

Final Minutes

59th MEETING OF THE EFSA ADVISORY FORUM PARMA; EFSA PREMISES; 8TH-9TH MARCH 2016

Chair: Bernhard Url

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Belgium	<i>Benoît Horion</i>
Bulgaria	<i>Boiko Likov</i>
Croatia	<i>Andrea Gross-Bošković</i>
Cyprus	<i>Popi Kanari</i>
Czech Republic	<i>Petr Beneš</i>
Denmark	<i>Flemming Bager</i>
Estonia	<i>Martin Minjajev</i>
Finland	<i>Matti Aho</i>
France	<i>Rozenn Saunier</i>
Germany	<i>Andreas Hensel</i>
Greece	<i>Eirini Tsigarida</i>
Hungary	<i>Ákos Bernard Józwiak</i>
Iceland	<i>Jon Gislason</i>
Ireland	<i>Raymond Ellard</i>
Italy	<i>Gaetana Ferri</i>
Latvia	<i>Aivars Bērziņš</i>
Lithuania	<i>Jurgita Savickaitė</i>
Malta	<i>Ingrid Borg Busuttil</i>
Netherlands	<i>Antoon Opperhuizen</i>
Norway	<i>Marie Louise Wiborg</i>
Poland	<i>Jacek Postupolski</i>
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Romania	<i>Alecsandra Dida Cozachievici</i>
Slovenia	<i>Urška Blaznik</i>
Slovak Republic	<i>Zuzana Bírošová</i>
Spain	<i>Ana Canals</i>
Sweden	<i>Per Bergman</i>
United Kingdom	<i>Penny Bramwell</i>

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<i>Julia Finger</i>	<i>Hans Verhagen</i>
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<i>Martin Moravek</i>	<i>Sosanna Tasiou</i>
<i>Doreen Russell</i>	<i>Marco Binaglia</i>
<i>Eric Barthélémy</i>	<i>Arthur Healy</i>
<i>Lesley Koschel</i>	

Apologies:

Luxembourg, Montenegro, Serbia, Turkey.

1. OPENING OF MEETING

Bernhard Url, EFSA's Executive Director (ED) and Chair of the meeting opened the 59th Advisory Forum (AF) meeting taking place in the EFSA premises.

The Chair welcomed new members to the plenary- Jurgita Savickaitė from Lithuania and Per Bergman from Sweden. On this occasion the Chair thanked Rozenn Saunier from France and Marie Louise Wiborg from Norway attending their last meeting for their work.

The Chair introduced Selomey Yamadjako, attending the AF meeting for the first time after having taken up her position as Head of the Resources and Support Department (RESU) towards the end of 2015.

The Chair informed that the minutes of the 58th AF meeting, which took place on 8-9 December in Luxembourg have been approved and published on EFSA's website.

In line with the requirements on independence, members were asked for additional Oral Declarations of Interest (ODoIs) and no additional interest was declared.

2. ADOPTION OF THE AGENDA

The draft meeting agenda was opened for additional items. The following items were raised for inclusion under agenda item 12 Any Other Business (AoB): Risk communication on honey by Slovenia, Meeting on African Swine Fever by Estonia, Workshop on foodborne viruses by the UK. The plenary then adopted the agenda.

3. MATTERS ARISING

3.a ED Progress Report

The ED Progress Report for March 2016 had been shared with the EFSA Management Board and circulated among the AF members before the meeting. No matters were raised for discussion.

3.b Action Points from last meeting

The Action Points of the last meeting had been updated with current status and circulated before the meeting.

3.c ED Country Visits

Bernhard Url gave the floor to Marina Koussathana to give an overview of the ED visits completed in 2015, agreed for 2016 and planned for 2017. Belgium asked for the possibility of having an overview and some details of the joint projects agreed within the framework of the ED visits, as this may help for the preparation of forthcoming visits. For this purpose it was agreed to circulate a presentation given at the last Focal Point (FP) meeting containing such an overview to members.

Action Point 1: EFSA to share presentation on ED visits from the 26th FP meeting with AF

3.d Geographical Representation of national networking

Bernhard Url gave the floor to Stef Bronzwaer to provide a short update on the graphic depiction of how EFSA interacts with the national organisations of the Member States (MS) through AF, FP, AFCWG, the Scientific Networks and the Art.36 list. A new version of the pictorial representations focussing on Scientific Networks in the area of DATA collection was also tabled. Both depictions are ready for distribution as electronic versions and hard copies.

4. STRATEGIC ISSUES SESSION: DATA COLLECTION AND MANAGEMENT

4.1 Proposed process for Data Quality Assurance

The Chair passed the lead to Hans Verhagen, Head of the Risk Assessment & Scientific Assistance (RASA) Department to co-chair the session.

