

SCIENTIFIC COMMITTEE & ADVISORY FORUM UNIT

MINUTES OF THE 44TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 14-15 SEPTEMBER 2010

Agreed on 9 November 2010

PARTICIPANTS

Scientific Committee (SC):

Albert Flynn, Corrado L. Galli, Anthony Hardy, Harry Kuiper¹, Klaus-Dieter Jany, Michael Jeger², Ada Knaap, John Christian Larsen, David Lovell, Alberto Mantovani³, Birgit Nørrung, Josef Schlatter, Vittorio Silano (chair), Frans Smulders and Philippe Vannier.

European Food Safety Authority (EFSA):

Stef Bronzwaer⁴, Frank Boelaert⁵, Hubert Deluyker, Alexandre Feigenbaum⁶, Anne Laure Gassin, Catherine Geslain- Lanéelle, Riitta Maijala, Pia Makela⁷, Barbara Rotovnik⁸.

Secretariat of the Scientific Committee:

Djien Liem⁹, Silvia Bellocchio, Bernard Bottex, David Carlander, Daniela Maurici, Theresa Mc Fadden, Francesca Piombini and Tomas Öberg.

European Commission (EC): Michael Walsh.

¹ Present on 14th September

² Present on 14th September

³ Present for agenda item 10 and 15

⁴ Present for agenda item 15

⁵ Present for agenda item 13

⁶ Present for agenda item 8

⁷ Present for agenda item 13

⁸ Present for agenda item 16

⁹ Present on 15th September

1. **OPENING**

The Chair welcomed the participants. Apologies were received from Sue Barlow, John Dan Collins, replaced by Birgit Nørrung (vice chair of the BIOHAZ panel), Andrew Chesson, replaced by Alberto Mantovani (vice chair of the FEEDAP panel)¹⁰.

2. ADOPTION OF THE DRAFT AGENDA

The agenda was adopted as tabled.

3. DECLARATIONS OF INTEREST

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) and Specific Declaration of interest (SDoI) filled in by the invited experts. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process.

4. FEEDBACK FROM EFSA ON ISSUES RELEVANT FOR THE SCIENTIFIC COMMITTEE

• Implementing EFSA's policy on Declaration of Interests

EFSA's new policy on the Declaration of Interests (DoIs) was implemented after the Management Board decision in 2007 together with the introduction of electronic application. Internal audits were carried out between 2008 and 2009 and an audit of the IAS (Internal Audit Service) of the Commission took place in 2009.

EFSA has now employed an external contractor to evaluate the screening process for the declaration of interests. In addition another external contractor will benchmark the DoI systems in other agencies.

Based on experience on implementation and the reports of contractors, Management Board will review the DoI policy at the end of 2010 as planned in the Management Board decision of 2007.

• Scientific cooperation with Member States

At the last Advisory Forum meeting, a medium term planning to further strengthen cooperation between EFSA and Member States was discussed. The purpose was to define concrete actions and also to reflect on the role and the work of the Advisory Forum in this context.

Member States were interested to know in which activities they could be involved in and asked for an overview on what type of cooperation is foreseen in the near future.

Experience gained with grants and procurement as tools to seek support of Member States in addressing EFSA's workload was presented. EFSA moved forward on grants and procurement facilitating the use of framework and multiannual service contracts for better

 $^{^{10}}$ Present for agenda item 10 and 15

flexibility and continuity leading to improved efficiency and effectiveness. A document has been prepared and will be discussed at the next Advisory Forum meeting to see if the needs of Member States have been addressed. Follow up of the discussion will be presented at the next Scientific Committee Plenary.

5. DRAFT OPINION ON NANOTECHNOLOGIES

The draft guidance document on risk assessment concerning potential risks arising from application of nanoscience and nanotechnologies to food, feed and pesticides was presented for discussion. The guidance builds upon the Scientific Committee opinion published in 2009 and aims to provide a general overview on how to perform a risk assessment of nanomaterials in the food and feed area. The document gives information to interested parties on how to generate the necessary data required for a comprehensive risk assessment (under various legislative acts) in the area covered by the EFSA's remit to the extent possible with the current knowledge.

The Scientific Committee welcomed the document. Several comments were made that will be considered by the working group at the next meeting. The draft guidance will be then circulated for a panel consultation before being presented again to the Scientific Committee for endorsement for public consultation. The finalisation of the opinion is expected in April 2011.

