Outcome of the public consultation on the discussion paper

Transformation to an "Open EFSA"

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1. Background

Transparency (access to data, information and documents) and openness (engagement) have been key values for EFSA since its creation in 2003. Adherence to these values helps to legitimise EFSA's work and ensure accountability to society. Over time, EFSA has implemented several measures designed to ingrain these concepts in its activities, adopting a number of corporate documents regulating the Authority's working practices, and policies aimed at enhancing EFSA's openness to its institutional partners and other interested parties.

In 2013, building on the recommendations issued by its Management Board, EFSA launched an initiative designed to facilitate public access to data used by the Authority and enhance transparency in its scientific decision-making processes. With the support of its Stakeholder Consultative Platform and Advisory Forum, EFSA created a discussion group on Process Transparency and Information Access to gather the views of its stakeholders and partners on these issues. Further, a Group on Process Transparency and Information Access was created as a spin-off of EFSA's Stakeholder Consultative Platform with the aim of identifying major trends and needs among EFSA's main interested parties.

In July 2014, EFSA published the discussion paper *Transformation to an Open EFSA* that is the subject of the present report. In line with the strategic objectives set out in EFSA's Single Programming Document 2015-2017, the discussion paper set forth a conceptual framework, a step-by-step methodology and a plan for the transformation of the Authority into an Open EFSA. The public consultation is part of the broader Open EFSA initiative and aims to further open up EFSA's scientific processes to meet society's expectations in the second decade of the 21st century and beyond by allowing the Authority to benefit from the opportunities offered by technical and policy developments.

2. Terms of reference

In the public consultation on *Transformation to an Open EFSA* the Authority sought input on these specific points:

1. Are you satisfied that EFSA has identified the societal and normative expectations it has to comply with or would you suggest additional ones that the paper does not capture?

2. How can EFSA increase its openness to meaningful contributions from individuals and organisations beyond its Panels and Committee? Should a two-way interaction between EFSA's Panels and interested parties be facilitated? What limits should be set to such interaction?

3. How can EFSA ensure that commercially sensitive information and data are protected while providing access to key information, data and documents necessary to make its assessments reproducible? Should EFSA embrace the principle of reusability? Who should be in charge of striking the balance between the need to allow reproducibility and respecting the rights of data owners? Can guiding principles and standards be established?

4. How can EFSA foster even further an environment of creative debate amongst its experts while striking the appropriate balance between availability and quality of information?

5. Would you identify any other strategic drivers, contextual elements or policy options for the Authority to consider when implementing its vision of becoming an Open EFSA?

3. Consideration of comments

3.1. Introduction

In the context of the development of plan for the transformation of EFSA into an organisation implementing Open Science and Open Government principles, a public consultation was arranged in order to gather the views of EFSA's interested parties on the actions the Authority had identified to foster the openness of its risk assessment processes.

During the public consultation launched on the discussion paper (Appendix A), EFSA received 189 comments from 52 interested parties or individual citizens. The comments received are listed in Appendix B. To enhance the effectiveness and flexibility of the consultation process, and respond to the concerns raised by the European Ombudsman in the context of a complaint lodged in 2014,[1] EFSA considered also comments on the discussion paper received by other means and those obtained within a reasonable time after the expiration of the deadline for submission.

3.2 Screening and evaluation of comments received

All comments were screened and compiled in a table with reference to the contributor and to the section of the draft paper to which the document referred. When contributions did not refer to the specific part or chapter, EFSA assigned them to the relevant chapter or the introduction. Duplicate comments received from the same contributor appear only once in the table and comments submitted by individuals in a personal capacity are listed anonymously. Comments received on behalf of an organisation appear with the name of the organisation. The response of the Authority to each comment is available in the last column of the Appendix B.

Table 1: Comments received per stakeholder category (the categorisation of stakeholders is reported in table 2)

Stakeholder category	Number of contributors	Number of comments
Public bodies	4	4
Academic institutions/research	7	34
Industry and trade/professional associations	19	88
Professional consultancies	3	4
Non-governmental organisations	10	36
Individuals	9	23
TOTAL	52	189*

* Number of comments as presented in the table in Appendix B. In order to optimise the assessment of the contributions, comments referring explicitly to more than one specific chapter of the Discussion Paper have been split and attributed to the relevant chapters; if several comments from the same contributor were referring to the same chapter, they have been merged to the extent possible.

The answers to the questions listed in the Executive summary are attributed to the relevant chapter as follows:

[1] Complaint 952/2014/OV brought by GM Free Cymru against the European Food Safety Authority. The complaint is available on the Ombudsman's website at the following address: http://www.ombudsman.europa.eu/en/cases/caseopened.faces.

1. Are you satisfied that EFSA has identified the societal and normative expectations it has to comply with or would you suggest additional ones that the paper does not capture? – 3.2. Complying with normative and societal expectations

2. How can EFSA increase its openness to meaningful contributions from individuals and organisations beyond its Panels and Committee? Should a two-way interaction between EFSA's Panels and interested parties be facilitated? What limits should be set to such interaction? – 4.2. Openness

3. How can EFSA ensure that commercially sensitive information and data are protected while providing access to key information, data and documents necessary to make its assessments reproducible? Should EFSA embrace the principle of reusability? Who should be in charge of striking the balance between the need to allow reproducibility and respecting the rights of data owners? Can guiding principles and standards be established? –3.2. Complying with normative and societal expectations

4. How can EFSA foster even further an environment of creative debate amongst its experts while striking the appropriate balance between availability and quality of information? – 3.1. Improving the overall quality of available information and data used for EFSA's outputs

5. Would you identify any other strategic drivers, contextual elements or policy options for the Authority to consider when implementing its vision of becoming an Open EFSA? – 5. Rolling out the change

Table 2: Comments received per contributor

Contributor	Country
EFSA external expert[f)]	IT
Individual person [f)]	DE
Association of the European Self-Medication Industry (AESGP)[c)]	BE
Association Française des Biotechnologies Végétales (AFBV)[c)]	FR
Association of Veterinary Consultants (AVC)[d)*]	IE
Bee Life[e)]	BE
The European Consumers' Organisation (BEUC)[e)]	BE
The Federal Institute for Risk Assessment (BfR)[a)]	DE
European Chemical Industry Council (Cefic)[c)]	BE
Individual person [f)]	FR
ClientEarth[e)]	UK
Confederazione Nazionale Coldiretti[c)]	IT
Corporate Europe Observatory[e)]	NL
Individual person [f)]	UK
Individual person [f)]	FR
DANONE[c)]	FR
Earth Open Source[e)]	UK
EAS Strategic Advice[d)]	BE
Individual person, Maastricht University[b)]	NL
European Network of Scientists for Social and Environmental ENSSER[e)]	FR
Individual person, Science and Technology Policy Research, University of Sussex[b)]	UK
EuropaBio[c)]	BE

Contributor	Country
European Crop Protection Association (ECPA)[c)]	BE
European Medicines Agency (EMA)[a)]	UK
European Ombudsman[a)]	FR
European Seed Association (ESA)[c)]	BE
European Specialty Food Ingredients Industries Federation (ELC)[c)]	BE
European Feed Manufactures' Federation (FEFAC)[c)]	BE
EU Association of Specialty Feed Ingredients and their Mixtures FEFANA[c)]	BE
Finnish Food Safety Authority[a)]	FI
Fondation Sciences Citoyennes[e)]	FR
Food Supplements Europe[e)]	BE
Global Alliance for Probiotics (GAP)[c)]	BE
GM Watch[e)]	UK
Individual person, Libgreen[f)]	FR
Individual person, University of Manchester[b)]	NL
InQpharm Europe Ltd[c)]	DE
International Probiotics Association (IPA)[c)*]	CH/US
Individual person [f)]	FR
Lallemand Health Solutions[c)]	ES
London School of Economics (LSE)[b)]	UK
Individual person, Centre national de la recherche scientifique CNRS[b)]	FR
Individual person, EFSA external expert)[f)]	IT
Individual person, University of Amsterdam[b)]	NL
Pen&Tec Consulting Group on behalf of the European Federation of Food Safety Consultants (EFFSACO)[d)]	ES
Pesticide Action Network Europe (PAN Europe)[e)]	BE
Primary Food Processors (PFP)[c)]	BE
Public Research and Regulation Initiative (PRRI)[b)]	NL
Individual person [f))]	AT
Syndicat national des Compléments Alimentaires (SYNADIET)[c)]	FR
Syngenta[c)]	CH
Yogurt Life and Fermented Milk Association (YLFA)[c)*]	BE

The following categorisation is established in accordance with the classification adopted by the EU Transparency Register. The Transparency Register provides information about organisation or self-employed individuals engaged in activities carried out with the objective of directly or indirectly influencing the formulation or implementation of policies, or decision-making processes of the EU Institutions.
(a): Public authority, other public or mixed entities
(b): Academic/research institutions, or think tanks
(c): Companies and Trade/Professional Associations
(d): Consultancies
(e): NGOs
(f): Individuals

4. Conclusions

The public consultation highlighted a rather fragmented picture of the views interested parties and individuals have of the concepts underlying the creation of an Open EFSA and of the implementation of the openness principle in EFSA's risk assessment processes.

EFSA discussed the comments at several internal meetings. The outcome of this process is reflected in this report, in which EFSA addresses each comment or input provided by the contributors. The answers to each comment provided in Appendix B hereto show EFSA's position on the points raised and how it will consider following up in the context of the transformation of the Authority into a body implementing Open Science / Open Government approaches.

Further, EFSA classified each input into one of the following classes:

Class 0: out of scope of the public consultation
Class 1: measure planned to be delivered
Class 2: measure to be submitted to cost/benefit analysis
Class 3: measure not considered suitable of further assessment
Class 4: measure not compliant with current regulatory framework
Class 5: measure not aligned with EFSA's remit
Class 6: general comment to be otherwise addressed
Class 7: measure already in place

The input received formed the background for the *Implementation plan of the first phase: Transformation to an "Open EFSA"* presented by the Executive Director to the Management Board in March 2015.

EFSA acknowledges the usefulness and quality of the comments received and thanks all stakeholders for their contributions and for the time spent in preparing their input. The Authority is aware of the prolonged effort it took its stakeholders to take a constructive and active role in this initiative and is particularly appreciative of the inputs provided by individual citizens, academics, and non-governmental organisations.

The Management Board of the Authority is informed of the outcome of this consultation and will be kept abreast of the outcome of the further categorisation and prioritisation to be performed according to the Implementation plan.

5. References

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European Food Safety Authority, Decision of the Executive Director of the European Food Safety Authority implementing EFSA's approach on Public Consultations on scientific outputs

European Food Safety Authority, Decision concerning access to documents, MB 16.09.2003 – ADOPTED

European Food Safety Authority, "Openness, transparency and confidentiality", MB 16.09.2003 – 13 – AGREED

Joint Statement of the European Parliament, the Council of the EU and the European Commission on decentralised agencies, and related Common Approach on decentralised agencies, 19 July 2012

O'Reilly, Emily, ReNEUAL conference - Closing remarks by the European Ombudsman, Brussels, 20 May 2014.

N. Kroes, European Commissioner and Vice-President of the European Commission responsible for the Digital Agenda, Opening up Scientific Data, speech given on 18 March 2013 on the occasion of the launch of the research Data Alliance in Stockholm

J. Potocnik, European Commissioner for Science and Research, The EU's Fifth Freedom: creating free movement of knowledge, Informal Competitiveness Council, Würzburg, 26 April 2007.

Appendices

Appendix A. The text of the public consultation from the EFSA website

EFSA has launched an open consultation on the discussion paper “Transformation to an Open EFSA”.

This document is a discussion paper released with the aim of collecting comments and suggestions from interested parties before drafting a policy document on Openness and Transparency at the European Food Safety Authority (EFSA). This discussion paper sets forth a conceptual framework, a step-by-step methodology and a plan for the transformation of the EFSA into an Open Science organisation over the next five years. The Open EFSA initiative aims to explore how EFSA can better meet society’s expectations in EFSA’s second decade as the EU food safety system’s scientific risk assessor. It also aims to understand the implications that increased openness and transparency could have for the Authority’s organisational set up.

You are asked to contribute specifically on these points:

1. Are you satisfied that EFSA has identified the societal and normative expectations it has to comply with or would you suggest additional ones that the paper does not capture?
2. How can EFSA increase its openness to meaningful contributions from individuals and organisations beyond its Panels and Committee? Should a two-way interaction between EFSA’s Panels and interested parties be facilitated? What limits should be set to such interaction?
3. How can EFSA ensure that commercially sensitive information and data are protected while providing access to key information, data and documents necessary to make its assessments reproducible? Should EFSA embrace the principle of reusability? Who should be in charge of striking the balance between the need to allow reproducibility and respecting the rights of data owners? Can guiding principles and standards be established?
4. How can EFSA foster even further an environment of creative debate amongst its experts while striking the appropriate balance between availability and quality of information?
5. Would you identify any other strategic drivers, contextual elements or policy options for the Authority to consider when implementing its vision of becoming an Open EFSA?

The outcome of the public consultation will feed into finalisation of the proposed approach, of a new Open EFSA policy and its follow up plan. Interested parties and the public at large are invited to submit written comments by 15 September 2014 (extended to 15 October 2014). Please use the electronic template provided with the documents to submit comments and refer to the relevant paragraph or part of the document. Please also note that a submission may not be considered if:

- it is submitted after 15 September 2014 (extended to 15 October 2014);
- it is not related to the contents of the document;
- it contains personal accusations, irrelevant or offensive statements or material; or
- it is related to aspects falling out of the scope of EFSA's mission and tasks.

EFSA will assess all comments from interested parties against the criteria above and address those relevant for this discussion paper.

Please note that all comments submitted will be published. Comments submitted by individuals in a personal capacity will be presented anonymously. Comments submitted formally on behalf of an organisation will appear under the name of the organisation.

Appendix B. Comments received during the public consultation on the discussion paper – Transformation to an "Open EFSA"

The document published for consultation is the version available at the following address:
http://www.efsa.europa.eu/en/corporate/doc/openefsadiscussionpaper14.pdf

No	Contributor	Chapter	Comments received	EFSA response
1.	Syngenta (Switzerland)	Executive Summary	Syngenta agrees that it is important for EFSA to be transparent and engage with all stakeholders. To do so both efficiently and effectively we urge EFSA to distinguish between lay persons seeking to better understand EFSA's organization, processes and outputs or to challenge these conclusions; and science professionals (Academic scientists, government risk managers, non-governmental experts and industry experts) who can contribute relevant data, specialist knowledge and practical expertise essential to the goal of an evidence based, risk informed, scientifically robust and proportionate EFSA opinion. Different processes and timing of engagement are required to reflect the different needs of lay persons and contributions of science professionals. A more open EFSA that was able to benefit from the timely participation of a full range of these science professionals whilst maintaining the independence of its decision makers would be a stronger EFSA. Not all scientifically robust conclusions are, or are ever likely to be, popular. The scientific community has a responsibility to inform the general public and if properly supported by other stakeholders, including politicians and the media, progress can be made in persuading a sceptical public. It is right that EFSA should play a leading role in this. But it doesn't follow that enhanced public access to information will necessarily create greater public understanding or even trust of EFSA. Open science is a bold ambition. As acknowledged, EFSA has important responsibilities including observing legal obligations to maintain confidentiality for example of commercially sensitive information it receives. There is growing recognition that the quality control around published research is often inadequate. Published literature may be biased by the tendency not to publish 'negative' results with the consequence that a literature review is blind to unreported true negatives. All of this means that it is increasingly important that EFSA help raise standards in published research by establishing clear and robust quality criteria expectations for their use in EFSA's work and provide the greatest transparency possible about how EFSA's conclusions were derived and confidence	EFSA considers that reliance on formal qualifications or acquired professional expertise may limit the potential benefits it could obtain from the implementation of Open Science / Open Government principles. Class 3. Accessibility of data owned by EFSA, or possessed by EFSA and whose disclosure is authorised by the owner, is without prejudice to compliance with obligations deriving from the processing of commercially sensitive information and personal data. Class 7 EFSA acknowledges the fundamental importance that regulatory data protection and protection of commercially relevant information has for the concerned sectors in order to be competitive on a global scale. For this reason, in 2014 EFSA substantially strengthened its approach to protecting commercially sensitive information recognised to be worth of confidential processing, by developing internal procedures to streamline its internal decision-making process for confidentiality

No	Contributor	Chapter	Comments received	EFSA response
			that the inputs represent the best expertise available. EFSA has important duties and often tight legal timelines in which to complete these. EFSA also has finite resources. Any initiative to broaden the source of scientific input upon which EFSA are to base their deliberations is contingent upon EFSA having a robust, transparent and efficient process to rapidly discriminate between potentially contradictory data of varying quality, reliability and relevance.	claims. EFSA has already undertaken or planned the necessary actions to ensure consistent decision-making processes regarding this matter and to review its current rules on access to documents, to take stock of the developments in the applicable legal framework and case law. Classes 1 and 7 EFSA acknowledges that enhanced public access fosters increased trust, and it is the purpose of this consultation process – and of the ensuing categorisation and classification that will be performed according to the Implementation plan – to identify where the Authority should strike the balance between openness and protection of commercially sensitive information. Class 2 EFSA acknowledges that publication bias is an issue to be aware of. EFSA addresses it in its guidance document "Application of systematic review methodology to food and feed safety assessments to support decision-making", available on EFSA's website. Class 7 EFSA strives to obtain the best scientific expertise,taking into account the availability of experts, and its policy on independence. Class 6

No	Contributor	Chapter	Comments received	EFSA response
2.	Association of the European Self-Medication Industry (AESGP) (Belgium)	Executive Summary	Association of the European Self-Medication Industry (AESGP) supports EFSA in its commitment to transform to an "Open Science" organisation. AESGP strongly supports EFSA as a credible and science-based organisation and in this context we particularly appreciate EFSA willingness to further open to a dialogue with EFSA stakeholders which we believe can increase efficiency of the scientific processes at EFSA.	Noted. Class 1
3.	BEUC - The European Consumers' Organisation (Belgium)	Executive Summary	Transparency and openness are essential elements to ensure consumer trust in regulatory authorities. BEUC supports EFSA's ambition to increase inclusivity and participation, but it is also important to stress the fact that risk assessment is an essentially scientific and objective activity and it should remain as such. To safeguard its independence and to remain credible to consumers, EFSA needs to keep its distance from the food industry whose products it assesses. The gap in financial resources, staff and expertise between food companies and civil society organisations is, and will remain, significant. This should be carefully considered and addressed when designing the new framework of interaction with stakeholders. While we understand that scientific opinions are not always clear-cut and easy to communicate, we believe more efforts should be made to make the opinions more straightforward and understandable for a lay-person. EFSA should be able to take a broad look at the issues that could impact on public health and consumers, rather than just responding narrowly to a mandate. Making the knowledge base on which EFSA informs its decision publicly available is a fundamental step towards improving transparency and gaining legitimacy.	EFSA confirms its continued commitment to deliver independent, high-quality and objective scientific advice. Increasing stakeholder engagement will not compromise the impartiality of the scientific advice delivered by the Authority. EFSA is aware of the implications that increased openness and different levels of information and availability of resources might have for the risk assessment processes it manages. EFSA is committed to devise a system that takes this into due account. Class 6 EFSA's communication department makes every effort to ensure its outputs are accessible and understandable. For that reason, new products have been developed over the past year to support EFSA's communications, e.g., infographics, lay summaries, an easier-to-navigate website. EFSA will subject the current language regime of its outputs to further categorisation and prioritisation, to be performed according to the Implementation plan. Class 2

No	Contributor	Chapter	Comments received	EFSA response
4.	European Crop Protection Association, CEFIC, EuropaBio, Federation of European Specialty Food Ingredients, AESGP, ESA, FEFANA	Executive Summary	Industry actively supports the efforts to transform the European Food Safety Authority (EFSA) into an Open Science Organisation. Transparency and Openness are key societal values and a balanced, fair and predictable approach for all stakeholders needs to be implemented. Most of the industry responses on the different questions raised on page 3 can be found in 2 documents submitted earlier this year (See annex). • In March 2014 detailed Principles for Balanced Transparency of Regulatory Data (1) were provided. These principles are Predictability, Fairness, Proportionality and Coherence. The initiative Transformation to an open EFSA should observe these principles. • Industry also submitted on 17 February 2014 detailed proposals on the different operational, procedural and scientific challenges for industries impacted by EFSA Beside these general comments, the Discussion Paper contains some new elements and questions. The most important for Industry are addressed below.	EFSA takes note of and has addressed the comments submitted in the letter mentioned through its contribution to a joint meeting between the European Commission, EFSA and the concerned associations. Class 7
5.	European Crop Protection Association (Belgium)	Executive Summary	ECPA acts as the ambassador of the crop protection industry in Europe and represents the industry's European regional network. We promote modern agricultural technology in the context of sustainable development, one which protects the health of humans and the environment, and, in doing so, seek to build understanding of our role on why pesticides are needed, recognition of our contribution towards an affordable healthy diet, competitive agriculture and high quality of life, and uphold informed dialogue about our views, values and beliefs. The ECPA network upholds high standards for human safety and environmental care in European agriculture, based on sustainable, productive, value-added, innovative and scientific farming methods. We embrace: Openness – We promote and value dialogue with all stakeholders Proactivity – We take the initiative on issues of concern to Society Cooperation– We work with stakeholders as partners Responsibility – We take responsibility for the safe and sustainable use of our industry's products through farmer education and training Transparency – We are open and transparent about our aims and policies	Noted. Class 0

No	Contributor	Chapter	Comments received	EFSA response
			We are committed to: -protecting and conserving water resources by introducing innovative crop protection solutions and promoting sustainable agricultural practices. -contributing significantly to a healthy, high quality, affordable food supply for all by maintaining plant health, increasing plant productivity and improving farm practices. -enhancing biodiversity and natural habitats within farming landscapes, by using our expertise in plant protection and agricultural practices to promote local harmony between nature and agriculture. -safe-guarding the health of farmers and the public by introducing innovative technologies and promoting best safe-use practices. -earning public trust in our industry and in the regulatory process, by increasing transparency and setting industry standards that align to current scientific norms to address societal concerns.	
6.	Individual contribution, (UK)	Executive Summary	Recognition of the central role of engagement with the public. The document gets off to a poor start by stating that it 'is designed to promote a discussion and to seek the input of EFSA's partners and stakeholders as well as experts and practitioners in the field of open government and open science,' The immediate impression is that the lay public has little authority in this process - it is yet again 'the experts' in fields not generally comprehensible to the actual end-of-line consumers of EFSA's services - the general public, or 'citizens' as EFSA prefers to refer to them. It seems to forget that many citizens are also experts in their own right, and who may have a far better grasp of science and politics than the average person in the street. The term 'stakeholders' is almost irrelevant to a description of those most intimately affected by EFSA decisions, and least able to do something about problems and issues when they do occur. In the absence of formal group structures and official recognition, many become labelled with the pejorative titles of 'activists' and 'campaigners', implying that they are so prejudiced as to become unacceptable sources of comment and debate. Indeed, many lay persons simply refuse to identify themselves with the description of stakeholder, and reject any implied participation in the process of decision-making. They see themselves as unavoidably passive recipients of decisions made elsewhere, with no real opportunity to engage' in the process. Consultation is meaningless if both parties do not have equal participation in decision-making. Ultimately, it is the supposedly non-expert general public that has to live with the consequences of EFSA's decisions on food safety. The consultation document fails to define a meaningful role for these ultimate	One of the main objectives of the initiative is to strive for better engagement with the public and interested parties on EFSA's scientific outputs. EFSA recognises the crucial importance of further engaging with interested parties, including laypeople, and is aware of the challenges ahead. Class 1 EFSA already has in place an open and inclusive consultation process for consulting with the general public and interested parties on key draft scientific outputs. In accordance with the Implementation plan, EFSA will further categorise and prioritise the development of additional tools to increase the level of public engagement in its risk assessment process. Class 2 EFSA has to operate within the boundaries established by its legal

No	Contributor	Chapter	Comments received	EFSA response
			'consumers' of EFSA decisions. Instead it emphasises the roles of 'stakeholders' and 'experts and practitioners in the fields of open government and open science' in this consultation, and there is a wide gulf between the involvement of these 'experts' and dialogue with the public. NGOs and others outside 'the system' often have vested, if not competing, interests, but may nevertheless have important, relevant and valuable views and knowledge. Their inclusion in decision-making provides a crucial mediating role in ensuring that complex EFSA risk analyses are actually meaningful in the real world inhabited by the general public. EFSA's and other EC bodies' dismissals of the views of such NGOs as 'activists' and 'campaigners' is highly offensive, and has led to absurd, harmful, and even unlawful decisions in the past. For example, the controversial issue of the addition of fluoride to foods, including drinking water, raises very serious concerns about the impartiality and resistance to challenge of both EFSA and other EC bodies. SCHER's refusal to acknowledge critical legal obstacles to the inclusion of fluoride for what is undeniably medicinal purpose permitted the continued illogical endorsement of its use in foods and the meaningless estimation of supposedly acceptable daily intakes of this toxin, as if it has an essential dietary and nutritive role. Well-informed 'lay' sources challenged this decision, yet have been (and continue to be) ignored by both SCHER and EFSA. Where additional knowledge, both social and legal, is possessed by NGOs and others, and revokes or challenges the opinions expressed by EFSA, then these views must be taken fully into account. The role of such independent sources of expertise needs to be strengthened by the adoption of 'lay members' on EFSA committees whenever such conflicts of approach or interest are evident and of significance.	and institutional framework; its outputs are either adopted by its Scientific Committee or Panels, by its staff, or national competent authorities. Interested parties are not supposed, or even required to, take part in the decision-making process. Class 4 EFSA is not in a position to comment on other scientific committees' opinions; this goes beyond the scope of the present exercise. Class 0
7.	ClientEarth (Belgium)	Executive Summary	We regret that EFSA has been unable to present a draft transparency policy after the several stakeholder meetings that have taken place.	EFSA acknowledges that the path towards the implementation of an Open EFSA needs to be structured and considers this as a necessary intermediate step to move forward to the development of the proper policy. Class 6

No	Contributor	Chapter	Comments received	EFSA response
8.	DANONE (France)	Executive Summary	The probiotic sector welcomes EFSA's initiative to collect comments before drafting a policy document on Openness and Transparency at the European Food Safety Authority (EFSA). Society' expectations should include industry's comments and concerns, namely when it refers to interactions between EFSA panels and food business operators who are submitting scientific dossiers for evaluation. Clear conditions should be placed on interactions with EFSA so that a "real" scientific dialogue between applicants and EFSA is possible.	It is EFSA's intention to include among society's expectations the concerns and limitations regarding the risk of disclosure of commercially sensitive information or protected data. Class 6 To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services). Class 7
9.	Public Research and Regulation Initiative (PRRI) (Belgium)	Executive Summary	General observation: as an organisation of public sector scientists, PRRI underlines the importance of transparency and openness in science in general and – as for example Directive 2001/18 shows - in risk assessment in particular. Yet, as the EFSA discussion paper correctly recognises, transparency and openness are not goals per se, but are a means to an end, i.e. in this case to strengthen the role of EFSA. Transparency and openness should be result driven, and not be seen as a matter of simply 'more is better'.	Noted. Class 1
10.	Individual contribution, (Austria)	Executive Summary	"This paper is designed to promote a discussion and to seek the input of EFSA's partners and stakeholders as well as experts and practitioners": Also mention individuals (from the public) who want to provide meaningful input to EFSA but need not necessarily be "experts", please. "This paper is designed to promote a discussion": Nevertheless it is hard to enter new ideas and arguments by commenting only on the suggested topics. For example: How can proper work of the adopted experts be assured? May the public criticise and/or may panel members be removed who are known, by their former work, to base their work on a biased view, possibly far off the public's desire to be protected also from questionable practices?	The purpose of this exercise was also to gather the views of individuals, as is the case in the context of all public consultations organised by the Authority. Class 1 Regarding the reference to EFSA's independence policy, it should be noted that according to EFSA's internal rules, EFSA is already in a position to dismiss scientific experts if they breach those rules or the trust relationship with the Authority. Class 7 Over the years, EFSA has implemented one of the most

No	Contributor	Chapter	Comments received	EFSA response
			Or: Should there be an instance which will deal with complaints, for example that an EFSA panel based its opinion on an outdated scientific view and/or allows, by clearly and only medical arguments, substances with the purpose of a medicine be added to normal food, which even might be illegal? (as is the case for some fluoride compounds)	stringent frameworks for the prevention of conflicts of interest among EU institutions, bodies and agencies. The Authority also intends to review its policy on the independence of its scientific decision-making processes, with a view to fully reflect in it the opportunities for enhanced transparency and engagement that will result from the "Open EFSA" project. These comments will therefore feed into this process as well. Class 6 Regarding the possibility of EFSA's reviewing its own outputs, the Authority is already subject to provisions obliging it to review its adopted outputs once relevant scientific data or information become available. Class 7. EFSA commits to perform further categorisation or prioritisation on the possibility of making publicly available all documents linked to a decision on whether to update an output or not. Class. 2.
11.	EuropaBio (Belgium)	Executive Summary	EuropaBio welcomes the opportunity to address the questions in the 'Open EFSA' discussion paper and would like to underline the importance of a number of crucial points that we believe have not been taken into consideration sufficiently. While the consultation paper puts a lot of emphasis on openness and societal needs, regrettably it does not mention the need to preserve the integrity, efficiency and predictability of the decision-making process for product approvals in order to grant market access to safe innovative products in a timely manner. EuropaBio promotes the efforts towards openness that provide a balanced, fair and	EFSA appreciates the need to preserve the integrity, efficiency and comprehensiveness of the scientific evaluation of regulated products, organisms, substances, processes or claims. These considerations will play an important role in the context of the further categorisation and prioritisation exercise to be performed in accordance with the

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			predictable approach towards transparency of regulatory data and recommends that any initiative to increase transparency should observe the following principles: • Predictability: industry needs to know in advance whether, how, and when data submitted to public authorities will be disclosed to third parties. • Fairness: A fair balance must be achieved between the right of the public to access documents of EU institutions and bodies (Art. 15 TFEU, Art. 42 Charter of Fundamental Rights of the EU) and the right to confidentiality and protection of professional and business secrecy and of property rights (Art. 339 TFEU, Art. 7, 15, 16, 17 and 41(2)(b) Charter of Fundamental Rights of the EU). The protection of confidentiality is particularly important for data submitted by companies in the context of regulatory procedures. • Proportionality: The scope and manner in which data is disclosed to the public or to a third party should be proportional to the interests at stake (i.e., risk that data gets in the hands of competing companies). • Coherence: Implementation of the Access to Documents Regulation (1049/2001) and the Aarhus Regulation (1367/2006) should be coherent with other parts of EU law and with international agreements concluded by the EU. In order to increase openness, EuropaBio recommends EFSA to focus 1) on better explaining to the public EFSA's role, the way it operates and its output in terms of product authorisations, 2) on better protecting information provided by applicants from misuse, and 3) on streamlining its processes in dealing with applicants. For detailed recommendations on how EFSA processes might improve in the view of EuropaBio, please also consult the 2011 EuropaBio's own-initiative report 'Approvals of GMOs in the European Union'.	Implementation plan. Class 3 EFSA acknowledges the fundamental importance that regulatory data protection and protection of commercially relevant information has for the concerned sectors in order to be competitive on a global scale. For this reason, in 2014 it substantially strengthened its approach to protecting commercially sensitive information recognised to be worth of confidential processing, by developing internal procedures to streamline its internal decision-making process for confidentiality claims. EFSA has already undertaken or planned the necessary actions to ensure consistent decision-making processes regarding this matter and to review its current rules on access to documents, to take stock of the developments in the applicable legal framework and case law. Classes 1 and 7 EFSA is committed to a consistent and sound implementation of the relevant provisions for the establishment of an Open EFSA. These include also those provisions mentioned in the contribution. EFSA is committed to increasing its efforts to address all three points on which the contributor recommends action. These are either on-going or planned, or will be looked at in the context of the further categorisation and prioritisation according to the Implementation plan. Classes 1 and 2

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12.	The Federal Institute for Risk Assessment (BfR) EFSA Focal Point (Germany)	Executive Summary	PART 1 We realise that the European Food Safety Agency (EFSA) has started several initiatives to increase transparency of its work, such as the implementation of public consultations on important scientific opinions as recently for bisphenol A or acrylamide, or on draft assessment reports elaborated by Member States as for glyphosate. Via a web interface comments can be transmitted by every interested party. After the consultation period a respective report containing all comments is published by EFSA. Furthermore all scientific opinions as well as results of outsourced research projects in the framework of grants and procurements are published by EFSA. In 2013 a pilot project was launched that allow observers from the general public to join scientific panel meetings (http://www.efsa.europa.eu/en/press/news/130702.htm). A meaningful tool is the publicly accessible register of mandates and requests EFSA receives. This register contains not only the request itself but also background documents of the requester like the European Commission, the European Parliament or a Member State. In our view, these above mentioned tools and the overall course of action constitute a clear added value to the work done at the level of the European Union and it matches the tasks of analysing and assessing risks in the fields within the mission of the European Food Safety Authority. The situation is different for direct access to data which in most cases are provided to EFSA by Member States or companies, respectively. According to the German Basic Law, the official controls of food and feed, cosmetics and other everyday products fall within the remit of the German Federal States. Therefore these bodies are the owners of the data. To make these data accessible to stakeholders, procedures for consultation with the Member States have to be elaborated, possibly similar procedures as in case of Member State consultations in the context of requests for access to documents according to Regulation (EC) No 1049/2001 (Public Access to Documents Regulation). It should also be noted that personal data may be affected that are covered by data protection legislation (e.g. food consumption data). As mentioned above it is rather the task of EFSA to analyse data and to assess the risks for the food chain as well as for human, animal and plant health than to only publish the data, in particular if the possibility of misinterpretation of the data exists, e.g. when taking risk orientated samples, or if the data are not representative.	EFSA takes note of the comments of the contributor acknowledging EFSA's efforts so far and its plan to further enhance openness and transparency. Regarding the procedures for the implementation of the Regulation on Public Access to Documents, EFSA plans to review its internal rules on this matter. Class 1 Regarding the risk that certain data made publicly available by EFSA could be misinterpreted, the Authority's intention is to publish, in addition to the data, certain metadata, which should help to mitigate this risk. Class 1 Regarding the need for harmonising access to data from assessment reports prepared by Member States, and the comment on creating a requirement for the registration of studies, these go beyond EFSA's remit. Class 5

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			So far no agreed procedures are established between the European and the national level regarding access to data of the Member States. It might be useful to explore the possibilities of gaining greater insight into the data and study results within application procedures. For the safety assessment of pesticides, e.g., huge information is available in the published draft assessment reports provided by the Member States. Whereas in some Member State reports only the direction of action caused by an evaluated pesticide active substance is included, the information content in other reports is higher due to the indication of concrete numerical values. A harmonisation effort regarding the draft assessment reports that aims at specifying values as precisely as possible should result in an increase of information for interested parties. The procedures for assessing pharmaceuticals could serve as a model for the food safety sector. This could include registering all studies and making abstracts of the study results publicly available. As a conclusion, the continuation and further development of EFSA's publication policy, the involvement via public consultation procedures, the further development of stakeholder initiatives as well as elaborating consultation procedures with the Member States regarding their data and defining clear criteria on what are sensitive data, should increase confidence of consumers in the European food safety system.	
13.	GAP's chair on behalf of GAP, IPA and YLFA (Belgium)	Executive Summary	This submission is made on behalf of Global Alliance for Probiotics (GAP), the Yogurt Life and Fermented Milk Association (YLFA) and the International Probiotics Association (IPA). The probiotic sector welcomes EFSA's initiative to collect comments before drafting a policy document on Openness and Transparency at the European Food Safety Authority (EFSA). Society' expectations should include industry's comments and concerns, namely when it refers to interactions between EFSA panels and food business operators who are submitting scientific dossiers for evaluation. Clear conditions should be placed on interactions with EFSA so that a "real" scientific dialogue between applicants and EFSA is possible.	To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7

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14.	Individual contribution, Istituto Superiore di Sanità, EFSA external expert (Italy)	Executive Summary	As long-standing EFSA expert (2003-12 FEEDAP Panel; 2012-till now PPR Panel) I have a general comment. This document points out the need to foster the values of openness and transparency; it is out question that a scientifically authoritative EFSA must develop these values as well. However, I miss the aim of the document and I have serious doubts on the emphasis put on some points. According to my EFSA experience, key indicators of EFSA work's success are the capacity for i) delivering timely and transparent (i.e., it is easy to understand conclusions and how they are reached); ii) eliciting updates/modifications of the EU framework of regulations and controls on food chains; iii) fostering developments in the science of risk assessment. Therefore it is important to interact with stakeholders and the growing use of public consultations has to be commended. Conversely, a "useful EFSA" should not expect to please all stakeholders at all times. An open, efficient and scientifically influential EFSA cannot drag and delay its deliverables because of lengthy negotiations with stakeholders. Moreover, for transparency's sake EFSA and EFSA Panels have to bear the full responsibility for their opinions. The (welcome) development of interactions and exchanges with stakeholders should not lead to "shared" (i.e., unclear) responsibilities with interested parties, however important may be their scientific inputs (e,g., some national authorities). Overall, it is commendable to refresh the EFSA strategy for openness and transparency in light of rapid cultural and societal changes (i.e., the development of the social network universe): however, the risk assessment of an (over) enthousiastic approach is recommended.	EFSA appreciates the contributor's concerns and acknowledges the need to adequately balance principles of openness with EFSA's obligation to operate efficiently. Class 1 EFSA also recognises that enhanced interaction should not lead to shared responsibility with interested parties. Class 1
15.	Pen & Tec Consulting Group (Spain) on behalf of EFFSACO	Executive Summary	Line 1 On behalf of EFFSACO, we are in favour of transparency in EFSA scientific processes & appreciates the chance to provide input as an EFSA stakeholder. EFFSACO also supports the principle that science should prevail & recommends a strong focus on scientists evaluating highly technical REPRO (regulated product dossiers), & fewer administrators involved in evaluation. EFFSACO supports EFSA access to all data & reports related to REPRO but is concerned that EFSA public opinions may reveal too much valuable confidential	The actual competences and respective responsibilities of EFSA staff and the Authority's external experts are rooted in EFSA's Founding Regulation and in the sectoral legislation. Class 4 EFSA acknowledges the fundamental importance that regulatory data

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			information, in violation of TRIPs, to which the EC is a signatory, & which obliges protection of applicant data that are obligatory for registration purposes. AVC proposes that EFSA limits public opinion to the conclusions of safety & efficacy studies (e.g. NOAEL, safety margin, minimum effective dose). The supporting study reports should never be made available following public or competitor "PAD" requests (Reg 1049/2001, public access to documents). EFFSACO supports the option of communication between applicants and EFSA prior to submission of a dossier (i.e. PRE-SUBMISSION MEETINGS). EFFSACO supports the creation of an "Appeal Office within EFSA" to allow the applicants their rights to appeal on the scientific opinions issued by EFSA. EFFSACO supports the need for the different Working Groups within EFSA to be composed scientists of recognized expertise within the required fields for an accurate evaluation of REPRO dossiers. EFFSACO supports the need for EFSA to work together with industry in order to achieve guidance and procedures fit for each purpose, so that only approvable applications are received by EFSA. EFFSACO proposes that for REPRO dossiers subjected to re-authorization processes, the scientific opinion of EFSA should not be published until the EU Commission votes at the Standing Committee meetings	protection and protection of commercially relevant information has for the concerned sectors in order to be competitive on a global scale. For this reason, in 2014 it substantially strengthened its approach to protecting commercially sensitive information recognised to be worth of confidential processing, by developing internal procedures to streamline its internal decision-making process for confidentiality claims. EFSA has already undertaken or planned the necessary actions to ensure consistent decision-making processes regarding this matter and to review its current rules on access to documents, to take stock of the developments in the applicable legal framework and case law. Classes 1 and 7 However, this needs to be considered also in the light of the Regulation on Public Access to Documents and Aarhus Regulation. Against this background, it seems difficult to conclude that EFSA may systematically and *a priori* exclude accessibility to all study reports. Class 4 To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7

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				EFSA commits to carry out further categorisation and prioritisation of the possibility to organise pre-submission meetings with applicants in the area of regulated products. Class 2 EFSA is already subject to provisions obliging it to review its adopted outputs once relevant scientific data or information undermining previously adopted conclusions is identified. Class 7. EFSA commits to perform further categorisation or prioritisation on the possibility of making publicly available all documents linked to a decision on whether or not to update an output. Class. 2. However, EFSA considers that the establishment of an internal Appeal Office would not be compatible with the applicable legal framework and as such may not be considered by the Authority. Class 4 EFSA is required by law to publish its opinions immediately after their adoption. Class 4
16.	Individual contribution, VU University Amsterdam, Department of Health Sciences (Nederlands)	Executive Summary	In its first decade, EFSA has performed far beyond the expectations of myself and of other academic nutrition experts. Much of Europe and indeed the world has come to rely on EFSA's Opinions and reports as a source of solid, independent scientific guidelines. The present paper now aims to "transform" EFSA. My concern here is: If it isn't broke, don't fix it! There is a real risk that these changes may damage the quality of what EFSA is doing. Throwing large numbers of data into a computer is not good science; what holds here is "garbage in, garbage out". More influence of commercial organizations and lay enthusiasts can only lower the quality of the EFSA output. EFSA is performing at a high level, and all paths from the summit	Noted. EFSA is committed to scientific excellence, and the quality of its scientific advice will not be compromised. Class 6

No	Contributor	Chapter	Comments received	EFSA response
			lead downwards.	
17.	Lallemand Health Solutions (Spain)	Executive Summary	Lallemand Health Solutions applauds EFSA for their initiative in striving towards an "Open EFSA" and for their invaluable commitment in giving interested parties the opportunity to contribute to this transformation through this consultation. We believe that dialogue and transparency are the key principles to good communication for a fair, just and informed decision-making process	Noted. Class 1
18.	Federation of European Specialty Food Ingredients Industries (ELC) (Belgium)	Executive Summary	ELC input to the questions addressed in this section have been included in the joint letter "Operational, procedural and scientific challenges for industries impacted by EFSA" signed by 12 European federations dated 17 February 2014.	EFSA addressed the concerns expressed by the 12 European federations in a dedicated meeting. Class 7
19.	Individual contribution, (UK), Science and Technology Policy Research, University of Sussex	Executive summary	As a scholar of, and commentator on, European Food Safety Policy-Making I very much welcome the publication of EFSA's Discussion Paper: Transformation to an "Open EFSA". There is a very great deal in the document to be welcomed by citizens, consumers, public interest NGOs and responsible companies, although there are quite a few loose ends and several problematic passages. The text makes it clear that the EFSA Board recognises 1) that the status quo is not one of sufficient openness or transparency and 2) that a process to transform EFSA into an Open Science organisation will entail financial costs as well as providing benefits. The document also recognises that the expenditure of public resources to transform EFSA into an Open Science organisation will need to provide benefits to more than just EFSA's reputation. The document does not however say what else would be required; surely the relevant benefits must include 'safer food and healthier diets' as well as improved protection of consumers' interests and enhanced democratic and scientific accountability and legitimacy. One of problematic features of the text is that it sometimes over-simplifies complex and contested issues. One such occasion occurs when setting the target that EFSA should "…better meet society's expectations…" (p 3) That wording seems to presuppose that those expectations constitute a unified or consistent set while the expectations prevailing in the population and firms of the EU are in fact rather diverse and sharply contested. Surely the role of EFSA should unambiguously be to put European consumers first, rather than to be neutral, or	EFSA provides a better definition of further categorisation and prioritisation in the Implementation plan, where the analysis will be limited to costs and benefits of the actions for EFSA. Class 6 EFSA's remit and powers are rigorously defined in its Founding Regulation and in the applicable sectoral legislation. Class 4

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			indifferent as between for example consumers' interests and those of the food industry? The references to 'cost/benefit' analyses are also too ill-defined, with a lack of clarity as to what would be counted as a 'cost' and/or as a benefit'. Near the start of the document the impression is given that EFSA might aspire to identifying and taking account of a very wide range of costs and benefits to a wide range of stakeholders, while towards the end, and in the context of referring to the use by EFSA of public resources, the impression is given that the main category of costs that EFSA would take into account are the increased marginal financial costs to itself of transforming itself into an 'Open Science organisation'; in which case the beneficiaries of the 'benefits' remains opaque. The ranges of possible 'costs' and 'benefits' that might be deemed pertinent could be rather broad. Are they simply the aggregated costs and benefits to any and all relevant stakeholders, or the costs and benefits to different categories of stakeholders to be considered separately? Are benefits to consumers, for example, to be deemed a higher priority than eg costs to corporate interests? Are all categories of 'costs' and 'benefits' to be deemed relevant, or only those that can be quantified? And amongst those that can be quantified, are monetised parameters deemed more or less important than non-monetary considerations? Are the cost and benefit considerations confined to those that might arise in the short-run, or do they include long-run changes? Will attention be devoted solely to direct costs and benefits or also to indirect effects? The text in Section 1 on page 6 refers to 'all direct and indirect risks related to the food chain', but it is unclear if the costs and benefits that EFSA will address, when adjudicating the details of its reform process, will be framed correspondingly widely. Moreover it is unclear if the plan is to gather estimates of all costs and benefits, and then simply to aggregate them and to see if 'on balance', benefits exceed costs, or whether trade-offs between costs and benefits will be judged with more nuanced criteria and by reference to particular groups of stakeholders. In the Executive Summary on page 3, 5th bullet point: the text suggests that EFSA assumes that there can be trade-offs between the 'availability and quality of information', but it is unclear why or under what conditions either might compromise the other.	

