revised in order to clarify this aspect.
FoodDrinkEurope	3. EFSA's core values	[After line 52] This principle of independence implies the independence from any external economic or political interests, but also from bias related to political, economic, social, philosophical, ethical, or any other non-scientific considerations. That being said, there is agreement that EFSA needs to have access to top quality science. Active top class scientists should not be automatically excluded from working with EFSA on the sole basis that they may have contacts with top scientific leaders in industry.	While this is true, as the aspects mentioned in the comment in question are subjective ones, it is impossible for EFSA from a practical point of view to consider these dimensions, unless they are reflected in an objective, traceable activity of the concerned person. The latter is part of the EFSA approach/DoI policy. This is why EFSA tries to have a balanced composition of its panels and working groups and frequently consults stakeholders. As regards the comment re. top class scientists, EFSA's draft policy recognises the principle that expertise comes with interests. Furthermore, as clarified in § 7,1, EFSA frequently uses its capacity to invite hearing experts to participate in discussions that require specialist knowledge, further broadening the scientific expertise at its disposal without directly influencing the scientific decision-making process. This allows the Authority to take stock of the data or expertise developed by industry, non-governmental organisations and other interested parties on newly developed practices, processes, substances and products.

University College Dublin	3. EFSA's core values	The Authority's core values are sometimes challenged when mandates are under negotiation because there is a perception that food safety is a food quality parameter and not a stand alone criterion that is a sine qua non for trade in food. This misclassification has to be guarded against both within and outwith the Authority. As an example see the EC's SCVMPH Opinion on Meat Inspection adopted 20-21 June 2001, a document that currently has been offered for consideration by EFSA Panels when addressing a number of mandates.	EFSA acknowledges the importance of differentiating food safety from food quality, which indeed is not related to EFSA's mission.
University College Dublin	3. EFSA's core values	EFSA's core values are sometimes challenged in the course of negotiation of mandates. There is a perception by those posing the question that food safety is one of a number of food quality parameters. This tendency has to be guarded against both within and outwith the Authority; otherwise the objectivity and primary function of the Authority is open to compromise. Food safety is a sine qua non for trade in food at every level and is not to be regarded or classified as another food quality "aspect" e.g. see Opinion of SCVMPH on meat inspection adopted 20-21 June 2001.	EFSA acknowledges the importance of differentiating food safety from food quality, which indeed is not related to EFSA's mission.

PAN Europe	3. EFSA's core values	• Realising high scientific standards? EFSA has a long way to go. EFSA is completely denying science produced by academic and independent scientists. So you could claim EFSA disregards science at large. Work is based entirely on industry-sponsored testing and it is questionable if you can call this science. As long as EFSA keeps on denying the entire scientific world, we think the EFSA claim of being a high ranking scientific institute is false. This basic mistake needs to be repaired urgently. Secondly looking at the panels, we see half of them being national civil servants, having published hardly anything in their life. The scientific level of panel opinions cannot be high if the panel is composed of people never seeing a laboratory from the inside, probably not following scientific progress in international journals, not visiting scientific meetings (beyond ILSI/SETAC-meetings) and not being used to deliver articles to peer-reviewed journals. This is a major handicap to the panels and probably also explains the reluctance to take 'real' science on board because they might not understand it. Assessing industry testing can be done in a more 'book-keeping' way by following the standard schemes of OECD and GLP administration. The second half of the panels is a mix of retired scientists, institute people who are probably looking for a profile to get contracts in the markets and hidden industry lobbyists. So generally the scientific output of EFSA cannot be but low, and might even be biased. If EFSA is serious in getting scientific top institute a radical change is needed. First of all scientists in the panels need to be paid because a 'real' scientist simply has no time because he/she is working in the laboratory, meet on symposia or working on fundraising. In the highly competitive world of science, you cannot spend time travelling to Parma without any revenues. Secondly, only real independent scientists should be allowed to the panels. It is not true that every scientist has links with companies. Enough scientists are available which do not have links to commercial parties, but they cannot work for free for EFSA. A quality criterion like a minimum of two peer-reviewed articles per year published (only original articles, no opinions, no reviews and no proposals/critics on risk assessment) should also be used to exclude non-publishing people. • Defend independent science and consider independent science to be of the highest level of reliability and quality. Independency of universities and institutes is threatened more and more by privatisation and market mechanisms. This makes it harder to find independent scientists and should make the scrutiny on interests stricter. At the same time EFSA is treating GLP-industry studies as those with the highest reliability (Klimisch ranking, see guidance on use of independent science). In this way EFSA is undermining independent science itself and self-destructing the aim of realising independence and high scientific levels. A big contradiction.	EFSA is not a research organisation, but rather an Union agency tasked with the provision of scientific advice and scientific and technical support to Union institutions and Member States. To accomplish its mission, EFSA relies on its scientific staff, national scientific organisations and institutes and independent experts. EFSA considers all scientific studies in its risk assessment processes. Study reliability must be judged solely on the basis of the study design and of the reproducibility of the findings reported. For example, EFSA's new guidance document for applicants seeking approval of active substances in pesticides makes clear that studies found in peer-reviewed open scientific literature should be considered. The composition of the Scientific Panels and Scientific Committee of EFSA derives from an open call for expression of interest aimed at selecting the best available scientific experts in the Panel's domains. In that context, every effort is made to secure an appropriate geographical and gender balance, taking into consideration issues such as the diversity of scientific expertise and disciplines.

4. Organisational governance			
Corporate Europe Observatory	4. Organisational governance	The management board should play a key role in guaranteeing the independence and soundness of EFSA opinions. Therefore, no industry influence should be allowed on the Management Board. [62-68] In March 2011, CEO wrote to EFSA and to Commissioner John Dalli to point out that four industry representatives were on the board. But according to EFSA's Founding Regulation, four of the 15 Management Board members "shall have their background in organisations representing consumers and other interests in the food chain". This means that there is at least one too many industry representatives (lobbyists) on the Management Board. EFSA has so far not taken action. Environmental organisations are also not represented on the board. In our letter, we highlight the fact that on its website, EFSA states that its board members "do not, in any way, represent a government, organisation or sector". Board members are appointed "intuitu personae" ("personal capacity") and "shall act in the public interest". It is not credible to claim that people employed by or otherwise directly linked with organisations with vested commercial interests, do not represent their employers or organisations, or to claim that they can be trusted to act in the public interest (rather than that of these organisations).	In accordance with a procedure foreseen in EFSA's Founding regulation Management Board members are appointed by the Council after consultation with the Parliament on the basis of a short list drawn up by the European Commission. EFSA plays no role. Management Board members act in the public interest and in accordance with EFSA's rules on DoIs, declarations of members of the Management Board are screened. In addition, members have voluntarily committed to a Code of conduct, which upholds core principles and values such as integrity, objectivity and serving in the public interest while providing guidance on standards expected by EU institutions and the general public. In September 2011, the Board adopted a revised version of its rules of procedure, which clarifies and strengthens even further the process for the screening of its members' DoIs. Furthermore, by law four members of the Board are from organisations "representing consumers and other interests in the food chain". Therefore it is by design that members of the Management Board have links with the food chain. They are selected for that very experience and expertise.

Euro Coop	4. Organisational governance	Lines 55 to 57: The separation of roles between risk management and risk assessment does not per se ensure that EFSA is free of any undue influence. Lines 65 to 72: Euro Coop strongly believes that it is of high importance to involve consumer representatives to an extensive degree in EFSA's Management Board. This would also help to reinforce European consumers' confidence in the European food safety policy. Euro Coop deems it is a key element to increase consumers' trust in EFSA's scientific opinions. Euro Coop would thus advice EFSA to support further involvement of civil society organisations in EFSA's Management Board such as in all stages of EFSA's activities. We appreciate EFSA's efforts in avoid any conflict of interest, but we still call for an accurate control of candidates to be appointed as part of EFSA's Management Board, as conflicts of interests happened even in the very recent past.	Lines 55 to 57: the draft policy does not claim that separation of risk assessment from risk management alone ensures that EFSA is independent. The draft policy ensures that other aspects such as social and economic ones are adequately handled by risk managers. Lines 65 to 72: in accordance with a procedure foreseen in EFSA's Founding regulation Management Board members are appointed by the Council after consultation with the Parliament on the basis of a short list drawn up by the European Commission. EFSA plays no role. Management Board members act in the public interest and in accordance with EFSA's rules on DoIs, declarations of members of the Management Board are screened. In addition, members have voluntarily committed to a Code of conduct, which upholds core principles and values such as integrity, objectivity and serving in the public interest while providing guidance on standards expected by EU institutions and the general public. In September 2011, the Board adopted a revised version of its rules of procedure, which clarifies and strengthens even further the process for the screening of its members' DoIs.

National Food Institute	4. Organisational governance	As the independent national risk assessment body of Denmark the National Food Institute has the following comments/questions to above mentioned document: A. Under the section 4 'Organizational governance' the texts seems to suggest that the functional separation of risk assessment and risk management is only effectuated at European level, i.e. not at national level. As we are aware that this functional separation also governs deliberations in a number of Member States, including Denmark, it would make sense if the text is revised to reflect this important state of affairs. Likewise the text in this section would seem to suggest that European risk assessment is performed only in EFSA. It would again be important if the text could reflect present reality, which is that basic scientific risk assessment work in Europe is performed primarily in Member States, while EFSA performs the important task of integrating and jointly evaluating such risk assessment data, permitting joint European scientific agreement in key areas. B. In section 9 'Organisational culture' the paper refers to the set of comprehensive EFSA rules and procedures for identifying and handling potential conflicts of interest. This procedure specifically states that earlier involvement in an opinion of a national authority may constitute a conflict of interest. The background for this principle is not clear. It should be noted that if the reciprocal situation was implemented a national panel member having been involved in risk assessment work for EFSA would not be entitled subsequently to engage in risk assessment work at national level, because of CoI. This outcome would presumably hinder the members states' experts participation in EFSA panels. Conflict of interest rules are typically implemented so that managers, stakeholders and society at large can be sure that undue influence is avoided when scientific risk assessment is developed. It would not seem clear – and would thus most likely be impossible to communicate – how the participation in previous scientific work regarding the question at hand would in itself constitute a conflict of interest? More specifically the implementation of these procedures would seem to result in a situation where Panel Members who participate in drafting opinions under EFSA contracts can potentially have a conflict of interest. The consequence of this will in some cases lead to situations where another expert in the Panel, who has not been involved in the assessment, would have to present the opinion at the Panel meeting, resulting in a sub-optimal use of resources, and in some cases a poor scientific outcome. Finally it would be interesting to have a clarification if earlier involvement in an opinion of an international authority may also constitute a conflict of interest? It is suggested to change this practice and have clear, concise and communicable procedures for implementation of these policies, avoiding listing previous scientific work per se as a potential for conflict of interest.	The text can be reviewed to better reflect the separation of Risk assessment from risk management at national level. It is not true that EFSA simply collates RA performed at national level. To the contrary, in addition to its networking tasks, EFSA regularly performs a high number of autonomous risk assessments, without any involvement of national competent authorities. For what concerns the comment on the assessment of previous involvement in a national authority, it should be borne in mind that in some specific instances it may be considered appropriate to consider that interest as a CoI, for instance when an expert from a national competent authority is called upon in EFSA to assess an opinion to whose development he or she has actively contributed.