Hans introduced Stefano Cappe from the Evidence Management Unit to present a proposal of three EFSA Units, Evidence Management, Finance (FIN) and Advisory Forum and Scientific Cooperation (AFSCO) to establish a strategic partnership with Art.36 organisations to ensure quality for data transmitted to EFSA. The purpose of the proposed project is to strengthen the process for engaging Member States in data transmission to EFSA and is directly linked to EFSA's Strategic Objective 2 - "Widen EFSA's evidence base and optimise access to its data". Stefano Cappe explained the proposal and its benefits to stimulate further discussions in the following breakout session. Members discussed a pilot phase in 2016 with volunteering MS, the possible coordinating role of FPs and the projects' benefits and challenges in a breakout session.

Denmark raised the question of the comparability of data. Stefano explained that the aim of data quality enhancement is to acquire very good meta-data (e.g. sampling strategy) to immediately distinguish the type and purpose of the sample, to be able to adequately select the data according to the need of the data analyst. High quality data can be seen as the foundation step for open data. Hans further clarified that current data quality is focussed on risk assessment, but this approach should be further developed in order to extend data re-use with the aim of opening data to the public.

Summary of breakout sessions:

Member states showed great interest to the proposal: The main benefits were seen as boosting data governance in Member States across data domains and involving an important co-ordination role for the focal point. The governance aspect was identified as an opportunity to streamline aspects such as the management of access to data (data ownership, data anonymization, data collected outside official control and monitoring programmes, data from non-governmental sources such as consumers, NGOs, academia and industries, data licensing and data protection matters) and the metadata governance (changes to standards and controlled terminologies in line with EFSA requirements agreed with Member States). Some countries favoured the establishment of multi-national coordination points (e.g. Baltic countries). In addition the focus on data quality, as a preparatory step to open data, was perceived as mutually advantageous to MSs and EFSA. The benefit of better quality data could be further exploited via the circle of trust initiative allowing MSs wider access to the data stored in the EFSA scientific data warehouse. The use of data quality Key Performance Indicator (KPIs) will allow the creation in the S-DWH of trend statistics for managers and system stakeholders to visualise data quality improvements. Regarding implementation the benefits were mainly seen in the simplified administration with lump sums and long term planning that the proposal was enabling.

The proposal was also seen to raise some challenges such as the specific role of the focal points and their responsibility/accountability for data provided to EFSA. The proposal should clarify the role of the data steward, in charge of the data quality and the relationship between these two roles. In particular, in relation to the focal point whether extra effort is needed to support the new tasks and the degree of overlap with their current role in data collection.

Data quality aspects should be further refined and KPIs should be clarified in advance and agreed with participant Member States (e.g. availability of limit of detection and quantification, sampling strategy) and if it is necessary to create specific working groups involving bio statisticians and laboratory experts to define KPIs.

The proposal, should be catered and configured on Member States specific needs and should include the outsourcing of specific subtasks (e.g. IT development) not performed directly by many Member States. The proposal should provide solutions for practical difficulties such as the formation of a single consortium umbrella for all data providers in a country.

From the financial perspective, the proposal should focus on value for money for Member States since challenges to complement the remaining part of the co-financing rate proposed by EFSA - current hypothesis is 50% of the costs) – could be met

Other issues also envisaged from some Member States concerned missing tools such as metadata elements and controlled terminologies currently not available in National languages. This will impede directly the use of standardisation tools at data entry level. During the discussions the need of a pilot testing, was suggested by the participants as a mean of clarifying many of the issues. EFSA proposed to have a small group of Member States (up to 5 countries) to pilot the proposal. It is essential that the pilot is tested across different data domains, providing a realistic case study from which the full scale project can be derived. Countries volunteering for this project were Austria (from the autumn), Croatia, Cyprus, Denmark, Finland, France (to be confirmed), Germany, Ireland, Italy (to be confirmed), the Netherlands (from the autumn), Norway and Slovakia.

During the pilot, terms of reference for the project will be fine-tuned and adjusted to fit as much as possible both the specific EFSA objectives and Member States

requirements. In addition another objective of the pilot project is to create the general terms of reference for the strategic partnership on data quality to be deployed after the pilot.

At the end of the pilot, the results of the project will be reviewed with specific attention to all questions raised during the discussions summarised above.

At that stage the project will be re-assessed by EFSA management and Advisory Forum for approval, taking into consideration EFSA's budget. The Advisory Forum will be updated about the proceeding of the project by a scoping paper and in plenary meetings.

Action Point 2: MS to express/ confirm interest in volunteering in a pilot project on data quality assurance

4.2 Data Warehouse

Stefano Cappe gave a presentation on the state-of-play of the Scientific Data Warehouse (S-DWH). Since the project was first presented to the AF a year ago, several data domains have been implemented, including chemical occurrence, additive occurrence, pesticide residues, zoonoses, antimicrobial resistance, and consumption. According to the DWH access rules, the S-DWH provides access to data to different user groups. Stefano presented the steps for concluding the project in the course of 2016, including the implementation of a tracking system for MS to trace back data that has been used in EFSA outputs.

