

ADVISORY FORUM AND SCIENTIFIC COOPERATION UNIT

Parma, 31 October, 2014
EFSA/AF/M/2014/PUB/FINAL

Minutes

**53RD MEETING OF THE ADVISORY FORUM
VENICE, ITALY 24-25 SEPTEMBER 2014**

Chair: Bernhard Url, Executive Director, EFSA

MEMBERS OF THE ADVISORY FORUM

Austria	<i>Klemens Fuchs</i>	Italy	<i>Giancarlo Belluzzi</i> <i>Silvio Borrello</i>
Belgium	<i>Benoît Horion</i>	Latvia	<i>Aivars Bērziņš</i>
Bulgaria	<i>Boiko Likov</i>	Lithuania	<i>Zenonas Stanevicius</i>
Croatia	<i>Andrea Gross-Boskovic</i>	Luxembourg	<i>Patrick Hau</i>
Cyprus	<i>Popi Kanari</i>	Malta	<i>Ingrid Busuttil</i>
Czech Republic	<i>Jitka Götzová</i>	Netherlands	<i>Antoon Opperhuizen</i>
Denmark	<i>Jørgen Schlundt</i>	Norway	<i>Astrid Bjerkås</i>
Estonia	<i>Martin Minjajev</i>	Portugal	<i>Maria Graça Mariano</i>
Finland	<i>Matti Aho</i>	Romania	<i>Nicursor Ciocanea</i>
France	<i>Rozenn Saunier</i>	Slovak Republic	<i>Zuzana Bīrošová</i>
Germany	<i>Andreas Hensel</i>	Slovenia	<i>Urška Blaznik</i>
Greece	<i>Eirini Tsigarida</i>	Spain	<i>Ana Canals Caballero</i>
Hungary	<i>Maria Szeitzné Szabó</i>	Sweden	<i>Leif Busk</i>
Iceland	<i>Jón Gíslason</i>	United Kingdom	<i>Penny Bramwell</i>
Ireland	<i>Raymond Ellard</i>		

OBSERVERS

FYR of Macedonia	<i>Svetlana Tomeska Mickova</i>	Switzerland	<i>Vincent Dudler</i>
Montenegro	<i>Nedeljko Latinovic</i>	European Commission	<i>Jeannie Vergnettes</i>
Serbia	<i>Vera Katic</i>		

GUEST SPEAKERS

Ministry of Health	<i>Stefania Dalfrà</i>
Scientific Committee	<i>Tony Hardy</i>
Chair of CONTAM Panel	<i>Diane Benford</i>

REPRESENTATIVES OF THE EUROPEAN FOOD SAFETY AUTHORITY

Advisory Forum Secretariat: *Jeffrey Moon, Saadia Noorani, Francesco Amoretti*

<i>Ana Afonso</i>	<i>Jeffrey Moon</i>
<i>Per Bergman</i>	<i>Saadia Noorani</i>
<i>Binaglia Marco</i>	<i>Tobin Robinson</i>
<i>Stef Bronzwaer</i>	<i>Sousanna Tasiou</i>
<i>Hubert Deluyker*</i>	<i>Bernhard Url</i>
<i>Marta Hugas</i>	<i>Alessia Vecchio</i>
<i>Juliane Kleiner</i>	

* by telephone

1. WELCOME AND OPENING OF THE MEETING

Bernhard Url opened the meeting by giving the floor to Clodovaldo Ruffato, President of the Regional Council of Venice, who welcomed the Advisory Forum to Venice under the auspices of the Italian Presidency of the EU.

Bernhard Url thanked Mr Ruffato for supporting the meeting and passed the floor to Silvio Borello, Advisory Forum member for Italy who welcomed members on behalf of the Italian Ministry of Health.

Bernhard Url welcomed new AF member for the UK, Penny Bramwell from the Food Standards Agency, the Chair of the Scientific Committee Tony Hardy and Chair of the CONTAM panel, Diane Benford. Bernhard Url noted apologies were received from Turkey, Poland and from Lars Hanssen, Norway who will be replaced at this meeting by Ms Astrid Bjerckås who attended the Advisory Forum for the first time.

Bernhard Url also noted that this was to be the last meeting to be attended by Jørgen Schlundt from Denmark, who has taken up Professorship on Global Decision Support and has stepped down as Director of the National Food Institute.