Testbiotech	4. Organisational governance	With regard to the role and the composition of the management board, some major deficiencies are evident that should be analysed and discussed properly. If “rebuilding public confidence" in EFSA is to be enabled, the reorganisation and new constitution of the management board is of a high priority. Since the risk manager is involved in the election of the members of the management board this is an issue that needs close cooperation with the EU Commission and the Council. First of all, the management board should strictly be protected against direct and indirect influence by the food and agricultural industry. Further, the rules concerning the management board should be revised to make sure that this body can become a reliable element in the control of EFSA's independence. The board should be reorganised to represent a truly broad spectrum of relevant stakeholders and especially those institutions dealing with the interests of consumers and the protection of the environment (since EFSA is also dealing with issues of environmental risk assessment). It should be possible for relevant stakeholders such as consumer and environmental organisations to participate in the process of electing the board members by naming their own candidates and commenting on the others. The members of the management board selected by such a process would be much more likely to function as an "internal watch dog" responsible for selecting staff members and panel experts and other relevant decision-making.	In accordance with a procedure foreseen in EFSA’s Founding regulation Management Board members are appointed by the Council after consultation with the Parliament on the basis of a short list drawn up by the European Commission. EFSA plays no role. Management Board members act in the public interest and in accordance with EFSA’s rules on DoIs, declarations of members of the Management Board are screened. In addition, members have voluntarily committed to a Code of conduct, which upholds core principles and values such as integrity, objectivity and serving in the public interest while providing guidance on standards expected by EU institutions and the general public. In September 2011, the Board adopted a revised version of its rules of procedure, which clarifies and strengthens even further the process for the screening of its members' DoIs. Furthermore, by law four members of the Board are from organisations “representing consumers and other interests in the food chain”. Therefore it is by design that members of the Management Board have links with a particular food sector. They are selected for that very experience and expertise.
Anses	4. Organisational governance	We suggest to precise that there can have a separation between risk assessment and risk management at national level.	The text can be reviewed to better reflect the separation of risk assessment from risk management in some Member States.
Eurogroup for Animals	4. Organisational governance	line 57 - The word ‘political’ needs to be inserted between ‘undue influence’ lines 57-58 - Openness and transparency would be increased if some selected stakeholders would be allowed to attend all meetings as observers (see additional points below). If confidentiality is an issue then observers can be authorised in advance and sign agreements.	Line 57: the text can be revised accordingly.

		line 65 - Surely more that 4 out of 15 members should have a background in representing consumers and other interests in the food chain? To be fully open and transparent ideally the management board would have individuals with a broader range of backgrounds including animal welfare, veterinary and human medicine, environment.	Lines 57-58: EFSA is currently looking into the possibility of opening up the meetings of its Scientific Committee and Scientific Panels when horizontal matters are discussed. In 2012, EFSA will test the feasibility of opening up the Risk assessment process to observers from interested persons. The text will however be revised in order to clarify this aspect. Line 65: In accordance with a procedure foreseen in EFSA's Founding regulation Management Board members are appointed by the Council after consultation with the Parliament on the basis of a short list drawn up by the European Commission. EFSA plays no role. In addition, members have voluntarily committed to a Code of conduct, which upholds core principles and values such as integrity, objectivity and serving in the public interest while providing guidance on standards expected by EU institutions and the general public. In September 2011, the Board adopted a revised version of its rules of procedure, which clarifies and strengthens even further the process for the screening of its members' DoIs.
Confederazione Nazionale Coldiretti	4. Organisational governance	Coldiretti believes it could be really helpful to spend some lines to explain the new EFSA's organizational chart, and the rationale behind. Furthermore, how it complies with the policy on Independence and Scientific Decision Making. A detailed analysis on how panels have been displaced and transformed in their scope once assumed under new Directorates could improve clarity.	EFSA's organisational structure aims at the proper and efficient functioning of the organisation including the implementation of the core value of Independence.

BEUC	4. Organisational governance	BEUC, the European consumer's organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panelists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups are being given preferential treatment and could affect EFSA's work on ensuring transparency and independence.	In a 2010 benchmarking report commissioned by EFSA to assess the main features of other agencies' independence policies, EFSA's DoI Policy scores as the most comprehensive one. In an external audit commissioned in the same year, the contractor found a 1-2% of cases of inconsistent or wrong screening by EFSA staff. This does not mean that the screening of DoIs cannot be improved, but it shows that the scrutiny is already very strict. EFSA will clarify in the text the so called breach of trust procedure, which is triggered in case of omissions made by experts. EFSA commits to report annually on the implementation of its Policy on Independence as of 2012. EFSA is currently looking into the possibility of opening up the meetings of its Scientific Committee and Scientific Panels when horizontal matters are discussed. In 2012, EFSA will test the feasibility of opening up the Risk assessment process to observers from interested persons.. The text will however be revised in order to clarify this aspect.
Food Standards Agency	4. Organisational governance	Lines 54-60. This section asserts that functional separation of risk assessment and risk management and a responsibility for risk communication, in themselves, will engender trust in EFSA and its messages, as well as operating in an open and transparent manner. We would agree these are key foundation stones for this outcome, but it is felt that these assertions would be more compelling if it was possible to refer to independent research which would support this eg about how the communication has impacted on consumer/stakeholder behaviours/opinions. It is also important to recognise the value of combining information on risk assessment and risk management when communicating with the public. This section should also perhaps refer to the rigorous implementation of the various elements in this policy being a key part of aiming to ensure EFSA's advice is demonstrably free of undue influence. The overall impact of ensuring that food safety policy appropriately takes into account relevant science requires frequent and good communication between risk assessors and risk managers, which can be challenging, particularly in a European context where these functions are not in close proximity. It may be useful to include some text (perhaps in a separate section) describing how EFSA meets this challenge in the context of application of this policy, especially in situations where speed is of the essence. Lines 68-71: With regard to declaration of interest, it states that the Chair of the Management Board	Lines 54-60: While respecting EFSA's independence from Union risk managers, EFSA is fully committed to ongoing and systematic interaction with these, including DG SANCO. EFSA has put in place a series of mechanisms that ensure effective interaction with the Commission (bilateral meetings, systematic presence of Commission officials at EFSA meetings, presence of SANCO representative on EFSA's MB etc). Lines 68-71: The text will be revised to clarify the collegial responsibility of the Board in the screening of DoIs. In that respect in September 2011, the Board adopted a revised version of its rules of procedure, which clarifies and strengthens even further the process for the

		checks the Annual Declarations of Interest (ADoIs) of Board members. The policy could usefully make clear how the checking of the Chair's ADoI is undertaken.	screening of its members' DoIs.
FoodDrinkEurope	4. Organisational governance	After line 59: To enhance the quality of a scientific opinion, EFSA may require additional information from individuals, petitioners or other stakeholders for the completion of a scientific opinion. In such cases, in particular, for example, invited face-to-face meetings, consultations, or hearings might be necessary and should apply in compliance with the fundamental requirements of ensuring full independence and autonomy of EFSA's panels. It should not be assumed that the independence of EFSA need be compromised by such bilateral meetings and guidelines should be drawn up by EFSA so as to allow such engagement with stakeholders, including industry, to take place at the stakeholders request. In cases where an opinion is prepared in light of information submitted by a stakeholder in response to specific regulatory requirements EFSA should, when appropriate, seek comments from the applicant on a draft of the opinion, and submit those comments to the Panel before the adoption of the opinion.	After line 59: The suggested text is already foreseen in the following paragraphs, such as § 5.3. the paragraph on organisational governance discusses the internal structures of EFSA.
Federal Institute for Risk	4. Organisational governance	Line 55-59: This sentence explains that at European level risk assessment and risk management is separated, and risk assessment is task of EFSA, while risk management is task of the European Commission, Council, European Parliament and the Member States. This sentence might be misunderstood since it might suggest that Member States only conduct risk management. In a similar way as at the European supranational level, risk assessment and risk management is institutionally separated in many MS. Thus we kindly request clarification of this important issue in the EFSA policy document.	Lines 55-59: the text can be revised to clarify that the separation of risk assessment from risk management applies also in some Member States and that Member States also carry out risk assessments.

Delft University of Technology	4. Organisational governance	On the independence of the management board: Even though the absence of member state representation might have led to a lower level of politicisation compared to other agencies' management boards, posts in the board have rotated among members from different countries and, as far as I know, the large member states have always been part of the board through a board member. How does the agency avoid the impression that the nationality of board members, in spite of the fact that they are appointed in a personal capacity, may thus nonetheless to some extent affect board decisions? Board members have 'to act independently in the public interest'. What does this mean exactly? Clearly, "the" public interest does not exist. Has the agency operationalized this in more concrete detail? The absence of member state representation in the board seems to have increased the Commission's role. It appears that members often follow the Commission representative. The dominant position of the Commission within the board is of course not surprising, in view of its information lead, particularly on staffing and budgetary matters, and its technical know-how and given the board's obligation to ensure that the work programme is consistent with the Commission's priorities. Yet, one may ask how the agency avoids that one particular board member, be it the Commission representative or another board member, dominates the discussions in the board. Particularly in light of the above, it appears strange that '[f]or any matters linked to the independence of members of the Board, the Authority might consult the Commission'. This sentence requires some clarification. On the independence of the director: The draft policy remains silent on how the independence of EFSA's director is ensured, notably when it comes to staffing and budgeting. As the draft policy is very much focused on independence in terms of scientific activities, it underplays independence in terms of administrative and procedural activities. Although perhaps more indirectly than in the case of the agency's scientific activities, such independence is of crucial importance for the agency's reputation as an independent entity.	In accordance with a procedure foreseen in EFSA's Founding regulation Management Board members are appointed by the Council after consultation with the Parliament on the basis of a short list drawn up by the European Commission. EFSA plays no role. Management Board members act in the public interest and in accordance with EFSA's rules on DoIs, declarations of members of the Management Board are screened. In addition, members have voluntarily committed to a Code of conduct, which upholds core principles and values such as integrity, objectivity and serving in the public interest while providing guidance on standards expected by EU institutions and the general public. In September 2011, the Board adopted a revised version of its rules of procedure, which clarifies and strengthens even further the process for the screening of its members' DoIs. Furthermore, by law four members of the Board are from organisations "representing consumers and other interests in the food chain". Therefore it is by design that members of the Management Board have links with the food chain. They are selected for that very experience and expertise. Regarding the suggestion to better specify how administrative independence is ensured, we believe that this is already addressed by the paragraph on the institutional separation of EFSA from the Commission.
Chiara Tomalino, Eurocoop and Nina Holland, Corporate Europe Observatory	4, Organisational governance	(...) we would welcome the creation of a public body which could collect contributions from industry and from which the resources could then be shifted to EFSA. What we for sure would avoid is to have a direct relationship between service and a payment for the service.	EFSA's role is limited by law to providing scientific advice or scientific and technical assistance to EU Institutions or Member States.