At the end of his presentation Stefano raised two questions to the plenary: 1) Can FPs authorise access to MS "governmental" data or specific data providers' data?; 2) Can we enrich chemical contaminants dashboards with positional statistics on concentration levels (mean, median, P95)?

Belgium suggested managing the access to the data (intended through the S-DWH up to the level of raw data) at national level, if this task should be given to the FP, which was widely acknowledged. Stefano explained that the access of national organisations other than the data provider requires agreement of the MS, i.e. from the requesting organisation to EFSA and redirected to the FP. As EFSA cannot decide about access authorisation to the data at national level, it would be essential to have somebody at national level authorised to decide which institution can access the data. France stressed the need to consider the variation of arrangements among the MS.

Stefano emphasized that the focus of the discussion was only on access to data by national (governmental) organisations and to national data that has been provided by another national organisation to EFSA. This discussion was excluding general access to data by the public. Regarding to this last point Stefano advised that a draft proposal will be discussed at the next Network meeting on chemical contaminants, where a minimum set of data in the area of chemical occurrence could be made public. EFSA's commitment to public access is interpreted as applying also to data and a pro-active opening of data will help avoiding specific requests of public access to data.

The Netherlands explained their approach to give general access to their national data, which could be facilitated in short terms in a pilot. Bernhard Url added that a selective public opening of data by a subset of countries could be also possible.

On the second question various MS requested more time to consult on national level. France requested an overview on who has access to which data, which can be facilitated. The UK underlined the value of testing it as a pilot, supported by Sweden.

Action Point 3: EFSA to provide overview of who has access to data at what level in the MS

4.3 Data Networks: Networks on Veterinary Medicinal Products Residues Data, Chemical Occurrence Data, Food Consumption Data and Zoonoses Data

Hans Verhagen introduced Doreen Russell and Francesco Vernazza from the Evidence Management Unit to present the four Networks in the area of data collection: The Network on Veterinary Medicinal Products Residues Data collection, Chemical Occurrence Data collection, Food Consumption Data collection and Zoonoses Data collection. The presentation suggested a new direction for Scientific Networks on Data collection to become the specific domain for data governance of the scientific data collected, with the AF being the top level domain to cover cross-cutting issues.

With regard to the Network on Veterinary Medicinal Products Residues (VMPR) Data collection, Spain raised the problem of collecting the data nationally, as no IT tool is available at national level to collect the non-aggregated data. Besides the missing IT tool problems derive from the fact that data will be asked aggregated and including much additional information. It was suggested that an EC Regulation is needed to solve this problem. Germany, in support of this view added that an EC regulation would be beneficial in order to get better data quality and asked EFSA to support this in discussions with the EC, as in absence of an EC Directive currently data providers only provide the minimum requested by the EC. The Netherlands pointed to EFSA's role in this context, as EFSA has been tasked by the EC to collect data and deliver a meaningful report, it should support a legal base in form of a Regulation to fulfil this task rather than solve problems on operational level with the MS. Bernhard Url confirmed that EFSA will take up this role, though the wish of MS to have less regulation have to be weighed by the MSs themselves in discussions with the Commission and European Council, as they have the political power to make a change. He pointed out that it is also a duty of MS to finance data collection in a useable way. Denmark remarked that national funding for sampling is scarce, which why only the minimum legal requirements can be fulfilled and economics remain the driving force. The Commission confirmed ongoing discussions on implementing rules on VMPR, as MS tend to favour a more risk-based system and a new proposal for official controls is needed to develop implementing rules.

Hans Verhagen summarised the general agreement of the forum to broaden the opening of data as well as the need of discussions with the EC and the recognition of challenges on national level. This will be the ground for further discussions in the Network and be brought back to the plenary in the June meeting.

4.4 Monitoring of Veterinary Medicinal Products Usage

Hans Verhagen gave the floor to Denmark to give a presentation on national monitoring of resistance and antimicrobial consumption in production animals. The study concluded on an effect of prudent use in food animals on human medicine by at the same time acknowledging the complexity of the epidemiology of AMR. On a question by Latvia Denmark confirmed to have data for aquaculture and other animals available. Finland remarked that the implementation of this system is quite costly while it could be more beneficial to apply a holistic approach to tackle the problem instead of focussing only on the use of antibiotics. Denmark confirmed the difficult balance between the use and the cutting of use of antibiotics, as animals with diseases have to be treated, however trying to prevent it from the disease could be an alternative approach. The project has to be seen as a starting point, with parameters to be further defined.

A number of countries expressed interest and suggested further discussions on the next AF meeting in June. The UK confirmed to contribute with a systematic review of the role of the food chain in AMR, Germany offered a follow-up on studies regarding pet animals, Italy informed about introducing a similar system starting in the Lombard region which is also considering issues of biosecurity and animal welfare and including an electronic prescription system. Hans Verhagen suggested involving

the European Medicines Agency (EMA) and possibly to invite them to the next AF meeting, as they have data and knowledge in this field.

