

## Update on the Transparency and Engagement in Risk Assessment (TERA) Project



*Management Board, 3 December 2015*



### **Note to the Management Board**

The present document aims at informing the EFSA Management Board on the overall progress of the TERA project. In particular, it provides an update on the implementation of a number of measures, including an update on EFSA's proposed new approach for stakeholder engagement that was discussed at the Management Board meeting on 1<sup>st</sup> October 2015.

Finally, in Annex 3 an update on the Impact Assessment study that will allow EFSA to take informed decisions regarding the implementation of further measures is also provided.

## **Introduction**

Following a wide-ranging consultation, in March 2015 EFSA presented the *"Implementation Plan – First Phase Transformation to an Open EFSA"* to its Management Board. The plan anticipated the introduction of several "measures" for enhancing transparency and engagement in EFSA's risk assessment workflow, through a tiered approach:

- Measures already planned or underway in EFSA's portfolio as part of the continuous improvement of its processes and that are implementable by 2017 ("Category 1 - C1 measures");
- Measures that might significantly change the nature of one or more steps of the risk assessment workflow and/or that might have a high impact on EFSA's resources ("Category 2 - C2 measures").

At the June 2015 Management Board meeting, EFSA clarified the evolution from "Open EFSA" to the current Transparency and Engagement in Risk Assessment (TERA) project, coordinating the gradual implementation of the above mentioned measures. EFSA also committed to present a report on the overall progress of the project implementation to the Management Board in December 2015.

Meanwhile, the EFSA Strategy 2020 has taken significant steps towards completion, confirming and further emphasising the importance of the TERA project and of enabling societal actors to access and interact in EFSA's risk assessment cycle.

### **1. Measure implementation update**

EFSA has committed to implement, by end of 2017, a set of measures that are part of the continuous improvement of EFSA's processes and are already planned through its portfolio of projects and programmes (C1 measures).

During 2015, EFSA has implemented six measures belonging to the C1 category (=50%) that are currently fully deployed in EFSA's Risk Assessment workflow. These measures and their features are described in Annex 1 (table 1).

The remaining six C1 measures will be included in the 2016 and 2017 Annual Management Plans and they will be delivered within the deadlines agreed at the Management Board meeting in March 2015.

In addition, along with the development of the EFSA 2020 Strategy, enhanced tools and platforms are being made available and will allow further "automating" of the measures so far implemented, hence decrease the costs related to their introduction in the risk assessment cycle and/or increase their effectiveness and impact. Two concrete developments follow:

The Talent Management project (within the Expertise Programme) among its deliverables will allow EFSA's experts to deliver their curricula information from existing networking platforms (e.g. LinkedIn, ResearchGate) to EFSA's website ensuring automatic updates as well as further enhance and systemise the administration of the information related to the Panel/WG expert selection.

Pre-notification of upcoming public consultations (today performed manually) will be possible through the Technology roadmap's deployment and introduction of the Identity & Access Management (IAM) platform, allowing extraction of the information directly from EFSA's Register of Questions and its publishing on the EFSA website.

### **1.1 Case study on measure implementation: Open Plenary Meetings (measure 5.1)**

- In 2014, a number of national and international organisations, including bodies in third countries, as well as sister agencies were approached to see if they had any formalised procedures for allowing Observers to attend their scientific meetings. This exercise underlined that, together with the UK FSA, EFSA is a frontrunner in opening up scientific meetings to the public.
- In 2015, following a preliminary cost assessment analysis, open plenary meetings were moved from Parma to Brussels in an effort to make these more accessible to NGOs. The possibility to extend the duration of open plenary meetings by half a day was also integrated to give more room for questions and interventions from attending Observers.
- While both registered and attending Observers have overall increased in 2015, the share of NGOs representation was not significantly altered by moving the meetings in Brussels. With respect to the half-day extension it was reported that even with increased interaction with Observers there was no need for an additional half day meeting. An overview on attendance per year and per Panel, and on affiliation is presented in Annex 2.
- By the end of 2016 over 15 open plenary meetings in Brussels, will have been conducted.