5. Scientific decision making processes			
INRAN	5. Scientific decision-making processes	109 5.3 Information gathering: data from Member States, applicants and scientific literature I would suggest to add a reference to 1) systematically collecting results from European projects (in the past the FlairFlow project was implemented in the 4th framework programme and was operative until the 90s. Unfortunately now the project is not active - http://cordis.europa.eu/fair/src/results.htm 2) developing systematic literature review database both for white (several websites) and grey literature (www.greynet.org) 3) db on regulatory system 4) access to WHO, FAO and UN respositories 5) other European DB, like http://www.echim.org/docs/EXT2/pres2.pdf	The text can be revised to indicate that results from research projects funded by the EU, WHO or FAO are systematically taken into account. This matter is also addressed in EFSA's draft Science Strategy.
Corporate Europe Observatory	5. Scientific decision-making processes	The EU institutions should undertake a radical change in the general standards for risk assessment in order to remedy a fundamental flaw in the way EFSA judges food safety of products: it should not rely on (unpublished) industry tests studies to judge the safety of products. Instead of the food industry delivering its own studies (commissioned from its own labs or from external labs), industry money should be collected at arm's length by a publicly-controlled institution which would commission independent studies from independent and publicly-funded laboratories in Member States. EFSA should actively demand such change from the EU institutions. There are many more areas where EFSA should make radical changes in order to be truly independent and seen as such. For example, EFSA tends to overly rely on tests done according to so-called "good laboratory practice" (GLP) standards. EFSA was recently criticised by David Gee of the European Environment Agency for ignoring studies that are not GLP, saying that "GLP doesn't say anything about the quality of the science." Finally, in recent pesticide regulation 1107/2009 the EU decided "scientific peer-reviewed open literature" should be taken into account from now on. In its draft guideline for this provision, EFSA proposes "to let industry do the search and evaluation of the scientific literature and allow such narrow search-terms (basically only tests similar to standard industry tests) that it is clear academic science will keep on being denied." (PAN Europe). EFSA -with its core value of "scientific excellence" and "independence"- however should be fully open for scientific peer-reviewed literature.	EFSA's role is limited by law to providing scientific advice to EU Institutions or Member States and scientific and technical assistance to the European Commission. While EFSA can commission research, it should be considered that the burden of proof of submitting data proving the safety of the relevant substances or products has been put by the legislator on the applicant. The fact that GLP standards must be adhered for such dossier should not be confused with ignoring evidence that would have come from non GLP studies.

FEFANA asbl	5. Scientific decision-making processes	Line 116: Indeed, the fact that general good risk assessment practices and methodologies have been developed, helps avoiding a case-by-case approach that could otherwise be detrimental to the impartiality of the work of EFSA's scientific experts or the coherence of the scientific output. FEFANA members experience at present very inhomogeneous questions to application dossiers - maybe as a consequence of EFSA's outsourcing of evaluations to different third party experts / consultants. The way external experts are used is not transparent to the public and therefore there is an issue with the outsourcing. It is not known who is used as expert, these experts are not mentioned in the reports, and we are not able to monitor how the conflicts of interest are managed. For these reasons, FEFANA is calling for transparency in this context.	Line 116: In order to maximise resources and use the skill sets of its external contractors and EFSA experts optimally, EFSA awards grants and procurement contracts where applicable for preparatory work for its working groups which will evaluate the external work and make recommendations of their own before submitting to scientific panels for their consideration. It is worth noting that EFSA has already extended its DoI policy to include contractors and grant beneficiaries. For what concerns external experts, they are selected via a procedure that taking into account the fact that draft outputs prepared by working groups are discussed, amended and, when appropriate, adopted by Panels, corresponds to the same criteria used for the selection of members of the SC and SP. This will be clarified in the revised text of the draft Policy.
FEFANA asbl	5. Scientific decision-making processes	Line number 95: A significant share of EFSA's work is deriving from self-tasked mandates. FEFANA recognises the self-tasking as an important and useful feature. FEFANA has however the following remark: fundamentally, a self-tasked activity shall be restricted to the purely scientific field. There, it is appropriate. It should however not enter the field of Risk Management or regulatory matters as the borderline between Risk Assessment and Risk Management might then be blurred. Moreover, we see a need to underline that parties upon which the self-tasked activity has a potential impact, are involved in an adequate way. We therefore propose a regular and timely consultation (be it public or of the concerned stakeholders) in order to find out whether or not a self-tasked mandate is appropriate in a given situation, and for to receive external advice before the launch. Room for such a consultation would be there when the involved Scientific Panel or Working Group is proposing the self-tasking to the Executive Director. The Executive Director might then launch the consultation in advance of taking the decision on the approval of the self-tasked mandate. If this happens on a regular basis, the appropriate involvement of the concerned parties can be assured.	The text will be reviewed clarifying that approximately 5% of EFSA outputs (to date) are a result of self-task. However, EFSA agrees and confirms that self tasks do not look at regulatory or legal matters, as they concern scientific issues falling within each Panel or Committee's remit. Generally self-tasks concern guidance documents and are subject of public consultation. This matter is also addressed in EFSA's draft Science Strategy.

Sanofi	5. Scientific decision-making processes	5.Scientific decision-making processes [lines 80-125] Sanofi welcomes the EFSA's initiative for streamlining its scientific decision making processes. In particular we appreciate the development of standard methodologies to guide the work of its scientific committee, panels and staff. However we would welcome more details and explanations on the scientific considerations that lead to a decision. For an applicant seeking authorisation of substances, products or claims it is critical to well understand the specific regulatory requirements that are taken into account for the scientific decision. We consider that more regular communication between EFSA and the applicant during the development and the application review will improve the understanding of the regulatory requirements. Ultimately, this will stimulate the development of new products and claims addressing public health needs and food and feed safety. 5.4 Working groups [lines 120-125] Minutes of each working group meeting could be more informative especially on the draft position agreed by the panel. For example, in the minutes of the working group on claims, the discussion section is very short and does not provide any information on the claims discussed.	It should be borne in mind that this is a document on independence and scientific decision making processes, rather than an explanatory document re. EFSA's scientific workflows. As regards the interaction between applicants and EFSA, the Authority is committed to continue improving its interaction with interested parties, including applicants. This is why it has created an Application Desk Unit, which is meant to manage all questions related to the application assessment process from applicants, risk managers and other stakeholders. This may be further developed in the next few years should a cost recovery system be approved by the Union legislators. However, the procedures provided in the vertical legislation needs to be respected. EFSA is also committed to holding regular meetings with NGOs on issues such as GMOs. This will be further clarified in the document. Lines 120-125: EFSA is working on enhancing the informative level of minutes while balancing that with the need of protecting confidential data and information in accordance with the Union legislation.
National Food Institute	5. Scientific decision-making processes	As the independent national risk assessment body of Denmark the National Food Institute has the following comments/questions to above mentioned document: A. Under the section 4 'Organizational governance' the texts seems to suggest that the functional separation of risk assessment and risk management is only effectuated at European level, i.e. not at national level. As we are aware that this functional separation also governs deliberations in a number of Member States, including Denmark, it would make sense if the text is revised to reflect this important state of affairs. Likewise the text in this section would seem to suggest that European risk assessment is performed only in EFSA. It would again be important if the text could reflect present reality, which is that basic scientific risk assessment work in Europe is performed primarily in Member States, while EFSA performs the important task of integrating and jointly evaluating such risk assessment data, permitting	A. The text can be revised to clarify that the separation of risk assessment from risk management applies also in some Member States and that Member States also carry out risk assessments.

		joint European scientific agreement in key areas. B. In section 9 'Organisational culture' the paper refers to the set of comprehensive EFSA rules and procedures for identifying and handling potential conflicts of interest. This procedure specifically states that earlier involvement in an opinion of a national authority may constitute a conflict of interest. The background for this principle is not clear. It should be noted that if the reciprocal situation was implemented a national panel member having been involved in risk assessment work for EFSA would not be entitled subsequently to engage in risk assessment work at national level, because of CoI. This outcome would presumably hinder the members states' experts participation in EFSA panels. Conflict of interest rules are typically implemented so that managers, stakeholders and society at large can be sure that undue influence is avoided when scientific risk assessment is developed. It would not seem clear – and would thus most likely be impossible to communicate – how the participation in previous scientific work regarding the question at hand would in itself constitute a conflict of interest? More specifically the implementation of these procedures would seem to result in a situation where Panel Members who participate in drafting opinions under EFSA contracts can potentially have a conflict of interest. The consequence of this will in some cases lead to situations where another expert in the Panel, who has not been involved in the assessment, would have to present the opinion at the Panel meeting, resulting in a sub-optimal use of resources, and in some cases a poor scientific outcome. Finally it would be interesting to have a clarification if earlier involvement in an opinion of an international authority may also constitute a conflict of interest? It is suggested to change this practice and have clear, concise and communicable procedures for implementation of these policies, avoiding listing previous scientific work per se as a potential for conflict of interest.	B. For what concerns the comment on the assessment of previous involvement in a national authority, it should be borne in mind that in some specific instances it may be considered appropriate to consider that interest as a CoI when an expert from a NCA is called upon in EFSA to assess an opinion to whose development he or she has actively contributed.
Testbiotech	5. Scientific decision-making processes	In short at least three major problems can be identified in the current scientific decision-making process of EFSA that are related to the chapters 5-9: 1.There are no clear criteria / definitions for judging independence / conflict of interests of experts for panels or working groups. We do not think that the explanation given - "a candidate is not considered anymore 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" - does serve to clarify matters. There needs to be a list of clear criteria to exclude, for example, experts with affiliations to industry-like institutions such as ILSI. The process for selecting candidates for working groups and expert panels also needs to be improved. Participation of relevant institutions and organisations that can function as a "watch dog" representing the interests of consumers and the protection of the environment has to be enabled by reorganising the management board. 2.There is a substantial weakness in the Guidance for risk assessment, at least in the context of genetically engineered plants. The comparative risk assessment used is not suited for exploring the specific risks related to this technology. The Guidance is mostly justified by referring to	**1.** The criteria for the adoption of preventive or remedial actions will be set out in the single implementing decision on declarations of interests. The draft policy highlights the main principles that will govern that decision, in addition to clarifying that the implementing rules will build on the current DoI policy. **2.** This comment falls outside the subject matter of the present consultation. **3.** EFSA operates under the legal framework foreseen by the Union legislators. The creation of a referee panel for the inclusion or rejection of scientific evidence would deprive the Panels of much of their deliberative power.