Action Point 4: EFSA/ NL to schedule session on monitoring of Veterinary Medicinal Products usage for next AF meeting, and to explore inviting EMA.

5. Advisory Forum Operation

The Chair passed the lead to Alberto Spagnolli, Head of the Communication and External Relations (COMMS) Department to co-chair the session.

Alberto Spagnolli introduced the session dedicated to the review of the AF. The review of the AF was completed in 2015 and entailed three follow-up elements: An Implementation Plan, the revision of the AF Rules of Procedures and the renewal of the Declaration of Intent. Alberto gave the floor to Jeffrey Moon to explain the next steps: AF Members were invited to comment on the Implementation Plan and the Rules of Procedures, which had both been shared before the meeting, until 23 March. The Rules of Procedure will be drafted by the AF Secretariat together with volunteering Members and be tabled at the next AF meeting. Volunteers were requested to take the lead on drafting the Declaration of Commitment, intended to update the Declaration of Intent at its 10th anniversary in September 2016. Jeff Moon indicated that the operating rules of the Advisory Forum will be updated to include new aspects regarding Art.30 of the Founding Regulation on scientific divergence and Art.36 regarding scientific networking. The implementation plan deriving from the review carried out in 2015 will serve as an additional operational document to keep the didactic character of the rules of procedures.

Bernhard Url emphasized the change in approach from a Declaration of Intent to a Declaration of Commitment to form the steering group of the RA community and strengthen the role of the AF to an increasing commitment for bringing forward the European project of public health across Europe. Members welcomed the documents and confirmed their importance as the role of the AF has not always been fully clear and simple redirection to the Founding Regulation not enough. Germany remarked missing a chronology of achievement of AF support to EFSA's work. A reflection on achievements would be encouraging as well as line out the importance of networking with EFSA as the connecting point. It would also be beneficial to include future oriented objectives. Alberto Spagnolli agreed suggesting three elements starting from achievements to the declaration of commitment and concluding with an outlook on future objectives. This would reflect the development of the AF from an advising body to a committee driving common projects of EFSA and the MS.

The plenary welcomed Sweden, Belgium and France volunteering to draft the Rules of procedures and Ireland to draft the Declaration of Commitment.

Action Point 5: AF to comment on implementation plan until 23 March

Action Point 6: AF to comment on draft rules of procedures until 23 March

Action Point 7: MS to volunteer for drafting the rules of procedures

Action Point 8: MS to volunteer for drafting the declaration of commitment

6. Progressing the EU Risk Assessment Agenda

Alberto Spagnolli gave the floor to Andrea Gross-Boskovic, AF Member from Croatia to provide feedback from the discussions in the AF Discussion Group on the EU Risk Assessment Agenda (EURAA). Following the completion of the Delphi study to identify priority topics for collaboration, the AF Discussion Group on the EURAA reconvened via teleconference on 26 February, with the main purpose to discuss the practical use of the

list of priority topics and the next steps. The group included representatives from Sweden, the Netherlands, Croatia, Italy, Slovenia and Germany.

The Discussion Group (DG) concluded that the list should not be subject to further refinement or changes and be used to identify projects for joint cooperation of the MS and that the list deriving from the Delphi study could be considered as a MS list for identifying collaborative projects. The identification of projects should not be restricted to the list, which will be one possible source also to be used in forward planning for both MS and EFSA. The group agreed that the emphasis should be on identifying activities under the topic headings suggesting each country to lead one topic finding interested partner MS. Spain asked for a background paper on the Delphi study for national distribution.

Belgium reminded of discussions on the last AF meeting on refining the list. Stef Bronzwaer confirmed that the DG acknowledged some topics being broad, but agreed to not reopen the methodology, but to start activities on base of the list. The refining will occur when translating the topics into projects. Sweden and Spain suggested links to rationales to further explain the topics instead of refining. Some MS welcomed keeping the current list, however many MS emphasized the need to have different approaches to the very heterogeneous projects. France underlined that the difference in topology might lead to cooperation in only few, reoccurring fields, leaving others apart. Germany remarked that perhaps many countries already deal with a big number of projects on the list, which continues duplication. It would be useful to develop a tool for sharing information on work programmes, for better cooperation and development of science. Bernhard Url welcomed the idea and suggested to ask the DG to develop a template for capturing MS interest and lead on topics and a tool for information sharing could be developed by EFSA.

Cyprus, Italy and Germany expressed concerns on how to make cooperation operational with regards to funding. The Commission should take note particularly of difficulties of small MS to obtain funding in context of Horizon 2020. Finland added that smaller countries could see the list as a source for inspiration and possible areas of cooperation. The Netherlands stressed the importance of regional projects. Stef Bronzwaer confirmed that the list is meant to influence national research agendas and altogether the Horizon 2020 programme. Alberto Spagnolli added to bring the list to the attention of the Risk Managers through the Head of Agencies (HoA) meeting. A group of volunteer MS would be needed to develop a plan on how to present this.