6. DRAFT DISCUSSION PAPER ON ENVIRONMENTAL RISK ASSESSMENT

Discussions within the Scientific Committee have called for a review of current practices for environmental risk assessment (ERA) within the different EFSA panels in order to identify commonalities and possible discrepancies. A draft working document on ERA has been prepared by an internal task force and was presented to the Scientific Committee for discussion. The document focuses on areas where, due to regulatory requirements, ERA forms a part of EFSA risk assessment.

Specific guidance documents have been developed by the different EFSA panels that carry out ERA as well as by the Commission. The approaches used by the different EFSA panels show several commonalities but also few discrepancy that are sometimes due to different legal requirements. Sometimes differences are found between ERA related to specific applications as compared to more generic issues.

The Scientific Committee asked for some clarifications on the document and suggested to include an explanation of the different competences and remit of environmental risk assessment activities in EFSA. The terminology used is considered particularly important as well as having a more specific description about the environmental risk assessment activities of the different panels.

A technical report will be presented to the Scientific Committee in February 2011 together with a proposal for an action plan.

7. DRAFT STATEMENT ON "UPDATE ON THE STATE OF THE PLAY OF ANIMAL CLONING"

EFSA received a request from the European Commission in May 2010 for an update on the state of play of the possible scientific developments on the issue of cloning of farmed animals for food production purposes. The current EFSA statement is based on a review of the most recent scientific research on animal clones and their offspring found in peer-reviewed scientific literature published since its previous statement in 2009, information gathered during the recent call for data from European research centres and elsewhere and further discussions with scientific experts on animal cloning.

The current statement provides an update on the scientific developments on the cloning of farmed animals for food production with respect to food safety aspects as well as those relating to the health and welfare of animal clones and their offspring.

Following a thorough review of the relevant scientific information, the Scientific Committee concluded that the information presented in the statement of EFSA does not require reconsideration of the conclusion and recommendations from the previous 2008 opinion and 2009 statement of EFSA.

The Scientific Committee expressed its appreciation for the efficient and effective work ensuring the preparation of the statement in a short timeframe.

8. UPDATE ON THE RE-EVALUATION OF FOOD FLAVOURINGS BASED ON REQUESTED NEW INCOMING DATA

The head of the CEF unit gave an overview on the food flavourings evaluation process in Europe.

With respect to flavouring substances, European Parliament and Council Regulation 2232/96/EC sets out the basic rules for the use of these substances in or on foodstuffs in the EU. Under this Regulation, the Member States have informed the Commission which flavouring substances are currently authorised for use in foodstuffs at national level. This information has been compiled by the Commission in a Register of about 2700 substances, adopted as Commission Decision 1999/217/EC, and amended by Commission Decision 2000/489/EC. The Register forms the basis for a five-year evaluation programme of these flavouring substances as adopted by Commission Regulation 1565/2000/EC. Since completion of the evaluation programme at the end of 2009, a Community-wide positive list of flavouring substances for use in foodstuffs is being established.

To fulfil its obligation, EFSA has outsourced a project to collect and summarise data and information of food flavourings. The data were then evaluated by two EFSA working groups and published as opinion adopted by the CEF panel. The evaluation grouped substances according to chemical structure and likely metabolism. Substances that showed a genotoxic or carcinogenic potential were not further evaluated. For 265 substances out of 360 with structural alert for genotoxicity the panel needed further information and requested data from

industry for 47 representative substances. At present, 2232 substances are ready for the Union list to be adopted by the Commission by the end of 2010; 405 substances are left on hold since additional data have been requested. By the end of 2010, the Commission will adopt a union list of flavouring substances authorised for use in foodstuffs.

The CEF panel has also published an opinion on data needed for the evaluation of new flavouring substances. The guidance was published in June 2010.

The Scientific Committee thanked the head of unit for the comprehensive presentation and asked for clarification regarding the consistency between the new guidance and the previous one.

The approach proposed in the new guidance is consistent with the former decision tree but some aspects of the risk assessment process are more systematic and have been further improved, based on the experience of previous evaluations made by the panel.