In opening the meeting, Bernhard Url also informed members of changes to the EFSA Management Team, with the resignation of Per Bergman as Scientific Evaluation Regulated Products Head of Department, Juliane Kleiner to move to acting Head of Department on Regulated Products (REPRO) and Tobin Robinson to act as Head of Department for Science Strategy and Coordination (SCISTRAT).

2. ADOPTION OF THE AGENDA

The final draft of the AF meeting agenda was shared with the members on Friday 12 September and all documents and presentations have been uploaded to the extranet prior to the meeting.

Bernhard Url asked for any additional items to be added to the agenda, noting items from Bulgaria (new genotoxicity test and Bluetongue), Latvia and The Netherlands (announcement of events).

Bernhard Url informed members that the EFSA's implementing rules on Declaration of Interest has been updated and shared with members.

In line with the requirements on Declarations of Interests, Bernhard reminded members of the requirements to ensure they have submitted an up to date Annual Declaration of Interests and asked members for any Oral Declarations of Interest for this meeting. None were raised.

3. MATTERS ARISING

The approved minutes of the 52nd AF meeting (adopted by written procedure) were circulated to members on 9 September.

Since the last meeting additional documents have been shared with members including an overview of stakeholder consultations and correspondence between EFSA and 11 European Federations (industry representative organisations) relating to 'operational, procedural and scientific challenges for industries impacted by EFSA', which was provided for information.

No additional matters arising were raised.

4. STRATEGIC DISCUSSION ON EFSA'S WORK WITH MEMBER STATES

4.1. Scientific Cooperation Roadmap

Stef Bronzwaer introduced the Scientific Cooperation Roadmap presenting the main changes, which addressed the comments received at the June meeting of the AF.

Comments on the document were noted from Denmark, Cyprus, Germany, Belgium and The Netherlands. Italy welcomed the budgetary overview and the various means of moving scientific cooperation forward such as mentoring, clustering and exchange of staff.

Finland raised the issue of how to involve the public in the consultation process on opinions. Bernhard Url outlined the ongoing Open EFSA initiative which would address this issue.

In response to the question on how to connect to younger scientists, The Netherlands noted the need for involvement with Universities.

The document was agreed by the members of the Forum.

Action 1: Members to provide any additional written comments by 10th October 2014.

4.2. Outsourcing Tools – Grants and Procurements

Sosanna Tasiou provided a structured overview of the EFSA's different financial instruments relating to grants and procurements to provide members with better understanding of the cooperation tools.

Spain suggested a summary of the differences between grants and procurements as presented would be beneficial. The UK raised a question on the ownership of the outcome of grant activities and Portugal noted the frequent short deadlines for applications to be submitted but had good experience with the Focal Point network in identifying partners for collaborating with on projects.

Finland questioned whether an impact assessment on the outcome of grants was conducted. Stef Bronzwaer referred to an external evaluation of the grants and procurement programme which had been carried out and would be reported later in the year providing information on the impact.

4.3. Launch of thematic grants

Stef Bronzwaer introduced the Thematic grants programme, which is to be launched by the end of the year. The scheme will encourage proposals from MS organisations under a given theme and is aimed at increasing scientific cooperation and capacity building.

Belgium welcomed the creative aspect of the grant and suggested a role for Focal Points (FP) in disseminating information on the grants to the Article 36 organisations and questioned how the future thematic areas would be selected. Portugal questioned whether the purchase of new equipment would be eligible costs under a grant and suggested that one future requirement would be to require involvement of young scientists in the thematic grant calls. The Netherlands questioned how the selection of the topic was made and whether EFSA could be part of a consortium. Stef Bronzwaer noted the proposal from Portugal on involvement of young scientists and explained that while the AF can suggest topics for future calls for proposals, the AF could not be involved in the selection of topics because of the potential conflict of interest, but explained that the choice of the theme was made with consultation with EFSA's scientific units and in line with the EFSA workplan for 2015. Marta Hugas informed members that according to EU rules, EFSA can not be a partner of a consortium applying for DG Research and Innovation funding, though it is possible to be on an advisory board following the granting of the proposal to a given consortium.

Action 2: Members to disseminate information and support formation of consortia after launch of the thematic grants.