Bernhard Url concluded that core value of the EURAA is mutual trust and sharing of workload. MS should acknowledge the work of others and EFSA instead of duplicating projects nationally.

Action Point 9: DG to develop a template for MS expressions of interest in topics and lead

Action Point 10: EFSA to send background paper on Delphi study to AF Members for national distribution

Action Point 11: MS to volunteer on developing a presentation of the priority list to HoA meeting

Action Point 12: EFSA to reflect on a tool of information sharing on workplans and worksharing

7. Focal Points – 2015 Activity Review

Alberto Spagnolli gave the floor to Stef Bronzwaer to present a short quantitative overview of the FP activities in the course of 2015, which was the first reporting year under the new FP grant arrangements. Stef underlined the important work of FPs in

supporting scientific cooperation. Spain confirmed the importance of the FP work, which has faced a huge increase over the last years and welcomed the leaning of the Art.36 procedures. Stef confirmed that the management of the Art.36 list will be brought to the AF meeting in June. Sweden pointed out that the quantitative indicator of requests sent through the FP network in the reporting is not very meaningful without an indication on the numbers of replies. Stef Bronzwaer expressed that the collection of this information will be further improved on the upcoming reporting season later in 2016.

Action Point 13: EFSA to further improve the collection of information on replies to requests for information sent through the FP network on the upcoming reporting season later in 2016

8. Risk Assessment Session

8.1 Exchange of information on Forthcoming RA activities

The Chair gave the floor to the Heads of Departments to facilitate the session on the exchange of information on Forthcoming RA activities. AF members had received a summary of new EFSA mandates and new MS RA activities as well as a summary of the "World Café" session held on the last AF meeting, to stimulate the identification of possible partnerships. Members engaged in discussion on particular items, particularly on BPA and RA in nanoparticles. In discussion on risk ranking, France agreed to provide more information on parameters in the risk ranking used by ANSES.

Greece and Germany pointed out that it would be helpful to share details of on-going RA ahead of plenary meetings as well as sharing the outcomes of RA, not only forthcoming RA activities. Bernhard Url confirmed that a pilot tool for information sharing to replace the IEP will come soon. He concluded that the forum made a real step forward by discussion on-going projects and possible divergence.

8.2 Water quality for human consumption to the nutritional value of infant formulae

The Chair gave the floor to Andrea Gross-Boskovic, AF member from Croatia, to present a scientific opinion on the influence of the composition of drinking water on nutritional profile of infant milk. The study came to the conclusion that the final micronutrients in water significantly exceed the recommended daily intake. The initial idea of making special recommendations for children food was thus suspended. Belgium noted having come to similar conclusions in a study in 2015. Juliane Kleiner and Hans Verhagen noted the importance of considering the Upper Level intakes for particular nutrients (instead of recommended daily intakes) which could serve as guidance values for risk managers and suggested further discussion between EFSA and Croatia on the issue.

Action Point 14: Belgium to share outcome on study on nutritional value of water for infant formulae

Action Point 15: EFSA to share information on upper safe levels versus recommended daily intakes, as well as their recent opinions on infant nutrition with Croatia

8.3 Pyrrolizidine alkaloids in tea infusions

The Chair gave the floor to Andrea Gross-Boskovic, AF member from Croatia, to present a scientific opinion on pyrrolizidine alkaloids in tea infusions on the Croatian market. The Netherlands informed about a Dutch health recommendation advising against high consumption of tea for young people. Germany added that pyrrolizidine alkaloids are not only problematic in tea but also in honey, as it is very difficult to avoid high pyrrolizidine alkaloid concentration, as plants can get mutually contaminated during the harvest. Marta Hugas informed that EFSA received a

mandate from the EC regarding human exposure assessment for pyrrolizidine alkaloids. The respective data is expected to be published in May.

8.4 Chloroamphenicol in food and feed

The Chair gave the floor to Marco Binaglia from EFSA's BIOCONTAM Unit, to inform about a potential scientific divergence between EFSA and Germany on Chloroamphenicol in food and feed. EFSA had published an opinion on Chloroamphenicol in food and feed in 2014. In December 2015 EFSA received a letter from BfR indication potentially diverging opinions concerning the conclusions that can be drawn on the basis of the available toxicological data on chloramphenicol. The respective position paper is tabled for discussion at the 77th CONTAM Panel meeting on 1-3 March and a joint meeting with BfR is envisaged for April. The Netherlands informed having an opinion on Chloroamphenicol that has not been published yet, waiting for the outcome of the abovementioned meetings. Marco Binaglia gave an overview on the discussions and main sources of divergence, as there are: 1) applicability of Margin of Exposure approach, 2) options to conclude on carcinogenicity, 3) antibacterial properties due to chloroamphenicol. It was agreed that the guidance on Article 30(4) scientific divergence agreed by the Advisory Forum in 2015 should be followed.