9. PUBLISHED DOCUMENTS LINKED TO SCIENTIFIC WORK IN EFSA

The Director of Risk assessment presented the document "EFSA scientific outputs and supporting publications". The definition of the 8 scientific EFSA outputs was published in 2008. At present, all EFSA scientific outputs are published in the EFSA Journal. The implementation of the new EFSA Journal has called for a revision of the definition of EFSA scientific outputs. Starting from January 2011, the technical reports such as those deriving from public consultations will only be published on the EFSA website whereas all the scientific outputs will continue to be published on the EFSA Journal. The new overall category (supporting publications) of outputs will be published only on the EFSA website and not in the EFSA Journal.

10. REPORT BACK FROM SCIENTIFIC PANELS

Panel on animal health and animal welfare (AHAW)

The self-mandate on the role of tick vectors associated with Crimean-Congo Hemorrhagic Fever (CCHF) and African Swine Fever (ASF) in Eurasia resulted in a publication of two scientific opinions adopted by the panel at the last plenary: the first one on "The role of ticks in the epidemiology of CCHF and ASF in Eurasia" and the second one on "The geographic distribution of tick-borne infections and their vectors in Europe and the other regions of the Mediterranean basin". These scientific reports are the results of an excellent collaboration with the ECDC (European Centre for Disease Control). A database has been generated in the framework of the development of these opinions update of which negotiations are currently ongoing with ECDC. The importance of the exchange of information between the two agencies on the overlapping issues regarding both animals and humans has been highlighted. It was agreed to share epidemiological data and to possibly further formalise the collaboration between EFSA and ECDC with a Memorandum of Understanding.

The Commission has requested advice from EFSA on modernisation of meat inspection of different species. In addition to public health hazards, implications of possible changes in

meat inspection on animal health and welfare will be evaluated. This is a very broad task that covers different fields and will be therefore addressed in collaboration with BIOHAZ and CONTAM panels, Zoonoses, Datex and AMU Units.

Another opinion was adopted on the potential implication of the current H1N1 pandemic influenza for animal health.

The head of the DG Health and Consumers Unit D1 (Animal Health), Dr Laddomada, participated at the last AHAW plenary in September. He presented the state of play of the new Community animal health policy, confirmed the important role of EFSA as scientific support for the Commission and presented the actions by SANCO based on EFSA opinions.

Panel on food additives and nutrient sources added to food (ANS)

The last plenary was held in July. Two scientific opinions on the re-evaluation of curcumin (E100) and lutein (E161b) as food additives, as well as a statement on the divergence between the risk assessment of lycopene by EFSA and JECFA, were adopted during this meeting. Several other opinions will be finalised in October. The panel will have an extra plenary meeting in November this year to fulfil the deadlines agreed with the Commission.

Panel on biological hazards (BIOHAZ)

The last plenary was held in July. The panel adopted two opinions related to animal-by-products (ABP). The next plenary is scheduled for next week. Five opinions will be tabled for possible adoption among which the "Use of recycled hot water as decontamination technique of carcasses" (in collaboration with the CONTAM panel) and the one on "Irradiation of foods (efficacy and microbiological safety)".

The mandate on meat inspection (see also AHAW panel) will require a lot of resources in the next few years. The first deadline for providing an opinion on pigs meat inspection is June 2011. The structure and the milestones of this very broad mandate will be discussed and the lesson learnt from the first working group on pigs will be used to develop a strategy on how better addressed the same issue on other species.

Panel on food contact materials, enzymes, flavourings and processing aids (CEF)

The panel worked on the finalisation of the opinion on Bisphenol a (BPA) that will be proposed for adoption at the next plenary at the end of September.

EFSA has held consultations with national experts from across Europe, as well as several international risk assessment authorities, on the subject of Bisphenol A in recent months, including the design of scientific studies on BPA, toxicological aspects and the strengths and weaknesses of certain individual studies.

Similar issues – as well as details of new risk assessments and studies carried out around the world – have also been discussed with the U.S. Food and Drug Administration (FDA), Health

Canada, Food Standards Australia New Zealand (FSANZ) and the World Health Organisation (WHO).

Panel on contaminants in the food chain (CONTAM)

The panel adopted the last opinion on marine biotoxins in shellfish (brevetoxin group). Nitrate in vegetables and polybrominated diphenyl ethers will be discussed at the next plenary in September.