4.4. Focal Point Agreements 2015

Stef Bronzwaer outlined the new FP agreements to be introduced in 2015. Members were informed that the new format would decrease administrative burden and offer more flexibility to the MS in handling their budget.

As it will be a requirement for the new agreements that FP organisations be on the Article 36 list, it was highlighted that those countries which still need to complete the requirements to be added must do so before the end of 2014.

Spain welcomed the new financial framework and stated that it would be beneficial in continuing to establish national networks in the areas of nanotechnology and emerging risks. The Netherlands welcomed the agreements and requested further details on the basis for the allocation of funds. Luxembourg noted the burden for small countries and suggested a minimum set of conditions should be met. Sweden acknowledged the different administrative systems in different countries and the wide range of tasks for focal points requiring the use of the resource to best effect. Norway noted that having the AF member, AFCWG member and FP member in the same organisation was very beneficial in coordinating activities.

In conclusion, Bernhard Url reminded members the new agreements would need to be signed by the FP organisations in December and encouraged the few countries who were not yet on the Article 36 list to conclude their applications by the end of the year.

4.5. Article 30 Procedure

Juliane Kleiner presented a draft document, which has been shared with members ahead of the meeting, outlining the procedure to be followed when there was an indication of diverging scientific opinions between EFSA and the MS.

Finland welcomed the proposal and saw a link with the Open EFSA initiative and questioned what the mechanism was for the exchange of opinions between MS. France welcomed the document and flowchart, but felt the process was too bureaucratic and roles were not clearly defined. France further suggested the Commission should be informed, but not always involved and that communication was an important issue to be further developed. EFSA agreed to a flexible approach to the Commission's involvement.

Sweden questioned whether there had been discussion with other agencies on the issue, noting that at national level there was liaison with the Environment Agency to ensure a consistent approach. Denmark noted that more emphasis should be on explaining differences when they occur. Germany welcomed the development of a procedure and suggested more should be done on the reasons leading to divergence.

Juliane Kleiner responded noting the comments made. In particular she stated the need for highlighting the reasons for divergence such as gaps in knowledge, especially among risk groups and advised that the approach is also applicable to EU agencies and international level where mechanisms also exist for dealing with potential scientific divergence.

Bernhard Url asked members to provide written comments by the end of October with the document to be updated for presentation at a future meeting.

Action 3: Members to provide comments on the proposed procedure by the end of October.

5. SCIENTIFIC COMMITTEE UPDATE

Tony Hardy presented an overview of the current activities of the Scientific Committee.

Sweden questioned whether public consultation on guidance documents was a burden on resources. Tony Hardy indicated that time and resources were much needed to run such a consultation, but the investment was necessary to get the best outcome. The Netherlands asked what can be expected in the area of guidance in the near future. Finland asked what activities were being carried out in the area of risk ranking. Germany posed the question of who the guidance was for and whether quality management procedures were the next step. Tony Hardy noted the collaborative process to develop guidance and indicated guidance on weight of evidence and biological relevance could be progressed. On risk ranking he noted the ongoing work being carried out by procurement

(involving the Netherlands, UK and Denmark) where a report is awaited. Tony Hardy indicated that the goal was to develop guidance in a positive way and the route of quality management procedures was not necessarily the only way forward.

6. NEW METHODOLOGIES IN TOXICOLOGY

6.1 MS activities

Germany provided an overview of considerations of High Throughput and High Content screening technologies in risk assessment, and highlighted various topics to be discussed when addressing the detection of adversity and the combination with *in vitro* methods. Germany also informed members of a forthcoming workshop on the application of Omics data in regulatory toxicology to be held in October.

6.2 International perspectives

Hubert Deluyker joined the meeting by telephone to provide information on the meeting of the Global Coalition for Regulatory Science Research, held in Montreal, Canada, August 21-22 which involved the US FDA, Japan, FSANZ and other third country agencies as well as EU Agencies such as EFSA and EMA. It is proposed that in October 2015 the Global Summit on Regulatory Science will be held in Parma, Italy.

6.3 Harmonisation of risk assessment methodologies Network

Tobin Robinson presented proposals for taking forward the harmonisation of risk assessment methodologies network following previous discussions with the members of the Forum. A new approach to replace the current network with a series of consultations with MS during the whole cycle of horizontal guidance preparation was proposed.