### **2. Measures used ad-hoc or piloted**

Thirty-five per cent (35%) of the remaining measures are currently being piloted or used on an ad hoc basis by EFSA. This is providing valuable information for both for the Impact Assessment study and to complete the implementation of the remaining C1 measures.

The Impact Assessment study has also been launched in September and will provide EFSA with the methodological approach to evaluate and weigh up the expected costs, benefits and effectiveness of implementing the remaining measures. The results of this study will allow an informed decision regarding their possible inclusion in EFSA's upcoming annual work plans.

A final decision on the extent of all remaining measures implementation is envisaged following the conclusion of the Impact Assessment study.

The measures used ad-hoc or piloted in 2015 and their features are described in Annex 1 (table 2).

### **2.1 Case study on measures used ad-hoc or piloted: Promoting Evidence Use in Scientific Assessments, PROMETHEUS (measures 4.4, 4.12, 6.2)**

- The PROMETHEUS project kicked off in 2014, addressing the EFSA Science Strategy 2012-2016 recommendations:

- Developing and harmonising methodologies to assess risks in the food chain;
- Further developing excellence of EFSA scientific advice;
- Ensuring that EFSA's advice is fit for purpose;
- Increasing trust in EFSA.

- In its first deliverable (June 2015), PROMETHEUS established the principles for dealing with evidence (i.e. impartiality, excellence in scientific assessments, responsiveness, transparency and openness) and described how the process for data collection, appraisal and integration could be carried out to fulfil those principles (i.e. plan, conduct, verify and document).
- The PROMETHEUS process was successfully piloted during 2015 in the ANS Panel opinion on isoflavones<sup>1</sup>. The WG produced a Protocol for the opinion upfront, before starting the formal data collection, analysis and synthesis. The Protocol clearly specified the objectives of the assessment, what data would be collected and how (eligibility criteria for data selection) and the method to be applied for appraising and synthesising the evidence.
- The Protocol was revised by the Panel and approved by the requestor, before being finalised. The entire process, methods and results were thoroughly documented (e.g. search processes, excluded studies and grounds for exclusion, appraisal of each individual studies, etc.).
- The final opinion was published along with the Protocol and the list of excluded studies. This case study was a successful example of how the principles of impartiality, transparency and openness, excellence and responsiveness can be fulfilled by applying the plan/conduct/verify/document process promoted in Prometheus.
- Currently PROMETHUS approach is being tested in a more complex risk assessment from the CONTAM Panel (Dioxins).

### **3. Update: Engagement outreach**

Ensuring that EFSA relies on an approach for stakeholder engagement which enables interested parties and stakeholders to contribute more widely to the Agency's risk assessment process will ensure trust and excellence in EFSA's work. To this end, EFSA is developing a new stakeholder engagement approach<sup>2</sup> which provides appropriate mechanisms for this interaction.

In July 2015, EFSA commissioned qualitative research work with a range of stakeholders, wider than those with whom the Authority has historically been engaging with or who lie outside current engagement mechanisms, to identify the strengths and weaknesses of its current approach and to better understand the views of stakeholders on best ways for engagement.

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<sup>1</sup> Risk assessment for peri- and post-menopausal women taking food supplements containing isolated isoflavones; <http://www.efsa.europa.eu/en/efsajournal/pub/4246>.

<sup>2</sup> In March 2015, the EFSA Management Board extended by one year the mandate of the current Stakeholder Platform to give time to the Authority to reflect together with its stakeholders and interested parties on how to best adapt EFSA's current approach to stakeholder engagement to be in line with the innovative "Open Risk Assessment" approach and reflect those societal and regulatory changes which have been taken place since 2005, when the Platform was created.

The project foresees an analysis of key demands resulting from all EFSA's stakeholder surveys and in-depth interviews with selected stakeholders.