8.5 Cyanogenic glycosides in apricot kernels

The Chair gave the floor to Hans Verhagen, to give an update on possible scientific divergence with Greece and Germany on the RA of apricot kernels. EFSA had received a request from the EC for a scientific opinion on the acute health risks related to the presence of cyanogenic glycosides in apricot kernels and products derived from apricot kernels in June 2015, which has been submitted for adoption at the 77th plenary meeting of the CONTAM Panel on 1-3 March 2016. Both EFET and BfR have published similar RA in 2015 and 2014 with divergence from the EFSA conclusions. Ireland informed having removed apricot kernels from the national market after reporting of cases of illness, the sale is also prohibited in New Zealand and Australia.

8.6 AoB

Some MS requested an update on the REFIT exercise by the Commission. The Commission informed that a first draft report is to be expected in June or July. The EC website provides actual information on the three parts of the REFIT exercise: the RASFF system, crisis management and food law. Spain added that the EC has opened a REFIT platform containing various aspects of the exercise and stakeholders have been asked for their comments.

The Chair then closed the meeting for the first day.

9. EFSA Scientific Panel Presentation: CEF Panel and FIP Network

Bernhard Url opened the meeting of the second day, welcoming Claudia Roncancio Peña, Head of the FIP Unit and Vittorio Silano, Chair of the CEF Panel, to the meeting. He then gave the floor to Vittorio Silano, who presented the roles and activities of the Scientific Panel on Food Contact Materials (FCM), Enzymes, Flavourings and Processing Aids (CEF Panel). Vittorio gave an overview on the work areas and procedures of the CEF Panel as well as the current process for revising the FCM guidance. He notably informed that the EFSA opinion outlining scientific rational for revising the FCM guidance has been published on 28 January 2016 together with the technical report on the public consultation. Also MS will soon be consulted on the development of a protocol detailing the strategy for hazard assessment in BPA.

Eric Barthélémy then provided an overview of the collaboration of EFSA and MS in the FCM area through the FIP Network. Eric outlined the objectives of the FIP Network and its FCM subgroup. He informed on the meetings, MSs' participation, topics of interest, and underlined the consensus of the Network on the need to harmonise the safety assessment of FCM substances and/or articles non-EU specifically regulated. The current mandate of the FIP Network will end in October 2016 and the plenary agreed to prolong the mandate.

Germany welcomed the ambitious work plan of the CEF Panel, highlighting that despite a long tradition of RA in this area, resources for research in FCM is limited. This impacts the knowledge and expertise available in public Institution and Agency. Increasing European funds allocated to FCM projects and involving experts from industry in the safety assessment process would be helpful. Juliane Kleiner confirmed the possibility to involve experts from the industry through hearings and invited the Commission to take note of the evident funding problem. The balance of transparency via additional knowledge has to be taken in consideration. Belgium suggested making use of the Network in order to identify needs for research. Claudia Roncancio Peña confirmed this, being also on the agenda of the next Network meeting.

The Netherlands recommended prolonging the FIP FCM Network with a mandate that should promote the harmonisation of guidances for the safety assessment of FCM substances and/or articles. Guidance would also be helpful for countries outside the EU who enter the market. Vittorio Silano underlined that the preparation of guidance is a competency of the Panel itself; the Scientific Committee being informed but not directly involved. As regards FCM, Claudia Roncancio Peña clarified that the mandate of the CEF Panel on EU regulated products is mostly on plastics and intelligent and active materials whereas the FIP FCM Network cooperates on non-EU-specifically regulated products (e.g. coatings, papers and boards, rubbers, printing inks). Existing MSs guidances on non-EU specifically regulated products are mostly based on the current FCM guidance also used by EFSA for plastic. Nevertheless it remains difficult to establish common guidances.

Action Point 16: EFSA to revise ToR of FIP Network to be tabled on AF meeting in September

10. Communications: EFSA Journal & Feedback from the AFCWG

Bernhard Url opened the regular session on communication activities, giving the floor to Arthur Healy to present the developments regarding the EFSA Journal. Following an external review editorials were centralised to reduce the burden of scientific units and the journal was outsourced to an external online platform, expecting its launch by April 2016. On question from Sweden, Arthur explained that one outsourcing criteria was a publisher able to deal with EFSA timelines. Asked for the future vision by Latvia, Arthur envisaged the journal to be placed in the centre of the RA community with its publications to become the source of RA in Europe.

Bernhard Url then gave the floor to Stef Bronzwaer, who gave feedback on the activities of the AFCWG in the course of 2016. The EU Insights project, an EU-wide risk perception survey is expected to have finalized results in June. The Terms of Reference of the AGCWG will be revised and the respective paper is meant to be validated by the AF in June. The June meeting of the AFCWG will be held as a back-to-back meeting with the AF Meeting in Utrecht in the Netherlands. Finland recommended the AFCWG to also consider issues relating to risk management, which cannot be treated separately.

11. GENERAL SESSION

11.1 Complicated Residue Definitions can trigger difficulties in Risk Assessment studies: The CS2 case

Cyprus informed members about problems in RA studies in the case of Dithiocarbamates expressed as CS2, concluding that more work needs to be done

regarding RA on complex RDs like Dithiocarbamates and a common approach on RA for Dithiocarbamates expressed as CS2 is needed.