		standards such as developed by the OECD and working groups of the FAO, without any consideration whether those are indeed fulfilling the requirements as foreseen by European regulations (which place a much stronger emphasis on the precautionary principle). So the international standards and bodies that are referenced by EFSA panels have to be assessed for their compliance with standards within the EU. A process of reviewing these standards should involve a broad range of independent experts and define higher standards for a comprehensive risk assessment. 3.During risk assessment, only a part of the available publications and findings are used to come to the final opinions; others are dismissed for several reasons. To be sure that standards such as GLP or OECD are not abused in dismissing relevant findings, a referee panel including a broad range of independent experts should be established for dealing case by case with the quality of publications that are taken into account or are dismissed by the expert panels. This referee panel should have the power to reintroduce relevant publications and findings that were already dismissed by the expert panels into the process of risk assessment again. The same mechanisms should apply concerning the comments of experts from Member States during the risk assessment of genetically engineered plants. So far only a small percentage of relevant comments by the experts of Member States is taken into account by the GMO panel and integrated in its final opinions. (also relevant for chapter 6,7,8,9)	

Eurogroup for Animals	5. Scientific decision-making processes	Section 5.1 - lines 95-97 - The possibility of self-tasking for EFSA is essential. It would be good to know what the general principles are on which a self-mandate is based and to establish a process for stakeholders to suggest topics to EFSA for self- mandates. Section 5.3 - lines 110-118 - We are very concerned about the way data is checked after collection, to ensure that the data received are reliable. Recent examples where official reports on the implementation of transport regulation must be provided to the European Commission have shown that data transmitted by Member States can be unreliable or incomplete. Data provided by Member States must be thoroughly checked before they are used, or EFSA's assessments could be based on misleading figures. Given that this report states the existence of an internal capacity in fields such as statistics it is essential that an internal, or external statistical expert(s) participates in all risk assessment processes to act in a QA capacity to validate all data upon which decisions are subsequently made. Section 5.4. - lines 119-125 - All stakeholders should be permitted to send an observer to attend working groups meetings. It is not clear from the document if this is allowed. In addition, the minutes that are currently published are not very informative about the content of the discussions and do not provide transparency to the process.	The points raised about data quality and quality assurance are very relevant even if they fall outside the scope of this document. They are addressed in the draft Science Strategy. Lines 119-125: EFSA is currently looking into the possibility of allowing the attendance of observers to its Scientific Committee and scientific Panels when horizontal matters are discussed. In 2012, EFSA will test the feasibility of opening up the Risk assessment process to observers from interested persons. This will be clarified in a revised version of the document.
Confederazione Nazionale Colduretti	5. Scientific decision-making processes	5.2 ll 107 While EFSA pretends avoiding case-by-case analysis and assessment as detrimental to a reliable and clear assessment, there are areas of work (ie, health claims) in which the case by case approach seems the milestone. Clarification on that is needed to gain an overall coherence. We believe that case-by-case analysis -if under a Guidance Document framework of reference- is in any case a base for risk assessment, and that individual characterization of the hazards needs a case-by-case analysis. For instance, the debate still going on Thresholds of Toxicological Concern (TTC) leans toward avoiding case-by-case assessment. We believe that to maintain Independence avoiding allegations of bias towards industry EFSA should carefully consider any departure from sound principles of risk assessment based either on ADI /NOAEL or MOE /BMDL principles.	Every assessment is done on a case-by-case basis. When a guidance document has been adopted, the competent Panel follows the approach outlined therein. This matter is also addressed in the draft EFSA Science Strategy.

Confederazione Nazionale Coldiretti	5. Scientific decision-making processes	5.1, ll. 83 97 In order to add clarity in front of the European citizens on EFSA's work, It could be helpful: • to explicit the level of self-tasking activities on the total. • To explicit the number of requests from the EC without private actors (applicants) behind • To explicit the number of assessments due to applications A formal guarantee that self tasking and public health responses cannot be overcome by private mandates could make sense. Or at least, to find some balance: a minimum numbers of self-tasking opinions as % on the total could be reasonably fixed in order to reflect independence. Furthermore, we note that in the document no reference is made about the still pending discussion on "fees" for applicants. Even if no conclusion has been reached, it could be relevant to include it in the debate, explaining what is going on. In particular, the new organizational chart poses great challenges with the formal separation between "commercial" Directorate (ie Regulated Products) and the Risk Assessment and Scientific Assistance. Since a new resources allocation is in place, a deeper explanation of the (possible) next moves could be done, enumerating the potential options at the time being and the virtual pros and cons of each one (fees, not fees, options for applicants having many requests, etc).	This draft document cannot be considered a comprehensive document providing all the background information for all EFSA activities. For facts and figures on EFSA scientific activities, please refer to the Authority's work programme, published on its website.
University of Tartu	5. Scientific decision-making processes	5.Scientific decision making processes 5.4. Working groups Lines 120- 125 It is not clear, e.g. kept timid, how many reviewers do investigate one particular project. From personal contacts with Panel scientists it has been known that due to the high workload of Panels only one person - here named as " RAPORTEUR of the working group presents the data which are thoroughly discussed, amended, endorsed by the working group." However, if the raporteur may make some mistakes (willingly, unwillingly) the Panel can't detect these and correct the statements offered by the raporteur even during the thorough discussions' in Panel. As a matter of fact, in the two rejections on probiotic bacteria of Estonia we detected fully wrong statements on the number of publications bound to the application of health claims. We have marked these in our Joint Comments to Mr. Basil Mathioudakis from March 11, 2011 Claim serial No: 0283_EE p. 3 and From May3, 2011 p.2, Claim ID 3025. Namely, in two separate cases the Raporteur did not find the Patented and printed issues on L. plantarum TENSIA and voluntarily dropped the papers of two clinical studies on L. fermentum ME- 3. The Panel took these false data as granted. Such a situation could not happen if there were more than one reviewer. This is the practice in EVERY evaluation Panel over EU: Why not in EFSA where so scientifically and economically hard decisions have been tried to compose. Please kindly correct the Procedure.	The use of a rapporteur to report on a preparatory work does not change the fact that the adoption of a scientific opinion is the result of a collective review and decision process. Regarding the specific case EFSA takes note of the comment, however no clarification is considered necessary on this point in the document.

BEUC	5. Scientific decision-making processes	BEUC, the European consumer's organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panellists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups are being given preferential treatment and could affect EFSA's work on ensuring transparency and independence.	See above
Federation of European Specialty Ingredients	5. Scientific decision-making processes	Lines 113 to 115: Concerned and impacted by the ongoing re-evaluation of already authorised food additives by the Panel on Food Additives and Nutrient Sources Added to Food (ANS), ELC members would suggest adding a reference to the case of data submission (i.e. unpublished studies, concentration levels) by stakeholders who are not necessarily 'applicants' per se, upon EFSA's requests. Besides in order to enhance the quality of the decision-making process from a scientific point of view, the ELC would suggest exploring which procedures, respecting EFSA's independence and confidentiality of information when applicable, could be put in place to avoid situations where the work of the EFSA Panel Working Group starts from an inaccurate basis by misinterpretation of the information delivered by industry: 1. At the time when all the data are collected, so that the data could be verified before the risk calculation is done. 2. At the end of the evaluation process, we would suggest that EFSA should give consideration to stakeholders having provided data and information by providing them an advanced copy in order to bring to the attention of EFSA factual inaccuracies when taking on board their contribution. Consideration could also be given to having an exchange of views with stakeholders when the exposure calculation raises concerns, before running the next tier.	Already today, EFSA regularly carries out public calls for data, in order to gather all the available and relevant scientific evidence. This is going to be reflected in a revised § 5.3. The second part of the comment falls outside the subject matter of the present consultation.

Food Standards Agency	5. Scientific decision-making processes	This provides a good overview of the processes involved. However, it would be useful to also include some text about how EFSA responds in relation to issues where speed is required in the context of meeting the overall objectives of this policy. The policy could also usefully include some discussion on how uncertainty is dealt with, both in terms of its acknowledgement and follow up action. In terms of approaches, mention could be made of how other aspects of scientific independence and quality control, such as related outputs from other risk assessment bodies and wider external peer review, contribute to the overall confidence in the independence of EFSA outputs. Section 5.2 – Development of methodologies Lines 102 -104: The policy currently points out EFSA's development of good risk assessment practices and methodologies to guide work of EFSA's Scientific Committee, Scientific Panels and its scientific staff, and there is a footnote which provides details of where more information can be found. It has been suggested that this section would benefit from being expanded a little to explain in more detail what the guidance is and how it can help to improve the scientific processes and standards eg how it compares to standard systematic review type approaches. Section 5.3 – Information gathering: data from Member States, applicants and scientific literature Should this section also specifically mention sources such as outputs from equivalent bodies from around the world eg WHO/FAO and how these are taken into account in EFSA's work. Line 110: More clarity is needed on the extent to which the policy of openness applies to data submitted by Member States. For example, there may be cases where data could be submitted to meet an EFSA deadline, before it has been possible to publish the data by a Member State. Member States should be able to flag up where data is considered to be sensitive, so that EFSA does not make it identifiable in the public domain until there is agreement to do so. Delaying submission of data until the evidence is published may mean missing an EFSA deadline, and this would be particularly anomalous if the data in question had originally been gathered in response to a call from EFSA. Lines 109-118: As referred to above, the importance of the social sciences could be highlighted more in this policy document, for example, in exploring food safety practices, particularly in light of EFSA's emphasis on risk communication and consumer trust. (The reference "Trust in Food" by Kjaernes, Harvey & Warde (based on comparative European research), is cited as demonstrating that sociological as well as technical issues are subject to wide variations across Europe.)	The scope of this consultation is limited to independence and related scientific decision making processes. However, these matters are rather fit in the draft EFSA Science Strategy.
FoodDrinkEurope	5. Scientific decision-making processes	After line 106: We appreciate the high standards of scientific processes and standards followed by EFSA used to develop good risk assessment practices and methodologies. Could the Policy also include provisions to ensure that such risk assessment practices and methodologies are executed in a harmonized and consistent way?	The scope of the draft policy is limited to ensuring the appropriate framework for ensuring EFSA's independence. It cannot be considered a Science Strategy or a comprehensive document providing all the background information for all EFSA activities. However, these matters are addressed in the draft EFSA Science Strategy.
University College	5. Scientific decision-making processes	The Authority's core values are sometimes challenged when mandates are under negotiation because there is a perception that food safety is a food quality parameter and not a stand alone criterion that is a sine qua non for trade in food. This misclassification has to be guarded against both within and outwith the Authority. As an example see the EC's SCVMPH Opinion on Meat Inspection adopted 20-21 June 2001, a document that currently has	EFSA acknowledges the importance of differentiating food safety from food quality, which indeed is not related to EFSA's mission.