The members agreed with the discontinuation of the existing network and the development of the new approach.

7. NETWORK ON NOVEL FOODS /TRADITIONAL FOODS: DRAFT TERMS OF REFERENCE

Juliane Kleiner updated the Forum on the current considerations on the mechanism to make best use of MS expertise in the process of assessing novel/traditional foods under the forthcoming revision to the novel food regulations.

The need for establishing a scientific network, which was suggested at the previous Advisory Forum meeting was discussed. It was agreed as discussions were still doing on within the Commission and the Standing Committee on Food Chain and Animal Health the item would be discussed further at a future AF meeting.

8. RESEARCH: HORIZON 2020

Jeffrey Moon presented the outcome of the consultation carried out earlier in the year on proposals to be submitted to DG AGRI and DG Research and Innovation for consideration in the Horizon 2020 Framework Programme, indicating that a report would be completed in November for circulation to the relevant Commission DGs.

Jørgen Schlundt provided a short update about the work of the Horizon 2020 Advisory Group that he participates in, highlighting the relevant priority areas.

It was agreed that DG AGRI and DG Research and innovation would be invited to a future AF meeting.

9. THE EXPERIENCE OF A MEMBER STATE ON PHYTOVIGILANCE

Stefania Delfra' from the Italian Ministero della Salute presented details of the National phytovigilance system which has been in operation since 2002 and covers food supplements, herbal preparations and homeopathic medicines. The number of reports has been increasing in recent years and mostly relate to food supplements.

Members welcomed the presentation with many supporting the initiative provided by Italy.

10. UPDATES AND RELATED MATTERS

10.1. Communication Activities: Results & the way forward

Alessia Vecchio presented an update on recent communication activities, including several high profile scientific such as BPA, vector-borne diseases and acrylamide, the latter which involved the development of an infographic which was produced together with Scandinavian colleagues.

Alessia outlined efforts made in 2014 to align communication activities with EFSA's wider strategic objectives of Trust, Sustainability and Fitness for Purpose, which has given more direction and purpose to the work of the Department.

Ireland questioned how many media enquiries were received by EFSA during the year. Alessia Vecchio indicated that the number was in the thousands, but that up to 30% of these were misplaced and EFSA was not the appropriate organisation to handle the enquiry.

Germany noted the challenges of new media which did not rely on verification of the accuracy of information generated by the users. Norway welcomed more engagement in communications to build trust through direct dialogue. Czech Republic asked whether media monitoring was conducted in house. Alessia Vecchio responded that the collection of information was outsourced, but that the information was reviewed internally to assess positive, negative and neutral coverage.

***Action 4:** Communications to share (via secretariat) analysis of media enquiries and in-house media monitoring with members.*

10.2. Matrix Project

Per Bergman introduced details of the MATRIX project, relating to the electronic submission and management of the regulated products applications, to inform Advisory Forum members about the objectives of the project, the target benefits for EFSA and all concerned stakeholders, and the project's timeline. The decision on whether to proceed with the project will be made in 2015 after conducting a cost/benefit analysis and survey to stakeholders.

Finland noted the benefits for applicants in such a system and Sweden noted the use of such an approach for a wide range of applications in other areas of regulation.

10.3 Forthcoming Risk Assessment Activities – Round Table

Bernhard Url opened the floor to members to share information on upcoming risk assessment activities. Members welcomed the opportunity to share such information and acknowledged the assistance that Focal Points would be in helping to gather the appropriate information before each meeting. Members requested clarification on the type of information that was to be shared and the process for identifying areas of potential overlap or collaboration.

Bernhard Url welcomed the members support on collating and sharing information on their risk assessment activities.

10.4 Extranet Development

Jeffrey Moon provided members with information relating to changes in the collaboration tool used to share information between EFSA and external stakeholders, including AF members, which would take effect in October.

Action 5: The Secretariat to keep members informed on the transition period between the systems of the sciencenet and Document Management System and access to archived documents. Action 6: The Secretariat to circulate link to contact details of AF members for updating.

11. PRESENTATION FROM A SCIENTIFIC PANEL: CONTAM PANEL

Bernhard Url welcomed Diane Benford, the chair of the CONTAM Panel and Marco Binaglia, CONTAM Team Leader to the meeting.