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20.	European Ombudsman	Executive Summary	I note that the discussion paper currently exists only in English. Furthermore, despite the fact that " *[i]nterested parties and the public at large are invited to submit written comments* there is no indication on your website that comments can be submitted in any of the 24 official EU languages. I understand, however, from the contacts between our services that EFSA would be willing to make the document available in other languages, upon request and that you are ready to accept comments in any of the 24 official EU languages. The Ombudsman recently opened an inquiry in relation to the mandatory use of an electronic template, which was allegedly particularly complex and not user-friendly, in the context of a public consultation conducted by EFSA. Please see case 952/2014/OV, available at: http://www.ombudsman.europa,eu/en/cases/caseopened.faces/en/54561/html.bookmark. As EFSA is in the process of developing its policy in this area, I wanted to take this opportunity to draw your attention to two important initiatives that my Office has been involved in. Earlier this year, I spoke at the European meeting of the Open Government Partnership (OGP). The aim of the OGP, in which 19 EU Member States now participate, is to make governments more open, accountable, and responsive to citizens. As European Ombudsman, I intend to do whatever I can to help the EU administration to live up to these expectations, in line with the provisions of the Union Treaties. I encourage you, therefore, to take inspiration from the work done within the OGP's four interlocking themes of accountability, citizen participation, transparency and the facilitating role of new technologies. My office also organised this year a conference of the Research Network on EU Administrative Law (ReNEUAL), which has drawn up model rules of administrative procedure, including procedures for the adoption of general rules ("rulemaking"). The latter could help EU institutions and agencies, including EFSA, to carry out rulemaking in a way that promotes participatory democracy and transparency, in the spirit of Article 11 of the Treaty on European Union. I attach the model rules, as a potential source of inspiration for your Agency, particularly as regards procedures that you might use to promote citizen participation when developing new rules and policies. I would encourage EFSA to examine the aforementioned material with a view to determining how it could be relevant to its efforts to become an 'Open Science' organisation. The material could also be relevant as EFSA embarks on its review of its Policy on Independence and Scientific Decision-Making Processes, which will begin in 2015.	EFSA is committed to making its outputs more accessible and understandable. EFSA will subject its current language regime to a further categorisation and prioritisation, to be performed according to the Implementation plan. Class 2 Without prejudice to the written opinion submitted by the Authority in the context of this specific complaint, EFSA underlines that it allowed the complainant to submit its contribution in a format different from that required by its “standard operating procedure”. Furthermore, upon receipt of the complaint, EFSA simplified the requirements in question and has already undertaken or planned the necessary actions to make its consultation system accessible to all citizens. Class 1 Without prejudice to the applicable legal framework, EFSA will, in its further categorisation and prioritisation according to the Implementation plan and in the implementation of the actions to be developed as a consequence thereof, consider the guidelines, standards and commitments made by the partners of Open Government Partnership as well as the text developed by the ReNEUAL. Class 2

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21.	Syngenta (Switzerland)	1. Introduction	Syngenta supports the need for openness and transparency in EFSA's activities and commends EFSA for opening up some scientific committee and panel meetings to observers and encourages EFSA to further extend this practice. The specialist nature of the science underpinning many of EFSA's opinions will realistically limit many citizens productive participation in the hazard characterisation, exposure characterisation and risk assessment phases of the regulatory decision-making process. But it is part of democratic accountability that these stakeholders are properly informed and can follow and where relevant engage in the risk mitigation and management phase of the regulatory process. The opportunity for broad public engagement in EFSA's risk communication initiatives is crucial. It is right that EFSA should explain to the broader public both the opinions it has reached and how these conclusions were derived. It is equally important that risk managers and risk assessors in government and society understand in detail how EFSA has reached its conclusions. There are however, other stakeholders for example in government, industry, academia, and certain interest groups (NGOs) who are both scientifically qualified to participate in the dialogue by which EFSA forms its opinions and more importantly have specialist knowledge and expertise essential to the goal of an evidence based, risk informed, scientifically robust and proportionate EFSA opinion. Currently, failure to adequately distinguish between these two groups of stakeholders typically limits the opportunity for the contributions of all of these stakeholders until a public "consultation" during the later phases of the EFSA process by which time EFSA are no longer able to consider new data or input, irrespective of its value to shaping the quality of EFSA's conclusions and output. It should be possible for EFSA to develop, using transparent criteria based on tertiary scientific education and professional qualifications, and years of relevant experience, a process that allows relevant stakeholders to apply for scientific professional status. EFSA should value and engage with all stakeholders but distinguish the different needs and contributions of scientific professionals and lay persons. EFSA's approach to raising the bar for implementation of the principles of independence and scientific decision making is based on a narrow definition of independence, the pursuit of which has come at a cost in terms of the expertise available to EFSA. Bias in exclusion criteria only results in bias in inputs received. Some stakeholders with vital specialist knowledge are currently denied the necessary opportunity to constructively contribute during the hazard	EFSA takes note of the suggestion that different weight should be attributed to contributions submitted by different contributors depending on their level of qualification regarding the matter at hand; however, EFSA considers that reliance on formal qualifications or acquired professional expertise may limit the potential benefits it could obtain from the implementation of the Open EFSA initiative. Class 3 EFSA acknowledges that the implementation of the Open Science / Open Government principles is also intended to allow the Authority to better exploit the resources and knowledge available elsewhere, while retaining the high level of independence expected from the members of its Scientific Committee and Scientific Panels, and their Working Groups. Class 1 EFSA commits to perform further categorisation and prioritisation according to the Implementation plan on the degree to which it should increment the recourse to "hearing experts". Class 2 The Authority also intends to review its policy on the independence of its scientific decision-making processes with a view to fully reflect in it the opportunities for enhanced transparency and engagement that

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			characterisation, exposure characterisation and risk assessment phases. A more open EFSA that was able to benefit from the timely participation of a full range of scientific professionals whilst maintaining the independence of its decision makers would be positive progress.	will result from the "Open EFSA" project. These comments will therefore feed into this process as well. Class 6
22.	FEFANA (Belgium)	1. Introduction	FEFANA supports the efforts to push further the European Food Safety Authority (EFSA) towards a highly performing and credible science organisation. However the consultation paper infers that, in order to gain credibility, EFSA should switch to an open science organisation. We believe that public participative assessment will not increase the credibility of the Authority, on the contrary. Citizens cout on EFSA to perform a good job. As citizens we want to be able to trust our institutions without embarking in duplicating or in need to monitor closely its work. Instead there should be room for scientific inputs by concerned parties at predictable points in the process, dialogue on this, and possibility for scientific challenging (as included in the table on page 14).	EFSA takes note of this consideration, although it believes that there is an underexploited potential outside its scientific governance bodies that could contribute to further improving the comprehensiveness and overall quality of some of its outputs. Forms of engagement will be part of the Implementation plan. Class 6
23.	Confederazione Nazionale Coldiretti (Italy)	1. Introduction	Given the value that Openness and Transparency have, it could be helpful to clearly catalogue all the actions made by Efsa along last years to achieve transparency and openness, in case, in a chronological order and not just as a non-exhaustive list of examples.	EFSA's actions to implement the general principles of openness and transparency are readily available on its website, and actions to further strengthen its visibility have already been undertaken or planned. Class 7
24.	BEUC - The European Consumers' Organisation (Belgium)	1. Introduction	BEUC, The European Consumer Organisation, welcomes the Discussion Paper "Transformation to an "Open EFSA" and the Agency's renewed commitment towards societal engagement. Transparency and openness are essential elements to ensure consumer trust in regulatory authorities and close the divide between the EU and its citizens. The societal and normative expectations identified by EFSA in the paper reflect the growing demands of civil society to have a voice in the risk handling process and for reliable, transparent information generally. We fully support EFSA's ambition to increase inclusivity and participation, but it is also important to stress the fact that risk assessment is an essentially scientific and objective activity, therefore should remain as such. In defining the framework of interaction with stakeholders, safeguarding the independence of risk assessment should always remain the priority. Stakeholders' involvement and participation enhance the senses of ownership, legitimacy and consensus. "Input legitimacy" is important, but for an independent scientific body like EFSA, "output legitimacy" should also be preserved. If the risk	EFSA takes note of the implications that enhanced participation could have for independence, according to this contribution, and will consider it during the review process of its policy on independence. Class 6

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			assessment process is too participative it is no longer independent and most of all EFSA would lose control and accountability of the final outcome.	
25.	Individual contribution, (UK)	1. Introduction	Equitability of contributions from all respondents. The key concept of 'Open Science' is that debate on all issues is indeed open and fully transparent. This means that the identity of authors is evident to all - this is why anonymous papers are not published in peer-reviewed Journals. Yet in this consultation EFSA proposes that submissions from independent contributors will be published anonymously, whereas the comments from correspondents from formal organisations will be published with the organisation identified. This is an absurdity, in both principle and implementation. It implies that more weight will be given to those comments originating from authors from 'respectable' institutions. There is no means of confirming that views published by contributors from such organisations actually represent the position of those organisations - again, it is common practice for authors to issue specific disclaimers regarding their own views as being distinct from the 'official' position of their employer when publishing their views. If EFSA is serious about constructing an 'Open EFSA' then the content of all correspondence (with perhaps the exception of actually sensitive commercial information) must be attributable to named individuals. This section notes, with apparent satisfaction, that "in 2013, EFSA opened up its Scientific Committee and Panel meetings to observers". From personal observation on just such a Scientific Committee in the UK over an extended period, it appears common practice for such Committees to be structured so that there are discrete cliques within the group, comprising a central core group and what may be referred to as 'Ordinary' Members. Members of the 'elite' group may meet in camera to decide policy in running the study, with 'Ordinary' Members excluded from such confidential debate. If such practices are present within EFSA, then how much less transparent must such secret decision-making appear to the privileged observers of whom EFSA appears so pleased to allow to watch from the sidelines?	EFSA acknowledges the criticism regarding the publishing of contributions to this public consultation anonymously and that a higher level of transparency might be appropriate. Therefore, the Authority commits to changing its approach in the future by asking all contributors for permission to disclose their names and affiliation pursuant to Regulation (EC) No 45/2001. Class 2. EFSA has already undertaken or planned the necessary actions to decide on the degree to which it should open its plenary meetings to observers (Class 1) and to which it should increment the recourse to "hearing experts" and the organisation of "public hearings". Class 2
26.	ClientEarth (Belgium)	1. Introduction	In order to clarify the objective and the understanding of EFSA's position it would have been useful to state the problem that triggered action. Openness and transparency are directly deriving from the Lisbon treaty, to which EFSA's policies should adapt. The Treaties of Lisbon underline 5 times that the European Union (EU) adheres to the principles of an open society. While the wording of Article 1(1) TEU constituted	In its daily work, EFSA is committed to fully respect the principles and provisions outlined in the Lisbon treaties and Charter of Fundamental Rights of the European Union. Class 7

No	Contributor	Chapter	Comments received	EFSA response
			a repetition of the text which existed already in Article 1 of the EC Treaty prior to 2009, the text of the other four provisions quoted is new. It underlines the commitment of the authors of the Lisbon Treaties to an open EU society. This commitment is further strengthened by the re-evaluation of the EU Charter on Fundamental Rights of 2000 which obtained, through the Lisbon Treaties, the same legal value as the Lisbon Treaties themselves and which gave EU citizens a fundamental right of access to information, stressing that the EU "placed the individual at the heart of its activities." Access to information on the environment plays a particularly important role in environmental policy, because the environment has no voice: eagles and fish, whales and foxes cannot defend their interests in discussions, and future generations of humans are in the same position. Much of EFSA's work and information it holds falls under the definition of environmental information as defined by Article 2(1)(d) of Regulation 1367/2006. 'environmental information' means any information in written, visual, aural, electronic or any other material form on: (i) the state of the elements of the environment, such as air and atmosphere, water, soil, land, landscape and natural sites including wetlands, coastal and marine areas, biological diversity and its components, including genetically modified organisms, and the interaction among these elements; (ii) factors, such as substances, energy, noise, radiation or waste, including radioactive waste, emissions, discharges and other releases into the environment, affecting or likely to affect the elements of the environment referred to in point (i); (iii) measures (including administrative measures), such as policies, legislation, plans, programmes, environmental agreements, and activities affecting or likely to affect the elements and factors referred to in points (i) and (ii) as well as measures or activities designed to protect those elements; (iv) reports on the implementation of environmental legislation; (v) cost-benefit and other economic analyses and assumptions used within the framework of the measures and activities referred to in point (iii); (vi) the state of human health and safety, including the contamination of the food chain, where relevant, conditions of human life, cultural sites and built structures in as much as they are or may be affected by the state of the elements of the environment referred to in point (i) or, through those elements, by any of the matters referred to in points (ii) and (iii); It would be important for EFSA to acknowledge that the Aarhus Convention is applicable to its work and that it aims at complying with its objectives. In	The same holds true concerning the Regulation on Public Access to Documents and the Aarhus Regulation. However, the latter is not applicable to all of EFSA's work. In cases where these provisions are applicable, EFSA complies with the requirements and objectives set in both texts. Class 7 EFSA has already undertaken or planned a review of its internal rules implementing these regulations in order to capture the developments brought about by EU Courts. Class 1

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			particular: (a) guaranteeing the right of public access to environmental information received or produced by Community institutions or bodies and held by them, and by setting out the basic terms and conditions of, and practical arrangements for, the exercise of that right; (b) ensuring that environmental information is progressively made available and disseminated to the public in order to achieve its widest possible systematic availability and dissemination. To that end, the use, in particular, of computer telecommunication and/or electronic technology, where available, shall be promoted.	
27.	DANONE (France)	1. Introduction	DANONE welcomes EFSA's initiative to enhance openness and transparency, and appreciates the benefits to be gained from increased EFSA engagement.	Noted. Class 1
28.	Public Research and Regulation Initiative (PRRI) (Belgium)	1. Introduction	The introduction states that "Openness is meant as an enabler for citizens to participate more closely in the decision-making process". It should be made clear that EFSA is an advisory body, and not a decision making body. The role of openness for advisory bodies is different than for decision making bodies. The introduction also states: "Decentralised agencies of the Union need to be particularly attentive to the need for openness, and of their operations being understandable and accountable to Union citizens and interested parties". While it is very true that EFSA's operations should be understandable to everyone, the phrase "accountable to Union citizens and interested parties" also suggests a political role that EFSA does not have. EFSA is accountable to the EU Institutions and Member States, and its binding principals are the law and sound science.	EFSA notes that the use of the expression *"decision-making process"* in the discussion paper refers to its scientific processes. This is clearly without prejudice to the fact that the Authority is not empowered to take binding decisions on the authorisation of regulated products, processes, claims, and organisms. Class 6 The fact that EFSA is accountable to Union citizens and interested parties derives from the objective consideration that EFSA receives the entirety of its budget from the EU budget. As such, EFSA is required to provide value for money and justify to the budgetary authorities the use of the public resources it receives. Class 4
29.	Food Supplements Europe (Belgium)	1. Introduction	Food Supplements Europe welcomes this discussion document and the initiative to transform EFSA into an Open Science organisation. We believe that engagement with all, in particular applicants who rely on EFSA for the assessment of their data in view of a legal authorisations, will contribute greatly to the transparency, open dialogue and credibility of the EFSA work and be able to address a number of	Noted. Class 1

No	Contributor	Chapter	Comments received	EFSA response
			criticisms currently voiced by society. Food Supplements Europe therefore supports this initiative and is committed to help EFSA achieve its goal. Food Supplements Europe welcomes very much the extensive explanation as background to the plans set out in the discussion paper describing the methodology and the way envisaged for the transformation of the EFSA into an Open Science organisation over the next five years. EFSA is soliciting views on a number of points, which will be covered under the relevant sections below.	
30.	Individual contribution, Maastricht University	1. Introduction	As the EU Treaties (Articles 1, 10 TEU; 15 and 298 TFEU) and the Court of Justice of the EU (e.g. cases C-41/00 P, Case C-28/08 P; C-92/09 & C-93/09) underline, the principles of transparency and openness enable citizens to participate more closely in the decision-making process and guarantee that the administration enjoys greater legitimacy and is more effective and more accountable to the citizen in a democratic system. These principles thus strengthen the democratic character of the EU institutions and the trust of the public in the administration. The General Food Law (Reg. 178/2002) thus requires EFSA to undertake its risks assessments in an independent, objective and transparent manner whereby EFSA must publish various documents. From this perspective the vision of EFSA enfolded in this discussion paper to open up more and to make information as to which data it used in its risks assessments accessible can only be applauded.	Noted. Class 1
31.	GAP's chair on behalf of GAP, IPA and YLFA (Belgium)	1. Introduction	The probiotic sector warmly welcomes EFSA's initiative to enhance openness and transparency, and appreciates the benefits to be gained from increased EFSA engagement.	Noted. Class 1
32.	Lallemand Health Solutions (Spain)	1. Introduction	Lallemand Health Solutions acknowledges and appreciates the recently implemented EFSA measures enhancing openness and dialogue with applicants including the creation of the EFSA Application Desk in 2012 and the initiation of workshops with stakeholders. While these measures are welcomed, it is our belief that in the case of the regulated products, these measures do not extend far enough. We believe that for some of the application processes, in particular the evaluation of health claims, the EFSA case-by-case approach requires a case-by-case dialogue and assistance to applicants. This should take place at the different stages of the decision-making process (before, during and after an EFSA opinion is released)	To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7

No	Contributor	Chapter	Comments received	EFSA response
33.	Individual contribution, (France)	1. Introduction	J'apprécie beaucoup que EFSA organise des consultations. La première chose à faire, est de mettre les textes lisibles à l'ensemble de la population européenne. je doute que les trois langues et en particulier l'anglais soient la l angue maternelle de celle-ci. Comment pouvons nous avoir une quelconque confiance des ces consultations digne de des traités en latin du moyen age. je suis a votre disposition pour tout aide permettant d'arriver à cet objectif de hisser le citoyen à toutes connaissances.	EFSA is committed to making its outputs more accessible and understandable. EFSA will subject the current language regime of its scientific outputs to a further categorisation and prioritisation, to be performed according to the Implementation plan. Class 2.
34.	Individual contribution, (UK), Science and Technology Policy Research, University of Sussex	1. Introduction	In the Introduction on page 6, 2nd full paragraph, the text indicates that EFSA's understanding of its responsibilities relates to 'all direct and indirect risks related to the food chain'; and that statement is welcome. On the other hand, there have been occasions in the past when EFSA panels have suggested that their approaches have been comprehensive when they have in fact been partial and selective. If the scope of EFSA's remit is 'all direct and indirect risks related to the food chain' then steps will need to be taken to ensure that all staff, panels and working groups comply with that stipulation. In the Introduction on page 6, the text refers to making outputs: "…more comprehensive, more understandable to those who contributed to their development and more relevant to the intended recipients." Why might comprehensiveness and understandability be more important for '…those who contributed to their development…' than for those that did not? Furthermore, it is unclear to whom the phrase: 'the intended recipients' refers? This needs clarification.	EFSA's operations comply with its legislative mandate as further specified in Article 22 of Regulation (EC) No 178/2002, and in sectoral legislation. EFSA's staff and its Scientific Committee, Panels and their Working Groups are required to operate in accordance with the limits laid down in Article 22 of Regulation (EC) No 178/2002. Class 0 The intended recipients of an output are mainly the bodies that formulated the request or mandate in the first place or, where appropriate, the applicant. The former may be the European Commission, an authorised body in a member state or third country pursuant to Article 49 of Regulation (EC) No 178/2002, the European Parliament or EFSA in its self-tasking capacity. Class 6
35.	Federation of European Specialty Food Ingredients Industries	1. Introduction	A minor comment on last line: "[…] and in 2013, EFSA opened up its Scientific Committee and Panel meetings to observers" It would be more accurate to indicate: "[…] and in 2013, EFSA opened up a few of its Scientific Committee and Panel meetings to observers" as all these meetings were not open to observers.	Noted. Class 2

No	Contributor	Chapter	Comments received	EFSA response
	(ELC) (Belgium)			
36.	Finnish Food Safety Authority (Finland)	1. Introduction	Finnish Food Safety Authority Evira warmly welcomes the published document (with relation to Open EFSA initiative) and considered it is step forward in strengthening both openness and transparency of EFSA´s scientific work and it´s risk assessment process. The document contains many objectives and good targets in the future we can agree/encouraged EFSA. Our comments below are offered to support Open EFSA initiative. We believe that having open meetings of panels and scientific committee (as EFSA has done since 2013) is important in terms of transparency but it also allows stakeholders understanding EFSA´s scientific working methods and the panels & committee function. Also we encourage EFSA to continue holding open consultations to support of the draft opinions particularly on issues with high level of scientific community and stakeholder interest (regardless of the fact that all public consultations are in English, which exclude from the consultation many people - e.g. some stakeholders - who don´t speak/understand official language in EU). However we suggested that scientific opinions produce by Panels and Scientific Committee should consider an external peer review process (involved external experts on EFSA´s scientific work before the output is adopted). This might increase the trust of EFSA and its scientific opinions in general to scientific community around the world and also to general public and stakeholders. We also suggested that risk communications should be targeted also more to general public (e.g. EFSA´s plan to published flash summary/abstracts immediately after plenary meeting could aim at general public). We think that guiding principles needed before proving wider access to key information, data and documents. Also pilot period e.g. with MS would be beneficial procedure to test the system prior to others. Finally we believe (even it is not mentioned in this document) that it would be beneficial for EFSA to be more open as to how Scientific networks are used by EFSA. In general we think that if the networks defined and worked well they will benefit all parties (e.g. MS organizations) to reach same level of know how.	EFSA takes note of the comments of the contributor acknowledging EFSA's efforts so far and its plan to further enhance openness and transparency EFSA is committed to making its outputs more accessible and understandable. EFSA will subject the current language regime of its scientific outputs to further categorisation and prioritisation according to the Implementation plan. Class 2 EFSA acknowledges the potential benefits that a peer review system would bring to its scientific work, and will look into the feasibility of establishing such a system in the context of the further categorisation and prioritisation exercise to be performed in accordance with the Implementation plan. Class 2 EFSA acknowledges the importance of stepping up its ability to communicate with the general public, and it confirms its willingness to undertake further categorisation and prioritisation, to be performed according to the Implementation plan, regarding the possibility to disseminate a flash summary/abstract immediately after the plenary meeting, and to use a broad array of communication

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				channels depending on the target audiences. Class 2 EFSA appreciates the suggestion to implement more openness as regards the recourse to EFSA's networks, and it commits to perform further categorisation and prioritisation on the possibility to grant increased accessibility to key data packages to Member States' competent authorities. Class 2
37.	EMA	1. Introduction	Dear Bernhard Subject: EMA comments on EFSA's discussion paper "transformation to an open EFSA" Thank you for informing us about the consultation on EFSA's discussion paper on transparency, which we have read with much interest. From the proposals in your consultation document we would like to make the following observations: We fully agree that there is a continued need and legitimate expectation for the EU regulatory Agencies to be more transparent and open. The approach to the open model of scientific discussion outlined in your consultation document represents a meaningful and positive step towards such objective. However, one of the main risks is that the decision-making process may become subject to external pressures from various directions. For this reason, publication of data held by the EMA only takes place once the decision-making process on an application for a European Union (EU)-wide marketing authorisation is complete. The same principle applies for the reactive release of documents submitted as part of applications for marketing authorisation through the Agency's policy on 'Access To Documents'. Indeed, Article 4(3) of Regulation (EC) 1049/2001 provides certain exceptions to the general rules on access to documents held by the EU Agencies in order to address the above risk. In addition, we thought it may be useful to provide you with some feedback from our own experience in the field of transparency acknowledging that the legal framework under which our Agencies operate may differ, and hope that this may help you in your journey to the transformation of EFSA into an Open Science organisation.	EFSA notes EMA's suggestion to make publicly available underlying data packages only after the adoption of the relevant output. Therefore, EFSA will consider the comments put forward in this contribution during the forthcoming further categorisation and prioritisation according to the Implementation plan. Class 2

No	Contributor	Chapter	Comments received	EFSA response
			Transparency and openness are two very important features also of EMA's operations. In fact, the Agency has always aimed at being as open as possible about how it works and how it comes to its decisions. Since its formation in 1995, the Agency has published detailed information on its scientific assessment work, through the European public assessment report (EPAR), a unique tool among medicines regulators in describing the basis for opinions of EMA's main scientific committees when recommending new medicines to be approved (or not). Over the subsequent years, the Agency has worked towards increasing the level of openness about how it works, through publication of information on its scientific and non-scientific operations and a continuous effort to explain its decisions and procedures. Many of these initiatives have been driven by the legislation but in some cases the Agency has gone beyond its legal obligations in order to increase transparency and openness. I have listed some relevant initiatives further down in this letter. The Agency has been engaging in dialogue with European patient and consumer organisations since it was established in 1995. As users of the medicines that the Agency evaluates, patients and consumers have specific knowledge and expertise to offer. They provide a crucial and unique 'real-life' perspective in the scientific discussions on medicines, which contributes to better outcomes within the regulatory process. In 2005, the Agency's Management Board endorsed a framework for interaction with patient and consumer organisations. This has made it possible for patients and healthcare professionals to be involved at key milestone during the lifecycle of the medicines from early development throughout the evaluation phase and during the post-marketing phase. More recently, the Agency, in its commitment to continuously extending its approach to transparency, has adopted a policy on the publication of clinical data1. The Agency believes that the release of data, which formed the basis of the Committees' opinions, is about establishing trust and confidence in the system, since it will allow the public to better understand the Agency's decision-making. It is also our strong belief that publication of clinical reports will also allow application of new knowledge in future research, help avoid duplication of clinical trials, foster innovation and encourage development of new medicines and, all this in the interest of public health. The policy has been shaped in the absence of any clear legal provision mandating the EMA to proactively publish documents submitted to the Agency by third parties. Consequently, a balanced approach was needed taking into account	

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			different stakeholders' competing interests, within the limitations of the current legal framework. This compromise allows access to clinical data but, at the same time, aims to discourage unfair commercial use of the data. The policy foresees a publication process governed by dedicated Terms of use (ToU). There are two sets of ToU applicable depending on whether an individual is content to watch the data on-screen only for general information purposes or if he/she needs to retrieve a hard copy of the document for academic and non-commercial research purposes. The clinical data held by the Agency may include commercially confidential information and personal data. Such information needs to be protected in accordance with the specific legal requirements governing the activities of the EU Agencies, Regulation (EC) 1049/2001 and Regulation (EC) No 45/2001. During the development of this policy one of the challenges faced by the Agency was the absence of a legal definition of the terms "commercially sensitive information", "confidential information" or "commercially confidential information". However, for the purpose of the policy, commercial confidential information (CCI) has been defined by EMA as 'any information contained in the clinical reports submitted to the Agency by the applicant/marketing authorisation holder (MAH) that is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the applicant/MAH'. In addition, the Agency has established clear guiding principles and standards concerning the redaction of such information prior to disclosure of data. These guiding principles and standards strike a balance between the need for transparency, the principle of reusability, and the protection of the economic interest and competitive position of the parties submitting proprietary data to the EMA. These principles have been established, through public consultation with all stakeholders, and will be applied in a consistent and uniform manner during the implementation of the policy. They also ensure a clear and transparent understanding on the part of applicants, and indeed all stakeholders, of the redactions of CCI the Agency is prepared to consider. Under the policy, applicants will be asked to submit clinical reports in view of their publication. If they believe that some elements should be redacted, then they may propose this together with the justifications for the redactions and the Agency takes the final decision on what is and is not to be redacted. Based on our experience, implementation of EFSA's transparency activities could be facilitated if such guiding principles were to be agreed with stakeholders, as appropriate, during the development of its transparency policies.	

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			Finally, there are also other activities of the EMA for which I would like to draw your attention as these might be helpful when you will be further considering your policy options. The activities described below take place during the Agency's decision making process: 1. Public hearings – Public hearings are a provision of the new pharmacovigilance legislation and the EMA is currently implementing a process that ensures that public hearings add value to the evaluation of medicines by enriching regulatory decision-making with valuable 'community knowledge' and alternative ways of learning and thinking about issues. Rules of procedure for the conduct of public hearings have been released for public consultation until 15 October 2014. http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/07/WC500170070.pdf 2. Patients' involvement in the benefit-risk evaluation – The added value of incorporating patients' views during evaluation of benefit-risk by the EMA Scientific Committees has already been demonstrated through existing EMA experience. Patients have already been involved during benefit-risk evaluations in specific cases and building on this experience the Agency will now apply a more structured approach to their involvement. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/09/WC500173508.pdf 3. Publication of agendas and minutes of Committee meetings and Management Board meetings – the EMA started in July 2012 to publish the agenda and minutes of selected Committee meetings. The publication was extended to all other committees and by the end of 2013, EMA was releasing agendas and minutes of the meetings of all its seven committees. Similarly, the agenda and minutes of the Management Board meetings are also published since early 2014. The principles for publication of agendas and minutes of EMA scientific committees are described in the link below. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/12/WC500158538.pdf 4. Submission of data during the decision making process for "Article 107" referrals - This type of regulatory procedure is triggered when a Member State or the European Commission consider that urgent action is necessary due to a safety issue with a medicine. The provision in the legislation gives the possibility for MAH, healthcare professionals and the general public to submit to the Agency information relevant to the procedure. http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000131.jsp&mid=WC0b01ac058061f6fb	

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			I hope that the above information is useful for you for the further development of your transparency initiatives. Please let me know if you would like to obtain any additional information on the EMA activities listed above, and I wish you all the best with the next steps of the project. Yours sincerely, Guido Rasi Executive Director	
38.	Syngenta (Switzerland)	2. Drivers of change	It is certainly true that global information technology has granted users faster access to information, but it does not follow that much of the information users can access is more reliable. It is often not. This is why the need for EFSA to earn and deserve recognition as a trustworthy source of impartial, objective and disinterested, but also discriminating, scientific advice is essential. Not all scientifically robust conclusions are, or are ever likely to be, popular. The scientific community has a responsibility to inform the general public and if properly supported by other stakeholders, including politicians and the media, progress can be made in persuading a sceptical public. It is right that EFSA should play a leading role in this. But it doesn't follow that enhanced public access to information will necessarily create greater public understanding or even trust of EFSA. However, a more transparent weight of evidence approach within EFSA would be very positive.	Noted. Class 1 EFSA is committed to making its outputs more accessible and understandable. Class 1 EFSA plans to establish a working group with the aim of developing a guidance document for increasing the level of transparency of the weight of evidence approach adopted by its Scientific Committee, Scientific Panels and their Working Groups. Class 1
39.	FEFANA (Belgium)	2. Drivers of change	EFSA might not be the place for societal considerations, as this actually falls already within the risk management remit. EFSA must keep a tight separation between risk assessment and risk management decision. The "citizen science" concept is mentioned in the "Science 2.0: science in transition" public consultation document by DG Research with a different angle from what EFSA's role is (i.e. from a research perspective that is not EFSA's remit). It remains very unclear how EFSA would include the concept of citizen scientist or other interested parties in the risk assessment process. Who would ensure impartiality and objectivity in such cases? Will those citizens or interested parties be obliged also to submit declarations of interest similarly to Panels' experts?	EFSA acknowledges the dividing line between risk assessment and risk management, and the risk of going beyond its remit or powers. Class 6 EFSA will consider the comment on the impartiality of individual contributors in the context of the review of its Policy on Independence. Class 6
40.	European Crop Protection Association (Belgium)	2. Drivers of change	ECPA is aware of the "gradual and steady grow in users` interest, involvement and participation in projects beyond their traditional spheres of influence". Therefore, crop protection industry understands that EFSA is trying to respond to a society demand of making the decision-taking process as open and transparent as possible. EFSA, however, should balance between transparency and protection of innovative climate, as highlighted in the join industry contribution, and maintain principles of fact-based and scientifically reasoned decision making process.	EFSA is committed to deliver scientifically reasoned decisions pursuant to its legal obligations. Class 6 As outlined in the discussion paper, the approach to openness and

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				transparency will take into account possible implications to be addressed to comply with the requirements in terms of confidentiality and data protection laid down in the relevant legal framework. Class 7
41.	Individual contribution, (UK)	2. Drivers of change	Societal trends EFSA's interest in emerging approaches such as crowdsourcing and citizen science to evidence collection is to be encouraged. But it needs to be fully aware of the defects in such sourcing methods. The absence of peer-review of information on the technical issues that are published on the Internet and social media presents a significant constraint on the value of public consultation in the fields covered by EFSA. However, many contrary opinions within the public media are written by well-informed expert authors, often with excellent scientific credentials. When such views challenge established dogma or the so-called 'consensus views' of standard scientific opinion, and they are clearly argued and supported by appropriate evidence, then EFSA must be prepared to consider them as a valid and meaningful contribution to debate. EFSA has not always given such 'eccentric' views appropriate consideration, nor has it always been willing to revise and retract its own earlier decisions. Today' eccentric views may well become tomorrow's accepted expression of reality despite having been initially rejected by those same consensuses. The authors of such views may well have had first access to data that confounds the consensus views, or whose opinions reflect a valid alternative intellectual approach. The so-called 'lateral thinkers', whose ideas expose weaknesses or unrecognised constraints embedded in conventional scientific understanding. Opportunities The potential contribution of such independent thinkers and experts to future EFSA decision-making must be recognised and embraced. They may provide crucial new perspectives on food safety, for example, that are currently not recognised - for example the role of ultra low level concentrations of supposedly harmless active substances such as glyphosate, that are responsible for alarming non-monotonic responses to their presence in foods that are not currently fully recognised by EFSA and many other authorities.. Challenges	EFSA agrees with the contributor that divergent opinions should be fully accounted for and considered in the context of EFSA's scientific opinions. Class 6 Legislators have even established a specific procedure aimed at avoiding, as far as possible, divergent opinions between EFSA and fellow EU bodies or Member State authorities. Moreover, one of the objectives of ensuring broader participation and engagement is to offer lateral thinkers an opportunity to express their informed position and to provide their scientific contribution to the development of EFSA's final outputs. In accordance with Article 38 of Regulation (EC) No 178/2002, opinions expressed by a minority of EFSA's Scientific Committee or Scientific Panels members are systematically published together with the opinions adopted by the majority. Class 7 Pursuant to Article 7 of Regulation (EC) No 178/2002, the precautionary principle belongs to the risk management phase of the risk

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			Reliance on 'confirmatory science' in risk assessment may be a reasonable strategy in deciding run-of-the-mill questions on food safety. But this approach obstructs rapid emergency response - the BSE epidemic and its implied linkage with new-variant human CJD in the UK demanded that the results of contemporary exploratory science be considered with the prospect of invoking the Precautionary Principle, even if only at least temporarily. Legal framework At present EFSA's linkage with the legal authorities of the EC seems to be less than sound when dealing with the complex area of classification of substances that may be added to foods. There is a very prominent compliance failure within certain Member States with respect to the demarcation between, for example, water for human consumption and medicinal waters. Despite recent clarification of this field by authorities such as Shaw and Barnett, EFSA appears to be confused as to what legislation applies, and at what point of reference. EFSA needs to improve its understanding of the limits of its own remit and authority when other branches of law apply to the products that it is examining. If it is illegal to produce and distribute a food product, then its scientific characteristics are irrelevant. Shaw D (2012) Weeping and wailing and gnashing of teeth: The legal fiction of water fluoridation. Medical Law International 2012,(1). 11-27. Barnett R (2014) Compulsory water fluoridation: justifiable public health benefit or human experimental research without informed consent? Chapman University Dale E. Fowler School of Law 2014 (Available at: http://works.bepress.com/rita_barnett/3)	analysis process and therefore falls outside EFSA's remit. Class 4 Concerns regarding food classification also fall outside EFSA's remit and should be redirected to the competent services of the European Commission. Class 4
42.	ClientEarth (Belgium)	2. Drivers of change	We disagree with EFSA's approach to transparency outlined in this part of the paper. It is stated that transparency and openness should therefore be result driven and not a goal per se, to ensure that EU citizens obtain value for the money invested in the EU project. We would contest that rationale. We believe that transparency and openness should be considered per se as drivers to better decision making and greater accountability. Therefore, any restriction of citizens' rights to open decision making should be interpreted restrictively and should in no case jeopardize the effectiveness of accessing information. Finally, we believe that the cost of protecting commercial interests should be transferred as much as possible to commercial operators. It should be borne in mind that EFSA is a public institution that works in the interest of the public and holds information in the interest of the public. In no case should	Openness and transparency are considered as drivers of better decision-making and greater accountability. Therefore, aspects of their implementation that are not mandatory should be thoroughly assessed in this light, to ensure that they deliver these (or at least one of these) two aspects. Class 1 EFSA acknowledges the principle according to which all documents should be accessible, except those for

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			EFSA's goal be to protect the interests of commercial operators. EFSA should not act in a way which would lead such operators to create expectations that this is their primary responsibility. Further, it is stated that greater involvement and participation could also hide potential risks, such as disproportionate influence of a limited number of actors or loss of control by the Authority over the content of a document: these risks clearly acknowledged in the paper. Further, the paper argues that "there may be negative consequences from the different ways of using the information and data offered. This in turn could trigger the need to put in place appropriate data protection and confidentiality protocols for commercially sensitive information and personal data." However, it should be clarified that the scope of what may be considered to be confidential business information should be clearly delimited. It should also be acknowledged that, in certain cases, disclosure cannot be limited on these grounds. The following elements should be considered when accepting a claim of confidentiality. All elements should coexist: • the information must be known only to a limited number of persons, i.e. it must not be in the public domain or general knowledge in the industry. Typically the registrant or third party would have undertaken specific measures to keep the information secret. • claims must be properly reasoned rather than simple statements. • the existence of a commercial interest must be demonstrated (the information must have some commercial value or legitimate commercial interests need to be at stake). • disclosure of the information must harm a registrant's or a third party's commercial interests and there must be a clear causal link between publication of the information and the potential harm; • Finally Article 4(4)(d) of the Aarhus Convention provides that confidentiality of commercial and industrial information is protected only where such confidentiality is protected by law in order to protect a legitimate economic interest. EFSA should also specifically recognise that its public mandate should take precedence over protection of commercial interests. If information is being used by applicants to justify approval of use of a substance, there can be no reason why, prima facie, that cannot be disclosed to those who need to be able to trust the advice of EFSA.	which one or more of the exceptions set out in Article 4 of Regulation (EC) No 1049 apply. In this context, and in that of the Aarhus Regulation, restrictions on citizens' right to access information are interpreted in a restrictive manner. The protection of commercial interests and sensitive commercially relevant information and data is an exception laid down in Regulation (EC) No 1049/2001. The elements put forward in the comment regarding the decision whether certain information deserves to be treated in a confidential manner are already duly considered by EFSA in the relevant decision-making processes. Class 7 Regarding the last suggestion that all information submitted by an applicant to justify the approval of the use of a substance should *prima facie* be disclosed, EFSA reiterates that, as a rule, a case by case assessment of each document and dataset for which disclosure has been requested cannot be waived in favour of general considerations. Class 4 EFSA acknowledges that exceptions to access to information based on the protection of commercial interests are not applicable if there is an overriding public interest in disclosure. Class 7 EFSA has already undertaken or planned the review of its internal

No	Contributor	Chapter	Comments received	EFSA response
				rules implementing these regulations in order to capture the latest developments. Class 1
43.	DANONE (France)	2. Drivers of change	Lessons should be learned from other sectors about dialogue, transparency and good practices, which would not undermine the independence of the EFSA scientists. Other authorities dealing with health claim evaluations (e.g. US, Canada, Switzerland, Korea, Japan) have already successfully implemented pre-submission consultations. European agencies from different sectors (i.e. the European Chemicals Agency and the European Medicines Agency) conduct pre-submission meetings on a regular basis.	To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7 EFSA commits to carry out further categorisation and prioritisation of the possibility to organise pre-submission meetings with applicants in the area of regulated products. Class 2
44.	Public Research and Regulation Initiative (PRRI) (Belgium)	2. Drivers of change	The text under “Opportunities” refers to the availability of information on the Internet and to concept of “citizen scientist”. This needs further clarification, to avoid misunderstanding. Meaningful medical diagnoses are drawn up by doctors, not by lay people who spent time on the Internet. The text under “Challenges” correctly recognises that greater involvement and participation could also hide potential risks, such as disproportionate influence of a limited number of actors or loss of control by the Authority over the content of a document	Noted. Class 1
45.	SYNADIET (France)	2. Drivers of change	APPLICATION DE L’ART. 13.5 DU RÈGLEMENT CE N° 1924/2066 : UN COUP D’ARRÊT À LA RECHERCHE ET À L’INNOVATION La méthodologie suivie jusqu’à présent par l’EFSA a conduit à autoriser seulement 3 allégations* sur les 146 déposées. A ce jour, les dossiers soumis représentent un investissement de 60 millions € pour la profession. Avec 3 avis favorables, cela porte à 20 millions d’euros l’investissement nécessaire pour sécuriser un produit alimentaire par une allégation de santé ! Nous sommes donc face à un obstacle clairement rédhibitoire à la Recherche et à l’Innovation, spécialement pour les PME.	Specific issues concerning the process of health claims authorisation in accordance with Regulation (EC) No 1924/2006 fall outside the scope of this discussion paper. Class 0

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			Le complément alimentaire est un des moyens utilisés par le consommateur pour préserver et maintenir bien-être, confort et bonne santé. Actuellement, les professionnels français sont confrontés à des contraintes de Développement qui, à la fois, sont inadaptées au secteur alimentaire et ralentissent, ou figent, les Investissements en termes de Recherche et d'Innovation. Il est urgent d'apporter des modifications au processus actuel d'évaluation des allégations nutritionnelles et de santé, en particulier celles concernant les demandes basées sur des preuves scientifiques nouvelles et conférant une propriété au demandeur (Article 13.5 du Règlement (CE) n°1924/2006). Il devient nécessaire de créer une évaluation alternative à celle du médicament en retenant une approche de santé et de prévention qui participe à la prise en charge des consommateurs par eux-mêmes et contribue à une diminution des coûts de santé pour la collectivité. * Allégations art. 13.5 avec protection des données évaluées par l'EFSA et ayant fait l'objet d'un règlement amendant le Règlement 432/2012 :ces 3 allégations sont listées dans le Règlement 851/2013 • «Boisson acide non alcoolisée reformulée ayant: 1) moins de 1 g d'hydrate de carbone fermentescible par 100 ml (sucres et autres hydrates de carbone à l'exception des polyols), 2) de 0,3 à 0,8 mol de calcium par mol d'acidifiant, 3) un pH compris entre 3,7 et 4,0. • Amidon lentement digestible Flavanols de cacao	
46.	EuropaBio (Belgium)	2. Drivers of change	In what follows, EuropaBio aims to address primarily the following question outlined in the executive summary: Would you identify any other strategic drivers, contextual elements or policy options for the Authority to consider when implementing its vision of becoming an Open EFSA? EuropaBio understands that one of the main drivers behind the 'Open EFSA' initiative is the growing societal demand towards making the decision-making process in the EU as open and transparent as possible. While we recognise this as a major societal challenge, EuropaBio underlines the paramount importance of unconditionally adhering to the democratically sound principles of fact-based and scientifically-reasoned decision making. EuropaBio strongly believes that ensuring a favourable innovation environment which allows safe innovative products to reach the EU market in a timely manner and maintains unceasing investments in product development, is also among the	According to EFSA's Founding Regulation, risk assessment shall be based on the available scientific evidence. EFSA does not, and does not intend to, depart from fact-based and scientifically reasoned decision-making. Class 1 Food security and trade are issues of strategic importance not falling within EFSA's remit. Class 0

No	Contributor	Chapter	Comments received	EFSA response
			major societal goals in the EU. Therefore, the objective to foster innovation should be prominently recognised as one of the drivers of change for modernising EFSA. With its high-quality scientific outputs, EFSA has a great role to play in making innovation happen in Europe and herewith, contribute to increasing Europe's competitiveness. The balance between transparency and the protection and maintenance of an innovation enabling climate should be well tipped bearing in mind that any undermining of intellectual property by misinterpretation of transparency rules regarding data access will have an immediate effect on research, development and innovation in Europe to the detriment of the region's prosperity and its societal well-being. In this context, EuropaBio emphasizes the importance of the advancement of innovation for fulfilling the goals of the EU 2020 Strategy and the so called 'industrial renaissance' for achieving smart, sustainable and inclusive growth in the EU. Therefore, we call upon EFSA to ensure its transformation and modernisation process are fully compatible with and facilitate the attainment of these overarching policy goals. EuropaBio would also like to draw EFSA's attention to two other equally important societal challenges which in our view EFSA should embrace as drivers of change – these are food security and international trade. The predicted increase by 2050 of the global demand for food by 70% will require a doubling of the food production, but not at the cost of over-cultivation of agricultural land and lack of environmental sustainability. The FAO acknowledged that "GMOs are an option that needs to be explored and can contribute to food security" (Nutritious Food for All, March 2013). In the strategy set in Horizon 2020, the European Commission also recognised biotechnology as one of the key enabling technologies to respond to society's 'Grand Challenges' of tackling, among others, resource efficiency, food security, and climate change. Turning now to trade, avoiding unnecessary distortions of trade flows is essential for EU's food security and competitiveness of Europe in the international marketplace. EuropaBio remains very concerned that due to the asynchronous approval of agricultural biotechnology products between the EU and its major trading partners, shipments thought to contain traces of EU unapproved GM crops are occasionally rejected at the European ports of entry. Without predictability in Europe, the food industry, commodity traders, and livestock farmers will face greater challenges in the future in obtaining sufficient raw materials and this will undermine further the EU's role as global food producer.	