The Commission asked EFSA to re-consider the consumption figure for shellfish which was applied in the exposure assessment of marine biotoxins in the light of the new consumption data provided by Member States. The statement was published in August 2010.

The chair of the panel expressed some concerns about the high workload linked to an exceptionally high number of new requests for opinions which were recently received from the Commission.

The EFSA Executive Director reassured the Scientific Committee that EFSA is working on a medium-long term planning with the Commission services. The document will be also important for Member States to allocate adequate resources on projects in collaboration with EFSA.

Panel on additives and products of substances used in animal feed (FEEDAP)

Three opinions were adopted at the last plenary in July. The panel is working on the revision of several published guidance documents to incorporate the gained experience.

It is foreseen to receive between 800 and 2500 request for re-evaluation of feed additives under art.10 of Regulation 1831/2003. The exact number is difficult to be foreseen since some applications can include more than one additive.

Panel on genetically modified organisms (GMO)

The GMO panel is developing in close cooperation with the AHAW panel a guidance document for the risk assessment of Genetically Modified animals. As for all guidance documents, EFSA will consult Member States and relevant stakeholders during the process. In addition, public consultation will be held on this guidance before it is finalised by the end of 2011. The guidance document will cover the area of food and feed safety as well as the safety of releasing GM animals in the environment.

Panel on dietetic products, nutrition and allergies (NDA)

The panel held its plenary last week. Work is still ongoing for the assessment of claims submitted under art. 13 of Regulation 1924/2006.

EFSA is organising a scientific meeting on 2 December 2010 in Amsterdam, on the scientific requirements for health claims related to gut and immune function. The meeting will follow a public consultation on a draft guidance document on this topic to be launched in October 2010. Comments received during the public consultation, together with the draft guidance

document, will be presented by EFSA's experts for discussion at this meeting. The draft guidance document will be revised taking into account the meeting's discussions and the comments received. This scientific meeting is intended for food industry scientists with expertise in claims related to gut and immune functions.

Panel on plant health (PLH)

At the last plenary in July, the panel adopted an opinion on the appropriate methodology to eliminate pine nematode from bark of pine trees. Six new mandates were received from the Commission among which one is related to the EU important requirements for bonsai topiary trees that are host plants.

Panel on plant protection products and their residues (PPR)

Two guidance documents will be proposed for endorsement for public consultation at the plenary next week, one on protected crops and another one on persistence in soil.

The panel is also preparing a scientific opinion on the development of specific protection goal options for environmental risk assessment of pesticides.

11. BUILDING A MORE EFFICIENT AND EFFECTIVE PROCESS FOR APPLICATIONS

The Director of Risk assessment presented an overview of the EFSA applications evaluation process. A close dialogue with the Commission is necessary to make the best use of resources and to support an efficient and effective process. The collaboration with Member States is essential as well as a medium-term planning to build a more efficient process for screening of applications. Best practices and approaches in different regulatory workflows will also be collected.

12. DG SANCO WORKSHOP ON THE APPLICABILITY OF QSARS AND COMPUTATIONAL APPROACHES IN CHEMICAL RISK ASSESSMENT, 30 SEPTEMBER-1 OCTOBER 2010

DG Health and Consumers, JRC and EFSA are organising a workshop on QSARs and computational approaches in chemical risk assessment. The objective of the workshop is to raise awareness and create a sustained dialogue between model developers/QSAR experts, users/stakeholders and risk assessors concerning the strengths, the limitation and applicability of different computational tools and approaches in the overall context of chemical risk assessment. Recommendations and follow-up actions will set priorities, address gaps and needs and promote the development of computational toxicology in line with the needs and requirements of users and chemical risk assessors. Some of the members of the Scientific Committee and panel experts as well some EFSA staff will take part in the workshop. Feedback from the participants will be given at the next plenary.

13. UPDATE ON ZOONOSES DATA COLLECTION

The head of the Zoonoses Unit presented an overview of the recent results achieved by the Unit.

EFSA is responsible for examining the data on Zoonoses, antimicrobial resistance and food borne outbreaks submitted by Member States in accordance with Directive 2003/99 EC and

for preparing the Community Summary Report (CSR) for the results. Data from 2008 were produced in collaboration with ECDC who provided the information on Zoonoses cases in humans. The AHAW and the BIOHAZ panel were also consulted on a regular basis to comment and provide inputs on specific issues.