Diane Benford gave an update of the activities of the Panel with particular focus to the last three years and the planned activities for 2015. The cooperation and interaction of the CONTAM Panel and its scientific secretariat with MS was also highlighted in the presentation.

Latvia asked for clarification on the consumption data needs. Diane Benford replied that the most comprehensive data for the whole of Europe was always required, particularly for different age groups (young children and infants) and specific population groups such as vegetarians and pregnant women, where there is relatively poor data available.

Finland questioned the interaction between food and feed issues and the cooperation between the EU Agencies and international level. Diane Benford noted that the balance reflects the mandates from the Commission and that there are links with ECHA on issues such as brominated flame retardants and collaboration and cooperation with, for example, JECFA. Sweden asked whether the prioritisation was for food consumption data or occurrence data. Diane Benford replied that it is variable, depending on the issue of concern, noting that consumption data had improved over recent years.

The Netherlands asked why recent guidance on methodology for establishing reference points of action for non-allowed pharmacologically active substances was issued by the CONTAM panel rather than the SC. Diane Benford indicated that such substances are viewed as contaminants in food, and the CONTAM panel has the expertise for dealing with this issue.

Germany raised the issue of the import of food and feed from outside the EU which may include contaminants not usually found within Europe and the potential difficulties posed to laboratories on analysis and whether there was a strategy to address this. Tobin Robinson referred to the REACH database which could be used to determine priorities and probability of contamination to the food chain.

Italy and Denmark raised questions on the development of the Acrylamide Opinion. Diane Benford noted the recent consultation on the draft, in particular that exposure assessments indicated that levels had not been reduced.

12. OTHER MATTERS RAISED BY EFSA AND MEMBER STATES

12.1. Operation of the Advisory Forum

Stef Bronzwaer introduced proposals to review the operation of the forum to ensure that the objectives set out in the founding regulation (Regulation EC 178/2002) were being met in the best way possible, indicating plans to conduct a survey during October and to follow up with a facilitated group session at the December AF meeting.

Germany welcomed the proposal noting the interaction between the Focal Points and networks and the difficulty of members representing all relevant organisations. Sweden, Hungary, Spain and Bulgaria supported the review with Bulgaria proposing a meeting between the Head of Agencies, AF members and FP. Stef Bronzwaer informed members that there would be a joint meeting of AF members and FP in October 2015.

12.2 New computer-assisted method for identifying the causes of disease outbreaks

Germany presented details of a new method for identifying and tracing the cause of food borne disease outbreaks, which would be implemented nationally in the coming year.

Luxembourg asked what type of data was needed. Austria questioned whether the food industry were willing to supply the necessary data. Germany stated that case history details, location, food manufacture details were necessary and that a step wise approach to gathering industry data was being taken, with official controls information being used first.

12.3 Foodstuff safety project

Portugal presented a details of a national initiative to informing school children on food safety issues. Members appreciated the very practical approach taken by Portugal.

13. ANY OTHER BUSINESS

13.1. Draft 2015 work programme for G&P in science

Juliane Kleiner provided an overview of the draft work plan on grants and procurement for 2015 which had been shared with the members for comment and replied to the comments received.

The UK commented that the programme seemed reactive to EC and Member States needs and suggested that in parallel, EFSA should think strategically of potential issues which could have an impact. The Chair agreed to take this suggestion onboard.

13.2. EXPO 2015 Scientific Conference Update

Juliane Kleiner informed members that the programme for the EXPO 2015 Scientific Conference was being developed and members would be provided with updates once a draft of the programme was available. Juliane Kleiner informed members that suggestions made by them for speakers were passed on to the programme committee for consideration.

13.3. Meeting the Executive Director – Country visits

Bernhard Url informed members of his intention to meet with AF members and national representatives over a two year period to discuss scientific cooperation in practice and amongst other things, how EFSA and each country can cooperate on joint projects.

Members were supportive of holding such meetings.

Action 7: Members to inform secretariat if interested to invite or visit the new ED

13.4. European Neighbourhood Programme – opportunities for involvement

Stef Bronzwaer provided information to members about EFSA's activities for the European Neighbourhood Programme (ENP). Members are asked to share information on projects and working relations on food safety they have in place with the AF secretariat.