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47.	GAP's chair on behalf of GAP, IPA and YLFA (Belgium)	2. Drivers of change	Lessons should be learned from other sectors about dialogue, transparency and good practices, which would not undermine the independence of the EFSA scientists. Other authorities dealing with health claim evaluations (e.g. US, Canada, Switzerland, Korea, Japan) have already successfully implemented pre-submission consultations. European agencies from different sectors (i.e. the European Chemicals Agency and the European Medicines Agency) conduct pre-submission meetings on a regular basis.	Without prejudice to the legal framework that may be applicable to other agencies or legal systems, and to increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7 EFSA commits to carry out further categorisation and prioritisation of the possibility to organise pre-submission meetings with applicants in the area of regulated products. Class 2
48.	Lallemand Health Solutions (Spain)	2. Drivers of change	Lallemand health Solutions supports additional ways in which two-way interaction between EFSA and applicants can be facilitated, as the establishment of pre-submission meetings. Other authorities outside the EU dealing with Foods (like FDA in the US, Health Canada in Canada) as well as other European agencies from other sectors (i.e. European Chemicals Agency and the European Medicines Agency) have already successfully implemented pre-submission methods and we see it as proof that such mechanisms are possible and would not undermine the independence of the EFSA scientists. Pre-submission meetings for scientific advice or protocol assistance conducted on a regular basis by the European Medicines Agency in the framework of drug marketing authorizations have proved to be very useful to address issues specific to upcoming applications. These meetings are focused on development strategies, and intended to answer questions posed by applicants regarding the tests and studies planned to prove the quality, safety and efficacy of their medicinal products. Diverging scientific opinion We believe it is essential that EFSA should exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the ones from other regulatory bodies, as mentioned in Article 30 of Regulation (EC) No 178/2002 on the establishment of EFSA. In order to promote the competitiveness of the EU as an innovative region, special	Without prejudice to the legal framework that may be applicable to other agencies or legal systems, and to increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which part of its catalogue of services. Class 7 EFSA commits to carry out further categorisation and prioritisation of the possibility to organise pre-submission meetings with applicants in the area of regulated products. Class 2 EFSA acknowledges the need to identify, at an early stage, a potential for diverging opinions and to correctly implement Article 30 of Regulation (EC) No 178/2002, if applicable to EU Member State or Union scientific bodies, and it has already undertaken

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			attention must be paid to situations in which EFSA's opinion diverges from the opinions of other agencies related to similar products. There have been some cases of divergence, especially concerning probiotics, where EFSA rejected a health claim, while another national or foreign Agency had approved a similar claim. In such cases, we believe that EFSA should make public the fact that they are aware of the contradictory opinion(s), and explain the reason(s) for the divergence.	or planned the development of internal procedures aimed at facilitating compliance with this requirement. Regarding the implementation of the Nutrition and Health Claims Regulation, EFSA has to comply with that specific legislative framework. Class 1
49.	PAN Europe (Belgium)	2. Drivers of change	The main driver for a change is that EFSA didn't live up to the expectations of society. In stead of trying to be an independent scientific body, EFSA got messed up in lobby policy of industry to give "regulatory science", scientific methodology developed generally by industry such as ILSI, a central place and make a joke of academic research. Industry employees got entrance in EFSA from 2002 on by the revolving door, industry linked experts massively entered EFSA's panels. EFSA had meetings exclusively with industry or ILSI, excluding others. It would be good to summarise this period because it is crucial for the situation EFSA is in now, a lack of trust and opinions not based on current scientific knowledge. EFSA could hide this for a long time but eventually it became known what the real situation was or is. Lessons have to be drawn from this. Any industry-link of staff/panels will damage the work of EFSA. The involvement of top-class academic researchers is key for improving the image of EFSA. Without fulfilling these two elements, any discussion on an "open" EFSA is a waste of time.	EFSA operates a robust policy on independence and provides in its implementing rules clear guidance to its scientific experts on how to avoid any potential conflict of interest in relation to their activities. Regarding the employment of staff members with previous experience in the private sector, EFSA is bound by the Staff Regulations and by the Charter of Fundamental Rights of the European Union. Class 4
50.	Individual contribution, (UK), Science and Technology Policy Research, University of Sussex	2. Drivers of change	Towards the bottom of page 7 the text refers to: "…the need to put in place appropriate data protection and confidentiality protocols for commercially sensitive information and personal data." But greater clarity and openness will be required as to the types of information that could be eligible for such protection. Responsibility for deciding on the categories of information that can be disclosed, and which might remain confidential, should not be in the hands of the companies. While companies might reasonably request that some of the technical details of their production processes remain confidential, it would not be appropriate for EFSA to consent to firms keeping the details of the characteristics of their products confidential, nor the studies and data that constitute the dossiers providing their safety cases.	Due account should be taken of the fact that with regard to several processes concerning regulated products, processes, claims, organisms and substances, the decision as to which confidentiality claims filed by the applicants should be accepted has been delegated to the European Commission by the Union Legislators. Class 4 For the remaining processes, where EFSA is required to take a decision regarding the applicants'

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				confidentiality claims, EFSA acknowledges the fundamental importance that regulatory data protection and protection of commercially relevant information has for the concerned sectors in order to be competitive on a global scale. For this reason, in 2014 it substantially strengthened its approach to protecting commercially sensitive information recognised to be worth of confidential processing, by developing internal procedures to streamline its internal decision-making process for confidentiality claims. EFSA has already undertaken or planned the necessary actions to ensure consistent decision-making processes regarding this matter and to review its current rules on access to documents, to take stock of the developments in the applicable legal framework and case law. Classes 1 and 7.
51.	FEFANA (Belgium)	3. Vision and goals	As the EFSA documents states "openness and transparency per se are not an aim. They are instruments used to achieve predetermined policy goals of sound public policy and legitimate decision-making." Article 22(7) of Regulation (EC) No 178/2002 - Mission of the Authority – refers to transparency in relation to EFSA procedures and methods of operation. Currently transparency on the assessment criteria is perceived to be insufficient, as well as the opportunities to contribute and possibly challenge the evaluations. On this later point, the fact that today it is practically impossible to challenge the science of an EFSA opinion (the legal ways including the EU court would unlikely touch to the science) can be seen as the real democratic gap that might need to be tackled. This transparency of the criteria is part of the constructive dialogue initiated with the regulated industries and Commission. The vision might be that openness and transparency should be reinforced on the risk assessment procedures and content, including in the opinions, so that all parties can be more confident about the scientific standards	According to the established case law of the Court of Justice, the Treaties on European Union and on its Functioning establish a complete set of means of recourse protecting the interests of the concerned individuals and States. This holds true also for the procedural aspects of EFSA's opinions, which are simply an intermediate step in complex decision-making procedures involving EFSA, Member States' authorities, the European Commission, EU Member States and the European Parliament.

No	Contributor	Chapter	Comments received	EFSA response
			applied. Objectivity of the assessment is closely related to scientific quality. This is the pivotal area where there are perceived gaps and where EFSA can enhance its credibility. The focus should be on scientific quality. Replies to stakeholders' input, through which the scientific community or other interested parties interact with EFSA, is considered scientifically weak and are dramatically damaging EFSA credibility. The work that EFSA started on horizontal guidance document intended to accompany the scientific work and the opinions appears to be a promising path that should improve both the objectivity of the work and the quality of the opinions.	Class 6 Regarding the remark about an alleged "democratic gap" in the existing procedures for the evaluation of the safety and efficacy of regulated products, EFSA considers that it was not delegated by the Union legislator the power to look at aspects beyond pure scientific considerations. Class 4
52.	European Crop Protection Association (Belgium)	3. Vision and goals	Ad. 3 Vision and goals In ECPA view, confidence of European and third countries` citizens in the EU ability to address food safety challenges is key. In our opinion, more transparent decision-taking process cannot be the only contributor. EFSA has to be a key player in explaining to citizens complexity of food safety issues such as multiple pesticides residues in food. European citizens are provided with safe food. The level of protection never before was so high, but still lack of reliable information from public authorities creates a feeling that the level of protection is decreasing, while in reality it is increasing. ECPA welcomes every EFSA initiative to communicate food safety issues in a more effective way. One good example can be a dedicated website explaining results of the EFSA annual report on pesticides residues. Such website should not only provide data but also explain to consumers basis terms, such as "what is MRL".	EFSA acknowledges that communicating food safety issues effectively is a key factor in increasing citizens' confidence in the Authority's work and the EU food safety system. Class 1 EFSA has developed an interactive tool explaining results of the EFSA annual report on pesticides residues in order to allow third parties to fully appreciate the achievements of the European Commission, the Authority and its institutional partners in this particularly demanding sector. Class 1
53.	ClientEarth (Belgium)	3. Vision and goals	ClientEarth agrees that it is important for EFSA to produce high quality of scientific information and to comply with laws and societal needs. However, we believe that EFSA's goal should be to provide reliable and independent scientific opinions about food and ensure that food in the EU is safe for humans and for the environment.	Noted. Class 6
54.	Public Research and Regulation Initiative (PRRI) (Belgium)	3. Vision and goals	It is indeed essential that the EU citizens trust the EU food safety system. However, that trust cannot be built of the political decision makers keep ignoring EFSA's opinions.	Noted. Class 5

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55.	Individual contribution, Maastricht University	3. Vision and goals	EFSA's vision document goes to the core of regulatory science: it envisages to shed more transparency and openness on its risk assessment and the data it uses in its risk assessment. Social sciences literature indeed shows that allowing stakeholders and the public at large to participate in scientific activities inter alia by allowing them to come up with data and comment on draft opinions would serve the purpose of enhancing the quality of the assessment and opinion delivered. In other words, it leads to better (regulatory) science. The approach adopted by EFSA to engage with society should therefore to be considered to be vital for (improving) the quality of the opinions adopted by EFSA. This will inevitably lead to more trust in EFSA's scientific work and the EU food system more generally, as literature indicates.	Noted. Class 1
56.	Individual contribution, CNRS Centre national de la recherche scientifique (France)	3. Vision and goals	As part of their campaign against GM crops, activists have repeatedly tried to undermine the credibility of the EFSA. The reason that the EFSA and its scientists have become targets is that individual EU member states cannot reach consensus on GMOs and as such, the decision falls to the European Commission, which (up to now) usually followed EFSA's advice. Given the political paralysis, the EFSA has become the de facto reference for risk management and, consequently, the target of political groups seeking a complete ban on GM crops. In addition, some post-modern discourses have sought to undermine the EFSA's science-based risk assessment. According to this ideology, science is not objective and its truths are heavily influenced by the opinions of scientists— risk assessment by the EFSA is merely a 'framing of truth' by a panel of people with shared presuppositions, which can be countered by any other group of people with their own frame or set of 'truths'. Such thinking can convince political authorities to abandon the division between scientific and non-scientific knowledge, and thereby open the door wide for what are called 'participative' policies. However, these 'participative' policies, and the involvement of stakeholders in the decision-making process for what are ultimately scientific questions, effectively hinders the progress of science. Since anti-GMO organisations have based their communication strategy on claims of risk that are by and large rejected by the scientific community, it is logical that these organisations, in their non-compromising political strategy, try to deconstruct science. Thus, anti-GMO groups and environmental organisations at large have a vested interest in teaming up with post-modernism as a vehicle to attack the science that stands against their agenda.	EFSA is aware of the post-modernist approach and of its implications. However, this initiative may not change the Authority's mandate or make EFSA take into consideration elements going beyond pure scientific considerations, documents or data. Class 5

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			In the face of alleged uncertainties, many politicians and citizens find it reassuring to examine several 'truths' and shifting paradigms in risk assessment. However, doing so with no reference to undisputable scientific knowledge renders risk assessment unscientific, increases uncertainty and paves the way for arbitrary decisions. This form of post-modernist assault on science has been difficult to grasp for many scientists, because it comes disguised in the clothes of democracy, freedom of speech and tolerance of opinion. However, as the GMO dispute has shown, this postmodernist approach has always failed to appease confrontation. In the contrary, it has encouraged extremists to become even more uncompromising. It is therefore highly dangerous that EFSA follows this path of "openness", which at the end of the day will turn out to be open to ideological views. More in the following papers (with various examples including EFSA): M. Kuntz (2012) The post-modern assault on science. EMBO reports 13 : 885-889 M. Kuntz (2013) Why the postmodern attitude towards science should be denounced. EMBO reports 14(2):114-6	
57.	Federation of European Specialty Food Ingredients Industries (ELC) (Belgium)	3. Vision and goals	Implementation of the EFSA vision and proposed policy goals will require a careful consideration of the protection of commercially sensitive information. Applicants must have confidence that EFSA will manage confidentially according to well-defined procedures, in order to prevent the possible use of disclosed data by business competitors. This is why it is of the utmost importance to differentiate between access to information and dissemination of such information. More particularly: 1. Consistency and predictably The extent to which data has been made available to the public in recent times appears to have been driven by political pressure. Whichever course of action is finally considered best reflect the interests of EU stakeholders, it is essential that clarity and consistency is brought to the decision-making system around transparency. An ad hoc approach to dealing with transparency cannot be acceptable. The ELC therefore welcomes EFSA's initiative to reflect systematically on the best policy and procedure to be applied. 2. What is EFSA aiming to achieve? ELC recognises that transparency is an important function of ensuring a system in which all stakeholders have confidence. However, transparency is not an end in itself, nor does it necessarily lead to increased confidence. A close and careful analysis of what is wrong with the current system would appear to be a good	EFSA acknowledges the fundamental importance that regulatory data protection and protection of commercially relevant information has for the concerned sectors in order to be competitive on a global scale. For this reason, in 2014 it substantially strengthened its approach to protecting commercially sensitive information recognised to be worth of confidential processing, by developing internal procedures to streamline its internal decision-making process for confidentiality claims. EFSA has already undertaken or planned the necessary actions to ensure consistent decision-making processes regarding this matter and to review its current rules on access to documents, to take stock of the developments in the applicable legal framework and case law. Classes 1 and 7.

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			starting point for further reform. Some actions taken by EFSA in the past do not appear to have had a clear rationale in this respect. For example, publishing the entirety of scientific data is one option that EFSA has chosen to 'improve transparency', but the added value or rewards of this approach is not self-evident. EFSA may choose a role of becoming a scientific library or database but the implications of doing so need to be carefully assessed. Where EFSA has published extensive data, to what extent has public confidence in EFSA's management of the particular issue been enhanced? 3. Costs to competition Transparency is often viewed through the prism of industry secrecy v. consumer access. However, the greatest concern for ingredient manufacturers is the potential competitive advantage that placing large amounts of scientific and technical data in the public domain could provide to competitors outside the EU. Intellectual property law may offer some means for limiting the subsequent use of this information for commercial ends. However, the scope of intellectual property law and its application in other countries is limited. Any benefits associated with extending transparency must be carefully weighed against these interests. 4. How far can EFSA independently develop a transparency strategy? As the competition issue illustrates, decisions on transparency have possible economic ramifications which, as a result, have the potential to either support or undermine broader Member State and EU policies on innovation and competitiveness. Two important questions in this context: a. Do the experts charged in EFSA with analysing transparency policy have the necessary expertise to gather information on the implications of transparency? b. Given the broader policy implications of EFSA's approach to transparency, can the agency independently develop a strategy without infringing upon national and European policies? What are the limits of EFSA's legitimacy in this exercise?	1. Noted. Class 1 2. The discussion paper links increased transparency not only to trust, but also to improved scientific quality of EFSA's outputs. Furthermore, EFSA is required to make publicly available its scientific opinions and "the information on which they are based" (Article 38 of Regulation (EC) No 178/2002), with the exception of commercially sensitive information. Class 1 3. Due consideration should be paid to the fact that such limits are not always systematically applicable to the range of exceptions set out under Regulation (EC) No 1049/2001 on public access to documents. Class 4 4. EFSA's goal is to put in place a framework for achieving the strategic objectives outlined in its Single Programming Document 2015-2017. Class 6 EFSA would like to exploit the potential offered by new technologies. EFSA will take a final decision on whether or not it will proceed in this sense only on the basis of the outcome of further categorisation and prioritisation. Class 2
58.	Individual contribution, (UK),	3. Vision and goals	I welcome the recognition in Section 3 on page 8 that: "…openness and transparency per se are not an aim. They are instruments used to achieve predetermined policy goals of sound public policy and legitimate decision-	EFSA disagrees with the statement that the Discussion Paper implies that EFSA's decision-making so far has not

No	Contributor	Chapter	Comments received	EFSA response
	Science and Technology Policy Research, University of Sussex		making…" That acknowledgement implies that EFSA's decision-making thus far has not always been sound and legitimate. When, at the end of that section, the text refers to: "…Complying with normative and societal expectations…" the comment is welcome, but it would be helpful if those expectations could be characterised less enigmatically. EFSA needs to make clear whose expectations, and which norms, count.	been sound and legitimate. Class 3 The intention of the text is to clarify the manner in which openness and transparency are perceived at EFSA, and how they will be implemented in the context of its risk assessment processes in the future. Class 1
59.	EuropaBio (Belgium)	3. Visions and goals	EuropaBio's responses to Chapter 3 of the discussion paper aim to address primarily the following questions outlined in the executive summary: How can EFSA increase its openness to meaningful contributions from individuals and organisations beyond its Panels and Committee? Should a two-way interaction between EFSA's Panels and interested parties be facilitated? What limits should be set to such interaction? EuropaBio strongly agrees with EFSA's vision that it is important to increase trust in the EU food safety system. Public trust in the approval system is essential for acceptance of product safety. However, it must also be recognised that public trust is largely undermined when policy makers take decisions in contradiction with the best available scientific evidence (e.g. in the case of national bans on EU-approved GMOs), or when they impose purely political requirements onto risk assessment (notably, the automatic requirement for 90-day feeding studies in Implementing Regulation (EC) 503/2013). EuropaBio suggests that the most effective contribution that EFSA could make to participate positively in the search to regain trust is to further explain EFSA's role to the public and to focus on the provision of even more understandable risk communication to the broader public. For example, information that all GMOs currently approved for the placing on the market have been found to be at least as safe as their conventional counterparts could be made clearly visible on the EFSA website. Furthermore, it should be clarified that any envisaged form of societal engagement with EFSA's scientific work must not sacrifice the best available evidence to societal preferences which are not science-based and may be difficult to reconcile. Guaranteeing that the best scientific expertise is in house remains of utmost importance for EFSA. Next, the risk assessment should be in line with internationally recognised scientific practices. Improving the communication between the applicants and EFSA should be at the core of the authority's efforts to increase the quality of available information and data used for its scientific advice.	EFSA agrees that it has to step up the way it communicates with the general public and is committed to making every effort to explain its role and responsibilities within the risk assessment process, including its risk communication mandate. Class 1

No	Contributor	Chapter	Comments received	EFSA response
			We believe that these objectives should have been further strengthened in the discussion paper.	
60.	PFP-association for the European primary food processing industry (Belgium)	3.Vision and goals	1.Are you satisfied that EFSA has identified the societal and normative expectations it has to comply with, or would you suggest additional ones that the paper does not capture? PFP believes that EFSA has rightly addressed a number of societal and normative expectations which are decisive to enable a better understanding of EFSA role and deliveries by the civil society in the future. Communication and outreach activities are essential to make EFSA better known to consumers and increase its links with the scientific community. Tailored-made risk-based scientific information on relevant topics ultimately contributes to increasing consumer trust. For example, the recent Understanding science videos clips are a good step forward. More should be done with the same approach to further increase knowledge. However, opening EFSA should not hamper its primary role in delivering risk assessments to the European Commission either on regulated products or following a mandate. Indeed, once an opinion is delivered by EFSA, it is then used by the risk manager to decide on which steps to follow. This exercise enables to balance the various risks with the situation at stake. Therefore any further opening of EFSA communication to the civil society should take this into account, to avoid misperceptions of consumers and scaremongering media activities. Risk perception vs. risk communication deserves to be addressed carefully. We welcome many good steps applied today to further increase exchange of information such as by providing comments during consultations on draft opinion and pre-warnings before publication (of draft opinion and final opinion) on specific mandates. This should be maintained in the future.	Noted. Class 1
61.	Individual contribution, (Austria)	3.1 Improving the overall quality of available information and data used for EFSA's	"More accessible data means higher quality data" This is not necessarily correct. EFSA panel members should not only rely on published information since this is known to be refuted or even retracted quite often in the fields of nutrition and medicine. EFSA panel members should be obliged not only to review, but to check also by themselves the validity of statements and conclusions made by authors concerning their work since also the conclusions are quite often biased or more comprehensive than scientifically justified by the work done by the authors. Panel members should be obliged to identify and assess also contradicting papers.	EFSA commits to keep providing evidence-based risk assessment in line with its guidance documents and Science Strategy document. This includes, *inter alia*, assessing the validity of statements made by the authors of studies. Class 7

No	Contributor	Chapter	Comments received	EFSA response
		outputs		
62.	Syngenta (Switzerland)	3.1 Improving the overall quality of available information and data used for EFSA's outputs	There is growing recognition that the quality control around published research is often inadequate 1,2,. Research may be flawed by poor execution, inaccurate measurement or systematic biases. For example, a protocol searching for a particular outcome rather than performing balanced hypothesis testing. Published conclusions can be vulnerable to exaggeration. False positives and false negative results happen and this is why evaluation of reproducibility and relevance are essential before conclusions are derived. Published literature may be biased by the tendency not to publish 'negative' results with the consequence that a literature review is blind to unreported true negatives. Any initiative to broaden the source of scientific input upon which EFSA are to base their deliberations is contingent upon EFSA having a robust, transparent and efficient process to rapidly discriminate between potentially contradictory data of varying quality, reliability and relevance. EFSA need to be aware of the workload consequences of a fully open approach. All of this means that it is increasingly important that EFSA help raise standards in published research by establishing clear and robust quality criteria expectations for their use in EFSA's work and provide the greatest transparency possible about how EFSA's conclusions were derived and confidence that the inputs represent the best expertise available. 3 • the quality, precision, reproducibility and compliance with internationally agreed guidelines of the data and literature that the conclusions are based on, • discussion of alternative sources of data and objective reasons why these data were or were not included in a weight of evidence • commentary on the validation of assays or models used to derive the conclusions • the rationale and sensitivity of the conclusions to any assumptions used to derive them • evaluation of the objectivity of hypothesis and sensitivity to systematic bias • qualifications and registered interests (not just links to industry) of all those stakeholders contributing the information upon which the conclusions are based. • qualifications and registered interests of those involved in reaching the conclusions	EFSA acknowledges that publication bias is an issue to be aware of. EFSA addresses this in the systematic review guidance available on its website. Class 7 EFSA commits to keep providing evidence-based risk assessment in line with its guidance documents and Science Strategy document. This includes, *inter alia*, assessing the validity of statements made by the authors of studies. Class 7 EFSA plans to establish a working group with the aim of developing a guidance document for increasing the level of transparency regarding the weight of evidence approach adopted by its Scientific Committee, Scientific Panels and their Working Groups. Class 1

No	Contributor	Chapter	Comments received	EFSA response
			References 1 Leaders - How science goes wrong. P 11, The Economist, Oct 19th 2013 2 Briefing -unreliable research : Trouble at the lab. P 21-24, The Economist, Oct 19th 2013 3 Comment – A standard for policy-relevant science P 159-160, Vol 501, Nature, Sep 12th 2013	
63.	Association Française des Biotechnologies Végétales (AFBV) (France)	3.1 Improving the overall quality of available information and data used for EFSA's outputs	Question 4: We believe that EFSA experts need to be able to debate amongst themselves behind closed doors. This is fundamental for their independence. Their own internal harmonization procedure must be maintained.	As is acknowledged in the Discussion Paper, EFSA's preferred approach would be to balance the gradual establishment of an Open EFSA with the need to protect a legitimate "space to think" for the members of its Scientific Committee, Scientific Panels or Working Groups, so they can share their views without being concerned by the pressure that may be linked to the disclosure of their individual positions. Under the current legal framework, EFSA's scientific opinions have to be adopted exclusively by its Scientific Committee and Scientific Panels. Class 6
64.	FEFANA (Belgium)	3.1 Improving the overall quality of available information and data used for EFSA's outputs	There is a fundamental difference between the data owned by authorities and those put at their disposal for pre-market assessment. These data have nothing to do with the democratic control of decision-making. The legislation on access to documents (Regulation (EC) No 1049/2001) provides already all necessary democratic guarantees. One should be careful that an "open books policy" would not deter the EU industry from seeking access to the EU market, with all consequences on the EU innovation and competitive positioning. EFSA should in this respect take care of not being exploited by specific interests. EFSA is not a decision-making public body. It is called to assess topics (risk assessment) in an objective way, and deliver neutral conclusions. This democratic control has to be shaped differently to other public bodies that are responsible for decisions. Science methodology when properly applied is intrinsically providing a large part of this democratic control. Exchange of knowledge is an important principle, but over-use of it kills the principle. We cannot place it before the data protection and confidentiality	Data submitted for pre-market assessment by the private sector are protected insofar as they relate to commercially sensitive information. For the rest, the Regulation on Public Access to Documents establishes the principle according to which all documents should be accessible. Class 7 As highlighted in several parts of the discussion paper, EFSA has no intention of breaching Union legislation, including those legal acts containing data protection clauses;

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			principles. Other parties (i.e. other applicants/competitors) may take advantage from data sharing which will go against the relevant regulated products legislations. One should also make a distinction between confidential data and the fact that data and other information in an application dossier should not be used for the benefit of another applicant. This is embedded in some legislation (e.g. Article 20 of Regulation (EC) No 1831/2003), but seems to be a fair principle in general. This also questions the "reusability" of the data that is mentioned in the paper.	nor is it EFSA's intention to deter unduly innovation or research & development activities. Class 1
65.	BEUC - The European Consumers' Organisation (Belgium)	3.1 Improving the overall quality of available information and data used for EFSA's outputs	In order to formulate its scientific opinions EFSA collects a large amount of data, scientific studies and other publications. Making the knowledge base on which EFSA informs its decision publicly available is a fundamental step towards improving transparency and gaining legitimacy. More open and systematic data sharing can significantly increase consumers' trust in EFSA work. To enhance scientific scrutiny, EFSA assessments should be fully reproducible by other scientists. In relation to section 4 of the options table, it is also important to stress that EFSA is looking at the totality of the evidence, to the extent possible - and not just for generic opinions, but also for applications. EFSA was set up to ensure food safety and protect public health and these principles should be reflected in its data gathering. Open and targeted calls for data/information (Policy option 3 in section 4 of the table, page 14) are therefore important, as well as EFSA ensuring that it supports the panels/Scientific Committee by way of robust searches etc. The onus should be on publication of data, rather than too cautious or narrow an interpretation of what is commercially confidential. In determining the types of data which can be disseminated – e.g. data contained in application dossiers – public health interests should prevail over commercial considerations. In addition to the source of the scientific studies and reports EFSA uses to formulate its opinions, it would be important to disclose who funded the research. The lack of public funding for research, including in the food area, generates a risk of having to rely only on industry funded research and the evidence shows that research results might be inappropriately influenced by bias.	The breadth of publications that EFSA may be in a position to consider when performing its scientific evaluations changes considerably depending on whether it assesses general matters or application dossiers of regulated products for which an applicant is responsible. In the former case, EFSA is responsible for considering the entire scientific literature available and deemed relevant to produce a comprehensive and up-to-date scientific evaluation. In the latter case, one needs to differentiate between application dossiers where the burden of proving the safety or efficacy of the substance, product, claim, organism or process lies exclusively with the applicant, and those where EFSA is required by law to consider the broader picture, e.g. by organising public calls for data. In the first instance, EFSA is expected to consider only the positive studies submitted by the applicant and the negative ones available to the Authority; while in the second instance, EFSA is supposed to consider all information available.

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				In either case, EFSA systematically checks for a risk of bias in the studies considered or submitted by the applicants. Class 7
66.	Individual contribution, (UK)	3.1 Improving the overall quality of available information and data used for EFSA's outputs	Improving the overall quality of sourced information and data EFSA clearly assumes that "more accessible data means higher quality data" This is dangerously flawed assumption. Member States routinely misrepresent data that inconveniently reveal that their policies are not founded on fact - the recent Public Health England publication on water fluoridation is a particularly egregious example. Public 'lay' scrutiny of such documents can be invaluable, Many retired professionals with valuable expertise could (and indeed, often do) act as moderators of data and debate within their special fields of expertise long after retirement, but this resource is largely ignored (including, it seems, in this consultation document itself). The pre-publication peer review process employed for scrutinising formal scientific papers has become an issue of concern in recent years, as the impartiality of those chosen for such tasks has increasingly come into question. Post-publication peer review, often through the electronic media, is increasingly revealing flaws on apparently reliable publications, forcing modification of policies founded on such defective sources. EFSA should explore ways in which such independent review can be encouraged and sourced, including in most certainly the review of its own draft decisions. This process of crowdsourced peer review is of course itself open to severe abuse. All too frequently, anonymous authors with undetectable personal bias and potential vested interests are able to enjoy equal opportunity for defaming otherwise reputable authors and reliable data and analysis. But still, crowdsourcing can provide valuable new perspectives on, especially, the social implications of draft analyses issued by EFSA and other agencies. The ability of individuals with special knowledge to identify weaknesses in data collection and processing methodology and to apply the data within the social structures of complex human communities is an important source of experience that is sometimes not available from within the research and academic communities themselves.	EFSA believes that public lay scrutiny would contribute to higher-quality outputs, as it will help ensure that errors are identified and the chance of misunderstandings is reduced. Therefore, EFSA considers that these objectives not only do not contradict each other, but that they are actually mutually inclusive. Class 1 EFSA is aware of the potential risks/ challenges intrinsic to the process of crowdsourcing. EFSA will subject also this measure to a further categorisation and prioritisation to be performed according to the Implementation plan. Class 2

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			Non-Governmental Organisations especially, as well as other independent experts, are frequently aware of issues that are opaque to institutional experts and governments alike. So EFSA needs to develop means of identifying such sources, vetting their value and reliability, and incorporating their expertise into its scrutiny and decision-making processes.	
67.	ClientEarth (Belgium)	3.1 Improving the overall quality of available information and data used for EFSA's outputs	ClientEarth believes that EFSA should aim at providing information that is comprehensive, independent, reliable and reproducible: • Comprehensive: should mean that all available information must be taken into account and that data gaps should be highlighted. All available information should necessarily include independent studies. • Independent: means that EFSA should minimize the influence of commercial parties that have an interest in its final outputs. To this end, any information about possible biases in the evidence taken into account by EFSA should be clearly disclosed and highlighted. Scientists involved in EFSA's outputs should not have conflicts of interest. • Transparent: Methodologies applied and reasons for their application should be documented, different views on the development of an opinion/advice should be documented as much as possible. • Reproducible: As a minimum, all studies used in the scientific opinions should be traceable and the relevance of each study should be understood by any scientist that would like to replicate the EFSA opinion. How can EFSA foster even further an environment of creative debate amongst its experts while striking the appropriate balance between availability and quality of information? We do not believe that transparency undermines freedom of speech. However, we do understand that there are individual limitations of being broadcast or speaking in front of a public. Personal integrity should always be sought. Indeed, we do not encourage EFSA to open its meetings to anyone interested in attending. Meetings should be open only when necessary and to selected representatives of society and when a level playing field about the participation of interest groups can be achieved. EFSA has a large number of meetings and panels and it would be impossible to believe that all could be opened to the public. However, the opinions expressed by experts participating to those meetings should not be the object of special protection. It is assumed that these are experts in their field, scientist who publish academic papers and participate to conferences. Their expert judgement should thus be made public.	Noted. The actual manner in which, or whether, these suggestions will be implemented will be specified following the completion of further categorisation and prioritisation according to the Implementation plan. Class 2 EFSA highlights that it already identifies such data gaps every time it adopts a scientific opinion. This notwithstanding, it commits to a further categorisation and prioritisation to be performed according to the Implementation plan on how to further improve this practice, and on whether it should reflect the entirety of data gaps of a dossier. Class 2

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68.	DANONE (France)	3.1 Improving the overall quality of available information and data used for EFSA's outputs	DANONE agrees that more accessible data means higher quality data. In this regard, two-way access to information and the ability to provide data throughout the evaluation process – in response to specific requests from EFSA, throughout the procedure for dossier evaluation – would help to fulfil this objective. In this regard, it would be particularly useful if EFSA could clarify its position on proprietary data, namely the basis for considering that the only way to retain the exclusivity rights is conditional on the non-publication of data. Providing raw clinical study data to EFSA panels, within the scope of a regulatory dossier, is a good practice, in particular with regard to the Data Transparency Initiative. The debate is not only on whether or not data will be made available, but also about who will have access to this data and in what context. Accordingly to the EFSA Guidelines for Observers (EFSA Guidelines for Observers; Parma, 16 December 2013), EFSA, together with the meeting Chair, decides on the accreditation of Observers. However, the document does not include the criteria on which the accreditation decision is based. This question is key, especially regarding publication of data prior to dossier submission but also on potential data access restriction (qualified professionals should be the only ones).	EFSA believes that the concept of regulatory data protection should be differentiated from that of confidential data. In several Union legal acts, the fact that certain information or a given study benefits from a data protection clause does not mean that it should be processed as confidential information and, as such, should not be disclosed (e.g. Regulations (EC) No 1829/2003 and 1831/2003). Class 4 An exception to this more common approach is represented by Regulation (EC) No 1924/2006, to which the contributor is probably implicitly referring, Article 21(1)(a) of which prescribes that data protection may be granted only to those applicants who had the exclusive right of reference to the data or study at the time the application was made. Class 4 EFSA commits to perform a further categorisation and prioritisation according to the Implementation plan regarding the degree to which it should increment the recourse to "hearing experts" and the organisation of "public hearings". Class 2
69.	Public Research and Regulation Initiative	3.1 Improving the overall quality of	The text correctly recognises that risk assessment follows a systematic methodology based on evidence. This paradigm should be repeated over and over again in the follow up reports and plans. The text also justly quotes that Data are "the lifeblood of the knowledge	Noted. Class 7

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	(PRRI) (Belgium)	available information and data used for EFSA's outputs	economy". However, the claim that "EFSA is likely to gain from receiving further input through its interaction with society" needs further thought, because EFSA's work may very well get clogged with such interaction. 4. How can EFSA foster even further an environment of creative debate amongst its experts while striking the appropriate balance between availability and quality of information? A prerequisite for a creative debate amongst experts is the possibility to allow them to express views and hypotheses in closed sessions, while of course ensuring that the final opinions (and any final dissenting opinions) are properly motivated and transparent.	
70.	ENSSER European Network of Scientists for Social and Environmental (France)	3.1 Improving the overall quality of available information and data used for EFSA's outputs	4) How can EFSA foster even further an environment of creative debate amongst its experts while striking the appropriate balance between availability and quality of information? Providing transparency in the form of free access to raw data used within risk assessment to allow for counter-examination by various forms of expertise and actors will improve "an environment of creative debate amongst experts". A further idea would be to invite a external experts to act as peer reviewers for each dossier. These external experts should be academic researchers that have published in the specific domain relating to the material submitted to risk assessment prior to its release on the market but without direct connections to industry or potential conflicts of interest. Furthermore, the definitions of the guidelines and opinions produced by EFSA could also involve a peer review process by experts external to the process. It is also essential that a balance of disciplines is achieved amongst the expert groups and that time is dedicated to exploring and understanding how expertise from different fields, backgrounds, paradigms and disciplines can lead to varying positions on what constitutes an appropriate and sufficient experiment/evidence.	To a certain extent, both the suggestion regarding the peer review of scientific outputs and the comment on the need to balance the disciplines represented in the panels and committees are already being implemented by EFSA. The former will be further evaluated during the categorisation and prioritisation to be performed according to the Implementation plan, so as to consider whether a more systematic approach in this area could represent an efficient option for EFSA. Class 2.

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71.	EuropaBio (Belgium)	3.1 Improving the overall quality of available information and data used for EFSA's outputs	The EFSA's discussion paper rightly emphasises the importance of high quality data. Data packages are notably supplied by applicants, which is why applicants should be at the centre of any strategy to improve quality of data. Clear requirements for, and appropriate information exchange with, applicants are the most effective ways of obtaining the highest quality data whilst at the same time achieving efficiency of resources. The growing challenges for applicants start with the very frequent updates of the requirements. For example, in 2011 alone, four new GMO specific guidance documents were published. However, EFSA does not foresee any transition period for compliance with the new requirements, but calls for their immediate and often retro-active implementation. Moreover, clarifications requested by applicants on new guidance documents are often not provided. The regularly occurring retroactive application of requirements additionally delays the risk assessment process and increases regulatory costs because studies that were in line with existing guidance at the time they were conducted and in accordance with internationally accepted protocols, suddenly and unpredictably become inadequate in light of new requirements. During the risk assessment process, additional regulatory data, provided at EFSA's request, has often been deemed insufficient or inappropriate. The applicants feel that the reasons for this lie in the lack of sufficient background given for the questions asked by EFSA or because EFSA changes the requirements after the data has been produced. In other cases, it may have been technically unfeasible to address EFSA's requests (e.g., no validated methodology available). Moreover, EFSA almost never informs the applicant or provides feedback about whether the additional data submitted is acceptable or not. EFSA should avoid that applicants are informed of a new interpretation of the requirements only when the question has been asked for several subsequent applications or when several years aft er submission of the dossier, questions are posed to applicants that could have been anticipated during the completeness check or at very early stages of the risk assessment. Although the EFSA's Applications Helpdesk was intended to ease the flow of communication with applicants, its full potential for streamlining the process is not being realised. Against this background, EuropaBio welcomes the recent initiative of EFSA to strengthen its support to applicants during the completeness check and	Without prejudice to the legal framework that may be applicable to other agencies or legal systems, and to increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7 EFSA commits to carry out further categorisation and prioritisation of the possibility to organise pre-submission meetings with applicants in the area of regulated products. Class 2 EFSA underlines that the European Medicines Agency operates under a different legal framework and context. For instance, it may levy fees to recover the costs linked to the services it provides to individual applicants. Classes 4 and 5

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			risk assessment process, e.g. via video conferences and would welcome further steps such as expert meetings with individual applicants. EuropaBio is convinced that the two-way communication between applicants and EFSA, including expert meetings with individual applicants, is a much more effective and efficient means of producing fit for purpose scientific outputs of high quality while minimising misunderstandings and delays. We take as an example other regulatory agencies, such as the European Medicines Agency (EMA), that actively encourage applicants to ask for pre-submission meetings. The EMA's structured exchanges with applicants ultimately result in a relatively high degree of planning certainty for its applicants as well as advanced information to the Agency and swift and timely processing of dossiers. Lastly, public scrutiny, may contribute to improve the overall quality of available information and data used for EFSA's output only if minimum requirements and standards are established for that scrutiny. Moreover, the process should be efficient and should avoid unnecessary delays to the risk assessment and market access of safe products.	
72.	GAP's chair on behalf of GAP, IPA and YLFA (Belgium)	3.1 Improving the overall quality of available information and data used for EFSA's outputs	The probiotic sector agrees that more accessible data means higher quality data. In this regard, two-way access to information and the ability to provide data throughout the evaluation process – in response to specific requests from EFSA, throughout the procedure for dossier evaluation – would help to fulfil this objective. In this regard, it would be particularly useful if EFSA could clarify its position on proprietary data, namely the basis for considering that the only way to retain the exclusivity rights is conditional on the non-publication of data. Providing raw clinical study data to EFSA panels, within the scope of a regulatory dossier, is a good practice, in particular with regard to the Data Transparency Initiative. The debate is not only on whether or not data will be made available, but also about who will have access to this data and in what context. Accordingly to the EFSA Guidelines for Observers (EFSA Guidelines for Observers; Parma, 16 December 2013), EFSA, together with the meeting Chair, decides on the accreditation of Observers. However, the document does not include the criteria on which the accreditation decision is based. This question is key, especially regarding publication of data prior to dossier	EFSA believes that the concept of regulatory data protection should be differentiated from that of confidential data. In several Union legal acts, the fact that certain information or a given study benefits from a data protection clause does not mean that it should be processed as confidential information and, as such, should not be disclosed (e.g. Regulations (EC) No 1829/2003 and 1831/2003). Class 4 An exception to this more common approach is represented by Regulation (EC) No 1924/2006, to which the contributor is probably implicitly referring, Article 21(1)(a) of which prescribes that data protection may be granted only to those

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			submission but also on potential data access restriction (qualified professionals should be the only ones).	applicants who had the exclusive right of reference to the data or study at the time the application was made. This was interpreted by the European Commission as excluding already published data, and EFSA abides by this interpretation. Class 4
73.	Lallemand Health Solutions (Spain)	3.1 Improving the overall quality of available information and data used for EFSA's outputs	Transparency and Access to documents We acknowledge the fact that EFSA shall ensure widespread access to the documents which it possesses to ensure transparency towards the public. However, we recommend that it should be possible to exclude from this scope the different types of confidential data. To this end, several Authorities have established measures allowing access to information to the public and protection of proprietary information at the same time. For example, the Access to Information Act in Canada entitles any interested party to request access to the information and records of a decision of Health Canada regarding any approval (claim, substance, policy, etc.). In particular, this Act specifies that the institution shall refuse to disclose any information containing "financial, commercial, scientific or technical information that is confidential information supplied to a government institution by a third party and is treated consistently in a confidential manner by the third party", or "information the disclosure of which could reasonably be expected to prejudice the competitive position of a third party". We stress again the need to strike a balance between transparency and protection in that EFSA would ensure the protection of the proprietary information of an applicant when giving access to documents in its possession.	The exclusion of commercially sensitive information is implemented by EFSA as a standard feature during the processing of applications under the Regulation on Public Access to Documents. EFSA has already undertaken or planned a review of its internal rules on reactive access to documents and information. Class 7 The reference to the Canadian AIA is appreciated, but due attention should be paid to the fact that EFSA is an agency of the European Union, and as such it is required to exclusively implement Union law and case law. Classes 4 and 5
74.	FEFAC European Feed Manufacturers' Federation (Belgium)	3.1 Improving the overall quality of available information and data used for EFSA's outputs	How can EFSA foster even further an environment of creative debate amongst its experts while striking the appropriate balance between availability and quality of information? Consistency of risk assessment methodology and structure of delivered opinion within and across panels is extremely important. This requires also consistency in the mandates delivered. Also important is the integration of risk assessment methodology developed in third countries.	Noted. Class 7

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75.	InQpharm Europe Ltd. (Germany)	3.1 Improving the overall quality of available information and data used for EFSA's outputs	4. How can EFSA foster even further an environment of creative debate amongst its experts while striking the appropriate balance between availability and quality of information? We support the idea for EFSA to conduct more frequent stakeholder meetings and "online" meetings such as webinars etc. Regularly updated guidance documents are very valuable for applicants, and we suggest making these documents more comprehensive. In general, communication with health claim applicants can be improved. E.g. any changes in EFSA's evaluation criteria should be published prior to them being applied and implemented. This would grant applicants sufficient time to adjust their applications accordingly. In general, more opportunities for dialogue with the panel experts should be made possible by EFSA.	EFSA agrees it should put in place a system of regular consultation on its draft guidance documents before these are adopted, and in some instances before the drafting begins. This will be duly evaluated in the context of further categorisation and prioritisation in accordance with the Implementation plan before a final decision is taken by EFSA. Class 2 To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7
76.	PAN Europe (Belgium)	3.1 Improving the overall quality of available information and data used for EFSA's outputs	Currently the quality of data is assessed by EFSA in an administrative way, using Klimisch criteria. This is wrong. The quality has to be assessed by reading articles and judging the design and outcome. In science peer-reviews are done and in fact EFSA should do the same. It is very unlikely staff or national civil servants will be able to do this work and the assessments needs to be done by specialised scientists. The main challenge for EFSA is to include specialised scientists in their work. Ity should never happen again that an EFSA panel on a very specialised topic like endocrine disruption, 19 out of the 22 emmebers of EFSa's panel have no knowledge at all about endocrine disruption and 3 some general knowledge. This is asking for trouble and indeed the EFSA opinion shamefully contradicted a report by top-level endocrinoligst made for WHO/UNEP. We propose, for every field EFSA works on, top-level scientists define the science in this field. This science then is used by EFSA for individual decisions. We propose that EFSA, for every health field, liases with the indepedent scientific organisations most academic scientist are member of, and ask this organisation (like the Endocrine Society) to summarise the current knowledge in the field. The organisation shopuld do this by appointing 10 leading scientists and ask them to make the summary. A meeting could be convened at the yearly congress of these scientific organisations.	EFSA does not recommend any specific criteria to assess the quality of the data used in the assessments. The Klimish criteria are mentioned in EFSA's guidance documents as only one of the methods that could be used to assess the quality of datasets. Class 7 Due account should be taken of the fact that the structure and competences of EFSA's Scientific Committee and Panels is laid down in its Founding Regulation and as such may not be changed by EFSA. Furthermore, EFSA's Scientific Committee and Panels may rely on the input of specialised Working Groups composed of the appropriate number of experts on the specific matter. Class 4