Two annual reports were produced for 2008: CSR on Zoonoses and food-borne outbreaks in EU; CSR on microbial resistance in EU. The reports cover the data analyses of 15 diseases.

The CSRs are important to raise awareness of current trends in Zoonoses in EU and to enable risk managers to consider needs for actions and to follow up the impact of control programmes. The data collected for 2008 showed that Campylobacteriosis and Salmonellosis continued to be the most commonly reported gastro-intestinal bacterial pathogens in humans in EU even if the number of notified cases decreased by 5% compared to 2007. Salmonellosis was again the second most often reported zoonotic disease in humans but the statistically significant decreasing trend in the notification rate of Salmonellosis cases continued. Already 20 Member States met their relative Salmonella reduction target set for 2008 in laying hens for the fifth consecutive year.

EFSA is working on the harmonisation of data collection to make the data fully comparable between Member States and over the years. Two reports have been issued to identify the best statistical and spatial methods to analyse annual Zoonoses data. Harmonisation of monitoring and reporting data has been achieved, among others, for reporting food-borne outbreaks, antimicrobial resistance in *Salmonella*, *Campilobacter*, commensal *E.Coli* and *Enterococci* in animals. Harmonisation is ongoing for survey methods for food born pathogen in foods and for vector borne zoonoses.

EFSA is also responsible for carrying out EU wide baseline surveys that provide a unique snapshot of the baseline prevalence of the pathogens in food and animal populations across EU. Some of the baseline surveys conducted are related for example on *Salmonella* in laying hens, in broiler flocks, in slaughter pigs and in turkey flocks. The ongoing survey relates to Listeria in ready-to-eat foods. Results will be available in 2011.

The issue of data collection and analyses at EU level remains a challenge, even if harmonisation has been achieved for the majority of the critical diseases and methods have been developed for the statistical analyses of the collected data.

The Scientific Committee congratulated the Zoonoses unit for the excellent work performed and for the quality of the reports that are used on a regular basis by the Commission for risk management decision and for follow up actions.

14. Draft technical report on endocrine active substances (EAS)

A draft report on endocrine active substances (EAS) was presented to the Scientific Committee. The report has been prepared by an internal taskforce, with the aim to clarify the state of play and to initiate the development of a common strategy towards EAS. In particular, the taskforce aimed at the identification of trend and developments in the assessment of the health risks of EAS.

The report gives an overview of the current activities and development within EFSA, the Commission and Member States and other European and international institutions. It considers also the work ongoing at OECD for the development of testing and assessment methodologies to detect EAS. At the end of the document, the taskforce gives recommendations on how to contribute to the work in progress in EU and internationally on EAS. This is important to ensure consistency between the approaches developed for risk assessment by different organisations, to establish a dialogue for developing a common strategy with the Commission, other EU bodies, Member States' competent authorities, internal organisations, as well as stakeholders.

The Scientific Committee congratulated the taskforce for the excellent report and endorsed the recommendations. The same document will be presented next week to Member States at the Advisory Forum. The report will be then published on the EFSA website.

15. REPORT BACK FROM WORKING GROUPS AND INTERNAL TASKFORCES

• WG Threshold of Toxicological Concern

Work is ongoing. The WG is optimistic that the TTC scheme could be suitable for wider use in some of EFSA's work but it is currently discussing some of the problems of the Cramer decision tree in classifying chemical structures into 3 groups. The WG aims to present the draft opinion for endorsement for public consultation at the SC plenary in April 2011.

WG Genotoxicity Testing Strategies

Work is in progress. The WG already discussed a series of key issues identified in previous meetings and is now starting to collect contributions to draft the opinion that will hopefully be presented to the SC plenary in April 2011 for endorsement for public consultation.

• WG Statistical Approaches

The WG is working on the issue of statistical significance versus biological relevance in risk assessment. A draft document is in preparation and will be submitted at the SC plenary in April 2011.

• WG Risk Assessment Terminology

The kick off meeting will be held in October 2010.