Indications received so far highlight that:

1. EFSA's engagement so far has been predominantly related to two key themes – the service it provides to applicants, and promoting external involvement in and feedback on EFSA's policies (on independence and transparency in particular). The established stakeholder engagement patterns - the APDESK user surveys, public consultations, Stakeholder Consultative Platform, alongside conferences with stakeholders tied to it - attract and retain established stakeholders but do not address the needs of those not involved in such activities, particularly organisations that are critical of EFSA's work.
2. Consider re-mapping EFSA's stakeholders, and segment within more engaged stakeholder groups to identify sections of these audiences who are less engaged with EFSA e.g. scientists.
3. Understand differences among the civil society/NGO audience more deeply.
4. Continue to engage with all stakeholders on both policy and pre- and post-market risk assessment and risk communication activities, but prioritise engagement in the risk assessment process.
5. Broaden engagement with academia and NGOs by considering new engagement models tailored to the needs of these stakeholders.

EFSA is currently benchmarking its stakeholder engagement approaches against best practises in EU and International bodies. In particular:

1. A workshop with the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) to exchange views on stakeholder relations, engagement with society and communications (Sept. 2015).
2. Guest scientist scheme:
  - a. EFSA's contributed to the development of the Stakeholders strategy for the Norwegian Food Safety Agency (VNM) – one-week staff exchange (Jan. 2015).
  - b. VNM contributed to the building of EFSA's stakeholder engagement approach – two-week staff exchange (Nov. 2015).

Feedback received from the EFSA Stakeholder Consultative Platform is also informing work in this area, in particular: break-out group discussions at the March 2015's Platform meeting, suggestions on the enhancement of the contribution of the Platform discussed at their June 2015's meeting and proposals on the role of the Platform in the new approach at their November 2015's meeting.

#### **4. Next steps**

As of May 2016, the Impact Assessment study outcome will allow an informed decision to be taken on the implementation of C2 measures and related implementation timelines.

In June 2016, the Management Board will be updated with regards to the progress of the implementation of the remaining C1 measures since December 2015 and a proposal on the way forward with regards to the C2 measures implementation.

As of March 2016, the work of the outreach package will inform the new Stakeholder Engagement Approach which will be presented to the Board. Following the discussion at the Board, EFSA will start working on the implementation plan of the new approach.

**Annex 1**
**Table 1 - C1measures implemented in the Risk Assessment workflow<sup>3</sup>**

<b>Step in the R.A.</b>	<b>Measure description</b>	<b>Core expected outcome (scope)</b>	<b>Features introduced</b>
<b>1. Define the mandate</b>	1.2 Simplification of requirements to take active role in public consultations	Ensure contribution of stakeholders in public consultation (All public consultations by EFSA)	Since March 2015 EFSA has enhanced its Public Consultation process allowing the submission of additional information (or entire files) to support the comments provided to the consulted document. To this purpose, a dedicated mailbox is now established and monitored together with the launching of each public consultation. A mailbox is created specifically for each consultation then closed immediately thereafter.
	1.3 Pre-notify interested parties of forthcoming public consultation	Ensure regular and ahead-of-time information to stakeholders (All public consultations by EFSA)	In June 2015 the list of planned upcoming consultations was first presented to the Stakeholder Consultative Platform.  Since November, the calendar of upcoming Consultations is available on EFSA's website, indicating the subject of the consultation and the consultation timeframe (i.e. launch/closing dates). The calendar will be updated each quarter.

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<sup>3</sup> For the full list of 35 measures please refer to: <http://www.efsa.europa.eu/sites/default/files/assets/150319-ax5.pdf>