France questioned the aim of the programme, and whether it could lead to duplication of other initiatives. Stef Bronzwaer noted the linkage to the Commission's European Neighbourhood Policy, explaining that the aim of this modest programme is to establish working relations and inform partners about EFSA and RA activities. Therefore the project aims to build on on-going initiatives and not to duplicate activities.

Action 8: Members to share information of any projects and established work relations-on-going with ENP countries.

13.5. Upcoming Events BfR

Germany presented details of upcoming events involving the BfR.

13.6. FinnPRIO – A Finnish model for ranking invasive plant pests

Finland shared information relating to an invasive plant pest ranking model.

13.7. Feedback from the Conference on Science Advice to Governments, 28-29 August Auckland, New Zealand

Hubert Deluyker and Germany provided feedback on the conference attended in August in New Zealand involving Chief Scientific advisors from around the world.

13.8. Bluetongue outbreak in Bulgaria

Bulgaria informed members of the current situation regarding the spread of Bluetongue. Romania also provided information on the same issue. Marta Hugas indicated that EFSA was aware of the situation which was to be discussed in upcoming PAFF meeting and the AHAW network in the coming months. Italy informed members of a conference on Bluetongue in November.

Bulgaria also raised the issue of a recent publication from the Bulgarian Academy of Sciences regarding a study on an innovative method for testing the influence of food additives on the human DNA. In the study several food additives and ingredients were tested. Per Bergman thanked Bulgaria for bringing the study to EFSA's attention, but noted that the study had some weaknesses and limitations, noting that the paper will be shared with the Scientific Committee Standing Working Group on genotoxicity.

Action 9: Italy to provide contact details and share information of Italian Bluetongue conference.

13.9. REFIT Regulation EC No. 178/2002

The European Commission informed members of the ongoing REFIT activity on Regulation EC No. 178/2002 with the objective to check 'fitness for purpose'. The review will look at the general food law requirement, the Rapid Alert System (RASFF) and the provisions of crisis management. Although EFSA will not be the subject of evaluation (having already been evaluated in the past), there may be involvement in the aspects being considered.

Bernhard Url welcomed the update and requested to be kept informed of the evaluation.

13.10. MRSA in pigs

Denmark briefly informed members of the occurrence of MRSA in pigs and the implications this may have on animal and human health.

13.11 Events

Latvia, Hungary and the Netherlands informed members of upcoming seminars and workshops

Action 10: The Secretariat/members to circulate information on the seminar on food supplements to be held on 6-7 Nov in Riga, conference in Hungary on 5-6 November, conference in Netherlands on 8 October and German workshop on new methodologies in October.

14. CLOSURE OF THE MEETING

Bernhard Url closed the meeting, thanking the hosts, the Veneto Regional Council and the Ministero Della Salute as well as the EFSA staff in attendance at the meeting, in Parma who joined the meeting and provided support and the AF secretariat.

The next meeting will be held on 10-11 December 2014 in Parma.

53RD ADVISORY FORUM MEETING

SUMMARY OF ACTION POINTS

Action Number	Agenda Item	Issue/Topic	Action
1	4.1	Scientific Cooperation Roadmap	Members to provide written comments by 10 th October 2014.
2	4.3	Thematic Grants	Members to disseminate information and support formation of consortia after launch of the thematic grants.
3	4.5	Article 30 procedure	Members to provide comments on the proposed procedure by end of October.
4	10.1	Communication activities	Communications to share (via secretariat) analysis of media enquiries and media monitoring with members.
5	10.4	Extranet Development	The Secretariat to keep members informed on the transition period between the systems of the sciencenet and Document Management System and access to archived documents .
6		Contact details	The Secretariat to circulate link to contact details of AF members for updating.
7	13.3	Country visits	Members to inform secretariat if interested to invite or visit the new ED
8	13.4	ENP	Members to share information of any projects and established work relations-on-going with ENP countries.
9	13.8	Bluetongue	Italy to provide contact details and share information of Italian Bluetongue conference
10	AOB	Events	The Secretariat/members to circulate information on the seminar on food supplements to be held on 6-7 Nov in Riga, conference in Hungary on 5-6 November, conference in Netherlands on 8 October and German workshop on new methodologies in October.