A final report was submitted to EFSA in the framework of the procurement that analysed 220 EFSA opinions issued between 2008 and 2009. The risk assessment terminology used in the summary and concluding sessions of the EFSA outputs was recorded in a database and a first analysis was done to highlight similarity and differences. The report will soon be published and the results will be presented at the next SC plenary in November.

The outcome and the database will be used by the WG as a starting point to develop proposals and recommendations on the way forward where harmonisation and a more consistent approach in risk assessment terminology is needed.

The issue will be also presented by the chair of the WG at the 2nd International Conference in Risk Assessment organised by DG Health and Consumers that will be held in January 2011 in Bruxelles.

• WG Default Values

The WG had the kick off meeting in July. The purpose of the activity is to make use of the DATEX overview of the default values used by EFSA panels and Units to identify where possible harmonisation (but not standardisation) of default assumptions would bring added value to EFSA assessments.

The WG foresees the need for a panel consultation before the opinion is presented for adoption by the Scientific Committee. The activity should run until the end of 2011.

• WG Compendium on Botanicals

The working group is in the process of updating the information contained in the Compendium of botanicals reported to contain compounds of possible concern with additional data received from the Member States' Competent Authorities via the EFSA focal points, and from the stakeholders. The review of the information received and the update of the compendium should be finalised by end of 2011.

• WG Benchmark Dose (II)

The first WG meeting was held in July. The objective of the activity is to produce a technical report illustrating with practical examples how to use the software available for dose-response modelling to derive BMDL. This report will summarise the outcome of a training workshop for EFSA Panels' Experts and EFSA Staff that will be held in Parma, beginning of December 2010.

• WG on training activities in the area of risk assessment

The kick-off meeting of the WG on training activities, coordinated by the Scientific Cooperation Unit, was held in the beginning of September 2010. The objective is to develop a technical specification for a training module on principles and methods of risk assessment. The training would then be offered to scientists involved in food and feed safety risk assessment at national authorities in order to expand both their theoretical knowledge and hands on experience in risk assessment to facilitate their participation in various scientific committees and bodies at EU and national level. EFSA panel members could possibly be involved as tutors to present specific case-studies as part of the training programme.

During the first WG meeting, a survey conducted by EFSA in the different EU Member States regarding training activities and training needs was presented and it will be used as a starting point for the development of the training specification.

The Scientific Committee welcomed the initiative and asked to be regularly informed about the progresses and the initiatives of the WG.

16. ANY OTHER BUSINESS

• 6th Chairs' meeting, 11-12 November 2010

The dates of the 6th meeting of Chairs and secretariats of EU Commission and Agencies Scientific Committees and Panels involved in risk assessment have been confirmed. The meeting will be held in 11-12 November in Copenhagen.

• Feedback from IUTOX 2010

The IUTOX meeting was held in July in Barcelona. Several EFSA staff participated at the conference presenting EFSA work in various sessions.

• EUROTOX 2011

The EUROTOX 2011 will take place in Paris. EFSA will coordinate sessions to present some of the ongoing work.

• Participation of EFSA in Scientific Conferences

Active cooperation between ESFA and the scientific community is a key objective for EFSA and a particular effort is made to organise scientific colloquia, big scientific meeting and joint events with Member States to increase awareness about EFSA's scientific work. The PIE unit, responsible for public information and events, presented the EFSA criteria for participation as an organisation to scientific events and conferences

A three-years planning (2011-2013) that lists possible EFSA participation to international scientific conferences and events is under preparation and will be discussed internally. SC members can submit their proposals to relevant scientific units.

• Emerging risks colloquium, 12 October 2010

The scientific colloquium on Emerging Risk will be held on 12th October in Parma. The objective of this Colloquium is to bring together international experts from different sectors related to food safety for an open scientific debate on key issues related to the identification of emerging risks, as defined by EFSA in 2007. The main objective is to provide inputs for the development of EFSA's methodological framework for emerging risks identification.

Discussions will focus on four main topics, namely on available methods to identify emerging risks, strategic sources of information and strategies for data collection, identification of drivers of change as underling causes of emerging risks, and on opportunities for the establishment of an international network to communicate on emerging risks.

The Scientific Committee welcomed the initiative. Feedback to the committee on the outcome of the colloquium will be given at the next SC plenary in November.

• Extra Scientific Committee plenary

The extra plenary of the Scientific Committee has been confirmed for the 7th December; it will take place in Rome.