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				EFSA acknowledges it needs to ensure that it systematically has at its disposal experts with the right level of knowledge and expertise in the relevant disciplines. To this end, and to ensure the comprehensiveness and reliability of the expert judgements expressed by the Authority's Scientific Committee, Panels and Working Groups, EFSA is willing to explore the most appropriate means to achieve this via targeted further categorisation and prioritisation, to be performed according to the Implementation plan. Class 2
77.	Individual contribution, (UK), Science and Technology Policy Research, University of Sussex	3.1 Improving the overall quality of available information and data used for EFSA's outputs	When in Section 3.1 on page 9, line 3 the text refers to '…its partners…' it would be helpful if the identity of the types of partners envisaged could be clarified. Does the phrase refer to consumers and commercial interests, and does EFSA envisage treating them entirely symmetrically, or does EFSA envisage prioritising consumers' interests over all others? In Section 3.1 on page 9 the text refers to making: "…EFSA's assessments more reproducible…" That aspiration is very welcome, but to the extent that evidence emerges that some of EFSA's assessments have not been reproducible, or only reproducible by adopting problematic assumptions, EFSA should indicate its willingness and intention to re-open those assessments and to provide new assessments that do satisfy the criterion of reproducibility. 4) How can EFSA foster even further an environment of creative debate amongst its experts while striking the appropriate balance between availability and quality of information? 4. EFSA has provided no explanation as to why it assumed a trade-off between the availability and quality of information? Unless and until it does so, there is nothing of substance on which to comment.	The concept of EFSA's partners is used by EFSA to refer to institutional partners, i.e. Union Institutions, fellow Union agencies and Member States' National Competent Authorities. Class 7 EFSA is already subject to provisions requiring it to review its adopted outputs once relevant scientific data or information become available. Class 7. EFSA commits to perform further categorisation and prioritisation on the possibility that it makes publicly available all documents linked to a decision on whether to update an output or not. Class. 2. EFSA acknowledges that the question was not clear insofar as it conveyed the impression that a trade-off

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				between quality and availability of information is inevitable. Class 6
78.	PFP-association for the European primary food processing industry (Belgium)	3.1 Improving the overall quality of sourced information and data used for EFSA's outputs	2. How can EFSA increase its openness to meaningful contributions from individuals and organisations beyond its Panels and Committee? Should a two-way interaction between EFSA's Panels and interested parties be facilitated? What limits should be set to such interaction? PFP believes that opening EFSA doors to meaningful scientific contributions can be a good approach on a case-by-case basis, instead of applying a general principle. When it comes to mandates requested to EFSA, two-way interactions between EFSA and interested parties would be a good approach if framed under certain transparent conditions. In this context, we would particularly support: - opportunities to provide comments during consultation on draft opinion and pre-warnings before publication (of draft opinion and final opinion) -opportunities to discuss in advance of the preparation of an opinion leading to a risk assessment for a specific mandate (e.g. contaminants or nutrition), particularly when it comes to data submission by industry. It should be noted that this practice is already in place on a case-by-case basis and is very helpful	EFSA takes note of the suggestion to put in place an "alert system" to pre-notify interested parties and individuals of forthcoming consultations, and it has already undertaken or planned the necessary actions. Class 1 Similarly, EFSA appreciates the support for the idea of putting in place opportunities to discuss the content of a specific mandate in advance, and it commits to consider this action in the context of further categorisation and prioritisation to be performed according to the Implementation plan. Class 2
79.	Joint Submission Bee Life, Corporate Europe Observatory, Earth Open source, Fondation Sciences Citoyennes, GM Watch, Pesticides Action Network Europe	3.1 Improving the overall quality of available information and data used for EFSA's outputs	4) How can EFSA foster even further an environment of creative debate amongst its experts while striking the appropriate balance between availability and quality of information? We do consider that transparency does not cover the field of "an environment of creative debate amongst its experts". Transparency towards European citizens means that EFSA's task is to ensure that EFSA's opinions are transparent, not necessarily its internal debates as indeed it is important that free speech rights of its experts is safeguarded (as the document points well, §1-2 p.11). Ensuring transparency through the pro-active and complete publication of applicants' files would help the Authority by enabling external analysis of these, but EFSA's proposal to open its meeting or to have pre-submission meetings is not about transparency towards the citizens, as those are not involved in this step and are probably only rarely able to.	In line with the Open EFSA goal of increasing openness and engagement regarding scientific processes, EFSA's open plenary meetings are open to interested citizens as well. Class 7 EFSA's drive to become a more open organisation is expected to be of benefit for a broad range of stakeholders, including EU industry and food business operators. Class 1
80.	Individual contribution, (Austria)	3.2 Complying with	Democratising science It is important that EFSA follows the precaution principle and that new science or newly found arguments can easily be regarded and that a later correction of an	The recourse to the precautionary principle goes beyond EFSA's remit, as this principle belongs to the risk

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		normative and societal expectations Democra-tising science	earlier (scientific) opinion can easily be done and that earlier limits established by EFSA can more easily be changed, compared to now. All panel members or working groups should be instructed also to correct earlier deficiencies, errors or too high limits, which will increase trust in EFSA instead of destroying it.	management phase assigned to the EU risk managers (European Commission, Council and Member States). Class 5 EFSA is already subject to provisions requiring it to review its adopted outputs once relevant scientific data or information become available. Class 7 EFSA commits to perform further categorisation and prioritisation on the possibility that it makes publicly available all documents linked to a decision on whether to update an output or not. Class. 2.
81.	Individual contribution, (Austria)	3.2 Complying with normative and societal expectations Increasing trust"	"Increasing trust" As an individual receiving some of EFSA's newsletters I am concerned about the fact that formal aspects (such as "the substance is sufficiently characterised") often seem to be more important to EFSA than the reliability and trustability of the data submitted by the applicant and all the other implications the use of this substance will have for the society. I cannot imagine that some or many applicants do not tend to supply EFSA with selected results finding a benefit while not mentioning studies having shown no or even an opposite effect, but it seems that some experts don't feel obliged to do further data collection and exploration or to study the overall outcome before positively or negatively assessing a substance. This should be changed in order to increase trust in this authority. "Protecting privacy and commercially sensitive information" Since EFSA's duty is to protect the public from possible damage EFSA should refuse to deal with "secret" substances or mixtures. Owners of rights always have the chance to protect their product by patents, but consumers have the right of being precisely informed about what they eat or feed their animals. Actually I feel a large shortcoming of information across almost all products in the EU, in part because producers or suppliers don't know the properties of what they sell, in part because they don't want to disclose them in order to make it impossible for the consumer to detect if the product is usable for him or in order to hide its	Under several legal acts regulating the evaluation of regulated products, substances, organisms, processes and claims, the burden of proof for demonstrating that a product is safe lies with the applicant. Class 4 EFSA does not deal with any secret substances or mixtures. On the contrary, its scientific opinions provide all the details needed to identify, in a sound an unambiguous manner, the products and substances it evaluates. Commercially sensitive data or studies to be subtracted from public scrutiny are usually dealt with by the European Commission. For the processes that fall within EFSA's responsibility, the Authority strives to maintain the highest possible level of transparency, keeping the number of details and studies treated

No	Contributor	Chapter	Comments received	EFSA response
			disadvantages. The EU, including EFSA, should try hard to force sellers to disclose all information about any product needed by the consumer for assessing advantages, disadvantages and usability of a product on the market.	confidentially as low as possible under the relevant legal framework. Class 7 EFSA does not have any legislative or regulatory capacity, nor enforcement or monitoring powers, which are prerogatives of the European Commission, European Parliament, Council or Member States. Class 5
82.	Syngenta (Switzerland)	3.2 Complying with normative and societal expectations	It is positive that EFSA prioritises increasing transparency and developing trust but it is important to maintain perspective when EFSA is pursuing a goal of "democratising science". Consideration of weight of evidence is an important approach to a judicious and proportionate scientific conclusion, but science is not a popularity contest. A single high quality study conducted under the highest regulatory science standards such as Good Laboratory Practice must be given appropriate priority over a multitude of lower quality data. A key normative and societal expectation is for evidence based policy making, and not policy based evidence making or evidence selection. It is critical that EFSA do not shy from delivering its best scientific judgment just because it is unpopular either to so-called public interest groups, the media or politicians. A further societal expectation is that commercial enterprises operating in a regulated industry are subject to an objective, efficient, proportionate and predictable regulatory decision making process. This includes predictability about safeguards for 3rd party access to and re-use of data submitted as part of this regulatory approval process. It is necessary and appropriate that EFSA must fully comply with the legal requirements to safeguard confidential information protected as confidential business information or through specific data protection rights granted under the regulatory framework. Syngenta would welcome additional transparency to increase quality of the public discussion. However, the way the regulatory framework currently works has absurd consequences: If a company publishes any of those high quality regulatory studies prepared for the EFSA review in scientific literature, these studies immediately lose their data protection rights for regulatory purposes. As a result, any third party can easily take commercial advantage by referencing these publications in a regulatory procedure, depriving the study	EFSA is committed to assess all studies according to quality criteria outlined in previously adopted guidance documents in the area of regulated products, guidance on assessment methodologies, or internationally recognised protocols in other areas. Class 7 EFSA has already planned the establishment of a working group with the aim of developing a guidance document for increasing the level of transparency of the weight of evidence approach adopted by its Scientific Committee, Scientific Panels and their Working Groups. Class 1 Without prejudice to the need of taking into account the peculiarities of each study and dataset, EFSA has already undertaken or planned a review of its internal rules on reactive access to documents and information. Class 1 Regarding the suggestion on the regulatory decision-making process,

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			owner from benefitting from its significant upfront investments. A change in the legislation that allowed the owner of regulatory studies to get appropriate compensation for use of protected data published in the scientific literature by a third party would better support the goals of transparency and open science.	EFSA underlines that it does not have any regulatory or adjudicatory powers, which are competences reserved to the EU risk managers. Class 5 EFSA acknowledges the fundamental importance that regulatory data protection and protection of commercially relevant information has for the concerned sectors in order to be competitive on a global scale. In 2014 it strengthened its approach to protecting commercially sensitive information recognised to be worth of confidential processing, by developing internal processes. EFSA has already undertaken or planned the necessary actions to ensure consistent decision-making processes regarding this matter and to review its current rules on access to documents, to take stock of the developments in the applicable legal framework and case law. Classes 1 and 7.
83.	Association Française des Biotechnologies Végétales (AFBV) (France)	3.2 Complying with normative and societal expectations	Question 1 comment: EFSA has in general succinctly described the societal and normative expectations it will need to comply with. We believe there are two additional expectations which do not appear explicitly. First, in an era of ever increasing globalisation in which actions and failures to act have planetary impacts, there is an urgent need to harmonize global regulatory systems for all regulated products (1) to facilitate registrations and product launches in a much more synchronized manner, in the interest of the planet; (2) to avoid needless repetition of good quality studies (in particular those which are GLP), (3) to minimize unilateral creation of new protocols for fundamental studies without consulting major countries and OECD; and (4) to control the extraordinary increase in regulatory costs which lead to commercialization barriers. Second, to attain transparency predictability is essential: to achieve global benefits of product	Due account should be taken of the fact that EFSA does not have any legislative or regulatory powers, and all comments aiming at changing the legal framework should be directed at the Union Legislators. Class 5

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			innovation for consumers it is necessary to observe a predictable per iod of time for examination and review of dossiers, and that is only possible if there is constant dialogue with applicants, without fear or other concerns, recognizing that applicants employ capable experts, and that applicants are partners, and not adversaries, in the registration procedure. All actors interfacing with EFSA seek on a two-way basis trust, openness and predictability. To illustrate our request that you consider harmonization as a goal, in our view protocols for a protein digestibility test or a 90-day rat feeding study should not vary from country to country, especially among those who have capacity and experience. EFSA could play a leading role in achieving global regulatory harmonization for the common planetary good.	
84.	Association Française des Biotechnologies Végétales (AFBV) (France)	3.2 Complying with normative and societal expectations	Question 3 comment: The current system for data protection and disclosure of scientific conclusions actually works well. Re-utilization of data by the data-owner to avoid unnecessary sacrifice of animals is a worthy goal which should be implemented. Reutilization by third parties can occur with the agreement of the data owner but in other cases the appropriate circumstances need to be defined and intellectual property protection must be maintained and compensation provided. Once again, global regulatory harmonization of requirements on basic studies, assuming they will be GLP, will go a long way to reduce unnecessary duplication of certain studies. This is also true in the case of a well-known protein. To achieve harmonization, multilateral agreements with Canada, USA, Japan, Australia, Brazil and Argentina would enormously facilitate global deregulation of products, in the interest of all consumers wherever they may be. As previously suggested, Europe (and EFSA) can play a leading constructive role in the harmonization process, in particular by collaborating with OECD.	As previously mentioned, due account should be taken of the fact that EFSA does not have any legislative or regulatory powers, and all comments aiming at changing the legal framework should be directed at the Union legislators. The global convergence of regulatory systems is one of these matters. Class 5
85.	ENSSER European Network of Scientists for Social and Environmental (France)	3.2 Complying with normative and societal expectations	1) Are you satisfied that EFSA has identified the societal and normative expectations it has to comply with or would you suggest additional ones that the paper does not capture? Three facts currently cast significant doubts on the validity of EFSA's assessment process and its ability to meet the societal and normative expectations of the European public: i) the fact that EFSA's opinions and decisions currently accept to a large extent the heuristic argumentation of applicants justifying to forego safety testing based on the applicants model of risk assessment, ii) that EFSA tries to accommodate principles and concepts designed for an as insufficient recognized model of risk assessment for European legislation in its new revised guidelines for risk assessment (e.g. re-incorporation and re-naming of the 'concept of substantial	EFSA disagrees with the comments according to which it would systematically accept the standards and studies of applicants. On the contrary, it frequently requests applicants to submit clarifications or additional information, to the point that several industry associations complain about the time it takes to evaluate dossiers as a consequence of questions on missing data and information. Class 7

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			equivalence' as 'comparative safety assessment' into its revised guidelines) and, iii) if applicants deem safety tests appropriate, EFSA relies on such data that applicants performed on their own products. This situation constitutes one of the main concerns and basis for the lack of public (and scientific) trust in EFSA and its processes. In such a context, improvement is urgently needed and could include: 1. Develop guidelines for scientific safety and risk assessment that are in full compliance with the normative and societal values of a large majority of the European public and place predominant emphasis on public interests rather than corporate or applicants interest 2. Institutionalise a practice of providing free access to the raw data used in safety studies and risk assessment in a reusable form (e.g. Excel file format). This will allow for reanalysis by scientists independent from the industry/applicant. An Open EFSA should mean the possibility for full transparency and public scrutiny of all the data used in the assessment and decision-making processes. 3. Establish the procedure that require all companies applying for the release of its products onto the market, provide samples of this material for independent environmental and health research. Ideally this material should be provided free of charge and without constraints on how the safety research is conducted, analysed or published. 4. Consider implementing a procedure by which industry provides EFSA or an independent body the material that will undergo assessment AND the same amount of money it would have spent in its partner-lab to perform the (eco)toxicological assessment and research. This material and money could then be allocated to one (or more) independent laboratory that would be requested to perform a toxicological assessment with full release of all the raw data in a usable form (e.g. published on the EFSA website) with free access to the public. The same should be done for both health and environmental safety research and assessment.	Regarding the suggestion to develop guidelines in full compliance with the expectations of a large majority of the European public, it should be noted that arguments or positions going beyond purely scientific considerations fall outside EFSA's remit. Class 5 EFSA commits to a further categorisation and prioritisation, to be performed according to the Implementation plan, on whether it would be appropriate or feasible to institutionalise a practice of providing free access to the data used or discarded in safety studies and risk assessments in a readable/reusable form. Class 2 The other suggestions provided by the contributor go beyond EFSA's remit and rather fall under the attributions of the European Commission and Union Legislators. Class 5
86.	ENSSER European Network of Scientists for Social and Environmental (France)	3.2 Complying with normative and societal expectations	3) How can EFSA ensure that commercially sensitive information and data are protected while providing access to key information, data and documents necessary to make its assessments reproducible? Should EFSA embrace the principle of reusability? Who should be in charge of striking the balance between the need to allow reproducibility and respecting the rights of data owners? Can guiding principles and standards be established? International agreements (e.g. the Aarhus Convention) and European legislation	EFSA is fully committed to a sound implementation of the Regulation on Public access to Documents and of the Aarhus Regulation, and has already undertaken or planned the review of its internal rules on reactive access to documents and information. Class 1

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			(e.g. Regulations 1049/2001, 178/2002, 1367/2006 and 503/2013) make it mandatory for the administration to grant citizens complete access to documents and information it retains, with clearly delineated and limited exceptions. No intellectual property right should be deemed to be more powerful nor justifiable than health and environmental safety. Thus, we recall that all the raw data used to generate health and environment risks assessments must be freely available and in a reusable form in order to allow counter-examination by independent scientists.	However, the latter is not applicable to all of EFSA's work. In cases where these provisions are applicable, EFSA complies with the requirements and objectives set out in both texts. Class 7
87.	FEFANA (Belgium)	3.2 Complying with normative and societal expectations	We do not see how engaging civil society in the EFSA scientific decision-making process will make outputs more valid. Shall citizens or other groups start being watch-dogs to ensure risk assessment is done properly? What if the result of this exercise is that EFSA scientific outputs differ from the relevant EFSA Panels' evaluations? Will EFSA revise its own scientific outputs? We think this will certainly not increase trust from civil society. The scientific community that interacts and/or watch EFSA's work is relatively limited (applicants', competitors', interest groups', scientific experts) and focus might have to be put on this community and on purely scientific issues. Multiple references to EU research policy are inappropriate. EFSA is not a research institution; it is a risk assessment body serving the regulatory decision-making by the risk manager. When EFSA commissions scientific studies, it shall be because it is necessary for the accomplishment of its mission (Articles 23(d) and 32 of Regulation (EC) No 178/2002).	The adoption of an output by the responsible Scientific Panel of EFSA or its Scientific Committee represents the last step of the risk assessment process. However, EFSA is already subject to provisions requiring it to review its adopted outputs once relevant scientific data or information become available. Class 7. EFSA commits to perform further categorisation and prioritisation on the possibility that it makes publicly available all documents linked to a decision on whether to update an output or not. Class. 2. While EFSA acknowledges that it is not a research institution, the Authority stresses that it must be up to date with the latest scientific research to fulfil its mission, especially with regard to the identification of emerging risks. Moreover, the Legislators gave EFSA the possibility to fund studies on all matters falling under its remit (Article 32 of Regulation (EC) No 178/2002). Class 5
88.	Confederazione Nazionale	3.2 Complying	Under "democratising science" It could be helpful to explicit why Efsa opted since its very beginning to work with	The composition and competences of EFSA's Scientific Committee and

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	Coldiretti (Italy)	with normative and societal expectations	Panels of experts selected from outside, and the implication this has in front of transparency and openness. In fact it seems an issue not quite known, while key to secure a proper understanding of Efsa's functioning.	Panels constitute the choice of the EU Legislator as outlined in Regulation (EC) No 178/2002, and EFSA may only implement this choice. Class 4
89.	Individual contribution, (UK)	3.2 Complying with normative and societal expectations	Complying with normative and societal expectations Failure to disclose criteria used to determine proportionality. Repeatedly it has been apparent that decisions that deal with the supposed 'proportionality' of a decision fail to accept that private sector interests (commercial 'confidentiality' issues) are not equitably balanced by the interests of the public (which may all too often be entirely different from what may be regarded as being 'in the public interest'). Having participated as an informed 'lay member' on a British government panel for over a decade, I am aware such 'lay' contributions can strongly and positively affect the outcome of deliberations and decision-making by expert panels, especially in the field of equitability and balance.	Noted. Class 1
90.	FEFAC European Feed Manufacturers' Federation (Belgium)	3.2 Complying with normative and societal expectations	1. Are you satisfied that EFSA has identified the societal and normative expectations it has to comply with or would you suggest additional ones that the paper does not capture? FEFAC welcomes the objectives of EFSA to allow civil society to improve its understanding of the nature of the scientific opinions / outputs. Democratisation of science must be encouraged and we do appreciate the initiatives taken by EFSA via educational tools to improve the understanding of risk assessment methodology. However, we would also like to stress that the basic mission of EFSA remains Risk Assessment to serve Risk Management. Confusion of roles might be detrimental to the perception by the public of the actual mission of EFSA.	EFSA acknowledges that the separation of risk assessment and risk management is crucial for its daily activities, and EFSA has always been committed to avoiding any confusion in this regard. Class 7
91.	FEFAC European Feed Manufacturers' Federation (Belgium)	3.2 Complying with normative and societal expectations	3. How can EFSA ensure that commercially sensitive information and data are protected while providing access to key information, data and documents necessary to make its assessments reproducible? Should EFSA embrace the principle of reusability? Who should be in charge of striking the balance between the need to allow reproducibility and respecting the rights of data owners? Can guiding principles and standards be established? As rightly pointed out in the discussion paper, sensitive information and data are protected by confidentiality clauses. Such rules shall be complied with. Whenever data are communicated to EFSA, in particular for non-product related risk assessment, we believe EFSA should secure prior consent of the data provider.	As acknowledged in the discussion paper, EFSA recognises the challenges for non-experts to interpret raw data. However, unrestricted access entails, by definition, also access for experts, and metadata should mitigate the risk of misunderstandings and misinterpretations by laypeople. Class 1

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			As a general standpoint, we are sceptical on the benefit of disclosing raw data to non-experts. Data are more than just a figure and their use requires often high scientific skills and we have doubts that EFSA has the resources to track incorrect use of the data it publishes.	
92.	ClientEarth (Belgium)	3.2 Complying with normative and societal expectations	On the one hand, we welcome EFSA's commitment to opening its governance model to allow all interested and concerned parties to participate and monitor the progress and outcome of EFSA's outputs. On the other hand, we have strong reservations about EFSA's concerns for the protection of privacy and commercially sensitive information: • The need to secure the agreement of the data owner: according to Regulations 1049/2001 and 1367/2006 the agreement is not necessary when it is clear that the information should be disclosed; • Protection of personal data: we believe that EFSA should not be overzealous on protecting the identity of scientific experts. Data protection should be aimed at protecting the personal integrity of the individual, but not the scientific advice they provide if such advice is used in the context of opinions given in the interest of the public. We also suggest that there are very different issues at stake in protection of personal data – which concerns personal integrity and non-disclosure of commercial information. In the latter case, there should be a very high threshold to be satisfied before the non-disclosure of information which is crucial to a regulatory decision can be justified. After all, the primary goal of EFSA is protection of the public interest not private commercial interest.	EFSA is fully committed to a sound implementation of the Regulation on Public access to Documents and of the Aarhus Regulation, to the point that it has already undertaken or planned the review of its internal rules on reactive access to documents and information. Class 1 However, the latter regulation is not applicable to all of EFSA's work. Information on the identity of EFSA's experts is publicly available on its website, as required by law. However, EFSA is of the opinion that some "space to think" should be preserved for the experts, so they can express their views without being concerned by the pressure that may be linked to the disclosure of their individual position. Full transparency should rather be ensured by procedural means and/or by subjecting outputs and certain underlying datasets to external scrutiny. The means in which the Authority will implement these principles will be identified following thorough further categorisation and prioritisation according to the Implementation plan. Class 2

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93.	ClientEarth (Belgium)	3.2 Complying with normative and societal expectations	Are you satisfied that EFSA has identified the societal and normative expectations it has to comply with or would you suggest additional ones that the paper does not capture? ClientEarth welcomes EFSA's initiative to have a strategy toward being an open and transparent institution. The Lisbon treaties place great emphasis the fact that the EU must adhere to the principles of an open society. After 5 years since the entry into force of the new treaties, this review exercise is needed. However, we feel that the document shows lack of urgency on the main problems that lead confidence in EFSA to be questioned. In order to achieve openness, EFSA should focus on ensuring that it conducts its work as independently as possible, but the paper does not address the need for EFSA to be perceived as more independent. To this end, a number of suggestions are made in the comments to the paper that we believe should be prioritised. Since EFSA states its intention to use cost benefit analyses in deciding which initiatives to implement, we believe that it should first indicate clearly which actions are more urgent in order to address the problems it faces with the public opinion. Further, we note with concern a lack of reference to EFSA's legal obligations deriving from the EU treaties, the Aarhus convention, Regulation 1367/2006 and Regulation 1049/2001 on access to documents. EFSA, as all EU institutions has a duty to disseminate environmental information as much as possible; this obligation should be acknowledged. Transparency and openness are not simply voluntary commitments. Clear reference to Article 4 and 5 of the Aarhus Convention, Article 4 of Regulation 1367/2006, Article 11 and 12 of Regulation 1049/2001 should therefore be made and the relevant information should be publicly accessible and actively disseminated accordingly.	EFSA has a robust system in place to safeguard the impartiality of its scientific work. Over the years, it has put in place a comprehensive and sophisticated system to ensure its independence, and it is committed to reviewing its policies and procedures to ensure they remain fit for purpose. In this context, avoidance of potential conflicts of interest represents only one, important, part of EFSA's Policy. Class 6 The definition of situations and instances where a conflict of interest may arise at EFSA are transparently laid down in EFSA's decision on declarations of interest, available on its website. EFSA has put in place, and further develops, one of the most stringent frameworks for the prevention of conflicts of interests (CoI) among Union institutions, bodies and agencies. This has been recognised by external audits. The Authority also intends to review its policy on the independence of its scientific decision-making processes with a view to fully reflect in it the opportunities for enhanced transparency and engagement that will result from the "Open EFSA" project. Class 6 The references to EFSA's legal obligations deriving from the EU

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				Treaties, the Aarhus Regulation and Regulation on Public Access to Documents are provided under this section of the discussion paper. While they do represent one of the legal backgrounds against which EFSA's initiative takes place, more precise references to these acts have not been considered appropriate in this envisioning phase. Class 6
94.	ClientEarth (Belgium)	3.2 Complying with normative and societal expectations	How can EFSA ensure that commercially sensitive information and data are protected while providing access to key information, data and documents necessary to make its assessments reproducible? Should EFSA embrace the principle of reusability? Who should be in charge of striking the balance between the need to allow reproducibility and respecting the rights of data owners? Can guiding principles and standards be established? Disseminating and allowing access to information are legal requirements that all EU institutions should comply with. These requirements derive from Regulation 1049/2001, Regulation 1367/2006 and from the Aarhus Convention. Information relating to emissions (i.e. any information relating to exposure to humans and the environment as well as hazard information on specific compounds) should not, in any case be considered confidential. It is recognised that access to documents is often resisted by commercial players on the grounds of intellectual property right protection. However, a clear distinction must be made between the legal mechanisms available to protect infringement of intellectual property rights by other commercial players and the compliance with mandatory regulatory duties by public agencies such as EFSA. This tension is common to other agencies, such as ECHA and EMA, and pragmatic solutions to protect intellectual property could be found without undermining transparency and openness. Secrecy would be an easy shortcut and the practice of reading rooms is not satisfactory as it would not lead to increasing scrutiny of independent external experts in the work of EFSA. Also, Article 4(1) of Regulation 1367/2006 requires active and systematic dissemination of environmental information as well as having environmental information in formats that are readily reproducible and accessible by telecommunications or by other electronic means. Therefore, what is clear is that the possibility to reproduce assessments must be provided.	EFSA is fully committed to a sound implementation of the Regulation on Public Access to Documents and of the Aarhus Regulation, to the point that it has already undertaken or planned to review its internal rules on reactive access to documents and information. Class 1 EFSA appreciates the possibility of developing pragmatic solutions and would be keen to receive some concrete suggestions allowing "to protect intellectual property [...] without undermining transparency and openness". Class 6
95.	DANONE	3.2	It is indicated by EFSA that the NDA Panel adopts a similar approach for its	While EFSA acknowledges the

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	(France)	Complying with normative and societal expectations	evaluation of science, whether it is generally accepted scientific evidence or new scientific evidence. However, EFSA's practice in the field of health claims does not always stick to the twofold approach regarding the nature of the scientific evidence needed to sustain claims. When implementing its vision of becoming more open, it would be useful for EFSA planning to clarify the apparent contradictions between EFSA's official scientific position (same level of expectations for all health claims) and the application of this in some of its opinions; this indeed requires more transparency on the technical grounds supporting EFSA's opinions.	importance of improving its internal processes regarding the development and implementation of guidance documents, it is also aware that a case-by-case approach may still be required in some instances, depending on the specificities of the subject. Class 6
96.	Public Research and Regulation Initiative (PRRI) (Belgium)	3.2 Complying with normative and societal expectations	The phrase "comply with societal expectations" raises some questions. While politically elected bodies may have a duty to comply with "societal expectations", EFSA's task is laid down in the EU's rules and decisions, not in societal expectations. In this context it should be noted that the Executive Summary lays down the objective of the discussion paper: " a plan for the transformation of the European Food Safety Authority (EFSA) into an Open Science organisation ". The phrase "Open Science organisation" is not explained. It would be important that this term be clarified to ensure that the process aims to strengthen transparency and openness within EFSA's legally binding task and not seek to alter its task. The text under "Democratising science" needs further clarification, as it could give the false impression that sound science can be replaced by popular vote. It cannot. The safety of vehicles on the road is assessed by mechanics, not by neighbourhood committee polls.	EFSA does not intend to overstep its mandate as defined in relevant provisions and legislation. Class 1 EFSA intends to update its operating processes to exploit the opportunities offered by developments in the institutional and technological sectors. Class 1
97.	Public Research and Regulation Initiative (PRRI) (Belgium)	3.2 Complying with normative and societal expectations	1. Are you satisfied that EFSA has identified the societal and normative expectations it has to comply with or would you suggest additional ones that the paper does not capture? PRRI proposes the following additional drivers: a) the expectations of the regulated community, of which public research is a part, that regulatory frameworks be implemented as they were designed, which for example for the regulatory framework for GMOs means: in a scientifically sound, predictable and proportional manner. b) expectations from actors outside the EU that the EU will contribute to the international debate and international harmonisation. In the field of GMOs, EFSA	a) EFSA commits to perform further categorisation and prioritisation according to the Implementation plan. Class 2 b) and c) These considerations go beyond EFSA's role and remit, as laid out in its Founding Regulation, and rather belong to the risk management sphere. At the international level, EFSA's role is limited to the provision of scientific and technical support upon request of the European Commission. Classes 4 and 5

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			has largely been absent in the discussions under the Cartagena Protocol on Biosafety. EFSA could play a more active role in clarifying its opinions and guidance outside the EU, and in particular in developing countries. c) the need for scientific innovation, in particular vis a vis the challenges of sustainable food production and food security.	
98.	Public Research and Regulation Initiative (PRRI) (Belgium)	3.2 Complying with normative and societal expectations	3. How can EFSA ensure that commercially sensitive information and data are protected while providing access to key information, data and documents necessary to make its assessments reproducible? Should EFSA embrace the principle of reusability? The current rules for protection of commercially sensitive information can work well. The question of reusability of data is too general – there are cases whereby reusability can be beneficial, provided it is done in accordance with rules for ownership of safety data. Further work is needed to strengthen the mutual acceptability of data. Many data accumulated in other parts of the world could be used directly by EFSA, and would not require repetition of expensive testing, which is particularly inhibitive for the public research sector	The fundamental question underlying the principle of reusability depends on the boundaries it may be subject to, in particular with regard to confidentiality and data protection clauses. Class 1 As EFSA is not in a position to change the relevant legal framework, it would appreciate receiving any concrete suggestions on how to best reconcile these principles. Class 6
99.	SYNADIET (France)	3.2 Complying with normative and societal expectations	1. UNE PROTECTION DES DONNEES INSUFFISANTE L'exclusivité d'une allégation de santé doit être octroyée pour une période de dix ans et pour toute information apportant des données nouvelles, même si elles ne sont que complémentaires de l'état de l'art. Pour les allégations fondées sur des preuves scientifiques nouvellement établies, la protection des données relevant de la propriété exclusive du demandeur peut être accordée pour 5 ans, soit une durée quatre fois inférieure à celle octroyée aux médicaments. Le développement nécessaire à l'octroi d'une allégation d'un aliment est long et coûteux. Les professionnels ont besoin d'une protection plus étendue pour justifier d'un tel investissement. Par ailleurs, la propriété des données devrait être accordée dès lors qu'une preuve scientifique nouvelle est apportée, même si elle vient s'ajouter à des données déjà établies disponibles dans la littérature scientifique. Les professionnels et SYNADIET proposent d'aligner cette durée de protection sur celle des brevets, soit 10 ans. 2. UN EFFET DÉMONTRÉ N'A PAS À ÊTRE EXPLICITÉ	1. The comment concerning the allegedly insufficient length of data protection granted by Regulation (EC) No 1924/2006 goes beyond EFSA's role and remit, as this lies within the responsibility of the EU Legislators. Class 5 2. The comment on the scientific evaluation performed by EFSA regarding the scientific substantiation of health claims made under Regulation (EC) No 1924/2006 goes beyond the scope of the present consultation. Class 0

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			Une allégation de santé doit être accordée sur un produit fini ayant fait preuve de son efficacité clinique, sans avoir à justifier la présence de chacun des ingrédients ni d'en expliciter le mécanisme d'action. Une demande de nouvelle allégation fonctionnelle concerne un produit spécifique et non un ingrédient unique. Or, actuellement, lorsque la preuve de l'effet physiologique d'un complément alimentaire est démontrée, il est demandé au professionnel d'apporter le détail de l'effet de chacun des constituants ainsi que leur mécanisme d'action dans l'effet revendiqué2,5. Cette méthodologie relève plus de la recherche fondamentale. Ces informations sont inutiles pour des constituants alimentaires utilisés à des doses nutritionnelles ne présentant aucun effet secondaire. Elles pénalisent en outre les professionnels dans la mesure où elles alourdissent en temps et en financement la Recherche et le Développement. 2: EFSA-Q-2013-00087. Sc ientific Opinion on the substantiation of a health claim related to Transitech® and improvement of bowel function which is maintained after cessation of consumption of the food pursuant to Article 13(5) of Regulation (EC) No 1924/2006. 5: EFSA-Q-2013-00973. Scientific Opinion on the substantiation of a health claim related to a standardised aqueous extract from white kidney bean (Phaseolus vulgaris L.) and reduction of body weight pursuant to Article 13(5) of Regulation (EC) No 1924/2006.	
100.	EuropaBio (Belgium)	3.2 Complying with normative and societal expectations	a) INCREASING TRUST EuropaBio feels that the 'enhanced openness to interested parties and external knowledge communities' which EFSA outlines as a model should respect the aim of producing 'complete, meaningful and high quality outputs'. It is very important to increase trust, but we believe that transparency by itself is unlikely to deliver more trust. Better communication about EFSA's processes and outputs would play a more important role in building trust. Society's understanding of science and scientific decisions is paramount to ensure trust in scientific institutions. b) DEMOCRATISING SCIENCE The concepts of citizen-scientist and the role of civil society in 'democratising	a) EFSA agrees it should further improve the efforts it makes to communicate and engage with society as a whole, especially in sensitive areas that are considered worthy of particular attention. This is also one of the reasons the Authority decided to undertake the present initiative and engage with those who are interested in following, and contributing to, its work. Class 1 b) The purpose of the document is to gather comments on how EFSA could update its operating processes in order to capture and exploit the

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			science' appear very vague. EFSA should ensure that this is not misunderstood as "replacing science with unfounded/unverified majority views". Whereas EuropaBio welcomes the opportunity for applicants to clarify issues before EFSA finalizes its opinion or for Member State Authorities to engage with EFSA in discussing and solving arising issues, the suggestion to openly share EFSA's draft scientific opinions with individuals concerns us given that there are no guarantees that parts of the public are not trying to influence the process and endanger the independence of EFSA. To pre-empt this, EuropaBio recommends that clearly defined limits are set regarding exchanges of information with the public. First and foremost, EFSA must ensure that its efforts to 'democratise science' do not lead to additional avoidable and scientifically-unfounded delays. Furthermore, EuropaBio recognises applicants as a particular stakeholder given that they are those who submit dossiers to EFSA's active review. This is why EFSA's treatment of applicants inevitably rests on different merits than the public at large. EuropaBio would recommend EFSA focuses on: 1) streamlining its processes in dealing with applicants in order to avoid increasing the workload within EFSA, due to missed efficiencies, leading ultimately to a backlog of non-assesse d products, as well as to higher regulatory costs for applicants, due to the need to redo or redesign studies in applications, and, 2) more frequent and more effective communication with applicants related to the EFSA guidance documents, submission of new dossiers and their risk assessment. For more details, see our reply to chapter 3 'Vision and Goals' and its sub-section 3.1. c) PROTECTING PRIVACY AND COMMERCIALLY SENSITIVE INFORMATION EuropaBio's member companies are required to submit extensive data packages to demonstrate the safety of biotech products. As agricultural biotechnology is one of the world's most R&D intensive sectors, this data results from years of resource-intense research and expertise and as such represents intangible business confidential value. This being said, it is important to bear in mind that full public disclosure of information contained in regulatory dossiers and its potential misuse by competitors - private or public, from within or outside the EU, can cause severe	opportunities offered by developments in the constitutional and technological sectors. EFSA has no intention of overstepping its legal mandate and mission. EFSA is also aware that its goal to open up its scientific processes should not come at the expense of decreases in terms of efficacy and efficiency. To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7 c) ..... hould a policy of proactive disclosure of application dossiers be developed or adopted by EFSA, it would not, and could not, have the effect of making information, studies or data that have been recognised as deserving to be processed in a confidential manner available to the public, since this would imply a breach of the legal framework currently in force. Class 4 EFSA considers that since January 2013 it put in place ample opportunities to engage with industry and commits to engage with applicants even further before the proper implementation phase

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			economic damage by undermining the value of companies' research and confidential business know-how. Therefore, with a view to granting "individuals access to raw datasets", very clear limitations have to be defined to protect privacy and commercially sensitive information. The discussion paper rightly emphasises that these obligations cannot be ignored. EuropaBio believes that for rolling out its plan to open its data, EFSA should first engage in a structured dialogue with applicant industry associations, including EuropaBio, given that applicants are the suppliers of scientific data for product specific risk assessment. This dialogue would need to address what data is released, when it is released and in what manner and format.	commences. Classes 7 and 1
101.	Food Supplements Europe (Belgium)	3.2 Complying with normative and societal expectations	1. Are you satisfied that EFSA has identified the societal and normative expectations it has to comply with or would you suggest additional ones that the paper does not capture? In our view EFSA has indeed covered the vast area of societal and normative expectations that determine EFSA's scope of activities. However, we believe that the very area of stimulating scientific research may not be covered to its full importance. EFSA has an important impact on the promotion and stimulation of new scientific methodologies. As EFSA develops guidance and data requirements which are based on generally accepted scientific knowledge, this is inherently conservative in that it relies on established methods for which there is general acceptance in the scientific community and generally refuses techniques or methodologies that are new and for which experience is not yet so rich. This may lead to a situation where investments of companies in new methodologies may be discouraged as the uncertainty as to whether these will be acceptable or not, is too important. As such the standards that EFSA establishes have the potential to steer scientific research into well-known territories and away from emerging science. This is most apparent in the area of science acceptable for supporting health claims. It is important therefore that EFSA keeps an open mind to new technologies and that discussion with scientists that develop such methodologies is stimulated for EFSA to remain at the forefront of science.	EFSA does not enjoy the power to set or establish any "standards". EFSA's role consists in the provision of scientific advice and communication, which are instrumental to the setting of such standards. Class 5 EFSA acknowledges it is fundamental for the Authority to keep an open-minded attitude to ensure it captures the latest trends and more recent scientific developments in every sector under its competence, in line with the scientific excellence requirement the Authority is required to comply with. EFSA also commits to further categorisation and prioritisation, to be performed according to the Implementation plan, on the possibility of conducting public consultations on a proportion of draft outputs outside the regulated products sector (class 2); as well as on the possibility to publicly consult on statistical models for analysis and to pre-publish the methodological approach chosen or to refer to the

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				relevant guidance document. Class 2
102.	GAP's chair on behalf of GAP, IPA and YLFA (Belgium)	3.2 Complying with normative and societal expectations	It is indicated by EFSA that the NDA Panel adopts a similar approach for its evaluation of science, whether it is generally accepted scientific evidence or new scientific evidence. However, EFSA's practice in the field of health claims does not always stick to the twofold approach regarding the nature of the scientific evidence needed to sustain claims. When implementing its vision of becoming more open, it would be useful for EFSA planning to clarify the apparent contradictions between EFSA's official scientific position (same level of expectations for all health claims) and the application of this in some of its opinions; this indeed requires more transparency on the technical grounds supporting EFSA's opinions. Protecting privacy and commercially sensitive information I welcome mentioning this topic, as it could be a critical aspect for reducing barriers toward the access to scientific data. EFSA should develop a stepwise discussion on problems for the use of commercially sensitive scientific information, as sometimes it steps out as a difficult and controversial problem in the field of regulated substances/products. Therefore this is one real issue for developing an open EFSA.	EFSA commits to further categorisation and prioritisation, to be performed according to the Implementation plan, on the possibility of conducting public consultations on a proportion of draft outputs outside the regulated products sector, as well as on the possibility to publicly consult on statistical models for analysis and to pre-publish the methodological approach chosen or to refer to the relevant guidance document. Class 2 While EFSA acknowledges the importance of improving its internal processes regarding the development and implementation of guidance documents, it is also aware that a case-by-case approach may still be required in some instances. As highlighted in the discussion paper, EFSA appreciates the importance of protecting personal and commercially sensitive regulatory data and would appreciate receiving concrete suggestions on how to ensure the achievement of this objective in the most effective and affordable manner.
103.	European Crop Protection Association, CEFIC, EuropaBio,	3.2 Complying with normative and societal	1. How can EFSA ensure that commercially sensitive information and data are protected while providing access to key information, data and documents necessary to make its assessments reproducible? It is very difficult to reach full reproducibility of EFSA's assessments based on scientific information provided by companies without disclosing company's	1. EFSA is bound by a general requirement to make background information on which the opinions are based publicly available, with the exception of commercially sensitive information. Furthermore, EFSA is

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	Federation of European Specialty Food Ingredients, AESGP, ESA, FEFANA	expectations	commercially confidential information (CCI). Data on risk assessments are already made available under sector-specific legislation. For instance: • Under the Plant Protection Products Regulation, the applicant's summary dossier and the EFSA conclusion regarding the assessment of active substances are made publicly available by EFSA (Art. 10 and 12(2) Reg. 1107/2009). • Under the Genetically Modified Food and Feed Regulation, the applicant's summary of the dossier is also made available to the public with the application for authorisation (Art. 5(2)(b)(ii) Art. 17(2)(b)(ii) Reg. (EC) No 1829/2003). • Under REACH, 'robust study summaries' of studies per formed by companies registering chemical substances are made available by ECHA (Art. 119(2) REACH). Those are detailed summaries of the objectives, methods, results and conclusions of a full study report "providing sufficient information to make an independent assessment of the study minimizing the need to consult the full study report" (Art. 3(28) REACH). Publication of the above data is a good way to fulfil the public interest objective of access to key data allowing independent assessments to take place without harming commercial interests. It should however be noted that for certain types of data or parts thereof, the company may request confidentiality (Cf. Art. 10 and 12 PPPR; Art. 119(2) REACH). Transparency is for the benefit of the public, not in order to satisfy individual interests. Industry is concerned that in the present consultation, EFSA does not distinguish clearly enough between the data which EFSA generates through scientific projects or publications and the data which EFSA receives from companies in order to conduct product safety assessment. Confidential business information should be protected from all disclosures and misuse at all time. Excessive regulatory transparency may open the door for companies requesting access to confidential information submitted by competitors under EU food and crop protection legislation, thereby undermining industry's trust in EFSA's procedures and the fundamental right of companies to confidentiality and protection of trade secrecy. This lack of safeguards and trust would prevent EFSA from fulfilling its tasks under EU food and crop protection legislation and achieving the public policy objectives set out therein, as companies would be less inclined to submit valuable data to the EFSA.	required to comply with the Public Access to Documents Regulation and with the Aarhus Regulation, which provide the general principles of accessibility of documents held by EU institutions, bodies and agencies, such as EFSA. 2. EFSA will consider the principle of reusability in a way to mitigate the legal risks linked to the potential adoption of the principle. To address the concerns of business operators, EFSA has put in place mechanisms for thorough consultation with interested parties on the Open EFSA process. In this spirit, EFSA commits to continue engaging with its interested parties on these matters. Class 1. EFSA is subject to a specific legal and institutional framework, and acknowledges the fundamental importance that regulatory data protection and protection of commercially relevant information has for the concerned sectors in order to be competitive on a global scale. For this reason, in 2014 it has substantially strengthened its approach to protecting commercially sensitive information recognised to be worth of confidential processing, by developing internal procedures to streamline its internal decision-making process for confidentiality