11.2 Glyphosate

Germany presented details on the determination of glyphosate levels in breast milk samples and in German beer noting that glyphosate was not detected in breast milk samples. In beer, the conclusions were that glyphosate residues are plausible but the small amount does not pose a health risk. Nonetheless, the issues caused a great deal of interest in the media including contrary statements. The Netherlands remarked that this is mainly a problem of risk communication for which a communication strategy is needed. The topic will be scheduled for the agenda of joint session of the AFCWG and AF meeting in the Netherlands and Austria and Ireland are welcomed to present their communication strategies.

Finland presented a study on carryover of glyphosate originating in GM-soya through poultry production into greenhouse cultivation. The study concluded the glyphosate in seeds cultivated in greenhouses intended for poultry feed contain measurable amounts of glyphosate. Therefore plant health has to be considered when discussion about glyphosate, as it is currently not clear where the glyphosate originates from. The Chair confirmed to involve the EFSA PESTICIDE Unit as well as the Plant Health (PLH) Unit and consult back with Finland.

Action Point 17: EFSA to consult with PESTICIDE and PLH Unit on glyphosate carry over and come back to Finland

11.3 Heavy metal exposure of Finnish children and preliminary cumulative exposure

Finland presented results of a recently published study on heavy metal exposure of Finnish children and preliminary cumulative exposure assessment. The study concludes that youngest children have the highest risk of exceeding toxicological reference values. The heavy metal levels in some food groups are different in Finland than in EFSA reports. An English summary of the study is available on the EVIRA website. The Netherlands informed about a similar study on intake currently ongoing and promised to give more information on the next AF meeting.

11.4 Animal welfare certification

Croatia presented details on a pilot project for the development of a certificate in the area of animal health and welfare, with the long-term goal to develop a recognized certificate as a guarantee of production and origin on food to consumers and easier placement on the market for producers. On question from Italy Croatia confirmed taking also into consideration the biosecurity requirements of farming as well as the requirements of the single animal. Finland remarked having pushed this duty upon the industry, as they have a benefit from respecting existing EU legislation on animal health and welfare in order to enter the export market.

11.5 EU Menu – Dietary Survey Updates (ENALIA 1 and 2)

Bernhard Url gave the floor to Spain to present the outcome of two Spanish dietary surveys. The first, ENALIA 1, was conducted from 2012-2014 among children and adolescents, the second, ENALIA 2 from 2013-2015 among adults, older adults and pregnant women. The surveys have provided harmonized data across the Spanish population and will be included in the EFSA Comprehensive European Food Consumption Database. Sweden welcomed the high response rate in this quite diverse group in which teenagers are the most challenging explaining that Sweden had run a pilot project with teenagers and asking if Spain had encountered similar difficulties. Spain emphasized that it is crucial to find an experienced contractor, who applied a particular strategy including rewards, contacting the parents and establishing an interactive webpage. Cyprus informed about working on a similar

study, facing complications because of a low response rate. In a second incentive they collected data through house visits, offering medical checks in return, with positive results. Spain confirmed also having undertaken many house visits and calls.

11.6 Customer Feedback Exercise

Lesley Koschel introduced a proposal for running a customer exercise with the AF. Customer feedback is an integral part of EFSA's Quality Management System (QMS) set in place for continuous improvement of services. In this context a customer feedback mechanism with DG Sante was installed, running successfully for the last 2 years and to be repeated in 2016. EFSA is seeking now feedback from the MS as its second customer upon agreement of the AF at its last meeting. MS were invited to express their interest in volunteering in the first exercise until the end of March. Lesley encouraged particularly MS from whom EFSA received requests in 2015 to take part.

Action Point 18: EFSA to send e-mail asking for volunteer MS in Customer Feedback exercise

Action Point 19: MS to express interest in volunteering in Customer Feedback exercise

11.7 Fellowship programme

Stef Bronzwaer informed members about the progress made in the development of the EFSA Fellowship Programme. EFSA has started preparation works and resources for the 2-year pilot. As hosting sites for the three specific training modules Austria, Germany and Greece have been confirmed. The induction programme will take place at EFSA for the first 12 months circle. Latvia, together with Norway, Germany and the UK part of the Fellowship Programme Committee established in January, explained that technical comments could be discussed in a wider group of MS to allow countries with more experience sharing information with smaller countries. Information about the call to be published and the fellow selection criteria will be provided to the AF in the June meeting.

11.8 Presidency priorities and invitation to joint workshop with AFCWG

Bernhard Url gave the floor to the Netherlands who invited AF members to the next meeting taking place in Utrecht, the Netherlands in occasion of the Dutch EU Presidency. The Netherlands gave an outlook on the main topics, among which included AMR and risk communication. Members were invited to bring items related to AMR to the agenda. As the meeting will occur back-to-back to the meeting of the AFCWG, members are welcome to join a joint workshop on crisis communication and strategy on June 7th, prior to the AF meeting. A respective flyer will be circulated and members are invited to express their interest.