		been offered for consideration by EFSA Panels when addressing a number of mandates. EFSA's core values are sometimes challenged in the course of negotiation of mandates. There is a perception by those posing the question that food safety is one of a number of food quality parameters. This tendency has to be guarded against both within and outwith the Authority; otherwise the objectivity and primary function of the Authority is open to compromise. Food safety is a sine qua non for trade in food at every level and is not to be regarded or classified as another food quality "aspect" e.g. see Opinion of SCVMPH on meat inspection adopted 20-21 June 2001.	
C. R.I.S.K. Consultancy	5. Scientific decision-making processes	Re: Sec. 5.3: Founding Reg. Art. 33 is not explicit, but if you do desire that scientific data be "fit for purpose" (lines 117-8), you cannot deny the logic that you must gather ALL available scientific data on an issue. Additionally you have some mandates to do exactly that, e.g. the new pesticide regulation (REACH also mandates that). So please state in this guiding policy statement that EFSA will always search for all relevant information on an issue before it, including (explicitly) the independent published scientific literature (always simply found in one database, PubMed). In evaluating the quality of the data, you must explain why the PPP mandate to collect it all does not imply that each study's quality should be evaluated. Instead, you simply declared any study not meeting a very narrow quality standard (e.g. Klimisch score, featuring OECD Guideline & GLP. All such studies that you accept as high quality in fact have a massive design flaw, the party with huge pots of money to make in it being declared safe enough to use gets to do the safety studies, including the key NOAEL setting study. These studies have other massive flaws, including only testing a tiny portion of the D/R curve; and killing the animals before they have a chance to develop hardly any disease that may have been induced. In sum, please make it clear that you will always both collect, and fully analyze, all available scientific data on a question, instead of grossly and with bias throwing out data when the EU forces you to collect it. Looking competently at all data is after all is why you were created!	The scope of the draft policy is limited to ensuring the appropriate framework for ensuring EFSA's independence. It cannot be considered a Science Strategy or a comprehensive document providing all the background information for all EFSA activities.
Robert Ollinson, independent consultant on food issues	5. Scientific decision-making processes	A very important difference is that once an opinion is published, it's published. What you need to have in the process is a process whereby the draft opinion can be scrutinised by independent science. I've spoken to an awful lot of independent scientists who are very frustrated about this, who would get involved, who would like to get involved, but they're not in a position to because they're not on the panel. So, if you could look at ways of opening that up to the wider scrutiny, which only goes along with the normal peer review process, then I think you would be overcoming an awful lot of problems.	EFSA is committed to engaging in a continuous dialogue with its interested parties to constantly improve its scientific outputs. This is already reflected in the current document. EFSA is currently looking into the possibility of opening up the meetings of its Scientific Committee and Scientific Panels when horizontal matters are discussed. In 2012, EFSA will test the feasibility of opening up the Risk assessment process to observers from interested persons. The text will however be revised in order to clarify this aspect and to link this to quality control.

Didier Yance	5. Scientific decision-making processes	When the risk assessment methodology are established, and that's maybe an area we should invest more dialogue and more effort. Once the methodology is there most of the people will behave in a fair way.	EFSA is committed to engaging in a continuous dialogue with its interested parties to constantly improve its scientific outputs. This is already reflected in the current document. EFSA is currently looking into the possibility of opening up the meetings of its Scientific Committee and Scientific Panels when horizontal matters are discussed. In 2012, EFSA will test the feasibility of opening up the Risk assessment process to observers from interested persons. The text will however be revised in order to clarify this aspect and to link this to quality control.
Nina Holland, Corporate Europe Observatory	5. Scientific decision-making processes	What we think should be changed is that there should be a strong conflict of interest policy, EFSA should proactively go out and call for independent scientists to join the EFSA panels and not just wait and see who replies to the call of interest (...)	This has been indeed an ongoing practice at EFSA for a few years. When it publishes a call for expression of interest for membership of its SC and SP, EFSA also proactively disseminates this information and tries to trigger as many qualified applications as possible.
6. EFSA's Scientific Committee and Panels			
Euro Coop	6. EFSA's Scientific Committee and Panels	Lines 133-135: As regards the composition of the Scientific Committee and Scientific Panels, Euro Coop very much welcomes the acknowledge from EFSA of the importance of guaranteeing the diversity of scientific expertise and disciplines. Euro Coop indeed considers that the effective application of this principle is essential to provide high-quality independent scientific advice.	No need to make changes in the draft policy.

Sanofi	6. EFSA's Scientific Committee and Panels	6.1 Selection of experts [lines136-146] Access to EFSA's external expert database is currently restricted to the agency, member states, EEA/EFTA countries and the European Commission with their declaration of interests only accessible to EFSA (see EFSA's document on the selection of scientific experts, p.10 http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf). To enhance transparency, we propose that this information is posted on EFSA website or could be available to stakeholders on request.	EFSA will explore the feasibility of this suggestion, but there are data protection issues which may prove problematic to overcome concerning the sharing of personal data. The text will not be revised.
National Food Institute	6. EFSA's Scientific Committee and Panels	Further comments from the National Food Institute: C. Section 6 .1 'Selection of experts' presents a clear and transparent procedure for the selection of experts for EFSA's Scientific Committee and Scientific Panels. However, there would not seem to be similar clear and transparent procedures for the selection of experts for working groups. It would be interesting to have this discrepancy explained, or maybe simply describe a transparent selection process for working group members also. D. Since EFSA, the European Commission and Member States all have an interest in the coordination of international food safety work, as pertains both risk assessment and risk management, it would seem remiss to not include in a paper of this nature a mention of the need for further international collaboration, also in relation to conflict of interest rules. More specifically a number of FAO/WHO risk assessment bodies would seem to operate under conflict of interest rules described in the UN system. Would it make sense for an EFSA policy paper to in some way acknowledge the need and potential for further international coordination also in this area? Best regards, Jørgen Schlundt Deputy Director	C. For, what concerns external experts, they are selected via a procedure that taking into account the fact that draft outputs prepared by working groups are discussed, amended and, when appropriate, adopted by Panels, corresponds to the same criteria used for the selection of members of the SC and SP. This will be clarified in the revised text of the draft Policy. D. The text will be revised clarifying that international cooperation will be sought in the field of conflict of interest and independence and that benchmarking with international bodies and partners will be maintained.

National Food Institute	6. EFSA's Scientific Committee and Panels	As the independent national risk assessment body of Denmark the National Food Institute has the following comments/questions to above mentioned document: A. Under the section 4 'Organizational governance' the texts seems to suggest that the functional separation of risk assessment and risk management is only effectuated at European level, i.e. not at national level. As we are aware that this functional separation also governs deliberations in a number of Member States, including Denmark, it would make sense if the text is revised to reflect this important state of affairs. Likewise the text in this section would seem to suggest that European risk assessment is performed only in EFSA. It would again be important if the text could reflect present reality, which is that basic scientific risk assessment work in Europe is performed primarily in Member States, while EFSA performs the important task of integrating and jointly evaluating such risk assessment data, permitting joint European scientific agreement in key areas. B. In section 9 'Organisational culture' the paper refers to the set of comprehensive EFSA rules and procedures for identifying and handling potential conflicts of interest. This procedure specifically states that earlier involvement in an opinion of a national authority may constitute a conflict of interest. The background for this principle is not clear. It should be noted that if the reciprocal situation was implemented a national panel member having been involved in risk assessment work for EFSA would not be entitled subsequently to engage in risk assessment work at national level, because of CoI. This outcome would presumably hinder the members states' experts participation in EFSA panels. Conflict of interest rules are typically implemented so that managers, stakeholders and society at large can be sure that undue influence is avoided when scientific risk assessment is developed. It would not seem clear – and would thus most likely be impossible to communicate – how the participation in previous scientific work regarding the question at hand would in itself constitute a conflict of interest? More specifically the implementation of these procedures would seem to result in a situation where Panel Members who participate in drafting opinions under EFSA contracts can potentially have a conflict of interest. The consequence of this will in some cases lead to situations where another expert in the Panel, who has not been involved in the assessment, would have to present the opinion at the Panel meeting, resulting in a sub-optimal use of resources, and in some cases a poor scientific outcome. Finally it would be interesting to have a clarification if earlier involvement in an opinion of an international authority may also constitute a conflict of interest? It is suggested to change this practice and have clear, concise and communicable procedures for implementation of these policies, avoiding listing previous scientific work per se as a potential for conflict of interest.	A. The text can be revised to clarify that the separation of risk assessment from risk management applies also in some Member States and that Member States also carry out risk assessments. B. For, what concerns the comment on the assessment of previous involvement in a national authority, it should be borne in mind that in some specific instances it may be considered appropriate to consider that interest as a CoI, for instance when an expert from a NCA is called upon in EFSA to assess an opinion to whose development he or she has actively contributed.
Testbiotech	6. EFSA's Scientific Committee and Panels	See chapter 5	See above

Anses	6. EFSA's Scientific Committee and Panels	It could be appropriate to precise the selection criteria and procedure for the experts working in the EFSA WG.	For, what concerns external experts, they are selected via a procedure that taking into account the fact that draft outputs prepared by working groups are discussed, amended and, when appropriate, adopted by Panels, corresponds to the same criteria used for the selection of members of the SC and SP. This will be clarified in the revised text of the draft Policy.
Eurogroup for Animals	6. EFSA's Scientific Committee and Panels	Section 6.2. - lines 152-154 - EFSA does not currently 'prevent any form of bias of its output.' See point above about making a decision based upon available and potentially 'biased' data. Section 6.3. - line 156 - If EFSA committees, panels and working groups are purely populated by scientists this in itself introduces a bias to the decisions. A mix of individuals with scientific, veterinary and/or medical backgrounds would be more appropriate given EFSA's remit.	Lines 152-154: See above Line 156: This is already the case now, as EFSA's interpretation of the term "scientist" includes also veterinarians, food technologists, statisticians, medical professionals, etc. The text will however be revised in order to clarify this aspect.
Confederazione Nazionale Coldiretti	6. EFSA's Scientific Committee and Panels	Par. 6.3 Collegial decision making We think that could really be helpful for a wider EFSA's acceptance in front of the external public to open up sometime some panels to observers. This proposal was formerly advanced by the EFSA's Legal Office. We think there are enough international successful cases in many agencies on that to speed up the implementation of that policy	EFSA is currently looking into the possibility of opening up the meetings of its Scientific Committee and Scientific Panels when horizontal matters are discussed. In 2012, EFSA will test the feasibility of opening up the Risk assessment process to observers from interested persons. The text will however be revised in order to clarify this aspect.
Confederazione Nazionale Coldiretti	6. EFSA's Scientific Committee and Panels	6.1, ll. 142-145 . Coldiretti welcomes the new ESS (Expert Selection System) and linked new electronic format of Declaration of Interests. In fact, it can be really helpful in tracking along time and over years potential conflict of interests which can raise prejudices on the EFSA's independence.	No need to make changes in the draft policy.