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			2. Should EFSA embrace the principle of reusability? In the consultation document, it is stated that EFSA should implement a presumption of reusability and lay down clearly the conditions when, or processes where, the principle should be validly applied. It is important to highlight that the principle of reusability as laid down in Commission Decision 2011/833/EU only applies to documents "produced" (and not "held") by the Commission, and does not in any case apply to documents for which the Commission is not in a position to allow their reuse in view of third parties' IP rights or to documents which are excluded from access pursuant to Regulation 1049/2001. Furthermore, certain information contained in documents produced by the Commission may have to be kept confidential pursuant to Regulation 1049/2001, as the Decision on the reuse of Commission documents is without prejudice to the latter. Industry supports the same criteria to be taken up by EFSA, meaning that the principle of reusability would be applied to documents produced by EFSA subject, however, to the exceptions established under Article 4 of Regulation 1049/2001. According to the consultation document, EFSA intends to make information and data available in a format that allows EU citizens and interested parties to use and re-use its data and documents for purposes other than those originally envisaged, i.e., to reproduce and verify EFSA outputs or to advance further science. Since company experts are not mentioned in the list of people who EFSA suggests to engage with, this would seem to indicate that these experts may be treated the same as any interested stakeholder. Therefore, the industry kindly requests EFSA to, first and foremost, draw a clear differentiation between data generated by EFSA and data provided to EFSA and herewith categorise the various groups of stakeholders. The industry would like to call on EFSA to engage in a structured dialogue with industry associations before rolling out its plan to open its data, as companies are the most important suppliers of scientific data for product specific risk assessment. 3. Who should be in charge of striking the balance between the need to allow	claims. EFSA has already undertaken or planned the necessary actions to ensure consistent decision-making processes regarding this matter and to review its current rules on access to documents, to take stock of the developments in the applicable legal framework and case law. Classes 1 and 7. I. The proposal of adopting a decision on confidentiality claims before the applicant submits its dossier is not in line with the provisions and procedures currently in force. The internal procedures adopted by EFSA aim at taking a decision on these matters as early as possible in the evaluation process, upon receipt of the application dossier. Classes 4 and 7 II. The right to be heard is duly granted in EFSA's recently adopted decision-making process for confidentiality claims, alongside the possibility for applicants to ask for an internal review, challenge the decision, or withdraw the dossier. Class 7. EFSA has already undertaken or planned the necessary actions to ensure consistent decision-making processes regarding this matter. Class 1 III. EFSA already duly considers the companies' views. Class 7

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			reproducibility and respecting the rights of data owners? This responsibility should remain with the public authority, in this case EFSA. But this also means that EFSA remains liable for any consequence stemming from data access and re-use. In general it may be possible to distinguish information that is not CCI and can be proactively published with no controls; information that is of a highly valuable nature that should not be disclosed at all; and a middle ground of information that may be disclosed but subject to controls on how it is used and further disseminated. This should be assessed in conjunction with each industry sector concerned. For instance, under REACH, a clear distinction is made between data that is presumed confidential (i.e. normally deemed to undermine the protection of commercial interests, e.g. details of the full composition of a preparation), data systematically made public (e.g. results of tox and ecotox studies) and data that is made public unless a valid confidentiality claim is submitted by the interested company (e.g. robust study summaries). An internal review procedure has been established within ECHA for enabling companies to challenge the rejection of confidentiality claim. Industry requires procedural safeguards to ensure predictability of the administrative decision-making with regard to data access and re-use: I. Before submitting the data to EU authorities, the company should know whether the data will be treated as confidential or not, and under which conditions (e.g. if a confidentiality request must be submitted). II. If the authority intends to deny confidential treatment, the company must be given the opportunity to make its point of view known (right to be heard). The supplier of the data needs to be consulted and have a reasonable timeframe to reply. The company must also be granted the right to request that a decision to disclose be reviewed by an independent administrative authority (right to administrative review). Finally, the company should have sufficient time to seek judicial suspension and annulment of the final administrative decision before disclosure (right to judicial review). III. Because companies know the economic and competitive conditions in	3. It is extremely challenging to depart from a case-by-case assessment, since there are numerous factors that need to be considered, but EFSA aims at developing some basic principles to guide the decision-making concerning the confidentiality claims on which it is required to decide. Class 1

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			which they operate, where a request for access is submitted with regard to data provided by a company, appropriate consideration should be given to that company's assessment of whether disclosure would undermine the protection of commercial interests. 4. Can guiding principles and standards be established? See Joint Industry paper on Principles for Balanced Transparency of Regulatory Data.	
104.	Lallemand Health Solutions (Spain)	3.2 Complying with normative and societal expectations	TRANSPARENCY With enhanced dialogue, more transparency occurs automatically. However, there must be a well-defined line between transparency with the applicant and transparency in EFSA's published opinions. We appreciate the fact that the current system allows the protection of proprietary data and believe this should be maintained. However, the protection of data from publication should be broader and not include any information for which its disclosure may affect the applicant's business, image, investments or know-how. As mentioned previously, the publication of negative opinions negatively impact the market in Europe and also at the international level, thus the publication of EFSA's negative opinion about a product or claim must be limited or edited in a manner providing clear explanations and giving the applicants the right to comment publicly and/or to ask for reconsideration.	EFSA appreciates, and complies with, the need not to disclose commercially sensitive information. Class 7 However, the consideration of a potential detrimental effect for the applicant in the case of publication of a negative scientific output belongs to a different discourse, and goes beyond EFSA's discretion, insofar as the Authority is required by law to make its opinions publicly available immediately after their adoption (Article 38 of Regulation (EC) No 178/2002). This is especially in cases where the scientific output is negative, as this highlights a safety or efficacy concern. Class 4 The right to publicly comment on or "appeal" against EFSA's outputs is not in line with the current legal framework. Class 4 EFSA commits to subject the possibility of developing an IT

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				interface and internal processes allowing EFSA website users to post comments on its scientific opinions once they are adopted to further categorisation and prioritisation according to the Implementation plan. Class 2.
105.	InQpharm Europe Ltd. (Germany)	3.2 Complying with normative and societal expectations	1. Are you satisfied that EFSA has identified the societal and normative expectations it has to comply with, or would you suggest additional ones that the paper does not capture? InQpharm maintains that, while consumer information is important, fostering innovation should be paramount. However, the request that any health claim can only be based on generally accepted science seems to contradict any strife for innovation, as it is inherent that innovation may not be generally recognized yet. Hence processes and judgments should also recognize the so-called "emerging science" to accommodate beneficial innovations. This also requires sufficient protection of the applicants' submitted confidential data and/or studies. The procedure currently in place, with applicants receiving a draft of the adopted opinion prior to publication, should be kept in any case. In order to increase confidence of applicants, stakeholders, and the general public in EFSA's processes, practices, views, and policies in relation to health claim applications and subsequent opinions released, InQpharm would welcome more detailed opinions addressing all notable points – positive and negative ones that lead to the final conclusion adopted by the NDA panel. Most importantly, this would help applicants to better understand the guiding principles behind such opinions, which are in our view often not laid out in a full transparent manner. Example: our own health claim application was rejected partly based on an alleged "risk of bias" without any clear rationale for such a judgment.	According to Regulation (EC) No 1924/2006, health claims shall be based on, and substantiated by, generally accepted scientific data. In its scientific assessment, EFSA has to comply with this legal obligation. Class 4 EFSA has already taken, or planned, the necessary actions aimed at identifying how best to increase the current level of transparency regarding the identification of key studies and the reasoning behind their acceptance or rejection. Class 1 Comments regarding specific opinions or applications go beyond the scope of this document. Class 0
106.	InQpharm Europe Ltd. (Germany)	3.2 Complying with normative and societal	3. How can EFSA ensure that commercially sensitive information and data are protected while providing access to key information, data, and documents necessary to make its assessments reproducible? Should EFSA embrace the principle of reusability? Who should be in charge of striking the balance between the need to allow reproducibility and respecting the rights of data owners? Can guiding principles and standards be established?	The general principle is that of transparency (EFSA's Founding Regulation) and accessibility of all documents held by EFSA (Public Access to Documents Regulation and Aarhus Regulation); exceptions to the

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		expectations	We believe that the owner of the sensitive information in question should decide how much disclosure is necessary or wanted. EFSA should provide input on how much disclosure would be required in order to make assessments transparent and comprehensible. EFSA is in charge of the process, however it should be possible for the applicant to find an agreement with EFSA. In case of individual and innovative submissions, first and foremost, the applicant's investment must be reliably secured as long as consumer safety is not compromised. For Health Claim applications, the procedure ensures this by sending a draft of the opinion to the applicant a few days prior to the opinion being published. In any case, we request EFSA not to disclose raw data, as data mining and statistical analyses of raw data by non-experts may lead to wrong conclusions. In our view, publishing raw data principally constitutes a serious breach of trust. If the data owner agrees, however, prepared data can be published by EFSA. As an idea, guiding principles could be established by conducting a survey among stakeholders to determine if there are any unifying opinions as to how far data and information disclosure is warranted or necessary. Based on this, a checklist could be generated for EFSA to adhere to during the publishing process. We agree with the suggestion that, in any case, the owner of data has to be informed whenever confidential data is being requested by a third party.	latter are only those set out in Article 4 of the Public Access to Documents Regulation. Class 4
107.	Joint Submission Bee Life, Corporate Europe Observatory, Earth Open source, Fondation Sciences Citoyennes, GM Watch, Pesticides Action Network Europe	3.2 Complying with normative and societal expectations	1) Are you satisfied that EFSA has identified the societal and normative expectations it has to comply with or would you suggest additional ones that the paper does not capture? We would first of all like to thank EFSA for taking this long-expected initiative to evolve towards a more transparent Authority. This is a demand we have been making for many years and we are glad that the Authority has listened to our concerns and published this first public draft of a concrete plan to reach that goal. A first observation is that there is a general tension in the document “Transformation to an open EFSA”, issued by the Authority for this consultation, between the need to improve the Authority's openness and transparency and the necessity to safeguard its independence. This raises several questions. We welcome EFSA's objective to become more transparent, especially with regard to the data it uses when carrying out risk assessments. In particular, we believe the mid-term objective that EFSA assigned to itself, namely to make its work “reproducible by interested parties” (§7 p.13), is fundamental to align EFSA's work	EFSA does not see a tension between the objective of establishing an Open EFSA and the principle of independence, since the ownership of final scientific outputs would remain exclusively with EFSA or its Scientific Committee or Scientific Panels. Enhanced transparency may only increase the level of reassurance for third parties regarding EFSA’s scientific experts, while at the same time subjecting the latter to enhanced scrutiny. Class 4 While the contributor claims that the need to regain public trust only comes from a perceived lack of

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			with general scientific methodologies. However such transparency must entail a meaningful public access to all the data held by EFSA, not only to the data EFSA says to have used for its risk assessments. This will enable an informed public debate about EFSA's scientific opinions, helping the authority to regain the credibility it lost due to many scandals where the Authority's independence was shown to be compromised. There is obviously a lot of work still needed to reach that stage but we are happy to contribute to it, to the best of our capacity. Regarding the term "openness", similarly, there is an ambiguity that would need clarification. Openness as a value is to be encouraged. However, we would criticise an openness that leads the Authority to increase its vulnerability to the influence of applicants and, generally, all interests aiming to capture the Authority's work for their private benefit. Experience with opening panel meetings to observers, for instance, shows that most "openings" to "stakeholders" are usually dominated by commercial players due to their substantial financial resources: a general and indiscriminate opening of the Authority's work to external contributions is therefore very likely to lead to an increased capture of the Authority's work. Independence is one of the core founding principles of EFSA. We lament the fact that the document fails to mention it when listing the "high standards" EFSA must adhere to (§2 p.6). While the "open government" model is an important reference for governments, EFSA's duty as an expert public institution is also to be independent and issue the best possible scientific opinions to protect public health and food safety. While one of the obvious reasons for the Authority to launch this initiative is to regain public trust, the Authority's real and perceived lack of independence from commercial interests was and remains a crucial reason why EFSA's credibility has been undermined. This is actually the reproach that could be made to the document's vision statement, "Society engages in EFSA's scientific work and gains trust in the EU food safety system" (p.8): to a large extent, and as this consultation illustrates, many members of the civil society already engage with EFSA's scientific work and this is why trust in the Authority's work was undermined! Giving more transparency on a compromised independence would just add to the problem: **EFSA's transparency and independence policies must be strengthened together. In other words, we consider that transparency and openness principles should be used to enable properly**	independence, this is only one part of the picture, since industry, consultants and producer associations also complain about EFSA's excessive scientific requests and lengthy procedures, and about the lack of sufficient opportunities to interact with the Authority. EFSA acknowledges conflicting views among contributors regarding the opportunity to implement the approach described in the Implementation plan. The means with which the Authority will be performing the further categorisation and prioritisation are indicated in the Implementation plan. In line with its high standards of transparency, EFSA commits to publishing the outcome of the further categorisation and prioritisation exercises to be performed according to the Implementation plan. Class 2

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			informed analysis of EFSA's work by society, but should not become ways for vested interests to influence the Authority's work or, worse, arguments to excuse the existence of this influence. A second observation relates to the methodology foreseen by EFSA for the assessment of the policy options it will consider: the "cost-benefit" analysis planned ("phase 3", p.12) is not clearly defined – nor is the identity of the person/institution who would perform the said analysis. While the implementation costs and benefits of policy options could perhaps be financially measured from EFSA's financial and accounting point of view, there are pending questions about the accountancy perimeter considered: will these costs and benefits only be assessed from EFSA's institutional point of view or will broader costs on industrial competitiveness and public health be considered too? Qualitative aspects must also be addressed, as the importance of certain policy options is not proportional to their financial implications for EFSA. However, the document is mute on the indicators foreseen, which undermines the transparency of the whole consultation exercise itself. Publishing the detailed cost/benefit analysis once it is performed would be very important for all to better understand the constraints EFSA is facing as well as where it stands regarding the various policy options considered. A third and last observation is that EFSA's calendar aiming at finalising the development of its initiative in 2016 is really long and probably too long. Developing this draft policy document already took more than a year! We think EFSA must consider the emergency to regain citizens' trust and shorten its calendar.	
108.	Joint Submission Bee Life, Corporate Europe Observatory, Earth Open source, Foundation Sciences Citoyennes, GM Watch, Pesticides	3.2 Complying with normative and societal expectations	3) How can EFSA ensure that commercially sensitive information and data are protected while providing access to key information, data and documents necessary to make its assessments reproducible? Should EFSA embrace the principle of reusability? Who should be in charge of striking the balance between the need to allow reproducibility and respecting the rights of data owners? Can guiding principles and standards be established? Transparency is legally required. International (Aarhus Convention) and European legislation (Regulations 1049/2001, 178/2002, 1367/2006 and 503/2013) make it mandatory for the administration to grant citizens complete access to documents and information it retains, with clearly delineated and limited exceptions. Such exceptions are to be interpreted in a restrictive manner, taking into account the public interest served by disclosure. Particularly, the exemptions relating to (inter	EFSA is fully committed to a sound implementation of its founding Regulation, the Regulation on Public Access to Documents and the Aarhus Regulation. Class 7 However, the latter is not applicable to all of EFSA's work. In cases where these provisions are applicable, EFSA complies with the requirements and objectives set out in both texts. Class 4

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	Action Network Europe		alia) commercial and industrial information (including intellectual property) but also information relating to inspections and audits may under no circumstances be applied to information that relates to emissions into the environment. Article 4(1) of EU Regulation 1367/2006 provides that "Community institutions and bodies shall make all reasonable efforts to maintain environmental information held by them in forms or formats that are readily reproducible and accessible by computer, telecommunications or by other means". Article 5 of the same Regulation provides that "the information that is compiled by them, or on their behalf, is up-to-date, accurate and comparable". The institutions and bodies shall also upon request "inform the applicant of the place where the information on the measurement procedures, including methods of analysis, sampling and pre-treatment of samples, used in compiling the information can be found, if it is available." Individual confidentiality considerations to protect the privacy of officials must be balanced against the public's right to know these persons' interests in their performance of public duties. This balance is the decision of the European Commission based on the existing legislation. The data contained must be accessible to everyone without justification or identification, and republishable. The available data (including raw data) should be published in a usable, editable format (e.g. spreadsheet) in order for the re-analysis work to be possible. Whichever option is considered, it cannot degrade EFSA's existing disclosure regime. Options proposed so far by industry such as a reading chamber are simply not acceptable from this perspective.	For what concerns the right of the public to be informed about the interests of the scientific experts involved in EFSA's evaluations, this is a legal requirement EFSA has complied with since its establishment, pursuant to Article 38 of Regulation (EC) No 178/2002. Class 7 The biographies of the members of the Scientific Committee and Panels are already available online. This notwithstanding, EFSA has undertaken or planned the necessary actions to further consider the suggestion to make publicly available full biographies of the members of its Working Groups as well. Class 1 The situation differs substantially with regard to staff employed by EFSA, who are subject to the Staff Regulations and entitled to the protection offered by the personal data protection regulation. Class 4 EFSA commits to a further categorisation and prioritisation, to be performed according to the Implementation plan, on whether it would be appropriate or feasible to institutionalise a practice of providing free access to the data used or discarded in safety studies and risk assessments in a readable/reusable form. Class 2
109.	Individual contribution,	3.2 Complying	On page 9, in Section 3.2, the text refers to 'regain[ing] the confidence…' of citizens. The recognition that such confidence has yet to be attained is very	By individuals EFSA means individual natural persons or legal entities,

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	(UK), Science and Technology Policy Research, University of Sussex	with normative and societal expectations	welcome. The top paragraph on page 10 in Section 3.2 refers to satisfying: "…the legitimate interests and expectations of concerned individuals in this context." That text fails to acknowledge that many of the interests with which it struggles are comprised not just of 'individuals' but also of commercial organisations; and while commercial organisations are represented by individuals, their commercial interests should not be confused with the interests of those individuals who represent them. The wording should be clarified.	which includes commercial organisations. Not all these subjects may have coinciding interests, and this is not assumed in the discussion paper. Class 6
110.	Individual contribution, (UK), Science and Technology Policy Research, University of Sussex	3.2 Complying with normative and societal expectations	Are you satisfied that EFSA has identified the societal and normative expectations it has to comply with or would you suggest additional ones that the paper does not capture? No. The Discussion Paper refers to 'societal and normative expectations', but the characteristics of those expectations are insufficiently clarified. Importantly, the document fails to acknowledge their diversity. It also fails to acknowledge that there can be, and often are, incompatibilities between the expectations of diverse stakeholder groups. EFSA should make it clear that the societal and normative expectations to which it is most sensitive are those of consumers, any others' expectations should be subordinate to those of consumers.	For what concerns its "sensitivity", EFSA is an agency of the European Union with a legally defined mandate that it is bound to comply with. Article 22(3) (Mission of the Authority) prescribes that "The Authority shall contribute to a high level of protection of human life and health, and in this respect take account of animal health and welfare, plant health and the environment, in the context of the operation of the internal market." Class 4
111.	Individual contribution, (UK), Science and Technology Policy Research, University of Sussex	3.2 Complying with normative and societal expectations	How can EFSA ensure that commercially sensitive information and data are protected while providing access to key information, data and documents necessary to make its assessments reproducible? Should EFSA embrace the principle of reusability? Who should be in charge of striking the balance between the need to allow reproducibility and respecting the rights of data owners? Can guiding principles and standards be established? Responsibility for deciding on the categories of information that can be disclosed, and which might remain confidential, should not be in the hands of the companies. While companies might reasonably request that some of the technical details of their production processes remain confidential, it would not be appropriate for EFSA to consent to firms keeping the details of the characteristics of their products confidential, nor the studies and data that constitute the dossiers providing their safety cases. All of the data concerning the characteristic and consequences of the use of those products should be in the public domain.	It is the responsibility of either the European Commission or, as a residual option, of EFSA to take a decision on the requests formulated by concerned applicants to keep confidential certain details of their respective application dossiers (see e.g. Article 18 of Regulation (EC) No 1831/2003 or Article 39 of Regulation (EC) No 178/2002). Class 4
112.	London	3.2	3.2 Making public ''earlier versions of an output'' to allow for the monitoring of the	Before being scientific publications,

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	School of Economics (UK)	Complying with normative and societal expectations	progress of an output is an interesting idea. However, this is quite a departure from widely accepted scientific publication practice. Scientists submit a paper for peer review and usually receive anonymous reviews of varying quality.	the outputs adopted by EFSA's Scientific Panels are primarily institutional outputs of an Agency of the European Union tasked with the mission of providing scientific advice to EU risk managers. Class 5
113.	European Crop Protection Association, CEFIC, EuropaBio (Belgium)	3.2 Complying with normative and societal expectations	Principles for Balanced Transparency of Regulatory Data in the European Union Recent reviews of access to documents policies by EU regulatory agencies have confirmed a trend to greater openness to access requests, coupled with more extensive proactive data dissemination. This trend is based on considerations that enhanced transparency increases public confidence in the institutions. The initiatives were prompted by requests from interested parties to gain access to detailed data on medicines, GMOs, chemicals and plant protection products and pressure to broaden public access rights to the data underpinning regulatory submissions or decision-making. Innovative companies are required to submit very detailed data packages to EU authorities under various regulatory procedures. These packages routinely contain commercially confidential information (CCI)1, which is an important intangible component of a company's valuable business assets. The possibility that CCI submitted to regulatory agencies may be disclosed to the public and thus available to unfair use can be a disincentive for innovation and investment in research and development - and can also detract from a more structured sharing of data between interested parties. This may result in lower competitiveness of the industry and can even jeopardize the survival of companies by providing competitors with an unfair competitive advantage. An adequate level of protection of CCI requires a fair balance between competing interests. However, recent developments have shown that this balance is not sufficiently implemented in EU law and that protection of CCI is increasingly conceded in face of increasing demands for "total transparency", at the expense of the competitiveness of EU companies and without proper evaluation of the merits of each case. Industry actively supports balanced transparency and calls for a fair and predictable approach towards access to regulatory data, implementing the Access to Documents Regulation (1049/2001) and the Aarhus Regulat ion (1367/2006) in	1. EFSA commits to considering, in the context of further categorisation and prioritisation, the option of a phased approach, and the partial disclosure (study summaries) of the data developed by applicants, so as to mitigate the risks linked to this approach. Class 2 2. EFSA will consider adopting the principle of reusability only for the data and studies it owns as a way to mitigate the legal risks linked to the potential adoption of the principle in the context of further categorisation and prioritisation. Class 2 3. EFSA is subject to a specific legal framework. EFSA acknowledges the fundamental importance that regulatory data protection and protection of commercially relevant information has for the concerned sectors in order to be competitive on a global scale. For this reason, in 2014 it has substantially strengthened its approach to protecting commercially sensitive information recognised to be worth of confidential processing, by developing internal procedures to streamline its internal decision-making process for

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			a manner that stimulates innovation and industry's competitiveness. Any initiative or practice to increase transparency of regulatory data held by EU institutions, agencies and bodies should observe the following principles: 1. Predictability. Industry needs to know in advance whether, how and when the data it submits to EU authorities will be disclosed to third parties. In practice, this means that: - Before submitting the data to EU authorities, the company should know whether the data will be treated as confidential or not, and under which conditions (e.g. if a confidentiality request must be submitted). - If the authority intends to deny confidential treatment, the company must be given the opportunity to make its point of view known (right to be heard). The supplier of the data needs to be consulted and have a reasonable timeframe to reply. The company must also be granted the right to request that a decision to disclose be reviewed by an independent administrative authority (right to administrative review). Finally, the company should have sufficient time to seek judicial suspension and annulment of the final administrative decision before disclosure (right to judicial review). - Because companies know the economic and competitive conditions in which they operate, where a request for access is submitted with regard to data provided by a company, appropriate consideration should be given to that company's assessment of whether disclosure would undermine the protection of commercial interests. 2. Fairness. A fair balance must be achieved between the right of the public to access documents of EU institutions and bodies (Art. 15 TFEU, Art. 42 Charter of Fundamental Rights of the EU) and the right to confidentiality and protection of professional and business secrecy and of property rights (Art. 339 TFEU, Art. 7, 15, 16, 17 and 41(2)(b) Charter of Fundamental Rights of the EU). The protection of confidentiality is particularly important for data submitted by companies in the context of regulatory procedures. - Proactive disclosure of data originating from companies should be possible only where EU authorities and bodies have an explicit and unequivocal mandate in the legislation to do so. - Increasing dissemination of such data cannot be justified by a need to reduce the administrative burden of EU authorities linked to the handling of access to document requests. - Where access to CCI is requested by a third par ty, EU authorities and bodies	confidentiality claims. EFSA has already undertaken or planned the necessary actions to ensure consistent decision-making processes regarding this matter and to review its current rules on access to documents, to take stock of the developments in the applicable legal framework and case law. Class 7 and 1 I. The proposal of adopting a decision on confidentiality claims before the applicant submits its dossier is not in line with the provisions and procedures currently in force. The internal process adopted by EFSA aims at taking a decision on these matters as early as possible in the evaluation process, upon receipt of the application dossier. Classes 4 and 7. EFSA has already undertaken or planned the necessary actions to ensure consistent decision-making processes regarding this matter and to review its current rules on access to documents, to take stock of the developments in the applicable legal framework and case law. Classes 1 and 7. II. The right to be heard is duly granted in EFSA's recently adopted decision-making process for confidentiality claims, as is the possibility for applicants to ask for an internal review, challenge the decision, or withdraw the dossier. .

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			should always carry out a careful weighing up of interests to determine whether there is an overriding public interest justifying disclosure. A mechanical approach of complete disclosure on the basis of an alleged automatic priority in favour of the general public interest in transparency does as a rule not allow for the optimal balancing of interests which will ultimately be in the public interest; nor is it consistent with the law2. 3. Proportionality. The scope and manner in which data is disclosed to the public or to a third party should be proportional to the interests at stake3. - In general it may be possible to distinguish information that is not CCI and can be proactively published with no controls; information that is of a highly valuable nature that should not be disclosed at all; and a middle ground of information that can be disclosed but subject to controls on how it is used and further disseminated. This should be assessed in conjunction with the sectors concerned. - The risk of commercial harm is more immediate where the data is proactively disseminated to the public (typically on a website) than where it is made available to individual persons upon their request, even though the latter are in principle free to further disseminate the information4. Hence, the proactive dissemination route should be used only for data of general public interest that is not commercially sensitive, unless other adequate safeguards can be provided. As soon as disclosure risks undermining the commercial interests of the data supplier, the information should -- subject to an overriding public interest that is established after consultation with the entity that submitted the data -- remain available upon request only. This allows the EU authority to balance the interests at stake, taking into consideration all the circumstances of the case, including the identity of the requestor and persons obtaining access (e.g. if disclosure leads to data becoming available to a competing company). In addition, the authority should take account of the potential uses and understanding of the information by the person obtaining access (e.g. the impact of detailed information related to medicines on patients who may not be able to interpret the data correctly). - Parameters for controlled access to highly sensitive data (e.g. use of reading rooms) should be explored on a case-by -case basis. This would allow access to detailed data for, for instance, interested experts, with adequate guarantees that the same data would not be used for competitive purposes by other companies. Such controlled access schemes can most efficiently be established by industry. - Finally, where data held by EU authorities contains personal data, the privacy rights of the data subjects must be respected.	Class 7. EFSA has already undertaken or planned the necessary action to ensure consistent decision-making processes regarding this matter. Class 1 III. EFSA already duly considers the companies'. Class 7 4. It is extremely challenging to depart from a case-by-case assessment, since there are numerous factors that need to be considered, but EFSA aims at developing some basic principles to guide the decision-making concerning the confidentiality claims on which it is required to decide. Class 1

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			4. Coherence. Implementation of the Access to Documents Regulation (1049/2001) and the Aarhus Regulation (1367/2006) should be coherent with other parts of EU law and with international agreements concluded by the EU. - Such implementation should not undermine the protection of confidentiality provided in sector-specific EU legislation (e.g. Art. 118(2) and 119(2) REACH Regulation (1907/2006), Art. 63 Plant Protection Products Regulation (1107/2009) and Art. 66 of the Biocides Regulation (528/2012)). It should also stimulate self-regulatory schemes, such as the principles for responsible clinical data sharing in the pharmaceutical sector. - It should not compromise the purpose and benefits of EU competition law, by leading to disclosure of strategic data, i.e. data that reduces strategic uncertainty in the market, including technologies and R&D programs, production volumes and supply relationships. - Finally, it should be consistent with the TRIPS agreement, and in particular Art. 39(3) thereof, which requires the EU to protect the secrecy of undisclosed data subject to two exceptions: where disclosure is necessary to protect the public or where steps are taken to ensure the data is protected against unfair commercial use.	
114.	Individual contribution, Istituto Superiore di Sanità, EFSA external expert (Italy)	3.2 Complying with normative and societal expectations	Protecting privacy and commercially sensitive information I welcome mentioning this topic, as ts could be a critical aspect for reducing barriers toward the access to scientific data. EFSA should develop a stepwise discussion on problems for the use of commercially sensitive scientific information, as sometimes it steps out as a difficult and controversial problem in the field of regulated substances/products. Therefore this is one real issue for developing a open EFSA,	In 2014, EFSA has substantially strengthened its approach to protecting commercially sensitive information recognised to be worth of confidential processing, by developing internal procedures to streamline its internal decision-making process for confidentiality claims. EFSA has already undertaken or planned the necessary actions to ensure consistent decision-making processes regarding this matter and to review its current rules on access to documents, to take stock of the developments in the applicable legal framework and case law. This is expected to continue in 2015. Classes 1 and 7

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				EFSA remains fully committed to protecting data recognised to be worth of confidential processing either by the Commission or by the Authority, depending on the relevant legal act. Class 7
115.	EuropaBio (Belgium)	4. Squaring the circle	EuropaBio's replies to Chapter 4 of the discussion paper aim to address primarily the following questions outlined in the executive summary: How can EFSA ensure that commercially sensitive information and data are protected while providing access to key information, data and documents necessary to make its assessments reproducible? Should EFSA embrace the principle of reusability? Who should be in charge of striking the balance between the need to allow reproducibility and respecting the rights of data owners? Can guiding principles and standards be established?	Noted. See replies under comments nr 11, 103 and 113.
116.	Individual contribution, Maastricht University	4. Squaring the circle	What an 'Open EFSA' now precisely means in practice is still a question that EFSA understandably struggles with. In addition to questions as how to protect commercially sensitive information and data and personal data, which I will leave to data protection specialists to comment on, EFSA is struggling to find answers as to which level of transparency and openness it should adhere to in its scientific work, in particular in relation to the meetings of its panels and committee where EFSA opinions are being prepared. The law is silent on this matter. Under reference to social studies of sciences (Hilgartner 2000; Bal, Bijker and Hendriks 2004) and distinguishing into procedural and substantive transparency, I feel confident to formulate a clear answer to that: limit procedural transparency and increase substantive transparency. In other words: keep meetings of the Panels and Committee closed so as to allow for a free discussion amongst the members of these panels and allow observers on request or invitation. This approach is for example followed by ECHA. And, importantly, at the same time: shed ample light on the substantive issues being discussed in those meetings, an approach that EFSA clearly embraces in this vision document. This would be in line with the ideas of Hilgartner's 'theatre metaphor' (Hilgartner 2000). Adapting this metaphor to the food area, into a kind of 'kitchen metaphor', it would mean that EFSA could keep its meetings closed (or allow for limit access) and be very generous about information on its scientific work. Society that is consuming the scientific opinion prepared by EFSA knows about how EFSA is preparing its opinion, which ingredients it uses etc, and where felt necessary or desirable could look into EFSA's kitchen. And yes, it would be important to have a two-way interaction between the panels/committee and interested parties, but this should take place outside of the	EFSA has already undertaken or planned the necessary actions regarding the degree to which it should open its plenary meetings to observers (Class 1) and commits to further categorisation and prioritisation, to be performed according to the Implementation plan, regarding the extent to which it should increment the recourse to "hearing experts" and the organisation of "public hearings". Class 2

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			ordinary panel/committee meetings. This could take the form of fora in which an exchange of ideas, knowledge and inform ation on substance could take place between members of the panels/committee and interested parties.	
117.	Individual contribution, (Germany)	4. Squaring the circle	Only a short general remark. The best result is that the applicants can understand the reason of the decision. The people who work with your results are normally not experts similar to the panel members. They are more or less experts in consumer safety, in the companies, the authorities with an totally different background of knowledge. To create publication is nice, but to create understandable publications is great. Maybe you need more "not experts in science - more customers" in your panels. And also to check public consultations with more than 200 pages in 6-8 weeks, where EFSA spent months or years it is mostly nearly impossible. you are only able to check base parameters, but not the whole document in details. Also this kind of remarks is not confortable for the consumers. With respect for your work and your target	EFSA's Scientific Committee and Panels are required to be composed of scientific experts in the respective fields of responsibility of these bodies (Article 28(4) of Regulation (EC) No 178/2002). Class 4 EFSA acknowledges the need to improve the readability and accessibility of its outputs, or at least of summaries thereof, for the general public and/or non-expert professionals. EFSA commits to engage in a further categorisation and prioritisation, to be performed according to the Implementation plan, aimed at looking into the feasibility of enhancing the opportunities for consulting with the public on the framing of questions and mandates and on the format of calls before they are launched. Class 2
118.	PFP-association for the European primary food processing industry (Belgium)	4. Squaring the circle	3. How can EFSA ensure that commercially sensitive information and data are protected while providing access to key information, data and documents necessary to make its assessments reproducible? Should EFSA embrace the principle of reusability? Who should be in charge of striking the balance between the need to allow reproducibility and respecting the rights of data owners? Can guiding principles and standards be established? When it comes to data submitted under EFSA calls for data following a mandate, existing practices of technical checks to ensure data meet their purposes are a useful tool. It is also very important to maintain that the provider of data continues to be informed and asked its consent before data are provided to a third party. In	EFSA already implements the principle that in cases where it intends to re-use data submitted by a private party, which enjoys the exclusive right of reference for these data, the Authority asks for the party's permission before reusing the material in question for a purpose different than that for which it was originally submitted. Class 7

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			that sense, providing those data to third parties before the finalisation of EFSA risk assessment would be detrimental to EFSA's role of risk assessor. Whilst we see the merit of EFSA providing data provided under a specific risk assessment to another risk assessor (for example JECFA or other risk assessors at International level), we would like to mention that making data meant to be assessed under an exposure assessment and subsequent risk assessment should not be disclosed as such to non-informed people. Indeed, it could run the risk to create misperception based on those sole data, whilst these would only have meaning within a risk assessment process.	For what concerns access to documents by third parties upon request, Article 4(4) of the Regulation on Public Access to Documents prescribes that EFSA check the views of the document's originator before disclosing it to the requestor, unless it is evident that the document shall or shall not be disclosed. EFSA is fully committed to a sound implementation of this provision. To capture the latest developments brought about by the case law of the EU courts, EFSA has already undertaken or planned actions to review EFSA's internal rules on reactive access to documents and information. Class 1
119.	Association of the European Self-Medication Industry (AESGP) (Belgium)	4.1 Transpa-rency	'How can EFSA ensure that commercially sensitive information and data are protected while providing access to key information, data and documents necessary to make its assessments reproducible?' AESGP believes that data owners – i.e. applicants and organisations submitting data to EFSA - need to have a legal certainty which information will be made publicly available in the final EFSA publication. AESGP, as a data provider to EFSA, e.g. on food additives and other substances used in food supplements, appreciates the current EFSA practice to consult a draft opinion prior to a publication to allow a final check against potential errors. AESGP also would like to highlight that EFSA – as an institution of public trust - needs to ensure that commercially confidential information/proprietary data submitted by industry to EFSA is protected against disclosure and misuse at all times.	EFSA is fully committed to achieving the highest standards of transparency while safeguarding commercially sensitive information submitted by applicants and recognised, either by the Commission or by the Authority, as being entitled to confidentiality protection. Class 7 EFSA has already undertaken or planned necessary actions to consider whether the current practice of pre-notifying applicants of draft opinions in advance of their publication is still appropriate, or if this practice needs to be modified or further refined. Class 1
120.	FEFANA (Belgium)	4.1 Transpa-rency	EFSA itself seems to sees the limitations of this "open EFSA" idea and it mentions in the paper the need to maintain the appropriate "room to think and work". Systematically opening EFSA work to public debates would be not appropriate in this respect and even decrease the scientific quality of the work versus public	To further increase the efficacy of the current system of open plenary meetings and the use of external expertise, EFSA has already

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			communication.	undertaken or planned the necessary actions to decide on the degree to which it should open its plenary meetings to observers (Class 1). EFSA commits to further categorise and prioritise the extent to which it should increment the recourse to "hearing experts" and the organisation of "public hearings". Class 2
121.	BEUC - The European Consumers' Organisation (Belgium)	4.1 Transpa-rency	In the Options Table (page 14) the consultation document indicates that EFSA mandates should capture societal needs. To achieve this, EFSA should be allowed to take a broad look at the issues which could impact on public health and consumers, rather than just narrowly responding to a mandate. EFSA must make greater use of its self-tasked role of supplementing the questions if needed. It should do this on nutrition/public health issues as well as food safety issues when relevant. The Agency should be allowed to modify the questions from the European Commission and to extend their scope if it considers it relevant from a scientific point of view. More generally, the Agency should be given the possibility to work on a subject on its own initiative. At present, the work assigned to EFSA by the Commission is defined by the political and regulatory agenda, not public health priorities. EFSA should be able to determine its priorities and agenda for itself, and not fully determined by the European Commission. In order for EFSA to get closer to EU consumers and be perceived as an organisation responding to consumers' needs, we suggest that civil society organisations have the possibility of submitting questions to the Agency. Representatives of Commission departments are entitled to be present in the meetings of the Scientific Committee, the Scientific Panels and their working groups. According to Article 28 of Regulation 178/2002, if they are invited to do so, "they may assist for the purposes of clarification or information, but shall not seek to influence discussions". The Chair of the Committee should ensure that this principle is fully respected, that the Commission participates purely in an observer capacity and that it does not attempt to influence the discussions.	EFSA's powers in terms of self-tasking are extremely important for its scientific and intellectual autonomy. Class 6 However, as becomes clear from Article 22 of Regulation (EC) No 178/2002, and contrary to the Authority's tasks in relation to food and feed safety, EFSA's mission in the area of human nutrition is limited to what is outlined in the sectoral legal acts. Class 5 The bodies authorised by Article 29 of Regulation (EC) No 178/2002 are the European Commission, Member States of the European Union, the European Parliament, and the Authority. The suggestion that civil society organisations should be able to submit questions to EFSA goes beyond EFSA's remit. Class 5 Since its establishment and in cooperation with the concerned institutional players, EFSA has consistently complied with the

No	Contributor	Chapter	Comments received	EFSA response
				principle of separation between risk assessment and risk management. Observers from the Commission's services may attend EFSA's scientific meetings pursuant to Article 28 of Regulation (EC) No 178/2002. Class 6
122.	Individual contribution, (UK)	4.1 Transpa-rency	Transparency EFSA'a objective of 'democratising science' is a laudable but ultimately unachievable goal. In general although the public has a vested interest in the application of science to food safety, it does not have access to the funding and infrastructural support in researching issues when the policies set by national risk management objectives do not accord with the wishes, perceptions and interests of the public. Individual members of the public, and smaller NGOs, have no effective access to the professional public relations skills and resources enjoyed by government and commercial vested interests. So where political and commercial interests are strong, there are far fewer financial obstacles to persuading the public towards a 'public opinion' that is more compatible with the interests of the State and industry. In such circumstances the opinions of a largely scientifically illiterate public can be, and all too frequently are, manipulated by commercial interests regardless of the scientific facts revealed by the risk assessment. Follow-up polls of public opinion then simply reinforce the effectiveness of the programmes that manipulate that deliberately managed opinion, a positive feedback mechanism that effectively prohibits support for contrary views for long after the active opinion management campaign has ended. Unless EFSA adopts mechanisms that by-pass this organised opinion-manufacturing process, and follows its own decisions on the science involved in its deliberations, reliance of public opinion as such to formulate or follow-up its assessments will itself introduce bias and devalue its own decisions. This may appear to be undemocratic, but reflects the real world in which the democratic process is already routinely abrogated by professional hired opinion manipulators. Separation of risk assessment and risk management Political objectives do not necessarily reflect public needs and wishes. The role of	The objectives of the outlined approach are limited to increasing the quality of EFSA's outputs and improving trust in its scientific processes. Considerations like the ones developed in the comment go beyond EFSA's remit and rather belong to the realm of constitutional reflections affecting the EU as a whole. Class 5 Since more than 12 years, and in cooperation with the concerned institutional players, EFSA has consistently complied with the principle of separation between risk assessment and risk management. Observers from the Commission's services may attend EFSA's scientific meetings pursuant to Article 28 of Regulation (EC) No 178/2002. Class 6 The recommendation regarding the need to entrust the Authority with the power of pro-actively monitoring risk management policies should be addressed to the Union Legislators and risk managers, since such competence would exceed EFSA's conferred powers. Class 5

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			EFSA needs to be very clearly defined. There is a vast and expanding gulf bet ween science and politics that challenges the entire field of the application of science in social management at national and international levels. EFSA must act as an arbiter of good science in the assessment of risk, but this role should not become inextricably linked with the role of politicians in risk management and policy formulation. Both sets of experts have their place, but EFSA's role must be to assess risk and to evaluate political policies of risk management to ensure that these do not worsen threats to public safety in the cause of political expediency. EFSA should be authorised to monitor risk management policies that apply to food safety that are implemented within Member States. The objective must be to ensure compliance with sound scientific decisions on food safety, and to issue unambiguous statements, and indeed reprimands, where aberrant policies do not reflect the science on which they are alleged to be founded.	
123.	ClientEarth (Belgium)	4.1 Transpa-rency	It would be important to note on this paragraph that it is very important to make sure that EFSA's outputs can be monitored after they are published in order to increase the accountability of EFSA's work and the quality of its outputs. For this reason, as far as possible, all aspects of a scientific opinion should be fully documented: • Methodologies adopted and reasons for preference of one over the other; • Transparency on the identification of key studies and detailed reasons to discard studies which document harmful effects. Further, the funding source of the studies taken into account should be clearly stated (industry, independent, NGO); • Possible financial and intellectual biases deriving from present or previous employment; • Any direct input from interested parties during the development of the scientific output (e.g. formal or informal submissions by applicants). • Any other aspect that contributes to the reproducibility of the scientific outputs; Regarding the issue of safeguarding free discussions, it is neither recommended not desirable that scientific panels are opened to everyone. As long as transparency in the opinion forming-making is guaranteed panel sessions should not be opened to all stakeholders unless balanced participation can be guaranteed. Further, participation of parties that have direct interests (or represent those interests) in EFSA's outputs should be strictly avoided.	EFSA is committed to producing transparent scientific outputs containing all the elements mentioned in this contribution. However, it acknowledges the need to increase even further its efforts in this sense. To further strengthen the efficacy of the current system of open plenary meetings and the use of external expertise, EFSA has already undertaken the necessary actions to decide on the degree to which it should open its plenary meetings to observers (Class 1). EFSA commits to further categorise and prioritise the extent to which it should increment the recourse to "hearing experts" and the organisation of "public hearings". Class 2 The request to disclose information on the funding of each study and publication finds no legal basis. EFSA

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				has no direct legislative, enforcement or regulatory powers to do so. However, EFSA has already taken, or planned, the necessary actions aimed at identifying how best to increase the current level of transparency regarding the identification of key studies and the reasoning behind their acceptance or rejection. Class 1
124.	DANONE (France)	4.1 Transpa-rency	Would EFSA be ready to consider the possibility of granting access to potential divergent opinions issued by EFSA panellists, paramount to any transparency aspirations? According to article 38 of Regulation 178/2002, EFSA shall ensure that it carries out its activities with a high level of transparency. It shall, in particular, make public without delay agendas and minutes of the Scientific Committee and the Scientific Panels as well as the opinions of the Scientific Committee and the Scientific Panels immediately after adoption, minority opinions always being included. This has not always been the case. In line with the same article of Regulation 178/2002, EFSA shall lay down in its internal rules the practical arrangements for implementing the transparency rules. Scientific risk assessment carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence is an important procedural guarantee, whose purpose is to ensure th e scientific objectivity of the measures adopted and preclude any arbitrary measures. Additionally, the probiotic industry call on EFSA panellists to provide feedback on the whole dossier that is submitted to identify all its strengths and weaknesses. This would be particularly useful as guidance provided by EFSA is based on opinions and would generally be valuable for applicants to get a better understanding of the dossier submission and evaluation process.	By law, EFSA's scientific opinions reflect the views of the members of the responsible Scientific Panel. Pursuant to Article 38 of EFSA's Founding Regulation, minority opinions are published together with the opinion adopted by the majority of members of the competent Panel whenever they are expressed and motivated. Class 4 To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7. Usually, EFSA's views on the standards implemented in the evaluation of regulated products, substances, organisms, processes and claims are laid down in scientific guidance documents. The comment on the specific process related to Regulation (EC) No 1924/2006,) goes beyond the scope of this exercise. Class 0

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			Moreover, we would ask for more transparency regarding EFSA's interpretation of some of the provisions of the regulations. For instance, EFSA's interpretation of the concept of "performing health claim evaluation of the highest possible level" stated in Recital 23 of the Nutrition and Health Claims Regulation is not clear enough. Based on the experience gained with the health claim evaluation process so far, it seems that EFSA's interpretation of those concepts seems to differ from the views of independent scientists from academia and from industry. Therefore, more clarity and transparency on how EFSA bases its interpretation would be welcome.	
125.	Public Research and Regulation Initiative (PRRI) (Belgium)	4.1 Transpa-rency	PRRI supports the notion that "EFSA must investigate whether a complete and unchecked opening up of scientific meetings is likely to diminish the qualitative and quantitative level of the scientific discourse. Science and regulatory science are not definitive disciplines. Total transparency may inhibit actors in these challenging sectors, preventing the correct recourse to "trial and error" processes, hindering creativity, the formulation of dissenting opinions or even of basic questions, and favouring entrenchment in mainstream thinking."	To further strengthen the efficacy of the current system of open plenary meetings and the use of external expertise, EFSA has already undertaken the necessary actions to decide on the degree to which it should open its plenary meetings to observers (Class 1). EFSA commits to further categorise and prioritise the extent to which it should increment the recourse to "hearing experts" and the organisation of "public hearings". Class 2
126.	SYNADIET (France)	4.1 Transpa-rency	L'ÉVALUATION SCIENTIFIQUE DES ALLÉGATIONS DE SANTÉ : OPACITÉ DU PROCESSUS Il apparaît essentiel d'établir un mode de communication entre les professionnels et le groupe d'experts scientifiques de l'EFSA lors d'une demande d'allégation nutritionnelle ou de santé, tout autant en amont des développements qu'au cours des évaluations. Pour produire la preuve de son effet physiologique, il est demandé au complément alimentaire de faire l'objet d'un développement clinique complet évalué par le groupe d'experts scientifiques du Panel Nutrition, produits Diététiques et Allergies (NDA) de l'EFSA. A ce jour, cette évaluation repose sur des bases mal ou non définies : • Seules quelques lignes directrices ont été élaborées pour certaines fonctions (immunitaires et digestives,…). Aucune indication n'a été fournie pour les autres fonctions physiologiques. Ainsi les règles d'évaluation sont très souvent inconnues des professionnels concernés préalablement au dépôt de leur dossier1. • Il est impossible d'entrer en relation avec le groupe d'experts en vue d'optimiser un plan de développement, en particulier dans les domaines pour	To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7.