<b>2. Define expertise</b>	2.1 Publish full biographies	Ability of public to scrutinise experts backgrounds (Experts working with EFSA)	<p>In June 2014, following the renewal of the ANS and CEF Panels, the expert biography was replaced by a comprehensive Curriculum Vitae including an overview of academic qualifications and, additionally, the most relevant scientific publications within the remit of the Panel, and a record of all previous employment. The CVs were made available on EFSA's website.</p> <p>In June 2015, following the eight Panels and Scientific Committee renewal, this was extended to all EFSA Scientific Committee and Panel Members.</p>
	2.2 Documentation of the criteria of selection of Working Group (WG) members	Auditability of expert selection process (Experts working with EFSA)	<p>Following the 2015 renewal of EFSA's Scientific Committee and eight Scientific Panels, the Terms of Reference of each WG are made available on the website.</p> <p>The selection procedure, including the criteria considered in selecting external experts for WGs were re-defined under Title II of the revised ED Decision on selection of experts (August 2015) and detailed in a Standard Operating Procedure (SOP) (September 2015), introducing the search and identification for external WGs expert, while reinforcing the documentation and record keeping requirements of each major step in the process, from the identification of the experts to the appointment of rapporteurs.</p>
<b>4. Prepare draft advice</b>	4.11 Consistent decision making on confidentiality of application dossiers	Ensure legal certainty (Applications dossiers)	A standardised procedure on confidentiality has been endorsed, harmonising the way EFSA processes, assesses and decides on confidentiality claims filed by applicants in areas under its responsibility. Final harmonisation was achieved with the provision of working instructions and awareness-raising sessions with respect to both the administrative and legal aspects of the procedures.
<b>5. Discuss &amp; adopt advice</b>	5.1 Open Panel plenary meetings extended by half a day/year/panel	Increased public engagement (Open Panel plenary meetings)	<p>In 2015, the meeting format was extended to allow for exchange of views between experts and observers and holding meetings in Brussels was piloted for four Panels and the Scientific Committee.</p> <p>In 2016, all the Panels and the Scientific Committee will hold open plenary meetings in Brussels, with the possibility to extend the meeting of half a day.</p>

**Table 2 TERA measures used ad hoc or piloted in the Risk Assessment workflow<sup>4</sup>**

Step in the R.A.	Measure description	Core expected outcome (scope)	Features introduced	Implementation (* = decision date, following result of Impact Assessment study)
3. Define R.A. methodologies	3.2 Open and/or targeted call for data/information	Widen EFSA's evidence base (Scientific outputs)	Calls for data during the risk assessment process are carried out at EFSA on an ad-hoc basis (n=8 in 2015). For example, EFSA collects on a continuous basis analytical results for chemical contaminants and residues in food and feed included in monitoring and control programmes. Member States, research institutions, industry, academia and any other stakeholders are invited to submit data on the presence of these substances. Data can be transmitted using the EFSA web interface "Data Collection Framework" (DCF) made available by EFSA. Data submitted are included in the EFSA data warehouse (DWH) and used in future EFSA scientific opinions and reports.	Q2 2016
	3.3 Consultation on the call for data/Information format	Clarity on requested data (Calls for data/information)	Measure tested on an ad-hoc basis, e.g. within the context of the food additive re-evaluation programme. To facilitate the collection of data on food additive usage from stakeholders, a tailored template to allow the submission of food additive usage data to EFSA was created. Stakeholders were consulted on the development of the template and their comments were incorporated during its development.	Q2 2016*

<sup>4</sup> For the full list of 35 measures please refer to: <http://www.efsa.europa.eu/sites/default/files/assets/150319-ax5.pdf>

<b>4. Prepare draft advice</b>	4.2 Proactive release of data/information in a readable/reusable format	Empower the public to scrutinise EFSA work (Information linked to the RA, except commercially sensitive one)	Since 2015 EFSA's data warehouse's database (DWH) is gradually being opened and different type of information are now going to be available at different level of granularity according to the access rules of the DWH. By the end of 2015 EFSA will have extended the opening of its DWH by granting access to about 150 organizations to test the enlarged access.	Q2 2016*
	4.3 Increased accessibility to key data packages of Member States	Build knowledge community (Member States data)	In 2015 a pilot 'user community' was established whereby Member States have a significantly extended access (with respect to the default proposed access rules of the DWH) to each other's raw data under defined conditions of a 'Circle of Trust' pilot.	Q2 2016*
	4.4 More feedback on the extent and on the reasons why certain data were/were not used	Empower the public to scrutinise EFSA's work (Scientific outputs)	<p>The Promoting Methods for Evidence Use in Scientific assessments (PROMETHEUS) project requires that selection criteria applied and data included/excluded from the assessment, along with the reasons for exclusion are documented in the opinion. When reporting the conclusions of the assessment, recalling the selection criteria with clear indication of whether the excluded evidence might have changed the conclusions is also required.</p> <p>In September 2015, EFSA concluded a first pilot on the application of PROMETHEUS on its recent Isoflavones opinion and a second pilot is now underway on an upcoming opinion on Dioxins.</p> <p>In 2016 EFSA PROMETHEUS will be piloted in four opinions from the RASA Department and four opinions from the REPRO Department.</p>	Q4 2016