BEUC	6. EFSA's Scientific Committee and Panels	BEUC, the European consumer's organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panellists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups are being given preferential treatment and could affect EFSA's work on ensuring transparency and independence.	See above
ILSI Europe aisbl	6. EFSA's Scientific Committee and Panels	Line 137-139: "Public-private partnerships are an established feature of research in the EU and worldwide and hence many of the scientific experts who contribute to EFSA will inevitably have links with the private sector." In our opinion, this statement does not adequately reflect the importance of public-private partnerships. We therefore would like to propose the following change to the text cited above: "Public-private partnerships are an established feature of research in the EU and worldwide. They greatly stimulate innovation (e.g. OECD 2004) and thereby human progress. Also, public-private partnerships are a key element in the 'fifth freedom' (free circulation of researchers, knowledge and technology) that should stimulate European competitiveness as outlined in the vision for the European Research Area (European Council, 2008). Hence, many of the scientific experts who contribute to EFSA will inevitably have links with the private sector." European Council (2008) Council conclusions on the definition of a "2020 Vision for the European Research Area" (http://register.consilium.europa.eu/pdf/en/08/st16/st16767.en08.pdf). OECD (2004) Public-private partnerships for research and innovation: an evaluation of the Dutch experience (http://www.oecd.org/dataoecd/49/18/25717044.pdf).	As this comment is in line with the overall Union policy on research, the text will be revised accordingly.

Food Standards Agency	6. EFSA's Scientific Committee and Panels	There is broad support for the independence of scientific experts championed by EFSA both in the way that experts are recruited to EFSA's Scientific Panels and the proportionate and pragmatic approach to potential conflicts of interest.	No need to make changes in the draft policy.
FoodDrinkEurope	6. EFSA's Scientific Committee and Panels	After line 158: Are there general rules established for the decision making process to adopt the output of the Scientific Committee, Scientific Panels and Working Groups (eg. How is a consensus reached, when is a majority decision taken...).	Those rules are foreseen in the rules of procedure of EFSA's scientific committee, scientific panels and their working groups, as clarified in § 6.2 of the document. However, as the scope of the document is limited to independence, the text will not be revised.
Federal Institute for Risk	6. EFSA's Scientific Committee and Panels	Line 130-135: While the selection procedure for EFSA's Scientific Committee and Scientific Panels is laid out in detail, this section provides no information regarding the selection of experts for the working groups. As the working groups carry out the basic work for the risk assessments of the Scientific Committee and the panels, a transparent selection process for the working group members might be necessary and is strongly recommended. Therefore a reference with regard to the selection of working group members in this chapter might be useful.	For what concerns external experts, they are selected via a procedure that taking into account the fact that draft outputs prepared by working groups are discussed, amended and, when appropriate, adopted by Panels, corresponds to the same criteria used for the selection of members of the SC and SP. This will be clarified in the revised text of the draft Policy.
ADAS UK Ltd	6. EFSA's Scientific Committee and Panels	Line 136: In addition to using experts from academia and research organisations, EFSA should explore the feasibility of making greater use of experts working in the commercial sector. Many of these are highly qualified individuals involved in the practical application of science, and their participation in Panels and Working Groups would enhance EFSA's risk assessment process. Potential problems associated with conflicts of interest can be avoided through the DoI process.	EFSA tries to gather all relevant scientific views through its meetings with hearing experts, who are invited to present their views to the scientific meetings irrespective of CoI. However, they do not become members of the SC/SP and cannot be involved in the drafting of EFSA's output. The text will be revised accordingly.

Delft University of Technology	6. EFSA's Scientific Committee and Panels	EFSA's committee, panels and working groups are collegial bodies, yet experts may adopt a minority opinion. As far as I know, the experience also in other agencies is that this rarely happens. The question is whether this is because deliberation has led to consensus among experts or whether consensus is forced upon experts. How does the agency ensure the former, while avoiding the latter? A key question underlying the scientific decision-making process is what criteria are used. Only scientific or also non-scientific (which are not necessarily political) criteria? Different from other agencies, notably EMA, where national authorities are represented in the board and their experts are involved in the assessment work, EFSA does not co-opt the national authorities in its managerial or scientific decision making structures (the Advisory Forum is merely consultative). How then does the agency involve national authorities and make sure their concerns are heard, whilst not compromising its independence?	This document is about EFSA's policy on independence and does not provide a detailed overview of all the processes and workflows enacted by the Authority. In its deliberations, only scientific criteria are used, and national authorities are regularly consulted via dedicated *fora* or networks and networking activities.
PAN Europe	6. EFSA's Scientific Committee and Panels	• ILSI, SETAC, etc. do not allow people who are heavily involved in industry lobby clubs to be represented in EFSA. On European level the organisations threatening independent science most are the many industrial "NGO's" like ILSI, ECETOC, SETAC etc. who are fully industry-sponsored and are no more than industrial lobby clubs. EFSA should keep full distance [from] these organisations. The EFSA meeting on genotoxic carcinogens sponsored by ILSI in November 2005 for instance was a big mistake and threatens EFSA's impartiality. This should never happen again. ILSI is restricted of access to WHO because ILSI	This is a public consultation on a draft policy document. No discussion of specific cases is allowed in this context.

		'has a demonstrated history of putting the interests of its exclusively corporate membership ahead of science and health concerns' (http://www.powerbase.info/index.php/ILSI). People who are heavily involved in these lobby-lubs like Alan Boobis who was even in Board of ILSI, and who is in EFSA panels and others like Harry Kuiper (GMO-panel), Angelo Moretto (PPR-panel formally), John Christian Larsen and Gerrit Speijers (ANS-panel), should never be allowed to participate as a neutral scientist. Reports published by CEO, EOS and Testbiotech should have alarmed EFSA. Being prominent in ILSI and similar means you are happy to endorse industrial campaigns on lowering safety factors, eliminating data requirements and opposing hazard approaches. If you would do a simple Science Direct-search for Boobis, you would see that his last 20 articles are mainly ILSI-opinions (no real science but largely proposals for deleting tests and reducing costs for industry) most likely written by ILSI staff and Boobis functioning as ghost writer to make it look independent given his 'flag' of university professor. Independence is the victim if you allow these people in EFSA panels. It is very remarkable to see that the one from EFSA responsible for this very consultation (Banati) was at the European Board of directors of ILSI. • Do not allow people in EFSA's panels from institutes/universities who have contracts or grants of any pesticide producer or intermediate to a pesticide producer, nor commission work to people of these institutes. Many institutes and universities are forced to get money from the market given the reduced grants available from governments. They turn to companies and loose their independence. It is widely known if you are commissioned to do a study for industry, an unfavourable outcome is not appreciated very much by the contractors and the automatic search for an alternative outcomes starts. If you start compromising, you loose your independence. We see for instance Institute ALTERRA getting parts of their work paid by industry while at the same time they work for Dutch pesticide authority CTbG and are part of EFSA's panels like in the case of Theo Brock. ALTERRA was also heavily involved in higher tier risk assessment methodologies HARAP and CLASSIC, sponsored by industry. These methodologies are part of European guidelines. If you want to get to a full independence, these links should prevent anyone being member of an EFSA panel. Any financial link between an institute and a commercial party is corrupting science. The policy of industrial spin doctors of course is get full grip on science (see book "Doubt is their products, Michaels, 2008) and eliminate independence.	Already today in the context of EFSA's policy on DoI experts who have been employed by a certain company or have provided advice to that company are automatically barred from participating to discussions on a product from that company. The text however will not be revised as this kind of detailed rules will be specified in the single implementing document on DoI.

7. Other elements of quality assurance			
Euro Coop	7. Other elements of quality assurance	Line 168: Euro Coop very much supports the objective of strengthening the dialogue with the civil society. Euro Coop welcomes the efforts to regularly consult and meet interested parties on key issues. Euro Coop indeed believes it is a key priority that should be supported further in order to guarantee a fair balancing of interests. Line 185: Euro Coop considers that guaranteeing full transparency of EFSA' scientific decision-making process is fundamental. Euro Coop would thus suggest EFSA to allow European citizens to access all documents supporting the scientific decision-making process, including the scientific advices which might be the most sensitive.	Line 185: EFSA has been doing this for years. All non-confidential supporting documents are either proactively published in EFSA's Register of Questions or are accessible upon request. In addition, EFSA has just created an Application Desk as a front office and support desk for applicants, Member States and other stakeholders who have questions regarding applications. In the future, it will also be responsible within EFSA for centralising and processing the initial administrative steps of all applications. This is clarified in § 7.2.
Sanofi	7. Other elements of quality assurance	7.1 Consultation: scientific experts from Member States, civil society, interested parties and partners [lines 167-183] Sanofi considers that a close collaboration with the European Commission and SANCO related agencies is critical for shaping a transparent and predictable regulatory framework and harmonized scientific decision making process in the field of food, health animal and plants-related work. We will welcome more regular interactions between these EU bodies and that a workplan of the activities undertaken under this collaboration be made public with outcome of the discussions.	Lines 167-183: While respecting EFSA's independence from Union risk managers, EFSA is fully committed to ongoing and systematic interaction with these, including DG SANCO. EFSA has put in place a series of arrangements that ensure effective interaction with the Commission (bilateral meetings, systematic presence of Commission officials at EFSA meetings, presence of SANCO representative on EFSA's MB etc).
Testbiotech	7. Other elements of quality assurance	See chapter 5	See above
Eurogroup for Animals	7. Other elements of quality assurance	Section 7.1. lines 167-174 - It is not clear who "partners" are and how networks are formed and used. It would be good to add a reference to EFSA's webpage on existing networks. It would be good for transparency reasons to also publish the annual workplans of these networks. line 178 - The term "hearing" experts might be confusing, especially when they are invited to participate in	Lines 167-174: The reference to the EFSA webpage on networks will be included in the revised text.

		discussions. It is not clear from this section of the document to which meetings these experts are invited, who selects them and on what basis. This should be clarified, as should the statement that 'they are invited to participate in discussions...without directly influencing the scientific decision making process.' lines 182-183 - Inviting stakeholder experts to technical meetings or workshops is very important, but the stage of the process at which workshops are organised is important too and it is not clear from the document that these workshops take place early enough to allow the results to feed into the preparation of EFSA's opinions and scientific reports. For example a technical meeting on transport took place only 6 weeks before final report which is a very short time to take the external stakeholders input into account. Section 7.2. lines 188-189 - The principles to be applied, as exposed in the guidance document linked to note 18, in paragraphs Data and data sources and Inclusion and exclusion of data, would not detect the risk of having wrong data submitted, especially by the Member States.	Line 178: The text will be revised to clarify the role of the hearing experts, and to which fora they are invited. Line 182-183: This document is about EFSA's policy on independence and does not provide a detailed overview of all the processes and workflows enacted by the Authority. Lines 188-189: The suggestion is already addressed by the text in § 5.3.
BEUC	7. Other elements of quality assurance	BEUC, the European consumer's organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panellists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups are being given preferential treatment and could affect EFSA's work on ensuring transparency and independence.	See above