Finally, the Netherlands informed about a Symposium on the future of RA and toxicity testing of chemical materials taking place on 18-19 May.

Action Point 20: The Netherlands to circulate flyer on joint workshop with the AFCWG

Action Point 21: MS to express interest in joint workshop with AFCWG

Action Point 22: MS to address AMR related topics for June meeting to the Netherlands

12.AOB

12.1 Thematic Grant Call

Stef Bronzwaer gave a presentation on the upcoming launch of the Thematic Grant call expected for the week before Easter. The deadline for submissions will be mid September. The overall theme of the project is "methodology development in risk assessment" which is divided into 4 Lots: 1) Methods and systems for identifying

emerging food risks; 2) Structured tools for the risk-benefit assessment of foods and diets in relation to human health; 3) Developing integrated methodologies for the risk assessment of mycotoxin mixtures in food and feed; 4) output-based methods for the assessment of the freedom of animal disease/infection.

12.2 Scientific Networks - Designation of members

Jeff Moon explained that the annual updating of the list of members and representatives in EFSA's Scientific Networks has been concluded. AF Members, competent for the nominations, were asked to confirm the final list that shared on DMS. AF Members agreed to the list. On question of Finland, Marta Hugas confirmed considerations about a second Scientific Network in the area of Zoonoses, as the existing Scientific Network on Zoonoses Data Collection focusses on Data Collection only. Further information will be given on the AF meeting in June. Spain explained that often two experts have to come to the meeting because of nationally shared competences. Jeff Moon explained that additional experts can be accepted on their own expenses and are entitled to use the EFSA shuttles when coming on the same flight as the expert receiving reimbursement.

In that context Spain informed about a national survey that had been carried out among the Spanish Network Representatives. The results have been presented at the Focal Point meeting in February and the summary report is now available and can be shared with the AF through the Secretariat.

Action Point 23: EFSA to share summary report on Spanish survey among national Network Representatives

12.3 Risk communication on honey – Slovenia

Slovenia informed the plenary about a risk communication issue on honey produced using illegally manufactured veterinary medicines, which brought the RA procedures under scrutiny. Further information can be given at the June meeting.

12.4 African Swine Fever – Estonia

Estonia gave an update on a high level meeting on African Swine Fever having taken place two weeks ago. The African Swine Fever is becoming a European wide problem and more data collection is needed. Bordering countries, particularly Belarus, Ukraine and Russia a needed to be involved more. A next meeting on the topic will take place in autumn in Poland including further discussion with the Commission.

12.5 Foodborne viruses workshop – UK

The UK gave feedback in the foodborne viruses workshop that had recently taken place in the UK and brought 130 experts from 30 countries together. A research agenda has been developed. Next steps are discussions with EFSA and promotion of the research agenda to the EC.

CLOSURE OF THE MEETING

Bernhard Url closed the meeting, thanking participants for their attendance and active contribution, and expressed special thanks to the EFSA colleagues supporting the meeting.

SUMMARY OF ACTION POINTS

Action Number	Action
1	EFSA to share presentation on ED visits from the 26 th FP meeting
2	MS to express/ confirm interest in volunteering in a pilot project on data quality assurance
3	EFSA to provide overview of who has access to data at what level in the MS
4	EFSA/ NL to schedule session on monitoring of Veterinary Medicinal products usage for next AF meeting, and to explore inviting EMA
5	AF to comment on AF implementation plan until 23 March
6	AF to comment on draft AF rules of procedures until 23 March
7	MS to volunteer for drafting AF rules of procedures
8	MS to volunteer for drafting AF Declaration of commitment
9	Discussion Group on EU RAA to develop a template for MS expressions of interest in topics and lead
10	EFSA to send background paper on Delphi study to AF Members for national distribution
11	MS to volunteer on developing a presentation of the list of priorities to the HoA meeting
12	EFSA to reflect on a tool of information sharing on workplans and worksharing
13	EFSA to further improve the collection of information on replies to requests for information sent through the FP network on the upcoming reporting season later in 2016
14	Belgium to share outcome on study on nutritional value of water for infant formulae
15	EFSA to share information on upper safe levels versus recommended daily intakes, as well as their recent opinions on infant nutrition with Croatia
16	EFSA to revise ToR of FIP Network to be tabled on AF meeting in September
17	EFSA to consult with PESTICIDE and PLH Units on glyphosate carry over and come back to Finland
18	EFSA to send e-mail asking for volunteer MS in Customer Feedback exercise

19	MS to express interest in volunteering in Customer Feedback Exercise
20	The Netherlands to circulate flyer on joint workshop with the AFCWG
21	MS to express interest in joint workshop with AFCWG
22	MS to address AMR related topics for June meeting to the Netherlands
23	EFSA to share summary report on Spanish survey among national Network Representatives

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