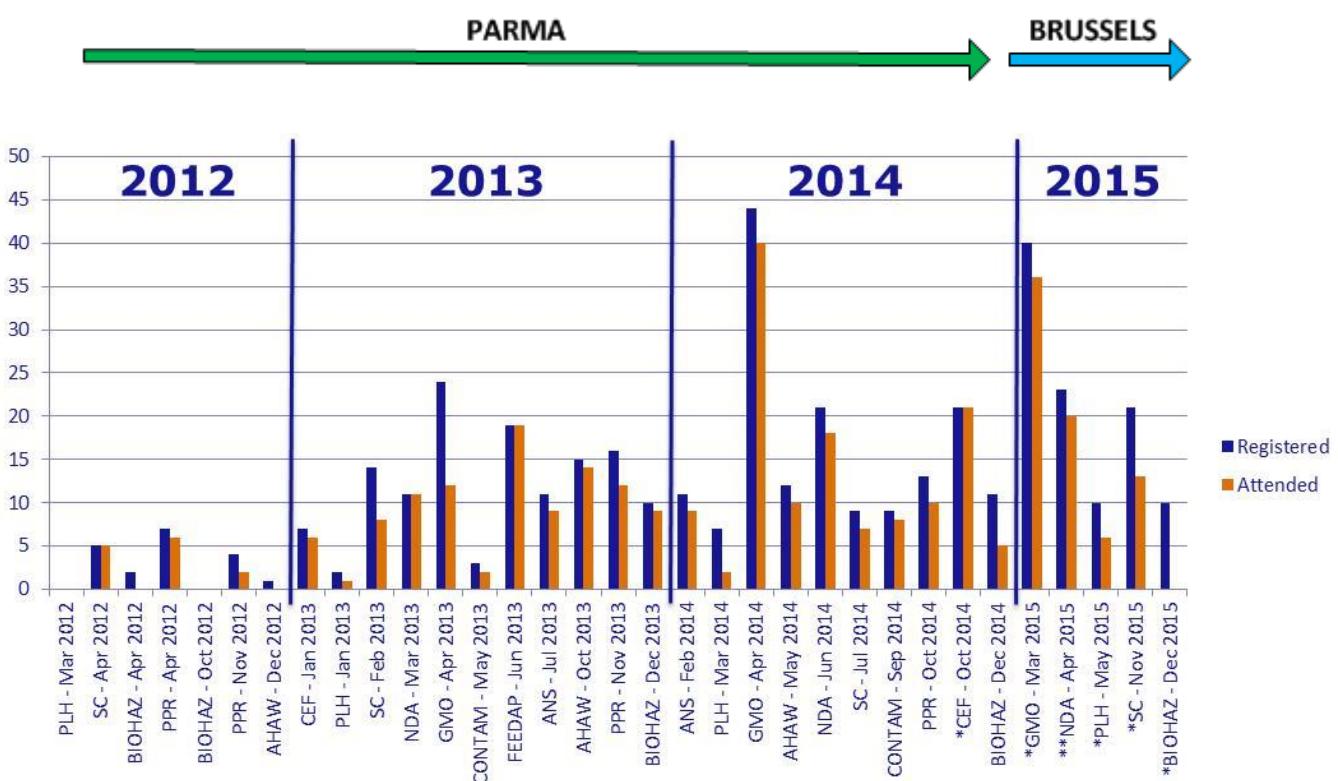
<b>4. Prepare draft advice</b>	4.6 Public consultation on draft opinions	Improve scientific quality and ownership (Scientific outputs, except application assessments)	Consultations are regularly carried out on draft opinions on an ad-hoc basis (20% of opinions/guidances adopted in 2015). In addition consultation are systematically now carried out for the development of all guidances. The exercise has been further piloted for consulting a first time on the outline of some opinions and at later stage on a draft opinion before its finalisation. For example, EFSA consulted on a discussion paper on the guidance revision on the scientific requirements for gut and immune function health claims, i.e. before drafting the guidance document. This was followed by a second consultation on the draft guidance concluded in February 2015.	Q2 2016*
	4.10 Increase transparency of the weight of evidence approach	Harmonised way of evidence integration (Scientific outputs)	In March 2015, the Scientific Committee kicked off the development of a new guidance document on the weight of evidence approach in risk assessment. The working group is currently developing qualitative and quantitative methods and testing their use through case studies for each area under EFSA's remit. A global framework using tiered approaches is currently being developed and tested on chemicals characterised by varying degree of available evidence (e.g. contaminants).	Q4 2016
	4.12 Transparency on the criteria used to identify key studies	Empower the public to scrutinise EFSA work (Scientific outputs)	<p>This measure is being implemented under the scope of Promoting Methods for Evidence Use in Scientific assessments (PROMETHEUS).</p> <p>PROMETHEUS requires that criteria applied to identify studies are documented in the opinion. When reporting the conclusions of the assessment, recalling the criteria is also required.</p> <p>In September 2015, EFSA concluded a first pilot on the application of PROMETHEUS to the Isoflavones opinion and a second pilot is being carried out now on an opinion on Dioxins.</p> <p>In 2016 EFSA PROMETHEUS will be piloted in four opinions from the RASA Department and four opinions from the REPRO Department.</p>	Q2 2016