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			lesquels il n'existe pas de lignes directrices1. • Aucun dialogue n'est possible avec le groupe d'experts scientifiques au moment des questions posées lors de l'évaluation du dossier (Stop Clock)2. Cette absence de transparence et de concertation est considérée comme un obstacle important par les professionnels français des compléments alimentaires qui souhaitent investir dans la Recherche et l'Innovation. 1: EFSA-Q-2012-00761. Scientific Opinion on the substantiation of a health claim related to Yestimun® and defence against pathogens in the upper respiratory tract pursuant to Article 13(5) of Regulation (EC) No 1924/2006. 2: EFSA-Q-2013-00087. Scientific Opinion on the substantiation of a health claim related to Transitech® and improvement of bowel function which is maintained after cessation of consumption of the food pursuant to Article 13(5) of Regulation (EC) No 1924/2006.	
127.	EuropaBio (Belgium)	4.1 Transpa-rency	EuropaBio draws attention to its statement on the principle of transparency (available on the EuropaBio's website). We believe that transparency policies based on Regulation (EC) 1049/2001 must ensure predictability for operators, respect for the owner of the data, respect of the international legal framework, protection of intellectual property and the international competitiveness of companies. We insist that EFSA has to inform applicants in advance whether, how, and when data submitted to its attention will be disclosed to third parties. These should be the guiding principles and standards for EFSA in its vision for the future. In the context of the present consultation, EuropaBio is concerned that EFSA does not distinguish clearly enough between the data which EFSA generates through scientific projects or publications and the data which EFSA receives from applicants in order to conduct product safety assessment. In addition, EuropaBio recommends EFSA puts a stronger emphasis on the protection of privacy and commercially sensitive data as an indispensable condition for securing the advancement of innovation in the EU. Confidential business information should be protected from all disclosures and misuse at all time. We would like to remind EFSA that Article 4 of Regulation (EC) 1049/2001 states that "access to a document where disclosure would undermine the protection of commercial interests of a natural or legal person including intellectual property" should be refused unless there is an overriding public interest. The balance between transparency and the protection of these rights should never be put at risk through actions by the authority. In addition, procedures spelled out in product specific EU legislation should be applied.	EFSA fully complies with the legal requirements set out in the Public Access to Documents Regulation, Aarhus Regulation, sectoral legal acts and its Founding Regulation. Class 4 Also for this reason, EFSA has already planned the review of its internal rules on reactive access to documents and information. Class 1

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			It is imperative that appropriate measures are put in place to implement the existing EU legal framework to protect regulatory data and prevent its possible misuse that could undermine industry's legitimate economic interests. For the sector of agricultural biotechnology, bo th the rules for protection of confidentiality, assigned to the European Commission, as described in the EU legislation on GMOs (Directive 2001/18/EC and Regulation (EC) 1829/2003), and the more general rules for data protection in the EU (Regulation (EC) 1049/2001), which also apply to non-confidential data, should be uncompromisingly adhered to.	
128.	Food Supplements Europe (Belgium)	4.1 Transpa-rency	2. How can EFSA increase its openness to meaningful contributions from individuals and organisations beyond its Panels and Committee? Should a two-way interaction between EFSA's Panels and interested parties be facilitated? What limits should be set to such interaction? We very welcome the policy options identified for exchanging views at all stages of the EFSA work. In particular we consider it of particular value to be able to share views where work is initiated or received, by means of consultation and meetings when it concerns more general scope and pre-submission meeting on regulated products. Also the efforts of EFSA to allow involving the most relevant experts in the area of their expertise is important. It is obvious that the leading experts are often solicited by industry for research in their field of expertise. Care should be taken that such experts are not a priori excluded when they have done research funded by industry and that final opinions are not just developed by the in-house EFSA panel members who may not have done research funded by industry but also may lack the necessary level of expertise in a specific area. We also welcome very much the possibility for hearings of the applicant in the stage of the draft opinion. Such hearings can clarify possible misunderstandings but also enable applicants to get a clear view on why the panel came to its conclusion. The Open EFSA options table given a complete overview of the EFSA's activities and measures envisaged. We believe it would be good to better differentiate between general EFSA work, commissioned by Regulators or self-tasked and assessments of applications in the context of a regulatory authorisation process. In	EFSA acknowledges the intrinsic challenge of the need to balance the importance of attracting the best scientific expertise available for joining EFSA with the expectation of "total independence" as expressed by some interested parties. EFSA has a robust system in place to safeguard the impartiality of its scientific work. Over the years, it has put in place a comprehensive and sophisticated system to ensure its independence, and it is committed to reviewing its policies and procedures to ensure they remain fit for purpose. In this context, avoidance of potential conflicts of interest represents only one, important part of EFSA's Policy. Class 6 EFSA has put in place, and further develops, one of the most stringent frameworks for the prevention of conflicts of interests (CoI) among Union institutions, bodies and agencies. This has been recognised by external audits. In this context, EFSA will consider the specific

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			this last flow of work, it is logic that the applicant who has compiled the scientific evidence should be the primary contact during the assessment phase to enable clarification where needed and the provision of additional information or input on the scientific conclusions when still in draft form. This is particularly important given that certain elements of the application are covered by confidentiality, which should be maintained. Comments from third parties can also be valuable at the stage that the opinion has been finalized. We agree that If EFSA fails to protect its experts' views, this could paradoxically lead to self-censorship and endanger frank and open scientific discussion. We can understand the concern and the fact that the panel should be able to discuss in closed session the conclusions of their assessment, However, once the panel has agreed its draft opinion, we see no reason not to open up the reasons behind the opinion for scrutiny. We have welcomed the possibility to attend some of the meetings of the panels, as made possible by EFSA's Observer Pilot Project. These have enabled stimulating discussion on the topics that were open for such open meetings. We would welcome that in future all topics are open for discussion. This does not preclude the kind of closed meeting mentioned above that the Panel would need to reach its conclusions on these topics.	suggestion to differentiate between activities to be undertaken in the regulated products area and those to be adopted in the context of the assessment of more general, public health related EFSA tasks. Class 6 To further strengthen the efficacy of the current system of open plenary meetings and the use of external expertise, EFSA has already undertaken the necessary actions to decide on the degree to which it should open its plenary meetings to observers (Class 1). EFSA commits to further categorise and prioritise the extent to which it should increment the recourse to "hearing experts" and the organisation of "public hearings". Class 2
129.	GAP's chair on behalf of GAP (Global Alliance for Probiotics), IPA (The European Chemical Industry Council) and YLFA (Yogurt and live fermented milks Association) (Belgium)	4.1 Transpa-rency	Would EFSA be ready to consider the possibility of granting access to potential divergent opinions issued by EFSA panellists, paramount to any transparency aspirations? According to article 38 of Regulation 178/2002, EFSA shall ensure that it carries out its activities with a high level of transparency. It shall, in particular, make public without delay agendas and minutes of the Scientific Committee and the Scientific Panels as well as the opinions of the Scientific Committee and the Scientific Panels immediately after adoption, minority opinions always being included. This has not always been the case. In line with the same article of Regulation 178/2002, EFSA shall lay down in its internal rules the practical arrangements for implementing the transparency rules. Scientific risk assessment carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence is an important procedural guarantee, whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary	By law, EFSA's scientific opinions reflect the views of the members of the responsible Scientific Panel. Pursuant to Article 38 of EFSA's Founding Regulation, minority opinions are published together with the opinion adopted by the majority of members of the competent Panel whenever they are expressed and motivated. Class 4 To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7.

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			measures. Additionally, the probiotic industry call on EFSA panellists to provide feedback on the whole dossier that is submitted to identify all its strengths and weaknesses. This would be particularly useful as guidance provided by EFSA is based on opinions and would generally be valuable for applicants to get a better understanding of the dossier submission and evaluation process. Moreover, we would ask for more transparency regarding EFSA's interpretation of some of the provisions of the regulations. For instance, EFSA's interpretation of the concept of "performing health claim evaluation of the highest possible level" stated in Recital 23 of the Nutrition and Health Claims Regulation is not clear enough. Based on the experience gained with the health claim evaluation process so far, it seems that EFSA's interpretation of those concepts seems to differ from the views of independent scientists from academia and from industry. Therefore, more clarity and transparency on how EFSA bases its interpretation would be welcomed.	EFSA commits to carry out further categorisation and prioritisation of the possibility to organise pre-submission meetings with applicants in the area of regulated products. Class 2 Usually, EFSA's views on the standards implemented in the evaluation of regulated products, substances, organisms, processes and claims are laid down in scientific guidance documents. The comment on the specific process related to Regulation (EC) No 1924/2006,) goes beyond the scope of this exercise. Class 0
130.	Lallemand Health Solutions (Spain)	4.1 Transpa-rency	TRANSPARENCY With enhanced dialogue, more transparency occurs automatically. However, there must be a well-defined line between transparency with the applicant and transparency in EFSA's published opinions. We appreciate the fact that the current system allows the protection of proprietary data and believe this should be maintained. However, the protection of data from publication should be broader and not include any information for which its disclosure may affect the applicant's business, image, investments or know-how. As mentioned previously, the publication of negative opinions negatively impact the market in Europe and also at the international level, thus the publication of EFSA's negative opinion about a product or claim must be limited or edited in a manner providing clear explanations and giving the applicants the right to comment publicly and/or to ask for reconsideration. Transparency and Access to documents We acknowledge the fact that EFSA shall ensure widespread access to the documents which it possesses to ensure transparency towards the public.	The requirement to publish all its scientific opinions is laid down in Article 38 of EFSA's Founding Regulation. Class 4 Currently, neither the Founding Regulation nor relevant legal acts establish an "appeal system" against negative opinions. Class 4 The exclusion of commercially sensitive information is implemented by EFSA as a standard feature during the processing of applications under the Regulation on Public Access to Documents. Class 0 The Authority is not a body established under Canadian law, but an agency of the European Union and

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			However, we recommend that it should be possible to exclude from this scope the different types of confidential data. To this end, several Authorities have established measures allowing access to information to the public and protection of proprietary information at the same time. For example, the Access to Information Act in Canada entitles any interested party to request access to the information and records of a decision of Health Canada regarding any approval (claim, substance, policy, etc.). In particular, this Act specifies that the institution shall refuse to disclose any information containing "financial, commercial, scientific or technical information that is confidential information supplied to a government institution by a third party and is treated consistently in a confidential manner by the third party", or "information the disclosure of which could reasonably be expected to prejudice the competitive position of a third party". We stress again the need to strike a balance between transparency and protection in that EFSA would ensure the protection of the proprietary information of an applicant when giving access to documents in its possession. Transparency in interpretation Conversely, more transparency would be needed regarding EFSA's interpretation of the provisions that entail some regulations. For instance, The Nutrition and Health Claims Regulation has been implemented, to our view, in a very restrictive way. Article 6 and recital 23 of the Regulation establishes that claims should be based on and substantiated by generally accepted scientific evidence and assessments should be done to the highest possible standard. Those concepts of "generally accepted scientific evidence", and "performing evaluation at the highest possible standard" are, in themselves, open to interpretation. We believe it would be very useful if EFSA would make an open call for an interpretation of those concepts. Based on the outcome of many dossier rs evaluated thus far, we believe that EFSA has interpreted and placed the "evaluation of the highest possible standard" on the scientific evidence rather than holding the evaluation process itself to the highest possible standard. In the example of the unilateral rejection of all probiotic health claims and the discounting of the vast body of evidence provided, we see indications that the interpretation of what is the highest level evidence and the highest level evaluation is not viewed the same way by the independent scientists from academia, from Industry and from EFSA. We believe that a consultation around this idea would be very valuable and would enhance the openness at EFSA.	as such required to implement exclusively Union law and case law. Class 5 The comment regarding transparency in interpretation goes beyond the scope of this consultation. Class 0

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131.	Individual contribution, (France)	4.1 Transpa-rency	La transparence passe par la traduction ! No transparency without translations ...	EFSA commits to undertake a further categorisation and prioritisation, to be performed according to the Implementation plan, regarding the current language regime of its scientific outputs and to consider the extent to which this may be reformed. Class 2
132.	EAS-Strategic Advice (Belgium)	4.1 Transpa-rency	Comments related to 4.1 Transparency section part: "Safeguarding free discussion": We would in this context like to provide some comments and impressions related to EFSA's OBSERVER PILOT PROJECT initiative opening some EFSA Scientific Panel meetings to observers. EAS has during 2013-2014 participated with great interest to some Scientific Committee (SC), ANS and NDA Panel meetings open to observers, and would like to encourage EFSA to increase such opening to observers to Panel meetings on a regular basis. In terms of the concerns raised in this section of the discussion paper: We do not think that the opening of the Panel meetings to observers has "diminished the qualitative and quantitative level of the scientific discourse". Also, the feedback we think observers have received in the meetings from the Panel chairmans and members so far has been that the meetings open to observers have contributed to the process of transparency without inhibiting the scientists in their challenging sectors. This has therefore in terms of this initiative, in no way as the EFSA discussion paper suggests could potentially happen, endangered certain initiatives opening more interaction with stakeholders: "hindered creativity, the formulation of dissenting opinions or even of basic questions, and favouring entrenchment in mainstream thinking." On the contrary, it seems that the observer attendance - also from verbal feedback we understand to have received via the Panels in these meetings - may have brought stimulating scientific questions from stakeholders to the Panel which were very welcomingly answered by the Panel chairman in the dedicated question and answer sessions at the end of each meeting. The stakeholder observer formula of such meetings therefore in our view contributes to "increased Transparency" and is not inhibiting the scientific work of the Panels.	To further strengthen the efficacy of the current system of open plenary meetings and the use of external expertise, EFSA has already undertaken the necessary actions to decide on the degree to which it should open its plenary meetings to observers (Class 1). EFSA commits to further categorise and prioritise the extent to which it should increment the recourse to “hearing experts” and the organisation of “public hearings”. Class 2.

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			We therefore think the concern in this context is not of application that thereby EFSA could "fail to protect its experts' views". To prevent this, in how t he EFSA observer PILOT PROJECT example was implemented and further built out over the past years, EFSA has in this excellent example, in our view well taken care of and considered how to best balance implementation of an Open EFSA (allowing stakeholders to observe meetings) while maintaining its scientists the appropriate "room to think". We therefore very much welcome and encourage EFSA to continue this route of increased stakeholder transparency, by continuing this OBSERVER attendance of Panel meetings initiative: with also possibly SC, NDA and ANS Panel meetings being more frequently opened to observers in future.	
133.	PAN Europe (Belgium)	4.1 Transpa-rency	Transparency at EFSA is quite good, except the answers to access to documents requests.	EFSA is fully committed to a sound implementation of the Regulation on Public Access to Documents, the Aarhus Regulation and the relevant case law in conjunction with the relevant sectoral acts. This is without prejudice to the fact that not all interested parties may be satisfied by the decisions EFSA takes in the process. Class 0 EFSA has already undertaken or planned to review its internal rules on reactive access to documents and information. Class 1
134.	Individual contribution, (France)	4.1 Transpa-rency	Bonjour, Le fonctionnement de l'EFSA est très critiquable. En particulier du fait des conflits d'intérêts de la part de ses membres. Actuellement plus de 50% de ses membres ont des intérêts personnels auprès des entreprises qui y demandent des autorisations de mise sur le marché. C'est tout simplement inadmissible. Le rôle de l'EFSA est de garantir la santé des populations lors de la consommation de ces produits. A l'heure actuelle elle garantit essentiellement les bénéfices des multinationales représentées par une majorité de ses membres, ce qui est juste	EFSA has a robust system in place to safeguard the impartiality of its scientific work. Over the years, it has put in place a comprehensive and sophisticated system to ensure its independence, and it is committed to reviewing its policies and procedures to ensure they remain fit for purpose. In this context, avoidance of potential conflicts of interest represents only

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			scandaleux. Les sociétés sont des personnes morales. Aujourd'hui ces multinationales n'ont plus de morale du tout : il s'agit de vendre et de réaliser des profits, quels que soient les dégâts collatéraux. Il est souhaitable que cette situation évolue très vite dans une perspective d'humanité retrouvée. Merci de votre attention. France	one, important part of EFSA's Policy. Class 6 EFSA has put in place, and further develops, one of the most stringent frameworks for the prevention of conflicts of interests (CoI) among Union institutions, bodies and agencies. This has been recognised by external audits. The Authority also intends to review its policy on the independence of its scientific decision-making processes with a view to fully reflect in it the opportunities for enhanced transparency and engagement that will result from the "Open EFSA" project. These comments will therefore feed into this process as well. Class 6
135.	Individual contribution, (UK), Science and Technology Policy Research, University of Sussex	4.1 Transpa-rency	In section 4.1 in the top paragraph on page 11 the text suggests that: "…Total transparency may inhibit actors in these challenging sectors, preventing the correct recourse to "trial and error" processes, hindering creativity, the formulation of dissenting opinions or even of basic questions, and favouring entrenchment in mainstream thinking." That suggestion is problematic and implausible. After all, the maintenance of the status quo, characterised by its lack of openness and transparency is far more likely to entrench prevailing orthodoxy that could increased transparency. If EFSA supposes that increased openness can be expected to entrench mainstream thinking, it is incumbent on EFSA to indicate mechanisms by which such entrenchment might occur, and to indicate how such outcomes could be avoided, consistently with EFSA functioning as a genuinely open and accountable organisation.	EFSA acknowledges that *total* and *unchecked* transparency and openness of its scientific process, as opposed to *increased* transparency and openness, may lead to the problems referred to in this comment. Class 6 This should be coupled with increased opportunities for interaction both before and after this stage, and should be accompanied by the most extensive disclosure possible in accordance with the relevant legal framework. Class 1
136.	London School of Economics	4.1 Transpa-rency	Section 4.1 Is there any evidence to suggest that discussion on scientific issues is constrained by open meetings? Most scientists of any worth attend conferences, where 'full and	EFSA's Scientific Committee and Panels are composed of members with varied expertise and

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	(UK)		frank' exchanges of views are common place. Of course commercially sensitive information may need protection (a closed part of a meeting), but I do doubt that open scientific discussion would promote self-censorship, endanger frank discussion and suppress dissenting opinions.	backgrounds, including academics, civil servants, employees of Member State authorities or laboratories, and of international organisations. Class 4 EFSA is required to deliver scientific advice to EU risk managers. Also for this reason, EFSA considers that individual views of its experts should be protected from external pressure and criticism, to ensure that the experts' personal positions can be aired without restrictions. Class 4 This is without prejudice to the disclosure of the content of such exchanges, which should be fully reflected in the minutes of the relevant meeting. Class 1
137.	Individual contribution, (UK), Science and Technology Policy Research, University of Sussex	4.2 Openness	How can EFSA increase its openness to meaningful contributions from individuals and organisations beyond its Panels and Committee? Should a two-way interaction between EFSA's Panels and interested parties be facilitated? What limits should be set to such interaction? 2. One essential conditions for EFSA adequately to increase its openness to meaningful contributions from individuals and organisations beyond its Panels and Committee will be to ensure that all relevant studies and data are in the public domain, and that relevant groups and interest individuals have sufficient time to analyse and comment on those data. Interactions between EFSA's Panels and interested parties should be reciprocal rather than unidirectional.	EFSA receives studies from applicants for the limited purpose of evaluating the respective dossier, and very often the proprietary rights of unpublished studies remain with the concerned applicant. Class 4
138.	Individual contribution, (Austria)	4.2 Openness	"Two-way interaction" EFSA should allow direct but open (documented) interaction(discussion) between certain panel members (who are occupied with parts of the task) and interested persons and provide means of identifying the appropriate panel members. Those should be obliged to justify immediately, not only after publication of the document, why they do or do not consider an argument coming to the panel from outside EFSA.	To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7. The suggestion to justify the reason for accepting or rejecting certain

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				arguments, data or studies immediately after their receipt will be evaluated in the context of the forthcoming further categorisation and prioritisation according to the Implementation plan due attention should be paid, however, to the need to comply with relevant legal deadlines and to avoid endless discussions incompatible with EFSA's mission. Class 2
139.	Association Française des Biotechnologies Végétales (AFBV) (France)	4.2 Openness	Question 2 comment: Practical innovation in our daily lives comes from new products that are registered and commercialized. For this to happen interaction between EFSA and applicants is fundamental, to avoid misunderstandings and delays. A pre-submission visit and discussion between EFSA and the applicant is critically important, to permit the parties to know each other, to understand the dossier and enable exchange on recommendations. This would enormously help to achieve transparency and predictability. Other areas of improvement in the interactions between EFSA and applicants: (1) a new data requirement should only be implemented when it is captured in a final, adopted and published guidance document and appropriate time for transitioning is foreseen to facilitate applicants' adaptation to the new requirements; (2) in case of a change in interpretation of existing guidance, it is important that applicants are informed on timely basis, and that this communication is not done on a product-by-product basis, b but rather to industry as a whole, for example by letter to relevant industry associations. Depending on the change required, EFSA should establish a clear and reasonable transition period; (3) on submissions and opinions: (i) the application desk should work as a platform for discussion between EFSA and applicants; (ii) a formal pre-submission meeting should always occur, as in EMA, in order to gain efficiency in the application process; (4) on the applicants' response to questions from EFSA: these should be accompanied by direct face-to-face meetings or conference calls with individual applicants and EFSA representatives, especially with the increasing complexity of the dossiers; (5) in regard to Correspondence: in order to reduce uncertainty and to increase predictability, applicants should receive an acknowledgement of receipt and an estimate of the time needed to answer the questions; even if the time necessary	To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7. EFSA commits to carry out further categorisation and prioritisation of the possibility to organise pre-submission meetings with applicants in the area of regulated products. Class 2 Regarding the concrete suggestions: (1) EFSA commits to putting in place a transitional period when it changes scientific requirements in the context of a review of its guidance documents, whenever this is not addressed by the risk managers. This is without prejudice to the need to allow for a case-by-case departure from a given guidance document following appropriate scientific justification. EFSA commits to increasing the level of transparency regarding the use of

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			represents months as opposed to the three weeks standard time, knowing this information is important to the applicant; (6) to ensure proper use of time and resources in the review process, EFSA should immediately provide information to applicants in situations when data submitted as part of an application is deemed not acceptable. Even if providing this information might lengthen the risk assessment procedure in some cases, this would still be preferable to an inconclusive Opinion where further delays would undoubtedly be the case; (7) inconclusive Opinions at the end of a review should be avoided at all cost; no purpose is served for EFSA , the applicant or the public in delivering an inconclusive opinion; and (8) with respect to applications for renewals, during pre-submission meetings between applicants and EFSA, dialogue should occur in order to achieve consensus on whether further information is or is not relevant with regard to safety evaluation. These are not costly recommendations -- they would greatly increase trust and save time and resources.	and reference to its guidance documents, and to performing a further categorisation and prioritisation according to the Implementation plan. Class 7 and 2 (2) See above on the adoption of catalogue of services. (3) See above on the adoption of catalogue of services. (4) See above on the adoption of catalogue of services. (5) EFSA agrees that acknowledging receipt and indicating an estimated timeline for when to expect an answer on the merit would comply with good administrative practices. EFSA therefore commits to evaluate concrete measures that could be taken to step up its practices in this field. Class 2 (6) See above on the adoption of catalogue of services (7) Even when the applicant or concerned parties are not able to provide sufficient data to demonstrate the efficacy or safety of a product or a substance, EFSA is still required to conclude the evaluation process with an official output explaining the reason why an inconclusive opinion is adopted.

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				(8) See above on the adoption of catalogue of services.
140.	Association of the European Self-Medication Industry (AESGP) (Belgium)	4.2 Openness	'Two-way interaction' 'How can EFSA increase its openness to meaningful contributions from individuals and organisations beyond its Panels and Committee? Should a two-way interaction between EFSA's Panels and interested parties be facilitated? What limits should be set to such interaction?' AESGP believes that a two-way interaction between EFSA Panels and interested parties, e.g. applicants, is an important element which is currently missing in the EFSA scientific evaluation processes. Such an interaction would allow clarification of scientific requirements related to a particular application dossier and would contribute not only to better quality of applications but also to increased efficiency of the evaluation process at EFSA, allowing optimal use of EFSA and applicants resources. Allowing a possibility to discuss all aspects of relevance for an application would reduce both the number of applications withdrawn at the very last minute and the valuable resources spent by EFSA on the assessment of insufficient dossiers. Evidently, such a direct interaction between applicants and EFSA scientific experts would need to be established in a transparent manner and there are various ways to achieve that, e.g. a member of EFSA staff could be present at such a meeting. In this context, we would like to note that such meetings are already taking place at other European Agencies dealing with applicants, e.g. at the European Medicines Agency (EMA). The AESGP members have a very positive experience with the EMA "Scientific Advice and Protocol Assistance" process and we are convinced that similar scientific advice meetings at EFSA would be helpful in order to get clarity on a number of scientific issues encountered by the applicants while preparing a dossier. EMA offers scientific advice and protocol assistance to the applicants either during the initial development of a medicinal product or later on. During meetings, the applicant has the opportunity to propose a development programme to ensure that the appropriate stud ies are performed or can obtain advice at any stage of the procedure to limit the risk of a negative outcome. This practice of an open and transparent dialogue is appreciated by the applicants as the expectations of EMA can be better understood/met and dossiers can be processed faster.	To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7. Unfortunately, the fact that these meetings take place at EMA is not conclusive for EFSA, since the agencies operate under different legal frameworks. Therefore, a practice adopted by one agency cannot be extrapolated to another.

No	Contributor	Chapter	Comments received	EFSA response
141.	Public Research and Regulation Initiative (PRRI) (Belgium)	4.2 Openness	2. How can EFSA increase its openness to meaningful contributions from individuals and organisations beyond its Panels and Committee? Should a two-way interaction between EFSA's Panels and interested parties be facilitated? What limits should be set to such interaction? While EFSA offers various opportunities for stakeholder groups to share views and experiences, in the field of GMOs EF SA diverts from what is good practice in the Member States and in other parts of EFSA, and that is the need to engage in direct dialogue with individual applicants prior to submission and during the processing of a submission.	EFSA engages systematically with the scientific community and stakeholders (e.g., via its Stakeholder Consultative Platform), including NGOs, food chain operators and industry associations, through the scope of its operations and competences. Further stakeholder engagement is a crucial pillar for moving forward Open EFSA. To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7.
142.	BEUC - The European Consumers' Organisation (Belgium)	4.2 Openness	A first step towards increased transparency of the scientific decision making process would be to ensure the minutes of the working groups are always available. In some circumstances, we were unable to access minutes of the EFSA meetings and on some occasions, when they were available, the reporting was not self-explanatory and understandable by someone who had not participated in the meeting or else they consisted of only one sentence. This generates the perception of a lack of transparency and an unwillingness to communicate to the public what was discussed during the meeting. The consultation document indicates that information on the selection criteria of the working group experts is available in the final output. In order to ensure greater transparency about how members of the working groups are appointed and how decisions are made on the balance of included expertise, we suggest that information is made available at the outset - as it is too late for stakeholders to point to missing expertise if only provided once the working group has concluded. We also encourage EFSA to better reflect its opinion in the summary. From our experience it emerged that some summaries where not fully consistent with the	EFSA has already undertaken or planned to further improve both the accessibility and clarity of the meeting minutes of its scientific bodies. Class 1 EFSA has already undertaken or planned to further improve the transparency of its expert selection process with regard to expertise and independence, so as to improve the overall transparency of the system and ensure the right balance of available expertise. Class 1 EFSA commits to undertake further categorisation and prioritisation, to be performed according to the Implementation plan, regarding the possibility to disseminate a flash summary/abstract immediately after

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			full opinion and this might lead to misinterpretation of EFSA scientific advice. While we understand that scientific opinions are not always clear-cut and easy to communicate, we believe more efforts should be made to make the opinions more straightforward and understandable for a lay-person. It would also be helpful to state at the beginning of each opinion the question of the Commission it intends to address in order to clarify the scope of the opinion and the specific tasks EFSA was assigned.	the plenary meeting and to use a broad array of communication channels depending on the target audiences. Class 2.
143.	ENSSER European Network of Scientists for Social and Environmental (France)	4.2 Openness	2) How can EFSA increase its openness to meaningful contributions from individuals and organisations beyond its Panels and Committee? Should a two-way interaction between EFSA's Panels and interested parties be facilitated? What limits should be set to such interaction? Panel and Committee meetings should be open to observers from the public and interested institutions. As a model could serve the practice in most UN negotiations: interested participants could be required to register for each event and numbers could be restricted to a reasonable number if necessary. A section of each meeting could then be open to questions and comments from the observers present at the meeting, and/or a section of the website could be open for input to the meeting prior to it taking place. Interactive events specifically designed to sponsor enhanced two-way interactions could also be sponsored at regular timepoints, at which a broad range of stakeholders and interested actors are invited to participate. Such events require that funding is available to support the participation of these actors. EFSA must ensure that it takes full account of all the published scientific literature: academic independent studies and papers need to be included and discussed in the dossier and taken into account in EFSA's assessments and decisions. Published papers also need to be given significant weight over unpublished research findings (e.g. from applicants). EFSA should not be viewed as having the authority to judge, discredit or reject a publication when this task has been performed through the peer-review process. The dossier should not give priority to unpublished GLP-compliant studies while ignoring or discrediting the academic studies published in the peer-reviewed literature. GLP rules were established to exclude fraud and misconduct by private, corporate applicants and NOT to serve as excluding mechanism for peer-reviewed publications from research carried out at European universities or accredited public research institutions.	To further strengthen the efficacy of the current system of open plenary meetings and the use of external expertise, EFSA has already undertaken the necessary actions to decide on the degree to which it should open its plenary meetings to observers (Class 1). EFSA commits to further categorise and prioritise the extent to which it should increment the recourse to "hearing experts" and the organisation of "public hearings". Class 2. While EFSA agrees that all relevant scientific publications and literature should be duly considered in its scientific evaluations and that this should be fully reflected in the final output, the Authority considers that the fact a publication has been peer-reviewed does not represent *per se* a sufficient guarantee of high standards. A case-by-case evaluation of each publication is therefore necessary, as outlined in the guidance on the "Application of systematic review methodology to food and feed safety assessments to support decision-making", available

No	Contributor	Chapter	Comments received	EFSA response
				via EFSA's website. Class 7.
144.	Individual contribution, (UK)	4.2 Openness	Openness Competing interests of members of panels. The public perceive expert panel members as being likely to have undisclosed competing interests that enable them to provide advice that has undue weight in EFSA decisions, even when such is not the case. This may be incorrect, but this is nevertheless the perception of 'the average man in the street'. In the past some experts have indeed demonstrated seriously prejudicial approaches to debate and decision-making, and such matters inevitably receive particular publicity when disclosed to the press and media. So the continued engagement of such individuals in the process of risk assessment invariably raises their public profile and fosters distrust within the general public at large. Entrenched bias may not be exposed by standard formal 'declarations of interest, but may be more evident from earlier published comment and work of these individuals, and as such are easily accessible to public view. So expert panel members must be carefully vetted- and seen to be vetted - and those who are found to have behaved in this manner must be excluded from further work with EFSA. If, despite this, they are retained, then EFSA must publish a full disclosure of how the decision to continue that expert's appointment was made, and this must be publicly available for scrutiny by concerned parties. To ensure that such objections are soundly based and not malicious, if any objection is raised to the appointment of an expert, then the identity of the objector, the precise objection raised, and the reasons for EFSA's decision to ignore it must be placed on public record. Protecting privacy and commercially sensitive information Personal and confidential information is easily anonymized, but 'commercially sensitive' protected data needs to be very carefully defined and restricted in scope to prevent concealment of data that reveal risks to public safety that are not fully disclosed (or even discovered) during the process of risk assessment by EFSA.	EFSA's procedures for the selection of experts aim at selecting the best experts available among those who express their availability to work with the Authority in an objective manner. These procedures are based exclusively on the candidates' knowledge and experience; subjective judgements on positions they may have expressed in the past have no place in the selection process. Class 7 EFSA commits to further categorisation and prioritisation, to be performed according to the Implementation plan, regarding the most appropriate measures for increasing the amount of information available to third parties on the selection criteria used for the selection of its Working Groups members. Class 2 Pursuant to Article 7 of Regulation (EC) No 178/2002, the precautionary principle belongs to the sphere of risk management considerations and, thus, falls outside EFSA's remit. Class 5 EFSA's mission is limited to the provision of scientific advice and scientific and technical support on all matters directly or indirectly related to food or feed safety, and the communication of risks in this area. Class 5

No	Contributor	Chapter	Comments received	EFSA response
			There is also a need to provide clear guidelines on the protocol whereby EFSA invokes the Precautionary Principle wherever there is doubt over the safety of a proposed intervention or the continued supply of a product to the public. Access of the public to review of political policies. At present there is little dialogue between politicians and the public when political objectives clash with the interests of the public (as distinct from 'the public interest'). The public has virtually no effective means to challenge political policies in food safety once they are in place, nor it its access to EFSA itself in any sense open. Even where legal rulings have been made that indicate that policies involving food safety are improper, and that urgent review by EFSA is needed to safeguard public safety, there is no simple mechanism whereby the general public can seek redress in a ruling that politicians will respect and with which they must comply.	More generally speaking, the issue of political accountability for policy choices made by decision makers goes beyond EFSA's remit. Class 5
145.	ClientEarth (Belgium)	4.2 Openness	On the "two ways interaction": this is a way of allowing vested interests to be allowed at any phase of the process. An open decision making should also be predictable and include precise windows of opportunities for interested and concerned parties to intervene. If unsolicited contributions were welcomed at all times, the opinion development process would be seriously undermined by allowing evidence to be collected and made available depending on the opportunity. Although consultations should be encouraged, they should have clear deadlines and should happen in very clear phases of the opinion development processes. Further, it is crucial that EFSA responds to all comments provided by third parties and states whether or not comments have been addressed; and, if not, the reason why. We welcome EFSA's acknowledgement of the need to address the issue of formats to disseminate or access information; because, in any event, this is a legal requirement stemming from the Aarhus Convention. How can EFSA increase its openness to meaningful contributions from individuals and organisations beyond its Panels and Committee? Should a two-way interaction between EFSA's Panels and interested parties be facilitated? What limits should be set to such interaction?	Noted. Class 6

No	Contributor	Chapter	Comments received	EFSA response
			Openness is increased by creating an environment in which all citizens are able to contribute to decision-making in a meaningful way. In some cases, citizens' interests may be mediated by interest groups such as public interest organisations, health professionals and industry associations. However, unlimited openness may lead to the possibility that those that have more means and higher commercial stakes in the work of EFSA capture its work, undermining its independence. Therefore, we believe that procedures should be in place to allow input from citizens and interested parties only at specific stages of EFSA's processes through public consultations and stakeholders meetings. It should also be borne in mind that a level playing field should be achieved between those that have the means, the interests and the resources to participate in EFSA's work and those that have limited resources. Thus, EFSA should avoid becoming a "stakeholder intensive" institution that would drain resources from public interest organisations making their participation unsustainable.	
146.	DANONE (France)	4.2 Openness	DANONE believes that two-way interaction is indeed necessary to provide meaningful and relevant input. In light of this, scientific dialogue between applicants and EFSA's panels would provide an efficient and effective way for the provision of meaningful input to EFSA, and vice versa from EFSA to applicants. As stipulated in EU Regulation 178/2002 Article 30, EFSA shall exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks. We believe this is essential to promote competitiveness of the EU as an innovative region.	To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7. EFSA acknowledges the need to identify, at an early stage, a potential for diverging opinions and to correctly implement Article 30 of Regulation (EC) No 178/2002, if applicable to EU Member State or Union scientific bodies, and it has already undertaken or planned the development of internal procedures aimed at facilitating compliance with this requirement. For what concerns the implementation of the Nutrition and Health Claims Regulation, EFSA has to comply with that specific legislative framework. Class 1

No	Contributor	Chapter	Comments received	EFSA response
147.	EuropaBio (Belgium)	4.2 Openness	The discussion paper reads that openness is an "enabler for citizens to participate more closely in the decision making process" so that interested parties "contribute to enhanced scientific scrutiny by facilitating their active contribution to EFSA's scientific processes and by creating the conditions to make EFSA assessments more reproducible by others" at every stage of EFSA's scientific decision-making process. We regret that the need to preserve the integrity, the efficiency, scientific excellence and the predictability of the decision-making process for product approvals, which is so critical for any industry impacted by EFSA's work, does not find a prominent mention in the paper. Therefore, EuropaBio would like to recommend that EFSA carries out an extensive impact assessment which is currently foreseen from 2016 onwards, before rolling out any actions resulting from this public consultation. Furthermore, since company experts are not mentioned in the list of people who EFSA suggests to engage with, t his would seem to indicate that these experts (who are the main generators of data) may be treated the same as any interested stakeholder without or with less expertise. EFSA may wish to clearly categorise the various groups of stakeholders. Next, EFSA intends to make information and data available in a format that allows EU citizens and interested parties to use and re-use "its data and documents" for purposes other than those originally envisaged, i.e., "to reproduce and verify EFSA outputs or to advance further science". Once more, first and foremost, a clear differentiation between data generated by EFSA and data provided to EFSA by applicants should be drawn. As the protection of confidential business information for GMO dossiers has already been reduced to an absolute minimum, EuropaBio is very concerned about the possible misuse or unfair commercial use of information rendered public. EuropaBio kindly requests EFSA to shed more light on the principle of reusability of data as it is our understanding that this principle is limited to documents produced by the European Commission or by private and public entities on its behalf (See Commission Decision 2011/833). Is it EFSA's intention to allow that any given citizen could redo the risk assessment? Would this imply that the full dataset submitted by an applicant would be accessible and reused? If this were the intention, EuropaBio would like to mention EFSA's statement in the discussion paper, where it says that any unilateral action to open the access to scientific publications available to EFSA as part of the application dossiers, would be	As anticipated in the discussion paper and further outlined in the Implementation plan, EFSA has identified a list of measures for which it will perform a further categorisation and prioritisation. Class 1 To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7. The principle of reusability mentioned in the document encompasses two facets: the first concerns the reusability of data by EFSA for purposes other than initially conceived; the second aspect regards the reusability of data by external users to enable them to reproduce EFSA's assessments. Except for the data it owns and those related to public health concerns or emergencies, EFSA needs to request, on a case-by-case basis, the data owner's agreement before it is allowed to embark on such initiatives. EFSA deems appropriate to undertake a further categorisation and prioritisation, to be performed according to the Implementation plan, on whether it would be appropriate or feasible to

No	Contributor	Chapter	Comments received	EFSA response
			overstepping its mandate. EuropaBio would also like to underline that any unilateral action to access and reuse data contained in regulatory dossiers submitted by applicants would constitute a breach of intellectual property rights. EuropaBio would like to call on EFSA to engage in a structured dialogue with industry associations, including EuropaBio, before rolling out its plan to open its data, as applicants a re the most important suppliers of scientific data for product specific risk assessment.	institutionalise a practice of providing free access to data used or discarded in safety studies and risk assessments in a readable/reusable form. Class 2
148.	Food Supplements Europe (Belgium)	4.2 Openness	3. How can EFSA ensure that commercially sensitive information and data are protected while providing access to key information, data and documents necessary to make its assessments reproducible? Should EFSA embrace the principle of reusability? Who should be in charge of striking the balance between the need to allow reproducibility and respecting the rights of data owners? Can guiding principles and standards be established? Food Supplements believes that not all activities of EFSA are of the same nature. There are tasks that are mandated by the risk managers (European Commission, Member States, etc). These task envisage opinions on safety-related issues. For these, EFSA relies on data, part of it possibly coming from food operators. The identification of risk management measures does not fall under the task of the risk assessor and should remain firmly separated. It is clear however that a risk assessment opinion can give indications on how the risks can be controlled. There may also be practical reasons why data gathering or obtaining reliable information is not easy. Therefore such opinions should be submitted to stakeholder consultation and possibly discussion before the opinion is finalized. Also in this case the provision of data by operators can be of sensitive nature and if such data are not eligible for protection, they could simply not be submitted. There may therefore be legitimacy for protecting such data and we would ask EFSA to clearly set out the conditions and limits of such protection. There are tasks that are self-mandated. Also for such activities, communication and possibilities for discussion should exist in the same way or even more extensive than for assignments by risk managers. A good example is for instance the work that EFSA has carried out on botanicals. Where the guidance has been subject to a public consultation, the ESCO report and EFSA compendium have not.	The approach EFSA will take with respect to openness and reusability of data should be differentiated according to the different kinds of activities, and legal frameworks, it operates under. Class 1 To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7. The suggestion to limit the “use” of vertebrate animals to a minimum falls outside EFSA’s remit. Class 5

No	Contributor	Chapter	Comments received	EFSA response
			We believe that consultations on such activities can improve the quality and acceptance of the EFSA work. We understand that EFSA can always accept comments on its work, but the fact that the work is only open for comments after it has finalized may deter people to formulate comments in the first place. Another type of tasks that EFSA carries out is the assessment of dossiers for applications (e.g. food improvement agents, novel foods, nutritional substances, health claims, etc). Such work is done in the framework of a regulatory procedure on request of an applicant, which makes the applicant the prime interested party. Applications also often contain information that is specific to the applicant and considered as confidential because disclosure can damage its competitive situation. Rules determining which information can be considered as confidential are laid down for a number of authorisation processes and should be complied with. Where not, EFSA should itself set out clear principles. As the data requirements are often complex and putting information on paper has limitations to capture all details that the panel would like to know. Today, such information is requested during the process by written procedure. This has the same limitations and the process is unsatisfactory. It would be leg itimate that applicants have direct access to the scientists to understand precisely what is needed and to discuss aspects relating to the dossier. In addition, today the opinion is published without the applicant having the possibility to provide material comments (except for a very short period of time granted to the applicant to highlight information that could harm its competitive position). The applicant therefore does not have the possibility to bring in relevant comments or clarifications to may be useful for the Panel to finalise the opinion. The principle of a hearing of an applicant on a pre-finalised opinion should be standard. Once the opinion finalized, everybody should have the possibility to submit comments. Whether data can be reused should be considered in the framework of the relevant legislation. Where authorizations are generic and data can be protected to ensure a sufficient protection of the return of investment, this would in principle overrule the possibility for reusing data. In addition, we observe that EFSA takes a strong stance for the need to redo studies if they have not been performed according to the latest scientific standards or guidelines. This also makes reusing data redundant. We consider it important that sacrificing animals should be kept to an absolute minimum and would ask EFSA to take this as one of its core values and consider as relevant also older research without the need to redo this or rely more to in vitro and experimental tests as alternative.	