Food Standards Agency	7. Other elements of quality assurance	Section 7.1 – Consultation: scientific experts from Member States, civil society, interested parties and partners. The arguments regarding public and stakeholder consultation would be enhanced if there was evidence cited of how the outputs have impacted on subsequent policy. Section 7.2 – Process transparency Lines 185-186: Consideration should be given to openness and the publication of industry dossiers. For example in the food allergy area, the exemptions from labelling requirements for a number of highly processed derived ingredients were based on dossiers submitted by industry, but the evidence, and more crucially the specifications for the derived ingredients, were not published. Highly refined soya oil is exempt from allergen labelling but the detailed refining process and the specification of the oil were not included in the EFSA opinion, which makes it difficult for businesses to know whether or not their specific ingredient should be labelled or not. Section 7.3 – Quality review programme Lines 192-193: The high quality of EFSA's scientific outputs is an asset in itself, for example in areas likely to invite public controversy, such as public perception of GMOs. At the end of line 192 should the word "programme" be replaced by "review"?	§ 7.1: After each public consultation, EFSA publishes a report outlining all the comments received and whether and how they were addressed in the final text. This document is not supposed to analyse the outcome of previous consultations, but simply to explain the different rules and policies in place that ensure the institutional independence of the Authority. Lines 185-186: EFSA is obliged already now to make public all background documents used for its scientific opinions but for those documents that are considered confidential by the Authority or by the Commission, when that is foreseen by the applicable legal framework. Line 192: The text will be revised.
PAN Europe	7. Other elements of quality assurance	• Develop strict rules on stakeholder participation and full balance in participation. We know industry lobbyist are knocking on EFSA's doors continuously to be involved in EFSA meetings as an "independent" expert. And we know, depending on the chairs of the meeting of EFSA, industry experts were invited in meetings while in no single case NGO's representing consumers were invited as an expert. So we would propose to develop a strict EFSA policy: it is either a stakeholder meeting with a balanced representation (one person from each 'interest' only) or a scientific meeting where never an industry representative should be allowed in the room.	Today EFSA does not allow industry representatives to take part in its scientific meetings, with the exception of hearing experts, whose presence is justified by the business need of acquiring certain data or information.

Bavarian health and food safety authority	7. Other elements of quality assurance	There is no definition for "key scientific issues" (L170) and therefore it remains open when a public consultation is (has to be) initiated. Both, the choice of the members of the network and the selection of topics for public consultation are subjective processes. This offers the possibility to intentionally exclude certain interested parties and to avoid certain scientific conflicts. A general inclusion of public consultations would rebut this objection and allow all interested parties to be heard.	This draft document aims at providing the necessary background information for the reader to conclude on EFSA's institutional independence.
R.I.S.K. Consultancy	7. Other elements of quality assurance	Sec. 6-10 my comment of issue of the critical issue of conflict of financial interests (fCoI) On lines 142-4 you say a consulted expert is forbidden if you decide their fCoI is of a too great "magnitude". Yet for staff you say you tolerate no fCoI at all (lines 208-9). Under your founding regulation, how can you tolerate such a discrepancy? Rather, given the thousands of fCoI-free academics who are expert in your various issues, is not your mission better served by recruiting experts without fCoI? After all, as the former editor of the BMJ Richard Smith once wrote, none of us can say what the effect of money on our subconscious and our actions really is (needs of our family, the prestige of being part of a powerful organization, etc. etc.). In fact, your mandate that EFSA parties shall undertake to act independently (line 218) is literally impossible once the nexus between the scientist or evaluator/staff and the financial benefit has occurred. You must acknowledge that there is no such thing as a potential fCoI, and state that you will strive much harder to eliminate all non-insignificant fCoI from your staff and advisors. That will minimize the bias to scientific data that money may have caused. On line 242 it is critical you delete from your definition of an fCoI the elective word: "...are CONSIDERED incompatible with that person's role" -- make it mandatory instead: "...are in conflict with that person's...".	Lines 142-144: The legal basis for staff on conflicts of interest provides a broader basis for action compared to the provision on independence laid down in Article 37 of Regulation (EC) No 178/2002. Line 242: The definition will be revised to incorporate the OECD definition of CoI (2007).
8. Enhanced contribution of scientific staff			
Euro Coop	8. Enhanced contribution of scientific staff	Lines 203-206: Euro Coop welcomes the efforts to re-define working methods developing a strategy which foresees the employment of internal resources for scientific advice. This could be a solution in further guaranteeing EFSA's independence - but we wish to underline that it could be undermined if fees should be introduced.	No need to make changes in the draft policy.

Testbiotech	8. Enhanced contribution of scientific staff	See chapter 5	See above
Eurogroup for Animals	8. Enhanced contribution of scientific staff	Lines 203-204 - See above point regarding the requirement for internal, or external statistical experts to review and validate data prior to its use within the decision making process.	See above
BEUC	8. Enhanced contribution of scientific staff	BEUC, the European consumer's organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panelists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be a member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups are being given preferential treatment and could affect EFSA's work on ensuring transparency and independence.	See above

Delft University of Technology	8. Enhanced contribution of scientific staff	On the independence of EFSA staff: Through the scientific and technical advice and secretarial support they provide, staff may in practice exert an important influence over the scientific decision-making process. It is therefore of great importance that they fulfill their tasks independently. In this light, one should be careful with enhancing the contribution of scientific staff, as is suggested under section 8. Whereas a minimal level of in-house scientific expertise is of course necessary for the agency to function, building up a permanent scientific staff (and relying less on external experts) could turn out to be detrimental for the agency's independence, as it could be difficult to control this group of internal experts. Scientific advice has to come from many different sources and be decentralized for both scientific demands and the agency's independence.	Internal scientific staff are already now involved in several scientific activities, including the drafting of certain EFSA's scientific outputs. However, an enhanced contribution from EFSA staff would be fully subject to the requirements of independence and impartiality applying to all EU staff. They would work full time with the agency, which would have control on any activity outside the institutional ones, including speeches and publications. This would prevent insurgence of conflict of interest with industry, other interested parties and national authorities. Finally, this body of internal scientists would not replace members of the Scientific Commitee, Scientific Panels or external experts, nor networking activities with Member States, but rather ensure an additional source of available scientific knowledge.

9. Organisational culture			
Corporate Europe Observatory	9. Organisational culture	We strongly object to the following statement: “The DoI system is based on the principle that high-quality scientific expertise is by nature based on prior experience, that interests are a natural and inevitable consequence of attaining scientific recognition at international level in a given field, and that some of those interests may conflict with EFSA’s aim to deliver objective scientific advice.” (231-234) Instead of using the current situation whereby privatisation of public research is being promoted by the EU and national governments alike (‘public private partnerships’), EFSA should demand a flourishing public research environment with its main clients: the EU institutions. It should also demand the resources to pay experts, so that public scientists More particularly, the EFSA Declaration of Interest system does not prevent Conflicts of Interest, and leaves it up to ad hoc decisions by heads of unit to decide when a CoI exists and to take measures. As we point out in our article published 15 June 2011 on conflicts of interest on the ANS panel, EFSA does not have any rules excluding anyone a priori from joining its panels, but instead makes decisions based on the individual case. This is unacceptable. There needs to be a list of clear criteria to exclude for example experts with affiliations to industry-alike institutions in particular industry lobby groups like ILSI. The definition given in the policy paper is ambiguous to the extreme: Conflicts of interest which shall be considered as any “situation whereby one or more of the interests held by, or entrusted to, a single person are considered incompatible with that person’s role in the context of his or her cooperation with EFSA”. Considered by whom? Based on what criteria? Stricter rules on conflicts of interest and fundamental changes in the way EFSA opinions are shaped are urgently needed. EFSA should also proactively identify and recruit independent experts for its scientific committee and panels. On cases of "revolving doors", the draft policy states: In order to foster even further the general obligation that EFSA staff operate in the public interest, EFSA has adopted implementing rules of the Staff Regulations that bind all EFSA staff leaving the Authority to get a prior authorisation for any occupational activity that they intend to engage in over a period of two years after the termination of service with the Authority (273- 276) But considering the ways in which the "revolving doors" cases of	Lines 231-234: EFSA’s role is limited by law to providing scientific advice or scientific and technical assistance to EU Institutions or Member States.

		Laura Smillie and Suzy Renckens were handled by EFSA, CEO considers that significant changes are needed to both the staff regulations, and how they are implemented, to ensure that they are effective in preventing conflicts of interest. These changes include: 1.Agreement on a comprehensive definition of conflicts of interest. 2. A mandatory cooling-off period of at least two years for EFSA staff members from entering lobbying or lobby advisory jobs 3.A clear ban on any EFSA staff member undertaking a sabbatical which involves lobbying 4.A clear ban on any EFSA staff member starting any new external post within two years of leaving an EU institution until authorisation has been given for the post concerned under the staff regulations. Application to all staff working in EFSA (including those on temporary or fixed-term contracts). 6. Application to all those joining EFSA who go through the "reverse revolving door". In practice, this would mean a mandatory two-year cooling off period for all staff joining EFSA from a lobby job.	Lines 273-276: EFSA is implementing the rules of the Staff Regulations. After having learnt some lessons from past cases, EFSA has adopted a strengthened framework decision for staff who leave EFSA, which better details the process and the steps that are to be followed. This has already been successfully implemented in one case, with the application of certain limitations to the staff member leaving EFSA. In addition, a DoI screening system similar to that adopted for experts has been applied also to staff members (administrators, contract agents FG IV and seconded national experts). This allows the Appointing authority to have at any time a complete picture of the interests of her staff, with a view to preventing the occurrence of a CoI (such as reassignment).
Imperial College London GBR	9. Organisational culture	Line 244: Reference is made to the "DoI pillar of this policy is implemented by a single decision of the Executive Director". It is not clear what this will entail, and whether there will be further detail that is publicly available. If so, no date is given for this occurring.	The content of the single implementing decision is described in lines 244 to 260.

Testbiotech	9. Organisational culture	See chapter 5	See above
BEUC	9. Organisational culture	BEUC, the European consumer's organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panelists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups are being given preferrential treatment and could affect EFSA's work on ensuring transparency and independence.	See above
ILSI Europe aisbl	9. Organisational culture	Lines 244-260: Is the implementation document the same as mentioned in line 279, and will it be open for public consultation?	Yes, it is the same implementing document. The principles of the implementing document are discussed in the draft policy. The public consultation and the workshop provided the appropriate opportunities on gathering suggestions on how to improve that further.
FoodDrinkEurope	9. Organisational culture	After line 258: There is an urgent need for clarity and transparency as to what is in the 'implementing document' and in particular precision as to whether being associated with exactly which, if any, non-profit science organisations would be considered a conflict of interest for scientists working in EFSA panels.	The principles of the implementing document are discussed in this policy. For the rest, the implementing document will build on the present Policy on Declarations of Interest adopted by the Board in 2007. That Policy does not differentiate between for profit and not for profit entities.