<b>6. Communicate advice</b>	6.2 Publication of applied assessment methodologies	Empower the public to scrutinise EFSA work (Scientific outputs)	<p>This measure is being implemented under the scope of Promoting Methods for Evidence Use in Scientific assessments (PROMETHEUS). PROMETHEUS requires that the method to be applied for appraising and synthesising the evidence for the risk assessment process is described ex-ante in the Protocol and reported in the opinion. In September 2015, EFSA concluded a first pilot on the application of PROMETHEUS to the Isoflavones opinion and a second pilot is being carried out now on an opinion on Dioxins.</p> <p>In 2016 EFSA PROMETHEUS will be piloted in four opinions from the RASA Department and four opinions from the REPRO Department.</p>	Q2 2016*
	6.5 Structured process allowing post comments on opinions	Empower the public to scrutinise EFSA work (Scientific outputs)	EFSA is procuring a detailed study to explore the possibilities of citizen science and crowdsourcing through innovative use of IT tools. This assesses its applicability to EFSA's work, its relevance in EFSA's transformation to an Open EFSA and to assess integration with EFSA's Information Reference Architecture under preparation within the Information Management Programme.	Q2 2016*

## Annex 2 – Open Plenaries: numbers and trends in figures

By mid-November 2015, EFSA has organised 32 open plenary meetings since the initiation of this project back in March 2012, with over 400 registered and over 300 attending Observers. As shown in Figure 1., record number of Observers have registered and attended the open plenary meeting of the GMO Panel in 2014 and in 2015. The average number of Observers per open plenary meeting has increased over the years and most of the interest remains in the area of regulated products, substances and health claims (see Figure 2). In terms of affiliation, Observers representing industry, industry associations or consultancy firms with close ties to industry account for over half of the attending Observers (see Figure 3.). A third of the attending Observers come from public bodies and universities in the EU and beyond, which over the years is slowly increasing. Despite the efforts taken in 2015 by moving open plenary meetings from Parma to Brussels the attendance of NGOs and the media has not improved and remain underrepresented compared to the other sectors.