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			An important element is that consultations should also be possible for EFSA opinions that have been published in the past and that have never been subject to a consultation. Such opinion should be reopened and subject to the same principles whenever there is a need to update or review them or when comments are submitted showing the appropriateness for a renewed consultation.	
149.	GAP's chair on behalf of GAP, IPA and YLFA (Belgium)	4.2 Openness	The probiotic sector believes that two-way interaction is indeed necessary to provide meaningful and relevant input. In light of this, scientific dialogue between applicants and EFSA's panels would provide an efficient and effective way for the provision of meaningful input to EFSA, and vice versa from EFSA to applicants. As stipulated in EU Regulation 178/2002 Article 30, EFSA shall exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks. We believe this is essential to promote competitiveness of the EU as an innovative region.	To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7. EFSA acknowledges the need to identify, at an early stage, a potential for diverging opinions and to correctly implement Article 30 of Regulation (EC) No 178/2002, if applicable to EU Member State or Union scientific bodies, and it has already undertaken or planned the development of internal procedures aimed at facilitating compliance with this requirement. For what concerns the implementation of the Nutrition and Health Claims Regulation, EFSA has to comply with that specific legislative framework. Class 1
150.	Individual contribution, Istituto Superiore di Sanità, EFSA external expert (Italy)	4.2 Openness	Principle of reusability "EFSA should implement a presumption of reusability and lay down clearly the conditions when, or processes where, the principle should be validly applied while avoiding unnecessary administrative burdens for interested parties and the Authority itself.": This is a most important point: it has to be thoroughly elaborated, possibly in a time-effective way , in order to implement an open EFSA Two-way interaction	The principle of reusability mentioned in the document encompasses two facets: the first concerns the reusability of data by EFSA for purposes other than initially conceived; the second aspect regards the reusability of data by external users to enable them to reproduce EFSA's assessments. Except for the data it owns and those

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			I am somewhat surprised that there is no direct mention of those two-way interactions that are most important for EFSA, i.e., that with relevant scientific and risk assessment bodies in the EU, such as ECHA, ECDC, non-food DG SANCO committees, FVO, JRC. How interactions has been developed till now? How should they be strengthened/improved in the near future ? Of course, the same questions should be applied to on-going and future two-way interactions with reference international institutions such as WHO, FAO, OECD, UNEP. Another important aspect of EFSA two-way interaction is how to increase a consistent input of new research findings into the activities of EFSA Panels. Of course this is already in place and significant progress has been achieved since the EFSA's beginnings; however, can improvements be envisaged ? EFSA is a major EU scientific body, thus the two-way interactions with the rich EU research milieu should be a main aspect	related to public health concerns or emergencies, EFSA needs to request, on a case-by-case basis, the data owner's agreement before it is allowed to embark on such initiatives. EFSA deems appropriate to undertake a further categorisation and prioritisation, to be performed according to the Implementation plan, on whether it would be appropriate or feasible to institutionalise a practice of providing free access to the data used or discarded in safety studies and risk assessments in a readable/reusable form. Class 2 In 2014, EFSA put in place its Multi-annual programme on International Scientific Cooperation 2014–2016 to enhance cooperation with fellow international or third-country bodies and agencies. Class 6
151.	Lallemand Health Solutions (Spain)	4.2 Openness	We acknowledge the fact that it is possible for an applicant or members of the public to make comments to the Commission relating to an EFSA opinion and in such cases, the Commission and the Member States await the EFSA response to the comments before proceeding with the final decision. We believe this is openness and transparence and must also be possible towards EFSA (for instance, on the EFSA website there is no place for applicants or the public to comment on an EFSA negative opinion, which has negative consequences not only in terms of approval of a product or a claim, but also on the reputation, innovative ability and competitiveness of a company in the eyes of the public. In order to better protect the image of the applicant, we recommend EFSA to allow the applicant to submit comments or ask for a consultation in the case of a negative opinion, prior to publication of the negative opinion.	EFSA will subject to a further categorisation and prioritisation, to be performed according to the Implementation plan, the possibility of enabling users to post comments on its opinions, or of otherwise establishing a structured process to allow for such interaction before a final decision is taken by EFSA. Class 2 EFSA underlines that it is already possible for any interested party,

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			We also ask for the right of reconsideration of a negative EFSA opinion. This is the essence of dialogue and th is would allow EFSA and the applicant to discuss issues related to an EFSA opinion on an application. The parties might clarify and justify their positions using the information made available to EFSA when the opinion was given. The request for reconsideration must be based on the same information and material as the original decision. The applicant could submit a comprehensive document outlining his position and including full supporting information/cross-referenced to previously submitted data. Where EFSA upholds its negative opinion, a final notice that sets out the reason(s) for it would be sent to the applicant. This mechanism already exists in other jurisdictions like Canada, where the Directorate for Natural Health Products successfully uses this process, which even in the event where the decision of refusal is upheld, the process allows a better understanding of the weaknesses of the application, should the applicant wish to resubmit in the future. Diverging scientific opinion We believe it is essential that EFSA should exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the ones from other regulatory bodies, as mentioned in Article 30 of Regulation (EC) No 178/2002 on the establishment of EFSA. In order to promote the competitiveness of the EU as an innovative region, special attention must be paid to situations in which EFSA's opinion diverges from the opinions of other agencies related to similar products. There have been some cases of divergence, especially concerning probiotics, where EFSA rejected a health claim, while another national or foreign Agency had approved a similar claim. In such cases, we believe that EFSA should make public the fact that they are aware of the contradictory opinion(s), and explain the reason(s) for the divergence.	including applicants, to share their comments and concerns with EFSA. However, in the absence of the submission of data or comments requiring the need to revise the adopted opinion, this may not result in a "right for reconsideration". Class 7 EFSA acknowledges the need to identify, at an early stage, a potential for diverging opinions and to correctly implement Article 30 of Regulation (EC) No 178/2002, if applicable to EU Member State or Union scientific bodies, and it has already undertaken or planned the development of internal procedures aimed at facilitating compliance with this requirement. For what concerns the implementation of the Nutrition and Health Claims Regulation, EFSA has to comply with that specific legislative framework. Class 1
152.	InQpharm Europe Ltd. (Germany)	4.2 Openness	2. How can EFSA increase its openness to meaningful contributions from individuals and organisations beyond its Panels and Committee? Should a two-way interaction between EFSA's Panels and interested parties be facilitated? What limits should be set to such interaction? InQpharm would like to suggest a widening of external expert input on a case-by-	EFSA commits to perform further categorisation and prioritisation in accordance with the Implementation plan on the possibility of increasing the transparency level applied to criteria and procedures for the

No	Contributor	Chapter	Comments received	EFSA response
			case basis. External experts could be approached for expert statements on specific questions; however we are not aware of a case when this option was made use of. Further, InQpharm (and we believe we resonate many other companies we are in contact with by this statement) would appreciate the opportunity for personal face-to-face consultation meetings with Panel members and EFSA staff, including drafting of protocols/minutes of such meetings. We would have no reservations if such meetings involved a reasonable charge to be paid by the applicant, if the outcome provides guidance on health claim application-related issues such as mode-of-action, study parameters, comments on study synopses, claim wordings, health benefits, and overall data requirements for a positive opinion. A frequent issue of confusion is that EFSA seems to reach conclusions that differ from those reached by FDA or other comparable authorities. A more in-depth exchange of information might provide transparency. We would also welcome more frequent updates of guidance documents to minimize the risk of the applicant conducting and/or submitting out-dated or wrongly designed studies.	selection procedures of EFSA's external experts. Class 2 To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7. EFSA acknowledges the need to identify, at an early stage, a potential for diverging opinions and to correctly implement Article 30 of Regulation (EC) No 178/2002, if applicable to EU Member State or Union scientific bodies, and it has already undertaken or planned the development of internal procedures aimed at facilitating compliance with this requirement. For what concerns the implementation of the Nutrition and Health Claims Regulation, EFSA has to comply with that specific legislative framework. Class 1 With regard to the example given by the contributor, it should be noted that the US FDA's powers are very different and much broader as compared to those of EFSA. Similarly, the requirements these two agencies need to satisfy may also be quite different. Class 5
153.	Individual contribution, (France)	4.2 Openness	La transparence passe par la traduction ! No transparency without translations ...	EFSA is going to subject its current language regime to a further categorisation and prioritisation, to be performed according to the Implementation plan. Class 2
154.	EAS-	4.2	Comments related to 4.2 Openness section part: "Two-way interaction":	To increase direct dialogue between

No	Contributor	Chapter	Comments received	EFSA response
	Strategic Advice (Belgium)	Openness	EAS welcomes EFSA's plans to "develop a system allowing proactive and unsolicited input from interested parties and qualified individuals at all phases of its internal decision-making process, and ideally also after finalisation of its outputs." In this context, we would also like to encourage EFSA to continue to invest in building on more possibilities of two-way interactions related to dossier application processes (APDESK rules) as indicated in our previous submitted comments on the EXECUTIVE SUMMARY part. Comments on question: Should a two-way interaction between EFSA's Panels and interested parties be facilitated? What limits should be set to such interaction? Finding solutions to facilitate two-way interaction between EFSA's Panels and interested parties is an important step forward to streamline clarifications on scientific issues in dossiers (during the EFSA Panel's evaluation process) that could otherwise delay the EFSA assessment and/or be misunderstood by the applicants. To increase such interaction is of key importance as it could be a factor to either delay the EFSA opinion considerably or even lead EFSA to an inconclusive dossier evaluation result, which might have been avoided by better communication. It is understood that finding a balance between EFSA's independence and increased stakeholder interaction/communication on dossiers is a difficult task for EFSA to agree, taking into account all concerns and requests from different parties. However, in terms of streamlining the dossier application process on clearly scientific facts, it should be possible, in a controlled and transparent way to facilitate more interaction between the Panels/Working Groups and applicants in case of need in the dossier evaluation process. EAS therefore welcomes the already announced new services of the Applications Helpdesk (APDESK) rolling out a series of initiatives to strengthen the applicants' support. EFSA has announced in July 2014 that it is in the process of implementing a multi-annual project to develop a customer-oriented approach for regulatory products. Some initiatives have already been implemented, while others are still under consideration. EAS has followed these developments with great interest and would like to encourage EFSA to continue on building this plan and welcomes in particular the following initiatives (that have already been partly been implemented):	EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7. Regarding the concrete suggestion to implement a completely paperless flow for application dossiers, EFSA's current approach is constrained by technical limits linked to the admissible size of enclosures that EFSA's servers can receive.

No	Contributor	Chapter	Comments received	EFSA response
			- requests for a teleconference to clarify important scientific issues raised by EFSA during the risk assessment process. The possibility o f such calls is already a good step forward and may indeed also be a good compromise for EFSA's staff in terms of time/budget constraints (of more time-intensive meetings). Nevertheless, the EFSA rules might be additionally widened to allow for special cases, which are carefully evaluated by the EFSA staff in case of very complicated scientific issues, that face to face meetings between applicants and EFSA staff may be agreed. - increasing the use of EFSA technical hearings: EAS welcomes that EFSA may, after examining the applicants written response, invite applicants to speak to the Authority's working groups - either in person or via teleconference - to clarify outstanding issues about their submitted data. - e-submisson of applications: we have noted the recently announced new APDESK rules on e-submission of dossiers (via USB-stick or CD rom). This will certainly streamline EFSA's internal process (no more need to scan).We would however like to remark that, although not a problem to submit files electronically, the system as now announced will not really bring advantages to applicants. We understand it is still required to submit an original signed cover letter with the USB stick/CD rom, which means still the need to send an envelope. A system whereas dossiers could be sent via a certified email address (e.g. PEC email address) as is already possible for the submission of dossiers to many national Ministries in the EU would be much more helpful. We would therefore welcome if EFSA could consider this additional way of (optional) e-mail submisson. Overall, we have already noted some movement in EFSA's plans to streamline the process, and while thanking EFSA for its increased efforts, look forward to next steps.	
155.	Individual contribution, University of Manchester (UK)	4.2 Openness	I welcome EFSA's commitment to becoming a more open and transparent organisation as set out in the Discussion Paper. From my perspective as a statistician, the key sentence in the paper is in Section 4.2: "... EFSA must ensure that the information and data it makes available are in a format that allows EU citizens and interested parties to use and re-use them to reproduce and verify EFSA's outputs, or to advance science further." For this aspiration to be realised, EFSA will need to make available to researchers raw data (sometimes known as micro-data) – i.e. data at the lowest level of aggregation. These data will need to be in a format such as an EXCEL spreadsheet	EFSA deems appropriate to undertake a further categorisation and prioritisation to be performed according to the Implementation plan on whether it would be appropriate or feasible to institutionalise a practice of providing free access to the data used or discarded in safety studies and risk assessments in a readable/reusable form. Class 2

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			so that they can easily be read into a statistical package. It is only by releasing raw data – anonymised to protect individuals' identities if necessary – that EFSA's conclusions can be checked and elaborated by further analysis. My experience with current EFSA policy, as it has been applied to data on GM crops is that EFSA has some way to go to attain the goals set out in the paper. For example, EFSA did make available some information about maize variety NK603, following a press release in January 2013 that was headed "EFSA promotes public access to data in transparency initiative." But the information that was released falls well short of what is needed if the aims set out in Section 4.2 of that paper are to be met. First, it is not easy for the user to navigate their way through a substantial number of files, some very large, without a guide to what has been made available. Second, and crucially, the material provided is some way from the raw data needed to verify Monsanto's analyses and to test further hypotheses based on the data. For example, pp.99-103 of Part 1 (Tech dossier) gives some information on a 90 day rodent feeding trial but there are no tabulated data and certainly no raw data are provided. There is a little more data in table form from the crop field trials but again this is insufficient to check Monsanto's claims. If, as se ems likely, EFSA scientists do not carry out their own analyses of data submitted to it from GM trials then they should enable independent scientists to do so. Moreover, it should be incumbent on companies submitting evidence to make all their data publicly available. This will be doubly advantageous: for EFSA as it will increase confidence in their judgements and for the companies themselves as it will allay any fears about the validity of their findings. To conclude, I hope EFSA will consider carefully the implications of the sentence in Section 4.2 of the Discussion Paper. By putting in place comprehensive data release policies, they will enable scientists to carry out independent analyses of the data used by EFSA to come to decisions about the safety of GM crops and of food products more generally.	Concerning the comment regarding the dossier for NK603 made available on EFSA's website, EFSA can confirm that it contains all elements and data not deemed to be commercially sensitive by the European Commission pursuant to Article 30 of Regulation EC No 1829/2003. Class 6 The suggestion regarding an amendment to the provisions of the relevant legal act concerning the decision-making process on confidentiality claims filed by applicants goes beyond EFSA's remit. Class 5
156.	PAN Europe (Belgium)	4.2 Openness	The "culture" of "love of industry" that ruled the first 10 years of EFSA's existence, is something that hinders openness. Without trust, a relation with EFSA is a problem. The many good words on transparency and openness however are useless, unless they are followed by change. Only concrete steps can help EFSA forward in the 21st century First of all, a change of management is necessary. People having been present at EFSA from the start will generally not be the right people in the change to modern	EFSA engages with all its stakeholders on an equal basis, without granting favours of any kind, and the Authority takes its decisions in absolute autonomy. Its scientific opinions are adopted by scientific groups made up of individuals cooperating with EFSA in the absence

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			policy. New management with an open mind to all stakeholders and an open mind to academic research are necessary. especially EFSA's communication has been a problem, many times being one-sided and with no intention to listen to what stakeholders say. Communication is a two-way thing and EFSA needs people who have the social qualities to listen.	of any formal hierarchical obligations. Class 6 For what concerns the comment regarding a change of management, this initiative has been spearheaded by EFSA's management, which has consistently strengthened its internal framework by implementing principles of transparency and independence. Class 6 EFSA listens attentively and takes the views of its stakeholders seriously. EFSA's focus is to strengthen stakeholder engagement.
157.	London School of Economics (UK)	4.2 Openness	4.2 Two way interaction Trust, as the sociologist Luhmann noted, is a substitute for knowledge. Relatively few citizens have the knowledge, interest or time to contribute to technical debates and risk issues. To suggest that EFSA should ensure that information and data made available are in a format that is accessible to EU citizens etc. is not only a tall order, but probably unachievable. That said, where citizens can comment is on matters of 'values' and what one might call 'public ethics'. Think of the case of cloning animals for the food chain. For the public the issue was not o ne of food safely but rather as Janez Potocnik, the sometime EU Commissioner for Research, said in another context – ''is it safe is always an issue, but we also need to ask; is this a world we want to live in?''	By law, EFSA's remit is limited to the consideration of purely scientific aspects. Arguments belonging to the ethical sphere usually fall within the concept of "other relevant factors", which may be considered exclusively by EU risk managers, such as the European Commission. Class 5
158.	Individual contribution, Libgreen (France)	4.2 Openness	Dear EFSA, I think that EFSA could increase substantially its openness, by publishing all raw data on industries trials before 'autorization to market' (including LONG TERM animal toxicology and blood testing data) Only with all those conditions, the EFSA could be considered as neutral, ethical, and with the right european level of expertise. Cordially,	EFSA deems appropriate to undertake a further categorisation and prioritisation to be performed according to the Implementation plan on whether it would be appropriate or feasible to institutionalise a practice of providing free access to the data used or discarded in safety studies and risk assessments in a readable/reusable form. Class 2

No	Contributor	Chapter	Comments received	EFSA response
			Consultant, Brussels at the moment	
159.	Individual contribution, (EFSA external expert) (Italy)	4.2 Openness	Dear Madam/Sir two comments: 1. Surprising that Tuomisto & Pohjola (2007) is not mentioned anywhere in the document: Jouni T. Tuomisto & Mikko Pohjola (2007) Open risk assessment. A new way of providing scientific information for decision-making. Publications of the National Public Health Institute, Finland https://www.julkari.fi/bitstream/handle/10024/78225/2007b18.pdf 2. Also, I would like to point out that EFSA Opinions might become more accessible to the public if they were easier to retrieve using Open Access search engines such as Google Scholar. I know that the EFSA Journal is Open Access, but for some reason Google Scholar is not normally indexing publications from the EFSA Journal. Try for example http://scholar.google.co.uk/scholar?q=%22Scientific+Opinion+on+the+risk+to+plant+health+posed+by+Parasaissetia+nigra%22&hl=en&as_sdt=0,5 However, it appears that some EFSA Opinions are retrievable in Google Scholar, when they have been posted on institutional repositories. Two example s: http://dial.academielouvain.be/handle/boreal:146381 http://library.wur.nl/WebQuery/wurpubs/454923 You can see that these EFSA Opinions do appear in Google Scholar http://scholar.google.co.uk/scholar?q=%22Scientific+Opinion+on+the+risk+to+plant+health+posed+by+Daktulosphaira+vitifoliae+%22&btnG=&hl=en&scisbd=1&as_sdt=0%2C5 and	1. The discussion paper does not refer to this academic publication. However, this and many other publications were considered by EFSA staff involved in the drafting of the paper, and only selected institutional sources were referenced. Class 7

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			http://scholar.google.co.uk/scholar?q=%22Scientific+Opinion+on+the+pest+categorisation+of+Clavibacter+michiganensis%22&btnG=&hl=en&scisbd=1&as_sdt=0%2C5 So my suggestion would be to make it mandatory to post EFSA Opinions on the OA institutional repositories of the WG members that drafted each EFSA Opinion. This way EFSA Opinions will appear in Google Scholar and it is more likely that the average researcher and citizen will encounter them (given that Google Scholar is becoming a very popular search engine). many thanks & best wishes	
160.	Joint Submission Bee Life, Corporate Europe Observatory, Earth Open source, Fondation Sciences Citoyennes, GM Watch, Pesticides Action Network Europe	4.2 Openness	2) How can EFSA increase its openness to meaningful contributions from individuals and organisations beyond its Panels and Committee? Should a two-way interaction between EFSA's Panels and interested parties be facilitated? What limits should be set to such interaction? EFSA must open itself to contributions from anyone in the EU and not just "interested parties and qualified individuals" as such a definition of who is legitimate to interact with EFSA is too restrictive. Procedures must however be designed to allow meaningful contributions from outside EFSA that at the same time prevent attempts to capture EFSA's work by vested interests, starting with applicants themselves in the case of regulated products or producers in the case of commercial products more generally, as is well pointed in the document *("greater involvement and participation could also hide potential risks, such as disproportionate influence of a limited number of actors or loss of control by the Authority over the content of a document"* §6 p.7). This echoes what was said above about the need to jointly develop EFSA's transparency and independence policies. In the current context where applicants perform the safety tests on their products and report the results, and in the light of EFSA's institutional and financial limitations, a good transparency policy will be one of the few real defence mechanisms available to EFSA against potential regulatory capture in the field of regulated products. This means, in principle, a complete, unrestricted and **proactive** online publication of full applicants' files when these reach EFSA in order to enable the reproducibility of the risk assessment performed (as opposed to the current reactive regime which is time and resource-consuming for the	The concept of "interested party" is extremely broad; it basically encompasses everyone, legal entity or natural person, with an interest in a certain topic. Class 6 EFSA is aware of the risk mentioned in the comment, and it intends to review its independence approach, so as to mitigate this risk. Class 6 EFSA commits to a further categorisation and prioritisation to be performed according to the Implementation plan on whether it would be appropriate or feasible to institutionalise a practice of providing access to raw data used in safety studies and risk assessments in a reusable form. Class 2 Regarding the suggestion to disclose experts' and staff DoIs on its website, EFSA underlines that, for experts, this is already done since several years, while the disclosure of staff members'

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			Authority). A way to both strengthen the transparency of the risk assessment process and its independence will also be to ensure the highest level of transparency about the interests of the decision-makers involved in the risk assessment process (EFSA experts and staff). This is an aspect that we think is insufficiently emphasised in the document. On this issue, EFSA must implement a proactive publication of declarations of interests of EFSA's experts (including Working Groups members) and employees, kept online for five years after their employment at EFSA has expired. These should be regularly checked for accuracy and completeness by the Authority by using all public sources of information available. In terms of the actual policy options considered, we now go through all of them with comments. The first figure refers to the step in EFSA's decision-making workflow, while the second figure is the policy option considered. **- 1.1 "Public consultation if a self task or issue of high public interest":** In general, we would not recommend this option because the mandate is the starting point of the whole work of EFSA, which means its wording is absolutely strategic. Most mandates received by EFSA come from the European Commission and comments should therefore be directed towards the European Commission on that point, not EFSA. We consider that EFSA's duty and responsibility is to deliver the best possible risk assessments: that should of course include closely monitor the evolution of scientific knowledge and societal debates to identify areas for self tasking, including remaining open to external suggestions, but we would not recommend systematically opening mandates formulation to public comment s. If a public consultation was still seen as needed by EFSA on this point, it should be transparent in terms of the contributions received and in terms of the reasons why comments were taken on board or not. **- 1.2 "Pre-submission meetings (in case of regulated products)"** This option has been proposed repeatedly over the past years by EFSA's management and criticised each time by both non-commercial stakeholders and EFSA's Management Board, all the more when such proposals were accompanied by the idea to introduce fees for applicants for additional advice. We repeat our criticism here and oppose the idea to introduce such meetings. EFSA has already created an Application Desk to answer applicants' questions. Panel members must	DoIs is limited to EFSA's management. Regarding the specific comments: 1.1 EFSA intends to perform a further categorisation and prioritisation according to the Implementation plan on the possibility to comment on draft mandates. This will also include the possibility that public consultations are held on draft self-tasks or external mandates, whenever the latter is possible. Class 2 1.2 and 1.3 EFSA believes it is key to have a system in place that guarantees effective interaction with parties and partners sharing an interest in its operations. EFSA intends to increase its interaction with both applicants and interested parties. To increase direct dialogue between EFSA, applicants and interested parties, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7. EFSA commits to carry out a further categorisation and prioritisation regarding the possibility to organise pre-submission meetings with applicants in the area of regulated products. Class 2

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			be protected from the pressures from applicants and the introduction of fees, on top of placing an additional burden on SMEs compared to large economic players, would introduce a commercial relationship between the Authority and applicants. This is unacceptable. EFSA is a public administration performing a public service, and this must remain so. Recent statements by the Authority to develop a "customer-oriented approach for regulated products" (October 2) are scandalous: the risk assessments performed by EFSA are not a commercial service provided to industry clients but a public responsibility to protect public health! We will remain vigilant in the future that EFSA drops this kind of unacceptable wording. **- 1.3 "Meetings with stakeholders and NGOs" (in case of general RAs)** We do not recommend this option for the same reasons detailed at 1.1. **- 2 "The mandate is published and explained in the context of previous work (if applicable)"** Yes. **- 3 Critical success factor** The "Critical success factor" of step 3, "Reassurance that the selection process reflects expertise needed to address mandate and that selection process is objective and unbiased" misses a key component: <u>independence!</u> The critical success factor should be "Reassurance that the selection process reflects expertise <u>and independence</u> needed to address mandate and that selection process is objective and unbiased". **- 3.1 "Publish biographies and Annual Declarations of Interests"** Yes, ADOIs of most WG members are already published but it is important that this practice becomes systematic. Publication of biographies on top of it would be a good means to help whoever interested determine their completeness, but public scrutiny cannot replace EFSA's proactive checks in all publicly available sources for this. **- 3.2 "Documentation on the criteria of selection of WG available in the final output"** Yes.	EFSA is fully committed to complying with the principle of independence enshrined in its Founding Regulation. The Authority also intends to review its Policy on the independence of its scientific decision-making processes, with a view to fully reflect in it the opportunities for enhanced transparency and engagement that will result from the implementation of the "Open EFSA" process. These comments will therefore feed into this process as well. Class 6 2. Noted. Class 1. 3., 3.1 and 3.2. Noted Class 7 3.3 These suggestions have already been implemented by EFSA. Class 7 4. EFSA agrees that all relevant scientific publications and literature should be duly considered in its scientific evaluations and that this should be fully reflected in the final output. A case-by-case evaluation of each publication is therefore necessary, as outlined in the guidance on the "Application of systematic review methodology to food and feed safety assessments to support decision-making", available via EFSA's website. Class 7. a. EFSA considers that public consultations on models for data analysis may be among the instances

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			- 3.3 "Open calls for hearing experts if appropriate" Yes, this would be the best means for EFSA to reach out to missing expertise while preserving its independence when independent experts with the required expertise would not be found. It must be absolutely clear though that the role of hearing experts is strictly limited to answering the questions of the WG members. The hearing experts' list must be made public and declarations of interests must be provided as with EFSA's staff and experts. **- 4 Critical Success Factors** The first "Critical success factor" of step 4, "Methodology/data/information meets EFSA's and international standards" is extremely important and is defined too restrictively. It should be completed as follows: "Methodology/data/information meets EFSA's and international standards when it concerns applicants' analysis". Furthermore, this risk assessment must not be limited to the application received: scientific literature at large must be taken into consideration. This scientific literature is to be considered not under regulatory standards but as fundamental science -Methodology/data/information guarantees that all relevant and publicly available scientific data is used, without giving certain studies superior status just because they would abide to certain regulatory toxicology standards such as OECD or GLP. Anecdotal evidence undermining the reliability of certain studies used in the past by EFSA must also be taken into account to update EFSA's relevant opinions. The second "Critical success factor" of step 4, "Documentation on the methodology/data/information used" is very important too; this documentation must be exhaustive. The unacceptable practice of selective citing and presenting only those data that fit the own preconceived safety assumption is unacceptable. EFSA must consider all kind of studies, no matter if the conclusion does not fit safety assurances, and those studies are to be listed in the opinion. Such studies are not to be considered individually. We consider that the third "Critical success factor" of step 4, "Ensuring reproducibility of the Risk Assessment", is absolutely paramount in this whole initiative and must be given top priority, with everything this entails in terms of data transparency. **- 4.1 "Public consultation, e.g. statistical data models for analysis, if**	where input from outside the Authority could prove more beneficial. EFSA will retain this as one of the actions to be subject to further categorisation and prioritisation Class 2 b. Noted. Class 1 4.3. EFSA will include this option among the list of actions to be subject to a further categorisation and prioritisation to be performed according to the Implementation plan. Class 2 a. Noted. Class 2 5.1 In accordance with the relevant legal act, EFSA systematically asks concerned applicants to provide missing information or data. Class 7 EFSA highlights that it already identifies data gaps every time it adopts a scientific opinion. This notwithstanding, it commits to a further categorisation and prioritisation to be performed according to the Implementation plan on how to further improve this practice, and on whether it should reflect the entirety of data gaps of a dossier. Class 2. EFSA is in no position to exclude any study based exclusively on the fact that it is funded by entities with an interest in the approval of the product or substance. Refer to previous point no.

No	Contributor	Chapter	Comments received	EFSA response
			applicable" We consider that public consultations are not an appropriate tool for EFSA to seek external contributions for such technical and strategic information. **- 4.2 "Consultation reports, including inclusion/exclusion criteria"** Yes, this is indeed very important to justify the bodies of evidence considered and excluded in the risk assessment work, a recurring criticism. See above comment for the second Critical success factor of step 4. **- 4.3 "Open and/or targeted call for data/information"** Yes, if needed. It must be very clear though that no information coming from entities with a direct or indirect commercial interest in the work being done should be accepted. **- 4.4 "Pre-publication of the methodological approach chosen or reference to a given guidance document upon which the assessment will be based"** Yes. **- 5.1 "Consultation on possible missing data/info to be considered by EFSA"** Two cases must be considered. If such consultations mean that EFSA asks the applicant about missing data / information in the application files, then yes, such consultations must occur as it is already the case. If such consultations are about missing data / information in the general scientific literature, then such consultations should also take place but here EFSA must exclude scientific studies sponsored and/or authored by individuals or entities with a commercial interest in regulatory approval of the product or substance. EFSA must also detail data gaps in its final opinion when this is the case. **- 5.2 "Proactive release of information used in a readable format"** Pro-active release of the information used is obviously good but readable format is not enough (what would be the point of releasing information in an unreadable format anyway?), the point is to release this information in an editable format enabling its reuse. In general, we agree that all data submitted for regulatory approval – including raw data – should be pro-actively published before it is used, in order to enable peer review (as opposed to the current reactive regime for the disclosure of such data).	4. 5.2 – 5.3 EFSA deems appropriate to undertake a further categorisation and prioritisation to be performed according to the Implementation plan on whether it would be appropriate or feasible to institutionalise a practice of providing free access to the data used or discarded in safety studies and risk assessments in a readable/reusable form. Class 2 5.4, 5.7. EFSA acknowledges the need to improve the completeness of its minutes and the reporting of scientific meetings. A further categorisation and prioritisation will be performed on these matters, according to the Implementation plan. Minority opinions are systematically reflected and published together with the main opinion, when put forward by the competent experts. EFSA has already undertaken or planned measures to increase the level of comprehensiveness and transparency regarding discussions and potential diverging views as reflected in the minutes of the relevant meetings. Class 1 5.5 EFSA notes that these are mandates for which it would possibly need relevant data and information. Therefore, EFSA will retain this as one of the measures to be subject to

No	Contributor	Chapter	Comments received	EFSA response
			- 5.3 "Proactive release of information not used in a readable format" Same comment as above: yes to proactive disclosure, and the point is about releasing editable formats for data reuse, not only readable. **- 5.4 "Minutes representing collegial discussions and eventual diverging opinions (Article 30)"** Yes. At the moment, WG meeting minutes hardly contain anything beyond agenda points; panel plenary meetings minutes are better but are sometimes incomplete. Procedures guaranteeing that minority opinions are duly recorded and published must be developed and implemented. **- 5.5 "Public meetings on Expert Knowledge elicitation" (EKE)** We do consider that EFSA is responsible for conducting a trustworthy risk assessment. This responsibility was given by the European Commission. Public consultation on self-task or vague "issue of high public interest" are therefore not in line with this approach. **- 5.6 "Public consultation on draft opinions"** Yes, this has been used a lot by EFSA since it was created to engage with the public upon its draft opinions and the practice should go on. The way EFSA has dealt with the input received in those consultations, though, has been widely criticised for its arbitrary and opaque character and clearer procedures should be defined to solve this problem. Particularly, these consultations should be transparent in terms of the contributions received and in terms of the reasons why comments were taken on board or not. **- 5.7 "Technical hearings in dedicated consultative meetings"** Yes – the minutes of these meetings should also be published and be comprehensive. **- 5.8 "Consultative meetings with Member States"** Yes, if need be – the minutes of these meetings should also be published, and, crucially, detail the position of each Member State. All Member States should be invited to contribute, thus avoiding the bias that can occur when only Member States with a strong interest in a certain outcome contribute. **- 6.1 "Open plenary meetings"**	further categorisation and prioritisation according to the Implementation plan. 5.6. The system recommended is already in place, as all comments received are considered and addressed in the output. Class 7 5.8 EFSA commits to perform further categorisation and prioritisation regarding the possibility to organise systematic pre-public consultation meetings with Member States. Class 2. 6.1 Under the current legal framework, EFSA's scientific opinions have to be adopted exclusively by its Scientific Committee and Scientific Panels. To further strengthen the efficacy of the current system of open plenary meetings and the use of external expertise, EFSA has already undertaken the necessary actions to decide on the degree to which it should open its plenary meetings to observers (Class 1). EFSA commits to further categorise and prioritise the extent to which it should increment the recourse to "hearing experts" and the organisation of "public hearings". Class 2". 6.2 – 7.3. EFSA commits to a further categorisation and prioritisation to be performed according to the Implementation plan on whether it

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			This has already been tried by EFSA for some time and the lessons from that experience show that the resource discrepancy between commercial stakeholders and the others causes an overwhelming and problematic domination of the first among the observers. Besides, even though there was a formal interdiction of exchanges between observers and panel members, this rule has been breached and will be breached again, as it is simply natural for human beings in a same room to exchange at one point or another! We do ask to stop opening panel meetings to observers: scientists' freedom of expression must be protected. Specific insurance schemes covering these experts' decisions against possible legal threats targeting their work within EFSA could be considered. **- 6.2 "Main decisions available shortly after the plenary meetings"** Yes, of course. **- 6.3 "Publication of a flash summary/abstract immediately after the plenary meeting"** Yes. **"Pre-notification"** Yes – this already happens. **- 7.2 "Publication in EFSA journal** a. Publication of the output-decision Yes, this already happens. b. Publication of data/info used and discarded Yes, on top of the proactive disclosure of all received information from applicants. This would be crucial to enable the reproduction of the risk assessment. Data gaps should also be mentioned whenever they exist. c. Publication of methodology used (i.e. analysis models) Yes, and this would be crucial to enable the reproduction of the risk assessment. **- 7.3 "Broad array of communication channels depending upon target audience"** Yes **- 7.4 "Follow-up meetings"** This policy option is not clearly defined. Meeting between who and whom? Just as we oppose presubmission meetings, we would oppose follow-up meetings between applicants and panel members, and in general contacts between commercial	would be appropriate or feasible to institutionalise a practice of providing free access to the data used or discarded in safety studies and risk assessments in a readable/reusable form, including publication of the methodology used. Class 2. Other suggestions are noted. Classes 1 or 6 7.4 EFSA commits to perform further categorisation and prioritisation on the possibility to establish a system of follow-up meetings regarding outputs adopted in the regulated products area. Class 2. 7.5, 8 See above under 4 Class 7 9. See under 1.1. Class 2

No	Contributor	Chapter	Comments received	EFSA response
			companies falling under EFSA's remit and EFSA's scientific panels and working group members. **- 7.5 "Consultation reports, including inclusion / exclusion criteria"** Yes, this is indeed very important to justify the bodies of evidence considered and excluded in the risk assessment work, a recurring criticism. See comments under about the second "Critical success factor" of step 4. **- 8 "The updated 'file' is publicly available"** The only policy option considered for the very important step 8 ("Monitoring/evaluation of new scientific evidence"), should be detailed further; relevant studies published in the scientific literature for instance could be added whenever they appear, which would provide a great public service of ongoing monitoring scientific evidence for whoever is interested in getting an overview of the available scientific evidence on topics followed upon by EFSA. This function could easily benefit from spontaneous contributions from the public as well as scientists who monitor these issues on an ongoing basis. **- 9 New (self) mandate accompanied by contextual risk communications** See comments for policy options 1.1 regarding self-mandates.	
161.	FEFAC European Feed Manufacturers' Federation (Belgium)	4.2 Openness	2. How can EFSA increase its openness to meaningful contributions from individuals and organisations beyond its Panels and Committee? Should a two-way interaction between EFSA's Panels and interested parties be facilitated? What limits should be set to such interaction? FEFAC itself does not have direct interest in the assessment of regulated products but has direct interest in generic risk assessment such as for contaminants. We acknowledge the openness of EFSA as regards the ability to sectors to provide data as basic elements of the scientific evaluation but would see also value in increasing openness to non-quantitative information that may also contribute to a more comprehensive risk assessment. In this sense, scientific hearings should play a bigger role.	To further strengthen the efficacy of the current system of open plenary meetings and the use of external expertise, EFSA has already undertaken the necessary actions to decide on the degree to which it should open its plenary meetings to observers (Class 1). EFSA commits to further categorise and prioritise the extent to which it should increment the recourse to "hearing experts" and the organisation of "public hearings". Class 2

No	Contributor	Chapter	Comments received	EFSA response
162.	FEFAC European Feed Manufacturers' Federation (Belgium)	5. Rolling out the change	5. Would you identify any other strategic drivers, contextual elements or policy options for the Authority to consider when implementing its vision of becoming an Open EFSA? Not at this stage.	Noted.
163.	Confederazione Nazionale Coldiretti (Italy)	5. Rolling out the change	Under "increasing public scrutiny" It could be helpful to underline the role of stakeholders' contribution into Efsa's workload (Stakeholders' Consultative Platform, as well as other thematic groups,i.e, STACG -ER). The public could be better aware of the positive interaction Efsa is having with concerned stakeholders, either NGOs, Associations, etc.	In this respect, EFSA has already undertaken or planned actions to increase the visibility of the role, and contribution, of stakeholders with regard to EFSA's processes and documents. Class 1
164.	European Crop Protection Association (Belgium)	5. Rolling out the change	Ad. 5 Rolling out the change Within point 5 "Rolling out the change", the table on page 14 (Open EFSA options table) highlights the workflow, success factors and policy options. ECPA concerns relate to the success factors for the mandates which state that the "Mandate captures societal needs". We believe that the mandates should focus on supporting the legislative needs – as the majority of mandates are developed in order to support compliance within a legislative framework. The focus on societal needs in the mandates seems to ignore the needs for a clear and predictable framework that will support existing legislative frameworks and the common needs of risk assessors and risk managers. We would suggest that the critical support factors for mandates should therefore be that: "Mandates to provide clear benefits in supporting the implementation of specific Regulatory frameworks managed by EFSA" and "Mandates take into account the common needs of risk assessors and risk managers"	EFSA's mission is to support policy-makers in the European Commission, European Parliament and Member States by providing them with useful and fit-for-purpose scientific advice or scientific and technical support. Class 5
165.	Individual contribution, (UK)	5. Rolling out the change	Phase 3 - further categorisation and prioritarisation. Commentators from the private sector are often infuriated by the failure of cost benefit analyses to reflect the costs to individuals of declarations on the safety of foods. Developments within the field of endocrine disruptive chemicals and their medical effects reveal that there are often subtle adverse medical effects at levels of concentration orders of magnitude below those that are conventionally claimed to be safe. Standard models of further categorisation and prioritarisation fail to reflect the personal health and financial impacts of such 'sub-threshold' effects, relying instead on cost savings to public sector interests that grossly distort the	The process of further categorisation and prioritisation will be performed according to the Implementation plan outlining the path to the establishment of an Open EFSA. Its results will be published together with EFSA's decision on which actions to pursue further. Class 1

No	Contributor	Chapter	Comments received	EFSA response
			apparent proportionality that is invoked whenever controversy erupts. A classic example is the issue of the cost saving alleged to be gained by the dental public health sector through fluoridation of public water supplies, without any consideration of the cost to children who become harmed and distressed by the disfigurement of dental fluoros is. The very high private sector costs of so-called 'cosmetic' dentistry can equal those of expensive university education in the UK, and far excede the claimed public sector cost benefits associated with fluoridation. Where EFSA decisions are to be subjected to formal further categorisation and prioritarisation, the views of informed members of the public must be sought in order to ensure that the process is both transparent and fair. Should the EFSA become a Facilitator of public accountability of Member States in matters of food safety? EFSA decisions can have profound impacts on the public when they are defective, or through inaction it may issue decisions that are manipulated by politicians in ways that cause harm to the public - again, fluoridation is a glaring example of such disruptive behaviour that has a very significant impact of public welfare. At present, exposing such problems involves considerable difficulty for members of the public seeking redress, whilst obtaining any form of legal resolution in extreme cases is almost impossible. Therefore, a facility needs to be established within EFSA in which the public is able to record its concerns, and demand a referendum on such issues. This may be through a crowdsourcing electronic petition facility, with a specified threshold beyond which Member States must request a decision for review by EFSA. Clearly, in such a process, all relevant opinion from both professional and lay sources must be given full and equal status. Moreover, a decision by EFSA must then be enforceable at the Member State level. The current system, whereby individual members of the public must exhaust all levels of judicial scrutiny (at their own expense) before gaining access to EC judicial review, is totally unacceptable. So EFSA should also seek powers that enable it to enforce its decisions at Member State level, or to refer them directly to the European Court when Member States	EFSA cannot but reject the request for a referendum, as this comment falls outside EFSA's remit. Class 5

No	Contributor	Chapter	Comments received	EFSA response
			refuse to comply with directions. Such a process must ensure that hearings are timely and draw upon best available science, particularly where political (and indeed, commercial) interests induce administrative policies, plans and programmes to veer away from the primary imperative of protecting public safety.	
166.	InQpharm Europe Ltd. (Germany)	5. Rolling out the change	5. Would you identify any other strategic drivers, contextual elements, or policy options for the Authority to consider when implementing its vision of becoming an Open EFSA? We still feel, that health claim application procedure still is not transparent enough to allow for a satisfying interaction between the Authority, the stakeholders, and the general public. We still feel that health claim application procedure still is not transparent enough to allow for a satisfying interaction between the Authority, the stakeholders, and the general public. We would very much appreciate a direct discussion with EFSA in the form of a pre-assessment meeting or scientific advice meeting, which is an established standard in the process of obtaining market authorization for drugs. Together, clear guidelines and transparent and objective processes (including the opportunity to have a dialogue with the NDA panel) would help companies like InQpharm Europe Ltd. to work more efficiently in bringing safe, effective and innovative products to the European community and consumers Based on our experience with the stop clock process in our own application, we would appreciate it if EFSA could highlight all, and not just singular weak points of a given application in order to make it possible for the applicant to address all issues during that stop clock window. If the panel already sees questionable points that may endanger a positive opinion, they should be clearly communicated to the applicant, so they can be addressed in the stop clock reply. Also a feedback on the applicant's stop clock reply by EFSA would also be very helpful. In case a negative opinion is adopted, all weak points of the application should be clearly and rationally addressed, and not just the ones leading to rejection, so in case the applicant is required to repeat a clinical trial, he is in a position to improve the clinical trial protocol in order to overcome all previous criticism We also would like to highlight the very short time frame for the clock stop	To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7. EFSA commits to perform further categorisation and prioritisation on the feasibility of highlighting all weak points in application dossiers to make it possible for applicants to address all issues during the “stop the clock” window. Class 2 For what concerns the specific case of the Nutrition and Health Claims Regulation, the deadlines for submission of clarifications or additional information are laid down in the law, and EFSA has no means to alter these. Class 6 Comments on specific opinions or outputs go beyond the scope of this exercise. Class 5

No	Contributor	Chapter	Comments received	EFSA response
			procedure (15 calendar days), which makes it extremely challenging to comprehensively answer questions by the NDA panel or to provide more data and analyses, should that be needed. Furthermore, we would appreciate it if EFSA applied the same scientific standards for all applications. EFSA claims to keep consistency in adopting their opinions; however, we rather notice that standards vary over time and across indications, which makes it difficult for health claim applicants to adequately prepare new submissions. Taking the example of the Glucomannan weight loss opinion (EFSA Panel on Dietetic Products, 2010); some studies did not even show a significant reduction in body weight, and although some of the studies had considerable methodological weaknesses, the NDA panel concludes that a cause and effect relationship has been established. However in our own application, no such befits of doubt were granted, and the application was rejected without solid rationale for the alleged "risk of bias". In the context of meaningful contributions, we suggest that the EFSA Help Desk should allow for requests that relate to new topics/questions and not just to previously published opinions. Al so a strong need to discuss clinical and scientific questions exists that EFSA should meet. Further, it would be extremely helpful to applicants to have verbal conversations or meetings at EFSA to discuss a request, as is the case with the BfArM in Germany or with the FDA in the USA.	
167.	ClientEarth (Belgium)	5. Rolling out the change	Cost benefit analysis: we disagree on the use of cost benefit analyses to determine the level of transparency that EFSA should achieve. Costs are easy to calculate, but on what grounds will the benefits be considered proportional to the costs? The risk of including cost benefits analysis in the transparency discussion threatens to jeopardize the entire process by introducing constraints which are not relevant to the requirements of openness and transparency. We would recommend, instead, a tiered approach, agreed with all stakeholders, where issues are prioritized. In the first instance, EFSA should prioritise compliance with legal obligations as this approach is fortunately not foreseen in any of the applicable texts. The options table: comments: 1. A request is received or initiated	EFSA has limited resources at its disposal, which it needs to manage in a sound and proportionate manner so as to be able to accomplish its mandate. This is also the purpose of performing a further categorisation and prioritisation exercise, which is outlined in more detail in the Implementation plan. Class 6 1. To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and

No	Contributor	Chapter	Comments received	EFSA response
			1.1 Public consultations are generally welcome. However the mandates usually stem from the European Commission, thus we don't think EFSA can modify these mandates. For other tasks, if consultations are carried ou t, all changes in the mandates should be explained and reasoned and all comments addressed. 1.2 Pre-submission meetings should be avoided as much as possible unless they are foreseen in the legislation as they open up the possibility that the decision making process will be distorted by undue pressure from commercial vested interests. 1.3 In cases of topics of interest to a large number of stakeholders, meetings with all interested parties would be welcome as long as the views of all parties are represented. 2. The request is accepted (final mandate): in case of comments received or meetings that take place, these should be clearly reported. 3. Panel discussion and establishment of working groups: all conflicts of interest should be avoided as much as possible. If this is not possible, the reasons should be clearly explained. Any source of financial or intellectual bias should be disclosed. 4. The risk assessment methodology is defined and data/information collection is performed: the choice of the methodology should be clearly explained; any input in public consultation should be addressed and made available in separate/appended tables. Inclusion and exclusion criteria should be specified for each study and the funding source for each study should be highlighted. 5. The draft output is prepared: 5.1: public consultation for gathering evidence is welcome when appropriate. I.e. in specific cases in which the knowledge base is so extensive that the scientific committees may miss some points. 5.2: It should be explained why the information was used, who funded it. 5.3: It should be explained why the information was not used, who funded it. 5.4: The minutes should aim at giving a good representation of the scientific debate which took place in the committee and, as far as possible, give an idea of the level of participation of all members in the discussion. 5.5. No comment 5.6. Public consultations on draft opinions are desirable as long as, at this stage,it is possible for experts to be able to und erstand the opinion-forming process. In case of general risk assessments and documents that would have larger impacts, public consultation should be prioritized. 5.7. No comment. 5.8. No comment	interested parties, which are part of its catalogue of services. Class 7. 2 These suggestions have already been implemented by EFSA. Minutes of meetings and comments received are duly recorded and published. Class 7 3. These suggestions have already been implemented by EFSA. The Authority also intends to review its Policy on the independence of its scientific decision-making processes with a view to fully reflect in it the opportunities for enhanced transparency and engagement that will result from the "Open EFSA" project. These comments will therefore feed into this process as well. Class 7 4. EFSA considers that public consultations on models for data analysis may be among the instances where input from outside the Authority could prove more beneficial. EFSA will retain this as one the actions to be subject to further categorisation and prioritisation. Class 2. The risk assessment methodology is regularly reported in EFSA's guidance documents and outputs. Class 7. In addition, EFSA commits to perform further categorisation and prioritisation on the possibility to systematically publish the

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			6. The output is adopted 6.1. As stated above, opening plenary meetings should be limited only to accredited stakeholders and, in no case, to the parties that are concerned with the opinion of EFSA. Since EFSA holds a large number of scientific panels, these panels should be accessible only when balanced participation could be guaranteed. 6.2. Timely information is desirable to the extent it is possible and should be prioritised for issues that have wider societal impacts. 6.3. Timely information is desirable to the extent it is possible and should be prioritised for issues that have wider societal impacts. 7. The output is pre-notified, published and communicated 7.1. We disagree with the need for pre-notification, public communication is more desirable. 7.2. As explained above, the publication of methodologies and information used and discarded should be accompanied by clear explanations and information on the possible biases that studies may have. 7.3. Dissemination of the output to all interested and concerned citizens is desirable and welcome. 7.4. We do not believe that, after the scientific opinion is made public, there should be follow-up meetings. If the opinion can be somehow modified clear procedures should be established. 7.5. Consultation reports are absolutely crucial for improving EFSA's transparency. Citizens should be able to understand which comments were taken into account and addressed and why. 8. Monitoring/evaluation of new scientific evidence: since legislation requires the possibility to review authorisation on the basis of new scientific evidence, it would be welcome if a procedure for triggering the revision of a decision/opinion is set up in order to allow predictability in the process and that revisions of scientific opinion is not only dependent on political pressure. Would you identify any other strategic drivers, contextual elements or policy options for the Authority to consider when implementing its vision of becoming an Open EFSA? We believe that apart from the issues covered in EFSA's Discussion Paper, it is important that EFSA focuses on transparency in risk assessment in order to guarantee its necessary and perceived independence. Therefore, it should avoid conflicts of interests as much as possible and, when it is not possible, it should	methodology used in all its scientific outputs. Class 2. While EFSA agrees that all relevant scientific publications and literature should be duly considered in its scientific evaluations and that this should be fully reflected in the final output, the Authority considers that the fact a publication has been peer-reviewed does not represent *per se* a sufficient guarantee of high standards. A case-by-case evaluation of each publication is therefore necessary, as outlined in the guidance on the "Application of systematic review methodology to food and feed safety assessments to support decision-making", available via EFSA's website. Class 7. The request to disclose information on the funding of each study and publication finds no legal basis. EFSA has no direct legislative, enforcement or regulatory powers to do so. However, EFSA has already taken, or planned, the necessary actions aimed at identifying how best to increase the current level of transparency regarding the identification of key studies and the reasoning behind their acceptance or rejection. Class 1 5. See replies 1 to 4 above. 6. To further strengthen the efficacy of the current system of

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			make them as transparent as possible. Intellectual bias should be tackled as well. Membership of professional associations and affiliation to specific institutions may also indicate a degree of bias. These cannot be eliminated, but should be represented and articulated. Finally, we believe that it is important to be transparent about what studies are taken into account and what studies are discarded; and, for each study, information about the funding source should be made available.	open plenary meetings and the use of external expertise, EFSA has already undertaken the necessary actions necessary to decide on the degree to which it should open its plenary meetings to observers (Class 1). For what concerns timely information about an adopted output, EFSA has undertaken or is planning the necessary actions to address this. Class 1 7 and 8 EFSA is already subject to provisions obliging it to review its adopted outputs once relevant scientific data or information undermining previously adopted conclusions are/is identified. Class 7. EFSA commits to perform further categorisation and prioritisation on the possibility that it makes publicly available all documents linked to a decision on whether to update an output or not. Class. 2. To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7. 7.4 EFSA commits to perform further categorisation and prioritisation on the possibility to establish a system of follow-up meetings regarding outputs adopted in the regulated products area. Class 2.