Federal Institute for Risk	9. Organisational culture	In line 224, the EFSA Document "Implementing Act to the Policy on Declaration of Interests: Procedure for identifying and handling potential conflicts of interest" is referenced as footnote 22. Chapter C III of this EFSA document (i.e. footnote 22) explains the procedure to assess and decide on potential conflicts of interest. Chapter C III No. 6 specifies the following: "…earlier involvement in an opinion of a national authority that will be assessed by the Scientific Committee or Panel may cause a conflict of interest for the concerned person". BfR strongly suggests revision of this exclusion clause for the following reasons: Regulation (EC) No 178/2002, the Founding Regulation of EFSA, states in preamble (51) the need to involve Member States in scientific procedures of EFSA and that EFSA is to assign certain tasks to organisations in the Member States. In addition Article 22 (7) states that EF-SA "…shall act in close cooperation with the competent bodies in the Member States carrying out similar tasks to these of…" EFSA. Considering above cited regulations, including recently published EFSA guidelines such as the brochure "Scientific Cooperation between EFSA and Member States", involvement of national experts in a national risk assessment is in our view a proof of competence and should be an asset to the group rather than a conflict of interest. In addition, mutual recognition of risk assessments conducted by risk assessors in Member States would help to enhance further cooperation between EFSA and the Member States in order to avoid double work, to use European resources efficiently and to relieve EFSA's scientific panels of their increasing workload. Recusing experts of national risk assessment bodies would impede the mutual assistance in the field of food safety, which is ultimately demanded in Regulation (EC) No 178/2002, Article 22 (7) and preamble (51). Cooperation of EFSA and Member States in the risk assessment of pesticides (PRAPeR, Pesticide Risk Assessment Peer Review), is an example for close cooperation between national risk assessors and EFSA. In a peer review process conducted by EFSA and MS the draft assessment report (DAR), which was prepared by risk assessors in one MS, is finalized and forwarded to the European Commission. This process supports the formation of a shared vision within EFSA and MS and increases the robustness and quality of the assessment. Therefore, it has been suggested to apply this approach to risk assessment activities in fields other then PRAPeR, e.g. novel foods or health claims. In the light of reasons listed above, it is not evident why the involvement of an expert previously involved in a national risk assessment might bear a conflict of interest when serving in EFSA panels or EFSA working groups. As a result of the present EFSA public consultation the "Implementing Act to the Policy on Declaration of Interests: Procedure for identifying and handling potential conflicts of interest" should be amended as described above. This amendment should be pointed out in the final and revised EFSA document on "Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority".	EFSA's cooperation with member states' authorities should not be confused with the independence of the members of EFSA's Scientific Committee, Scientific Panels or of their Working Groups. In this respect it should be borne in mind that in some specific instances it may be considered appropriate to consider that interest as a CoI, for instance when an expert from a NCA is called upon in EFSA to assess an an opinion to whose development he or she has actively contributed.

Delft University of Technology	9. Organisational culture	Beyond declarations of interests: Throughout the draft policy, a lot of attention is paid to the declarations of interest that members of EFSA's bodies are supposed to submit. However important such declarations may be, they are not more than "paper promises"; it eventually comes down to the actual practice of the members of EFSA's bodies, ie whether they refrain from activities that could result in a conflict of interest or that are likely to be perceived as such by the public. In this regard it is also important to point out that in order to refrain from such activities, the members of EFSA's bodies should all be fully aware of the (kind of) activities that could result in a conflict of interest or are likely to be perceived as such by the public. In other words, there should be some level of common understanding of what are such activities and shared norms about the desirability to refrain from them. This not only requires individual members of EFSA's bodies to submit declarations of interests, but also necessitates active efforts from the organization and its management to foster a common understanding and shared norms, all the way from recruiting people, to training and promoting them (as well as, if necessary, firing them). The draft policy - even though it has a section 9 titled 'organizational culture' and the first paragraph of this section does indeed outline some of the agency's efforts - could be much more specific on the arrangements used to nurture a real culture of independence in which conflicts of interests are simply 'not done'.	As clarified in § 9, EFSA does organise training sessions for its staff and for the scientific experts so that they are fully aware of what they are expected to declare.
Rod Harbinson, independent consultant (CEO)	9. Organisational culture	My question to EFSA is: have you considered looking at approaches to a grading system because I think that the EMA has, and you're all regulatory organisations together and there may be lessons to be learnt.	EFSA's Policy on DoI foresees since its adoption in 2007 a grading system comparable to the one enacted by EMA in 2011. However, the text will be revised to clarify that the new implementing act will better detail that grading scheme.
Nina Holland, Corporate Europe Observatory	9. Organisational culture	(...) what I found interesting in the morning session, the European Medicines Agency has developed a new policy setting clear criteria for interests that are not allowed on the panels, that is a radically different approach from EFSA. My question to EFSA right now is why don't you consider a similar approach as the EMA?	
Ortwin Renn, University of Stuttgart	9. Organisational culture	(...) it would be very important to see that interest is not just economic interest and I think we are negating and we are denying all social science evidence that commitment to one course or the other can be caused by money, by power, by prestige and by value commitment and they are equally strong... if you just stigmatise economic bias we are on the wrong path.	It is widely acknowledged that CoI can be also of a non-economic nature. EFSA's draft policy tries to capture all relevant interests that may be considered prejudicial to the independence of the concerned persons, insofar as those are reflected in an objective, traceable activity of the concerned person.

Dr Schlundt, DTU	9. Organisational culture	I think it's a very important thing to take that out and to bring in conflict of interest in relation to economical conflict of interest and only that.	It is widely acknowledged that CoI can be also of a non-economic nature. EFSA's draft policy tries to capture all relevant interests that may be considered prejudicial to the independence of the concerned persons, insofar as those are reflected in an objective, traceable activity of the concerned person.
Dr Christoph Then, Testbiotech	9. Organisational culture	We would propose to have a new institution which is dealing with conflict in scientific opinions	EFSA's role is limited by law to providing scientific advice or scientific and technical assistance to EU Institutions or Member States.
Mariana Nicholls, European poultry industries	9. Organisational culture	We would very much like to see more industrial experts on the boards or in the committees, just a few of them because we have so much data that we would like to share.	EFSA does its utmost to select the best available scientists, irrespective of their background, as long as that does not result in conflicts of interest. Waivers are foreseen and recorded in the minutes of the relevant meeting.
Arnaud Apoteker	9. Organisational culture	And perhaps something like an annual reporting may be something that is needed to further communicate on what happens over a year, how we deal with it. So that could be perhaps even part of our annual reporting system.	The draft Policy will be amended in order to reflect this new EFSA commitment to report annually on the implementation of its Policy on Independence as of 2012.

10. Staff operating in the public interest			
Testbiotech	10. Staff operating in the public interest	The case of Suzy Renckens (http://www.testbiotech.org/en/taxonomy/term/180, http://www.testbiotech.org/en/node/316) shows significant weakness in the implementation of EFSA´s rules that "bind all EFSA staff leaving the Authority to get a prior authorisation for any occupational activity that they intend to engage in over a period of two years after the termination of service with the Authority". It should be explained if and how the case of Suzy Renckens was used to strengthen relevant rules and procedures.	Without reference to individual cases, this is addressed and explained already in lines 273-276 of the draft policy. Nonetheless, the text has been reviewed to make it clearer that EFSA has adopted a streamlined procedure to address this kind of instances.
Confederazione Nazionale Coldiretti	10. Staff operating in the public interest	Beyond the DoI document, panellists' Curriculum Vitae should be public on the EFSA's website in order to let citizens have a direct scrutiny on who decides about food safety (= their health) in Europe. If EFSA intends to take seriously the perception about independence, a complete and detailed C.V. should be the ordinary rule.	This is already the case since some time. Please check EFSA's website.
Eurogroup for Animals	10. Staff operating in the public interest	This comment concerns section 11. on implementation but it is not listed. Lines 277-282: The document does not explain how the application of the principles outlined in this policy is going to be controlled. Will an external audit be carried out at one point? If this is part of another EFSA procedure, a reference should be included.	EFSA will review the text clarifying that the system on DoIs will be systematically submitted every other year to a comprehensive evaluation or audit. It should be borne in mind that EFSA has had already several audits of the existing system (internal audit, internal audit service of the Commission, Court of Auditors).
Confederazione Nazionale Coldiretti	10. Staff operating in the public interest	Overall issues: With regard to the Call for tender for an EFSA's External Evaluation, 2011/ S1 00173, published last 04-01-2011 on the Official Journal of the European Commission, we wonder if there is any prejudice on the Authority's independence considering that the proposals are expected to be delivered to EFSA's hands for scrutiny and selection of the executor.	EFSA's approach as outlined in that call for tender is in accordance with Article 61 of Regulation (EC). No 178/2002 (EFSA's Founding regulation).
Confederazione Nazionale Coldiretti	10. Staff operating in the public interest	Par. 10, ll. 278-282 While it is very welcome this policy against "revolving doors" between industry and the Authority, we think it could be better formulated. We think that it could be useful to focus also on getting authorization and screening for human resources coming from industry and entering EFSA, not only for researchers departing from EFSA to start other for-profit activities. In general, the revolving doors operate both at the beginning and at the end	The text will be revised in order to clarify that CoIs are prevented also when a staff member is assigned to his or her post.

BEUC	10. Staff operating in the public interest	BEUC, the European consumer's organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panelists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups are being given preferrential treatment and could affect EFSA's work on ensuring transparency and independence.	See above
Chiara Tomalino, Eurocoop	10. Staff operating in the public interest	(...) revolving door effects should be avoided. We know that it's costly but we think that the only way out is to put in place a cooling down period, which in our opinion should be of three years.	The text will be revised in order to clarify that CoI are prevented also when a staff member is assigned to his or her post.

APPENDIX

A. TEXT OF THE PUBLIC CONSULTATION FROM THE EFSA WEBSITE

Public consultation on a Policy on Independence and Scientific Decision making processes of the European Food Safety Authority

Deadline: 16 September 2011

The European Food Safety Authority (EFSA) has launched an open consultation on its Draft Policy on Independence and Scientific Decision-Making Processes. This document provides a comprehensive overview of the various measures in place at EFSA to safeguard independence and scientific integrity.

In line with EFSA's policy on openness and transparency and in order for EFSA to receive comments from all interested parties, EFSA has launched a public consultation on the draft policy. Interested parties are invited to submit written comments by 16 September 2011. Please use exclusively the electronic template provided with the documents to submit comments and refer to the line and page numbers. Please note that comments submitted by e-mail or by post cannot be taken into account and that a submission will not be considered if it is:

- submitted after the deadline set out in the call
- presented in any form other than what is provided for in the instructions and template
- not related to the contents of the document
- contains complaints against institutions, personal accusations, irrelevant or offensive statements or material
- is related to policy or risk management aspects, which is out of the scope of EFSA's activity.

EFSA will assess all comments from interested parties which are submitted in line with the criteria above. The comments will be explored in more detail in a dedicated meeting that EFSA will hold in the autumn. Feedback from the consultation and the outcomes of this meeting will be compiled in a report and, where appropriate, incorporated into a revised draft of the policy to be presented to the EFSA Management Board for possible adoption before the end of 2011.

Publication date: 7 July 2011