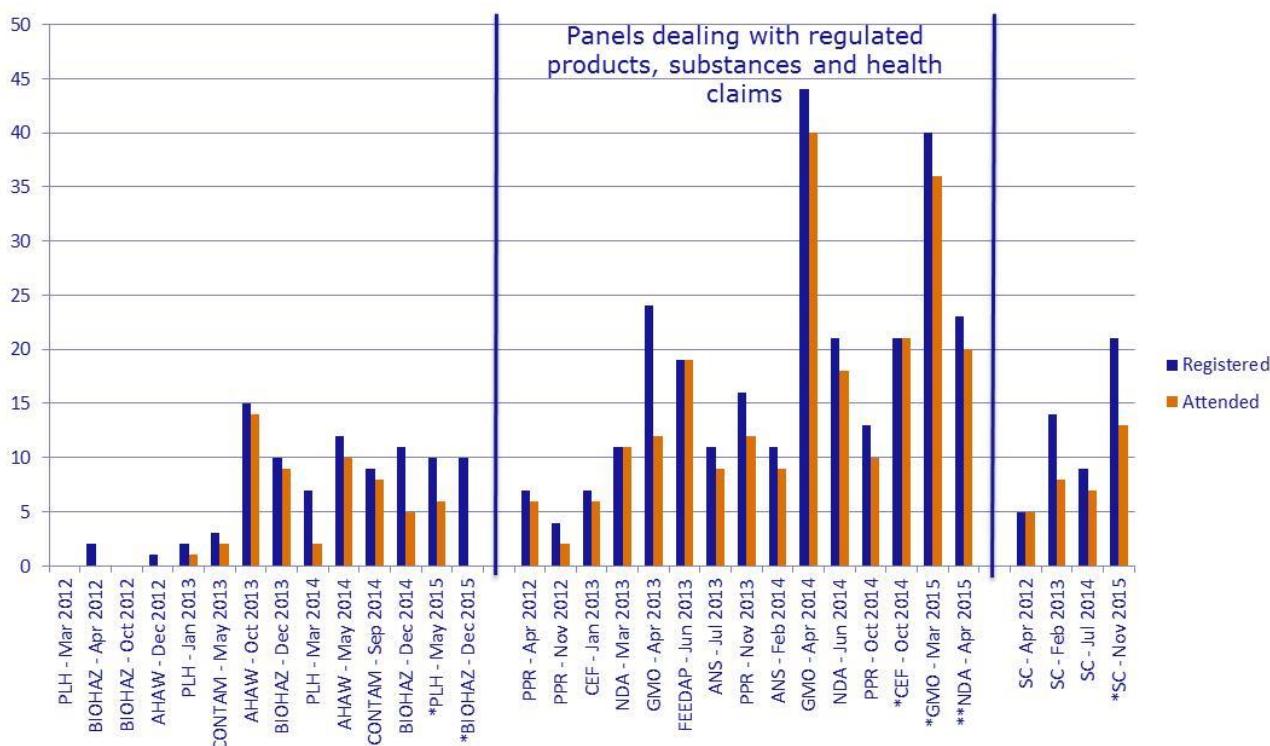
Figure 1. Number of registered and attending Observers per open plenary meeting (March 2012 – December 2015) – in chronological order