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				Regarding the additional comments on the need to expose, in a transparent manner, possible bias that may result from side interests of experts involved in EFSA's processes, the Authority has already been implementing such a policy for some years, by publishing the experts' DoIs including all relevant information on membership in associations or professional organisations. EFSA will consider these comments during the forthcoming review of the outlined policy to make sure it reflects the opportunities freed by the "Open EFSA" initiative. Class 6
168.	DANONE (France)	5. Rolling out the change	Seeking more transparency regarding EFSA's assessments, a very high level of transparency could be ensured if EFSA's basis for opinions would be published and available to the public and applicants, with detailed scientific references, principles and precedents driving its conclusions. The case-by-case basis does not always allow for the reproducibility of EFSA's assessments. DANONE welcomes EFSA's openness to include pre-submission meetings (in the case of regulated products) as a policy option to improve EFSA's scientific decision-making. DANONE also supports additional ways in which two-way interaction between EFSA Panels and interested parties, in particular applicants, can be facilitated: - EFSA could allow for written submissions of applicants' draft dossiers in the pre-assessment stage. Feedback from panel members would help applicants to submit high quality dossiers more likely to satisfy EFSA's requirements in each particular case, in line with the case-by-case dossier evaluation. - EFS A could compile and publish an FAQ document consisting of questions and answers asked during the stop-the-clock procedure. Such a document would	To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7. EFSA will perform a further categorisation and prioritisation according to the Implementation plan on the possibility to draft a Q&A document on issues raised in the context of "stop the clock" procedures. Class 2 EFSA acknowledges that the criteria for the assessment of scientific substantiation should be available prior to the submission of an application dossier. However, this is without prejudice to a case-by-case

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			provide applicants with additional information while preparing a claim submission. - Documentation on the criteria taken into account by EFSA when assessing the scientific substantiation should be available for applicants and interested parties prior to the submission of the application/dossier. Whilst some specific guidance documents have been published (e.g. Guidance for health claims related to gut and immune function), this is not currently included in EFSA's policy options. Such interaction would allow for the exchange of data in a more systematic and regular manner. We believe that such measures would provide high added value for EFSA in carrying out its mandate, and would lead to concrete gains.	assessment departing from these criteria on duly justified grounds. Class 6 To provide more feedback to applicants, the Authority has put in place a number of initiatives as part of its catalogue of services. Class 7
169.	Joint Submission Bee Life, Corporate Europe Observatory, Earth Open source, Fondation Sciences Citoyennes, GM Watch, Pesticides Action Network Europe	5. Rolling out the change	5) Would you identify any other strategic drivers, contextual elements or policy options for the Authority to consider when implementing its vision of becoming an Open EFSA? As transparency involves the publication of the applicants' full dossiers, it also involves the content of those dossiers. Applications should not only include the raw data but also the detailed protocols and research material used (whether biological or technical, such as the name of the software used by the applicant and all information needed for the exhaustive comprehension of the operation, use of the software and the obtained results: design of experiments and the materials used are indeed critical for making sense of the raw data), the names of the laboratories that led the experiments and funding sources for this experiment. Similarly to the new Clinical Trials Regulation, applications should include all the data related to risk assessment which industry has in order to avoid the applicants selecting only favourable data to be submitted. We suggest adding a policy option to step 4: developing standards for reporting in the dossiers all available relevant biosafety evidence. This should be demanded and enforced and punished if not followed - e.g. dossier returned for revision or rejected. Again, the core issue is trust and transparency alone does not enable that. People with links to commercial entities falling under EFSA's remit must be prevented from joining EFSA's panels and working groups, which is not currently the case. Making conflicts of interests more visible will not help the Authority regain public	EFSA deems appropriate to undertake a further categorisation and prioritisation to be performed according to the Implementation plan on whether it would be appropriate or feasible to institutionalise a practice of providing free access to the data used or discarded in safety studies and risk assessments in a readable/reusable form. Class 2 The requirement for applicants to report all available relevant biosafety evidence in their dossiers already exists. In cases where an application dossier does not include the requested information or dataset, the Authority may issue a negative or inconclusive opinion, as appropriate. Class 6 EFSA underlines that it implements, and further develops, one of the most stringent frameworks for the prevention of CoIs among EU institutions, bodies and agencies. As part of the review cycle, the Authority

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			trust, far from it.	will also review its Policy on the independence of its scientific decision-making processes with a view to fully reflect in it the opportunities for enhanced transparency and engagement that will result from the "Open EFSA" project. Class 6
170.	Public Research and Regulation Initiative (PRRI)	5. Rolling out the change	PRRI supports the step described as "EFSA then identified different options at its disposal for meeting the critical success factors, including a legitimacy check to ensure that it complies with application of the institutional and legal frameworks." 5. Would you identify any other strategic drivers, contextual elements or policy options for the Authority to consider when implementing its vision of becoming an Open EFSA? One of the key drivers should be to constantly keep an eye on the legal role EFSA.	Noted. Class 6
171.	SYNADIET (France)	5. Rolling out the change	LE COMPLÉMENT ALIMENTAIRE : ÉTABLIR UN DÉVELOPPEMENT EXIGEANT MAIS ADAPTÉ A ce jour, l'évaluation clinique de l'efficacité d'un produit alimentaire repose sur les critères utilisés par l'industrie pharmaceutique pour l'évaluation des médicaments. Or, ces critères ne peuvent être appliqués à une denrée alimentaire qui, lorsqu'elle est consommée aux doses recommandées, ne présente aucun risque, le rapport bénéfice / risque étant de facto et a priori favorable. En outre, l'observation de l'ensemble des résultats ne devrait pas reposer sur une évaluation de chacun des critères individuels, mais sur un résultat multicritères : l'amélioration globale du bien être des sujets. D'une part, l'effet d'un aliment est plus difficile à mettre en évidence que l'effet d'un médicament. Les données cliniques requises par l'EFSA dans le cadre du Règlement Allégations doivent être établies sur la population saine pour laquelle les symptômes sont par définition moins importants que ceux d'une population malade dont les pathologies sont avérées. Il est donc moins facile de mettre en évidence l'efficacité d'un	This comment falls outside the scope of the present consultation. Class 0

No	Contributor	Chapter	Comments received	EFSA response
			produit, la marge d'amélioration étant beaucoup plus faible chez ces sujets « sains ». Il est également à noter que les protocoles d'études cliniques thérapeutiques visent à mettre en évidence les effets d'une substance chimiquement définie alors que l'ingrédient ou le complément alimentaire représente des matrices plus complexes pour lesquelles le modèle molécule/récepteur ne fonctionne pas3,4. Ensuite les outils de mesure ne sont pas validés sur la population de l'étude. Au sein d'une population malade, les symptômes sont bien définis et il existe des méthodes de mesure fiables, des échelles et instruments de contrôle adéquats. Or, la population que l'on demande de considérer dans le cadre du Règlement Allégations se situe à la limite incertaine entre le sujet sain, mais se plaignant de signes non systématisés, et des sujets peut être à des phases très précoces ou peu symptomatiques de pathologies vraies. Ce type de population n'a de fait que très rarement été inclus dans des essais ou évaluations de soulagement symptomatique, d'où l'absence d'instrument spécifique3,4. Enfin, l'observation des résultats doit juger de l'amélioration globale des patients. L'ensemble des résultats ne doit pas reposer sur une évaluation d'un critère unique avec un seuil de significativité fixé à 0.05, qu'il n'est pas possible de mesurer convenablement au sein de la population non symptomatique, mais sur un résultat multicritères : l'amélioration globale des sujets. Prendre en compte l'ensemble des critères permettrait de conclure à la supériorité d'un produit alimentaire sur un placebo et à une amélioration globale significative du confort de vie des sujets. A ce stade, SYNADIET se propose de travailler avec la DGCCRF, avec le soutien de statisticiens, pour élaborer une position officielle de la France en matière de critères d'appréciation et de jugement3,4. 3: EFSA-Q-2011-01113. Scientific Opinion on the substantiation of a health claim related to glucosamine and maintenance of normal joint cartilage pursuant to Article 13(5) of Regulation (EC) No 1924/2006. 4: EFSA-Q-2013-0087. Scientific Opinion on the substantiation of a health claim related to a combination of lutein and zeaxanthin and improved vision under bright light conditions pursuant to Article 13(5) of Regulation (EC) No 1924/2006.	
172.	PFP-association for the	5. Rolling out the change	4. How can EFSA foster even further an environment of creative debate amongst its experts while striking the appropriate balance between availability and quality of information?	Cooperation with Member States is one of the key drivers of EFSA's operations. Class 6

No	Contributor	Chapter	Comments received	EFSA response
	European primary food processing industry (Belgium)		EFSA cooperation with Member States and at international level should be further enhanced. Scientific issues handled by EFSA have repercussions at international level and a regular exchange of information and cooperation between regulatory authorities are crucial for a better functioning risk assessment system. It is also important of having EFSA views heard in different EU institutions. We believe that this will also increase knowledge-sharing on science and avoid compartmented policy. In terms of planning, PFP welcomes the foreward planning ahead of major upcoming issues, which also helps stakeholders be prepared. In that context, pre-warning before an opinion on a specific mandate is published is a particularly useful tool. Ensuring availability of information across EFSA panels on linked issues is also primordial and should be fostered. We note that on some occasions, EFSA opinions do not refer to previous opinions either of the same panel or of another panel on a linked issue, which would deserve to be mentioned and taken into account. Having clear implementing processes in place to ensure this would enable integrated and coherent opinions within the same panel and across panels.	Without prejudice to occasional omissions, EFSA strives to ensure consistent self-referencing of relevant previously adopted scientific outputs. Class 6
173.	ENSSER European Network of Scientists for Social and Environmental (France)	5. Rolling out the change	5) Would you identify any other strategic drivers, contextual elements or policy options for the Authority to consider when implementing its vision of becoming an Open EFSA? Transparency requires that the full applicants' dossiers are freely and publicly available, together with all the raw data. Experts with present or former links to the agrifood industry and/or lobbies funded by it, both in panels and working groups, should be excluded from having decision-making power within EFSA panels and working groups. ENSSER does not agree that experts are not available in sufficient numbers to staff EFSA's panels. To our understanding there are experts independent from industry available in sufficient numbers and in our point of view these experts are currently rather discouraged in various ways from joining EFSA's panels. To offset any shortage of experts we would expect that EFSA would deplore this publicly and approach the appropriate EU institutions and civil societies alerting them to this situation and demanding that measures are taken to ensure a sufficient basis of independence in public sector science and research in the EU in the interest of the EU public.	EFSA acknowledges that it needs to keep investing in, and improving, the identification of the most appropriate scientific human capital. To this end, and to ensure the comprehensiveness and reliability of the expert judgements expressed by its Scientific Committee, Panels and Working Groups, EFSA is willing to explore the most appropriate means to achieve this via targeted further categorisation and prioritisation, to be performed according to the Implementation plan. Class 2 EFSA has a robust system in place to safeguard the impartiality of its

No	Contributor	Chapter	Comments received	EFSA response
				scientific work. Over the years, it has put in place a comprehensive and sophisticated system to ensure its independence, and it is committed to reviewing its policies and procedures to ensure they remain fit for purpose. In this context, avoidance of potential conflicts of interest represents only one, important part of EFSA's Policy. Class 6 EFSA has put in place, and further develops, one of the most stringent frameworks for the prevention of conflicts of interests (CoI) among Union institutions, bodies and agencies. This has been recognised by external audits. As part of the review cycle, the Authority will also review its Policy on the independence of its scientific decision-making processes with a view to fully reflect in it the opportunities for enhanced transparency and engagement that will result from the "Open EFSA" project. Class 6
174.	Food Supplements Europe (Belgium)	5. Rolling out the change	4.How can EFSA foster even further an environment of creative debate amongst its experts by striking the appropriate balance between availability and quality of information? One element that could help further creative debate is to install a system of peer review for the publication of its opinions, similar as what is applicable in the scientific world for publishing research data.	EFSA commits to a further categorisation and prioritisation, to be performed according to the Implementation plan, on the possibility, or extent, of such a peer-review system being implemented by the Authority. Class 2
175.	GAP's chair on behalf of GAP, IPA	5. Rolling out the change	Seeking more transparency regarding EFSA's assessments, a very high level of transparency could be ensured if EFSA's basis for opinions would be published and available to the public and applicants, with detailed scientific references, principles	To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services

No	Contributor	Chapter	Comments received	EFSA response
	and YLFA (Belgium)		and precedents driving its conclusions. The case-by-case basis does not always allow for the reproducibility of EFSA's assessments. The probiotic sector welcomes EFSA's openness to include pre-submission meetings (in the case of regulated products) as a policy option to improve EFSA's scientific decision-making. The probiotic sector also supports additional ways in which two-way interaction between EFSA Panels and interested parties, in particular applicants, can be facilitated: -EFSA could allow for written submissions of applicants' draft dossiers in the pre-assessment stage. Feedback from panel members would help applicants to submit high quality dossiers more likely to satisfy EFSA's requirements in each particular case, in line with the case-by-case dossier evaluation. -EFSA could compile and publish an FAQ document consisting of questions and answers asked during the stop-the-clock procedure. Such a document would provide applicants with additional information while preparing a claim submission. -Documentation on the criteria taken into account by EFSA when assessing the scientific substantiation should be available for applicants and interested parties prior to the submission of the application/dossier. Whilst some specific guidance documents have been published (e.g. Guidance for health claims related to gut and immune function), this is not currently included in EFSA's policy options. Such interaction would allow for the exchange of data in a more systematic and regular manner. We believe that such measures would provide high added value for EFSA in carrying out its mandate, and would lead to concrete gains.	for applicants and interested parties, which are part of its catalogue of services. Class 7. EFSA commits to carry out further categorisation and prioritisation of the possibility to organise pre-submission meetings with applicants in the area of regulated products. Class 2 EFSA also commits to a further categorisation and prioritisation to be performed according to the Implementation plan on the proposal to compile and publish an FAQ document containing questions and answers regarding the "stop the clock" procedure. Class 2
176.	Lallemand Health Solutions (Spain)	5. Rolling out the change	We believe that for some application processes, like the evaluation of health claims, the EFSA case-by-case approach requires a case-by-case dialogue and assistance to applicants. We are in favor of introducing pre-submission meetings with applicants. They would be beneficial to both EFSA and the applicant by reducing the volume of unnecessary data in a submission, thereby reducing the time needed to review the applications and increasing efficiency. The applicants could better prepare their application and allocate resources to the studies as needed to substantiate the	To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7. EFSA commits to carry out further

No	Contributor	Chapter	Comments received	EFSA response
			dossier. This is particularly pertinent in the case of health claims, where the scientific data for substantiation consists mainly of human clinical studies requiring considerable investment by the applicants. Pre-submission meetings are intended to provide guidance on the needed information for an appropriate submission only. They are not intended to pre-assess the information. We understand the initiation of such pre-submission meeti ngs would entail the establishment of some mechanism in order to preserve the independence of the reviewers, as well as a potential selection criterion for applications open to pre-consultation. This could include industry sectors or categories of products/applications where the applicants are in real need of advice, for instance the probiotic health claims applications: given the complex scientific nature of probiotics (living organisms, lack of recognized biomarkers, unknown mechanism of action) coupled with the vague EFSA evaluation criteria and lack of constructive dialogue between EFSA and applicants thus far has lead to a situation where probiotic applicants do not know before preparing and submitting a dossier what is required to secure a positive EFSA opinion. The case of the evaluation of health claims for probiotics is a good exemple of a poor communication between EFSA and industry that could benefit from improvement. In spite of the significant and internationally recognized body of scientific evidence supporting the health benefits of probiotics, more than 300 probiotic claim applications have been rejected by EFSA. The main reason cited was a lack of characterization, which was in fact, a lack of common understanding of what was needed in the submissions. The high number of unfavorable opinions of probiotic health claims has made this category the most negatively affected by the Nutrition and Health claims regulation. This in turn has adversely impacted the industry and the consumer's perception of these products. We strongly believe the implementation of pre-submission meetings or consultations* between EFSA and the applicants can potentially be an effective way to improve the process for probiotic submissions within the current legislative framework and would definitely be proof of increased dialogue with industry. Therefore we highly recommend and request EFSA to study the possibility of putting these meetings in place. * In addition to the pre-submission meeting, EFSA could allow submission of written questions regarding applicants' draft dossiers in the pre-assessment stage to the EFSA Panel in charge of the evaluation.	categorisation and prioritisation of the possibility to organise pre-submission meetings with applicants in the area of regulated products. Class 2
177.	London School of	5.Rolling out the	Open EFSA Options Table Allocating scarce resources	Noted. Class 6

No	Contributor	Chapter	Comments received	EFSA response
	Economics (UK)	change	Some decisions draw upon an extensive scientific literature and as such are relatively routine and uncontentious. Others may need to take account of 'known unknowns' and even recognise that there may be 'unknown unknowns'. Ortwin Renn's risk escalator would be a good basis to identify those issues that should be treated as routine and others that require the more detailed, costly and time consuming efforts to engage stakeholders	
178.	Federation of European Specialty Food Ingredients Industries (ELC) (Belgium)	5. Rolling out the change	ELC is pleased that the proposed policy options generally reflect factors for improvement that are important to applicants. A few suggestions though: • Rows 1 & 2 Critical success factors are identified as "mandate captures societal needs" for reception or initiation, and acceptation of a request by EFSA, whilst such "societal needs" are not defined in the paper. It is important to frame the concept of "societal needs" in this context, i.e. societal needs in terms of food safety, based on regulatory obligations and on identified and emerging risks. • Row 4 – Option 3 "open and/or targeted call for data/information" It would be useful if interested parties could be consulted on the format of the call prior to its launch, in order to help design it in a way that would stimulate and facilitate their contribution (templates, deadlines, clear definitions of data expected (list of scientific references, full dossiers) etc.). This is particularly important to prevent the "learning by doing" approach experienced e.g. in the re-evaluation of food additives. In case of open calls on generic authorisations (i.e. non-holder specific authorisation), it would also be useful if EFSA engages first in a discussion with identified parties in the Stakeholder Consultative Platform. This could help it map presumed other interested stakeholders and identify the risk of absence or low contribution (e.g. due to the lack of awareness of manufacturers not located in the EU). In addition, the procedure should include a systematic pre-call of interest followed by the publication on the EFSA website of the names of the interested parties (as was done in the call for scientific data on selected food additives published on 24 March 2014). • Row 5 – Option 1 – Consultation on possible missing data/info to be considered by EFSA	Rows 1 & 2 As transpires from the document, EFSA believes that the concept of societal needs is broader and also includes expectations resulting from "constitutional" developments in the EU Treaties as well as enhanced expectations with regards to the accessibility of EFSA's outputs and their added value for EU citizens. Class 4 Row 4 Option 3 EFSA will include this option among the list of actions to be subject to a further categorisation and prioritisation according to the Implementation plan. Class 2 The Stakeholder Consultative Platform will remain a cornerstone of EFSA's engagement with interested parties. Class 6 Row 5 – Option 1 In view of the specific legal acts regulating the sectoral evaluation procedures, EFSA acknowledges that the first and privileged interlocutor concerning the completeness of application dossiers will have to be the relevant applicant or food

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			In the case of regulated products, EFSA should first ask applicants for information about an application in compliance with the new initiative presented by EFSA on 10 July 2014, i.e. the possibility of a request by applicants of a teleconference with EFSA staff to clarify the issues raised by the Authority. • Row 5 – Option 6 – Public consultations on draft opinions Criteria that underpin the EFSA decision to submit a draft opinion to a public consultation must be clearly defined and published. • Row 5 – Option 7 – Technical hearings in dedicated consultative meetings It should be clear that the concept of "technical hearings" encompasses the invitation of applicants/interested parties at the request of EFSA to meetings of the Authority's working groups – either in person or via teleconference – to answer questions and to clarify outstanding issues about their submitted data, in compliance with EFSA initiative announced on 10 July 2014. • Row 6 – Option 1 – Open plenary meetings Plenary meetings should be systematically open to observers except where confidential data is discussed, and not solely once a year per Panel as was the case in 2013 and 2014. • Row 7 – Option 1 pre-notification Whilst the sharing by EFSA with respondents of certain draft opinions "under embargo" prior to their publication understandably aims at allowing the respondents to prepare their own related communication, the procedure would benefit from a systematic sharing and longer embargo period to allow respondents enough time to analyse and identify any possible inaccuracies. This would prevent the necessary re-publication of the EFSA opinion, and avoid detrimental confusion in the market (see the case of the re-evaluation of lutein as a food additive).	business operator. The precise manner in which this interaction will be strengthened is outlined in EFSA's catalogue of services. Class 7. Row 5 – Option 6 EFSA has already begun, or planned, to put in place a system to enhance the transparency of EFSA's public consultation approach. Class 1 Row 5 – Option 7 To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7. Row 6 – Option 1 EFSA has already undertaken or planned the necessary actions to decide on the degree to which it should open its plenary meetings to observers. Class 7 Row 7 – Option 1 EFSA has already undertaken or planned necessary actions to consider whether the current practice of pre-notifying applicants of draft opinions in advance of their publication is still appropriate, or if this practice needs to be modified or further refined. Class 1
179.	Individual contribution, (UK),	5.Rolling out the	The comments at the bottom of page 12, in Section 5 in Phase 3 Cost/Benefit Analysis are particularly problematic. The suggestion that such analyses should be carried out is far less problematic than the lack of clarity about which costs,	The costs to be considered during the classification and prioritisation exercise are exclusively those to be

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	Science and Technology Policy Research, University of Sussex	change	incurred by whom, are to be analysed. Similarly, we are not told what would, in this context, count as a benefit, nor who might be deemed relevant beneficiaries. Perhaps the underlying idea is that the relevant 'costs' are just those that might be borne by EFSA, and by members of its panels and working groups? An alternative interpretation might be that the categories of relevant costs might include those borne by eg commercial organisations or by consumers as a consequence, for example, of consuming food or drink products that harm their health. Moreover, it is unclear what might be deemed a relevant 'cost'. Might they only include countable parameters, and of those might they be only those than can be parameterised and estimated in monetary terms, or is EFSA intending to acknowledge that 'not everything that counts can be counted'. Will the costs, and/or the benefits, include only those that emerge in the short-term and for some stakeholders, or would they include long-term consequences for any and all stakeholders? Will they be only direct costs and benefits or will the scope also extend to indirect costs and benefits? Unless and until those issues are clarified, the meaning of EFSA's proposal to conduct 'cost/benefit' analyses will be opaque rather than transparent, and its legitimacy and adequacy will be compromised. The Open Options table on page 14 in Section 5 contains many welcome elements, but in several respects it remains too enigmatic. For example, in row 4 of Scientific Decision Making Workflow, the text says that: "The risk assessment methodology is defined …" but we are not told by whom. EFSA should clarify where responsibility for making those decisions should be located. My view is that those decisions are policy matters that should properly be decided by risk managers, given their responsibility for policy-making. (see eg E Millstone, 'Can food safety policy-making be both scientifically and democratically legitimated? If so, how?', Journal of Agricultural and Environmental Ethics, 2007, Vol. 20, pp. 483-508; DOI: 10.1007/s10806-007-9045-x – copy attached) When making those decisions, risk managers should be informed by risk assessors and others on what is known, and what is uncertain, about the consequences of adoption, or failing to adopt, a range of alternative methodologies. Responsibility for selecting risk assessment methodologies should not lie with the risk assessors themselves, as those decisions have policy dimensions that scientific considerations alone cannot settle. In row 3 of the Open Options table on page 14 in Section 5, in the column headed CRITICAL SUCCESS FACTORS, the text says that what will be needed will include: "Reassurance that the selection process reflects expertise needed to address [the]	borne by EFSA as a whole, including its governance bodies. The concept is further defined in the Implementation plan. Class 1 EFSA has been consistently implementing the risk analysis process as defined in EFSA's Founding Regulation, including the functional and structural separation between risk assessment and risk management. Class 7 Row 3 – Regarding the comment on the absence of conflicts of interest and bias, EFSA has a robust system in place to safeguard the impartiality of its scientific work. Over the years, it has put in place a comprehensive and sophisticated system to ensure its independence, and it is committed to reviewing its policies and procedures to ensure they remain fit for purpose. In this context, avoidance of potential conflicts of interest represents only one, important part of EFSA's Policy. Class 6 EFSA has put in place, and further develops, one of the most stringent frameworks for the prevention of conflicts of interests (CoI) among Union institutions, bodies and agencies. This has been recognised by external audits. The Authority also intends to review its Policy on the independence of its

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			mandate and that selection process is objective and unbiased." But what will be no less critical than an unbiased selection process will be the selection of advisers who themselves are unbiased and who are not characterised by any conflicts of interest. That vital requirement should be explicitly acknowledged. In row 4 of CRITICAL SUCCESS FACTORS, the text says that what will be needed will include: "Methodology/data/information meets EFSA's and international standards…" My view is that such standards as may be in use internationally are often neither transparent nor legitimate, and therefore EFSA should aspire to operate in ways that exceed prevailing international standards, and indeed that will raise the benchmark by reference to which international standards could then be improved. (ef E Millstone 'Science, risk and governance: radical rhetorics and the realities of reform', Research Policy, Vol 38, No 4, May 2009, pp 624-636, doi:10.1016/j.respol.2009.01.012 – copy attached) In row 5 of CRITICAL SUCCESS FACTORS, the text calls for: "Substantiation/traceability of decisions…" That is a welcome commitment, and it would constitute a substantial improvement on the status quo ante. In row 1 of the column headed POLICY OPTIONS, the text refers to 'public consultation'. Amongst the issues on which public consultation will be required, if EFSA is to achieve and reconcile both scientific and democratic legitimacy, will be public consultation on issues of 'risk assessment policy'. Those deliberations need, amongst other things, to comply fully with the commitments made by the EU at the Codex Alimentarius Commission meeting in Rome in 2007, in relation to risk assessment policy. (See Codex Committee of General Principles, Proposed Draft Working Principles for Risk Analysis for Food Safety for Application by Governments, Appendix VIII, paras. 16-19, p. 62, available 1 Sept 2014 as http://www.codexalimentarius.net/download/report/681/al30_33e.pdf) In row 5 of the column headed POLICY OPTIONS, the text refers to the proactive release of information both 'used' and 'not used' in a readable format. Those provisions are very welcome, and constitute significant progress on EFSA's part and a marked improvement on the status quo ante. For example I submitted a substantial dossier of evidence to the ANS panel in relation to its review of aspartame, but the materials that the panel chose not to discuss have not been acknowledged or made publically available by EFSA. The same cell also refers to 'public meetings', 'public consultations on draft opinions', 'technical hearings' and	scientific decision-making processes with a view to fully reflect in it the opportunities for enhanced transparency and engagement that will result from the "Open EFSA" project. These comments will therefore feed into this process as well. Class 2 Row 4 – It is a fact that, in some areas, EFSA has to take due account of international standards before issuing its own advice and scientific outputs on the matter. Class 6 Row 1 of Policy options – As clarified above, EFSA considers that international standards should be duly considered by the Authority when developing its outputs, without prejudice to the fact that it is not legally bound by them, and that it may depart from the conclusions they reach for duly scientifically justified reasons. Class 6 Row 5 of Policy options – This option will be subject to a further categorisation and prioritisation, to be performed according to the Implementation plan, before any firm decision is taken on its implementation. EFSA contests that the meetings it organises with Member States, stakeholders, other institutional partners and members of academia are mere formalities, and it underlines that they are key in

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			'consultative meetings with Member States'. The text however fails to acknowledge the importance of EFSA providing adequate and comprehensive responses to those meetings and consultations. Those will be indispensable if the procedures are to be authentically open rather than wasteful procedural rituals. Would you identify any other strategic drivers, contextual elements or policy options for the Authority to consider when implementing its vision of becoming an Open EFSA? EFSA need to aspire to, and actively pursue arrangements of its affairs, and for its interactions with DG-SANCO, the European Parliament and its committees, the Council of Ministers and the administrations of EU Member States, that provide for accountability of food safety policy-making. Those arrangements should be sufficient to achieve and to reconcile scientific and democratic legitimacy.	contributing to the scientific completeness of EFSA's outputs. EFSA commits to perform further categorisation and prioritisation regarding the possibility to organise systematic pre-public consultation meetings with Member States. Class 2. The recommendation to actively interact with its partner DG at the Commission, the Parliament, the Council and the Member States' NCAs is addressed on a daily basis in the context of EFSA's operations. Class 6
180.	Association Française des Biotechnologies Végétales (AFBV) (France)	6.Open EFSA: the way ahead	Question 5 comment: In its transition towards a more open EFSA, EFSA must maintain its regulatory role and its supreme scientifique expertise, for Europe, and for all countries of the world who wish to hear and utilize its assessments/opinions/recommendations. It must be able to continue to recruit and rely upon true scientific experts and avoid blocking situations initiated by parties having an ideological orientation and who do not contribute to facilitating the daily work of EFSA.	Noted. Class 1
181.	InQpharm Europe Ltd. (Germany)	6.Open EFSA: the way ahead	In summary, we welcome that health claims are regulated in Europe, however we see shortcomings in the transparency of the process, communication with the applicants and lack of consistent scientific guidance to the applicants. We sincerely hope, that through the "Open EFSA Initiavite" these shortcomings will be addressed soon, to foster healthy innovation for European consumers. Best regards, Matthias Miller, InQpharm Europe Ltd	To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7.
182.	ClientEarth (Belgium)	6.Open EFSA: the way ahead	It should be stressed that certain actions are more urgent than others. In particular, it is crucial that EFSA focuses on increasing its transparency activities with the goal of giving confidence that it is an independent agency. Independence, as much as transparency and openness, is stated as a core value of EFSA. Thus, it should avoid, as much as possible, working with experts that have conflict of interests; and, when conflicts of interest are unavoidable, they should be clearly highlighted and explained. Further efforts should be made in highlighting the source of funding in the studies and information used in the scientific outputs.	EFSA underlines that it implements, and further develops, one of the most stringent frameworks for the prevention of CoIs among EU institutions, bodies and agencies. EFSA's Policy and rules on Declarations of Interests set out criteria for the screening for and

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			Further, EFSA should focus on increasing the reproducibility of its own scientific inputs, allowing scientists to access raw data, and understand the process leading to a specific outcome. Reproducibility would increase EFSA's accountability and lead to excellence in its scientific outputs.	prevention of conflicts of interest; these criteria are pre-determined in a transparent manner. The outcome of the screening is recorded in the minutes of the relevant meetings as well as in the final outputs. Class 7 The Authority also intends to review its Policy on the independence of its scientific decision-making processes with a view to fully reflect in it the opportunities for enhanced transparency and engagement that will result from the "Open EFSA" project. These comments will therefore feed into this process as well. Class 6 EFSA is committed to assessing the possibility of making its scientific assessments reproducible by others. It is in this context that EFSA commits to a further categorisation and prioritisation to be performed according to the Implementation plan on whether it would be appropriate or feasible to institutionalise a practice of providing free access to the data used or discarded in safety studies and risk assessments in a readable/reusable form. Class 2
183.	DANONE (France)	6. Open EFSA: the way ahead	Are there any lessons we can extract from the functioning of the European Medicines Agency that can benefit transparency or any of the above objectives? DANONE believes that 2016 as an estimate date for rolling out necessary actions to improve two-way interaction between EFSA's panels and interested parties is probably a long time. Several of the above suggestions can be implemented with relatively little effort and resources; and provide short term solutions that are	EFSA acknowledges that the path towards the implementation of an Open EFSA needs to be structured and considers this as a necessary intermediate step to move forward the development of the proper policy. Class 6

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			urgently needed for certain food categories. We propose to implement pilot projects to test efficiency of the suggested policy option of pre-submission consultations with the probiotics industry.	EFSA commits to carry out a further categorisation and prioritisation regarding the possibility to organise pre-submission meetings with applicants in the area of regulated products. Class 2
184.	SYNADIET (France)	6. Open EFSA: the way ahead	CONCLUSION Afin de maintenir un niveau élevé d'investissements et de libérer l'Innovation, il est urgent de définir un modèle de Recherche et Développement spécifique au complément alimentaire qui ne soit pas la simple transposition d'un modèle de l'industrie pharmaceutique. Contrairement aux médicaments, les denrées alimentaires ne présentent pas d'effets indésirables et la population à laquelle elles sont destinées n'est pas malade. Il serait donc nécessaire, pour cela, de retenir 4 priorités : - Établir un dialogue avec les experts de l'EFSA - Juger de l'efficacité d'un produit alimentaire sur plusieurs critères - Démontrer l'effet sans nécessairement avoir à l'expliciter - Allonger la durée de protection des données à 10 ans.	The ultimate goals of maintaining a high level of investment, freeing up innovation or remodelling R&D policies fall outside EFSA's remit. Class 6
185.	PFP-Association for the European primary food processing industry (Belgium)	6. Open EFSA: the way ahead	5. Would you identify any other strategic drivers, contextual elements or policy options for the Authority to consider when implementing its vision of becoming an Open EFSA? Opening EFSA is an important step forward, but it should not hamper its primary role in delivering risk assessments to the European Commission either on regulated products or following a mandate. Any steps taken should always consider the cost-benefit of providing information, in order to further demonstrate EFSA role in delivering scientific risk-based assessments.	Noted. Class 2
186.	AVC Association of Veterinary Consultants (Ireland)	6. Open EFSA: the way ahead	AVC input under Executive Summary Line 1 1. AVC is in favour of transparency in EFSA scientific processes and appreciates the chance to provide input as an EFSA stakeholder. 2. AVC also supports the principle that science should prevail & recommends a strong focus on scientists evaluating highly technical REPRO (regulated product	1. Noted. Class 1 2. Noted, without prejudice to the attribution of tasks between EFSA staff and its scientific experts prescribed in Regulation (EC) No

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			dossiers), & fewer administrators involved in evaluation. 3. AVC supports EFSA access to all data & reports related to REPRO but is concerned that EFSA public opinions may reveal too much valuable confidential information, in violation of TRIPs, to which the EC is a signatory, & which requires protection of applicant data that are obligatory for registration purposes. AVC proposes that EFSA limits public opinions to the conclusions of safety & efficacy studies (e.g. NOAEL, safety margin, minimum effective dose). The supporting study reports should never be made available following public or competitor "PAD" requests (Reg 1049/2001, public access to documents), unless the appli cant agrees to such public dissemination. 4. AVC supports the option of communication between applicants and EFSA prior to submission of a dossier (i.e. PRE-SUBMISSION MEETINGS). 5. AVC supports the creation of an "Appeals Office within EFSA" to allow applicants to appeal on the scientific opinions issued by EFSA, to be subject to arbitration by independent experts appointed by the EU Commission/Member States. 6. AVC supports the need for the different Working Groups within EFSA to be composed scientists of recognised expertise within the required fields for an accurate evaluation of REPRO dossiers. 7. AVC supports the need for EFSA to work together with industry in order to achieve guidance and procedures fit for each purpose, so that only valid & approvable applications are received by EFSA, to be coherent with current, achievable science. 8. AVC proposes that for REPRO dossiers subjected to reauthorisation processes, the scientific opinion of EFSA should not be published until the EU Commission votes at the Standing Committee meetings, to avoid unnecessary disruption of the market for products with a long history of safe & effective use.	178/2002. Class 4 3. EFSA acknowledges the fundamental importance that regulatory data protection and protection of commercially relevant information has for the concerned sectors in order to be competitive on a global scale. For this reason, in 2014 it has substantially strengthened its approach to protecting commercially sensitive information recognised to be worth of confidential processing, by developing internal procedures to streamline its internal decision-making process for confidentiality claims. EFSA has already undertaken or planned the necessary actions to ensure consistent decision-making processes regarding this matter and to review its current rules on access to documents, to take stock of the developments in the applicable legal framework and case law. Classes 1 and 7 4., 7. To increase direct dialogue between EFSA and applicants, the Authority has put in place a number of services for applicants and interested parties, which are part of its catalogue of services. Class 7. 5. EFSA is already subject to provisions obliging it to review its adopted outputs once relevant

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				scientific data or information undermining previously adopted conclusions are/is identified. Class 7. EFSA commits to perform further categorisation and prioritisation regarding the possibility that it makes publicly available all documents linked to a decision on whether to update an output or not. Class. 2. EFSA, however, considers that the establishment of an internal Appeal Office would not be compatible with the applicable legal framework. Class 5 6. Noted. Class 6 8. The unilateral implementation of the suggestion that EFSA delays the publication of its opinion until a decision is taken by the Commission would be in breach of Article 38 of EFSA's Founding Regulation. Class 5
187.	GAP's chair on behalf of GAP, IPA and YLFA (Belgium)	6. Open EFSA: the way ahead	Are there any lessons we can extract from the functioning of the European Medicines Agency that can benefit transparency or any of the above objectives? The probiotic sector believes that 2016 as an estimate date for rolling out necessary actions to improve two-way interaction between EFSA's panels and interested parties is too late. Several of the above suggestions can be implemented with relatively little effort and resources; and provide short term solutions that are urgently needed for certain food categories. The probiotic industry proposes to implement pilot projects to test efficiency of the suggested policy option of pre-submission consultations with the probiotics industry.	EFSA acknowledges that the path towards the implementation of an Open EFSA needs to be structured and considers this as a necessary intermediate step to move forward the development of the proper policy. Class 6 EFSA commits to carry out further categorisation and prioritisation regarding the possibility to organise

No	Contributor	Chapter	Comments received	EFSA response
				pre-submission meetings with applicants in the area of regulated products. Class 2
188.	London School of Economics (UK)	6. Open EFSA: the way ahead	Open EFSA The distinguished paper sets out a laudable plan. Transparency and openness are both an end in themselves (good governance) and a means to various ends (building trust and confidence in stakeholders). However, it is difficult to comment intelligently on the pros and cons of different options without some idea as to the cost involved. On the face of it, the costs will not be inconsequential. One wonders whether the Discussion Paper may raise expectations that are simply not deliverable. That said, I do recognise that it is intended to ensure efficient use of funds with cost/benefit analyses. 1. Lessons from elsewhere When then Human Genetics Committee and the Food Standards Agency were set up in the UK under the Blair government in the late 1990s, the HGC opted, against the advice of the civil service, for open meetings and transparency. Anecdotal evidence suggests that this has contributed to confidence and trust amongst stakeholders, including the media, and the public. In the US the publ ic are often engaged in the policy developments of the FDA through public hearings and invitations to submit 'evidence and opinions'. When a decision is taken there is an obligation to respond to 'critical voices' in the Congressional Record. What this does, I would argue, is not only to give a ' voice' to any interested party but also, crucially, to show that the 'voice' has been heard and given consideration. My point from the two above examples is that relatively simple tried and tested methods should not be overlooked. One should not let perfection be the enemy of the good. And over time the good can always be improved with experience.	EFSA is keen to learn from examples taken from the experience gained in comparable bodies. The examples mentioned appear to support EFSA's case. Class 1
189.	Individual contribution, (UK), Science and Technology Policy Research, University of Sussex	6. Open EFSA: the way ahead	In Section 6 at the bottom of page 15 the text refers to "…benefits from concrete gains resulting from activities financed through the EU budget…" One key set of considerations that must be included in changes deemed in that context as 'benefits' must be safer food, healthier diets and enhanced consumer protection. One consideration, conspicuous by its absence throughout this document, is the lack of any acknowledgement that science alone cannot ever decide policy issues, and therefore that the only scientifically and democratically legitimate form of advice that EFSA should provide to DG-SANCO (and to EU Member States) should be plural and conditional advice that indicates what is known and not known about the consequences of following or failing to follow a range of available policy	By law, EFSA's scientific opinions reflect the views of the members of the responsible Scientific Panel. Pursuant to Article 38 of EFSA's Founding Regulation, minority opinions are published together with the opinion adopted by the majority of members of the competent Panel, whenever they are expressed and motivated. Classes 4 and 6

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			options. The only conditions under which it would be appropriate for EFSA to provide DGSANCO with monolithic and prescriptive advice, recommending singular specific policy decisions, would be if the normative goals and assumptions required for policy-making had been comprehensively and transparently articulated by DGSANCO. Otherwise only plural and conditional advice could contribute to legitimacy.	Since 2006, when its Scientific Committee adopted the first scientific opinion on transparency in risk assessment, EFSA has acknowledged the need for, and continuously works towards, strengthening the level of transparency, and clarifying remaining uncertainties and underlying assumptions in its opinions. Class 6 However, under the current legal framework, EFSA's powers remain limited to the provision of scientific evaluation, with no pretence to "ever decide policy issues". Comments on the democratic legitimisation of scientific advice go beyond EFSA's remit. Class 5

Glossary and Abbreviations

1-2-1 meetings	Meetings where the Authority meets with one interested party each time
Authority and EFSA	European Food Safety Authority
BfR	*Bundesinstitut für Risikobewertung* (Federal Institute for Risk Assessment)
Commission	European Commission
DG SANCO	Directorate General Health and Consumers of the European Commission (as of 1 January 2015, DG SANTE)
EFSA	European Food Safety Authority
EFSA's Founding Regulation	Regulation (EC) No 178/2002 of the European parliament and of the Council of 28 January2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 031, 1.2.2002
EMA	European Medicines Agency
FDA	US Food and Drugs Administration
HGC	Human Genetics Committee
Nutrition and Health Claims Regulation	Corrigendum to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, L12/3 of 18.1.2007.
OP	Open government Partnership
Q&A	Questions and Answers
ReNEUAL	Research Network on EU Administrative Law
REPRO	EFSA's Department responsible for the Scientific Evaluation of Regulated Products
UK	United Kingdom of Great Britain and Northern Ireland
US	United States of America