\* open plenary in Brussels

\*\* open plenary in Leuven

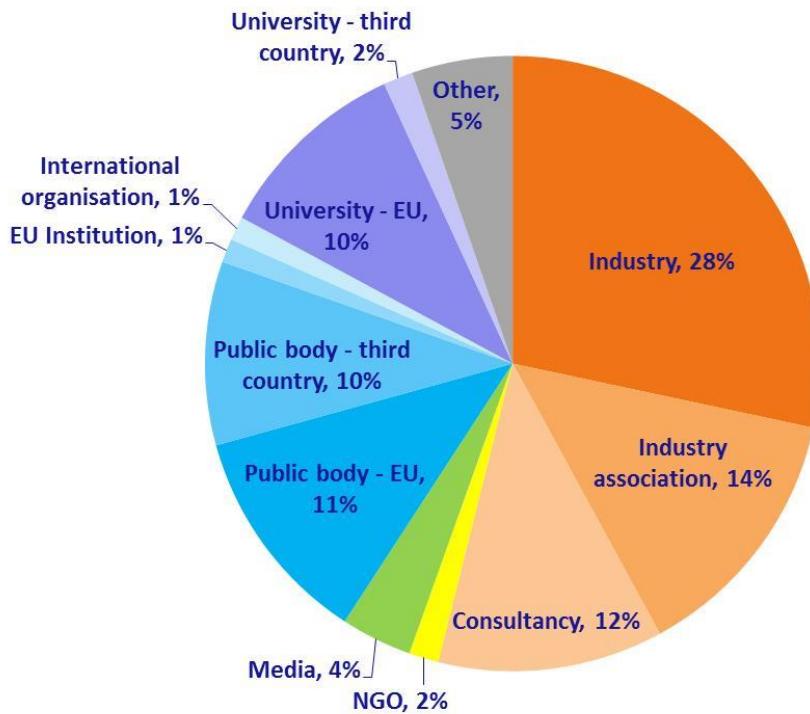
Figure 2. Number of registered and attending Observers per open plenary meeting (March 2012 – December 2015) – RASA vs. REPRO Panels in chronological order



\* open plenary in Brussels

\*\* open plenary in Leuven

Figure 3. Attending Observers by affiliation (March 2012 – December 2015), (n=321)



### Annex 3 - Methodological approach for the Impact Assessment

An Impact Assessment study is in progress to provide ex-ante information on measures implementation and in order to choose the most (positively) impactful ones.

In an in-house workshop carried out in July this year, 12 measures were selected as considered particularly challenging according to set criteria. Among these, 10 measures were prioritised to undergo a fully-fledged Impact Assessment study as a decision supporting tool for their implementation within the EFSA risk assessment workflow. The measures concerned were:

- 1.1 Public consultation of framing of mandates and questions
- 1.4 Pre-submission meetings with applicants
- 1.5 Meetings with Stakeholders
- 3.1 Consultation on the RA methodologies
- 4.10 Increase transparency of the weight of evidence approach
- 4.2 Proactive release of data/information in a readable/reusable format
- 4.5 Minutes reflecting the flow of the discussions
- 5.2 Flash summary/abstract after the plenary meeting
- 6.4 Publication of information on applications (except sensitive data) including gaps where they exist
- 6.5 Structured process allowing post comments on opinions

At the beginning of September 2015, the study was awarded to an external contractor who is developing:

1. an Impact Assessment methodology to be applied to the 35 measures
2. a preliminary impact assessment for all 35 measures
3. a fully-fledged Impact Assessment for the 10 prioritised measures

The study will make use of several methods for analysing and comparing the measures, including cost-benefit analysis, cost-effectiveness analysis and multi-criteria analysis.

Cost-benefit analysis is used to perform a financial appraisal of different initiatives and can help in judging whether or not to implement a particular measure. It is typically used where the benefits and drawbacks of a measure can be monetised. In practice, however, the return on EFSA's proposed measures are likely to be difficult to estimate – and the assumptions required to make a monetary estimate could make the estimate too uncertain, potentially obscuring other important benefits and costs.

Cost-effectiveness analysis is an alternative to cost benefit analysis, it compares the differential costs involved in achieving a given objective or outcome but also provides a measure of the relative effectiveness of different interventions at a given resource base. The method can be used to identify the preferred implementation option which is not only the least expensive one, but also one that is likely to have a greater positive impact.

Multi-criteria decision analysis is a comprehensive, structured process which can be used for selecting a measure, drawing on information about stakeholder preferences and value judgments as well as risk analysis. Multi-criteria analysis incorporates information about the expected performance of a measure with decision criteria and weightings, allowing visualisation and quantification of the trade-offs involved in the decision-making process.

The outcome of the impact assessment study is expected by May 2016 and it will be presented to the Management Board at its meeting in June 2016.