ECDC Management Board

Minutes of the Twenty-second Meeting of the ECDC Management Board

Stockholm, 15-16 June 2011

Adopted by the Management Board at its Twenty-third meeting, 9-10 November 2011

Contents

Summary of Proceedings – ECDC 22nd Management Board meeting

The Twenty-second ECDC Management Board (MB) meeting convened in Stockholm, Sweden, on 15-16 June 2011.

Opening and welcome by the Chair (and noting the Representatives)

Introduction from Dr Marc Sprenger, Director, ECDC

Marc Sprenger, Director, ECDC, welcomed the members of the Management Board to Stockholm. He referred delegates to the brand new tabled ECDC brochure entitled "Excellence in prevention and control of infectious diseases", which includes the new internal ECDC Organisational chart. He also extended a special thank you to Mojca Gobec and her Slovenian colleagues for having hosted a highly successful joint meeting with the WHO Regional Office for Europe in Ljubljana the previous week.

Item 1: Adoption of the draft agenda (and noting the declarations of interest and proxy voting, if any) *(Documents MB22/2 Rev.2; MB22/3 Rev.1)*[1]

The Chair informed the MB that it was not possible to present the Draft Memorandum of Understanding between the European Centre for Disease Prevention and Control (ECDC) and the Israel Center for Disease Control (ICDC), since ECDC was still awaiting final confirmation of the text from the Ministry of Health of Israel. Once completed, the draft MoU will be submitted for final comments to DG SANCO. He assured the MB will be duly updated on the progress of this important item.

The Director of ECDC informed the MB that, as a result of legal complications, the "Framework Partnership Agreement between the European Centre for Disease Prevention and Control (ECDC) and the coordinating Competent Bodies (CCBs): allocation and provision of grants" paper had been withdrawn from this meeting. ECDC will liaise further with the Commission on this matter. This item will be revisited in the forthcoming MB meeting.

During the previous MB meeting in Dublin, in respect to the item, "A sustainable Agenda for ECDC", it was agreed that document MB21/13 needs to be further developed and as such was not included in this meeting due to the existing highly ambitious programme.

It was announced that proxy had been given to John F Ryan on behalf of Line Matthiessen-Guyader from the European Commission; Denmark had given proxy to Sweden, Germany to France and Malta to Greece.

The Management Board unanimously adopted the Draft Agenda (Documents MB22/2 Rev.3; MB22/3 Rev.2).

Item 2: Adoption of the draft minutes of the 21st meeting of the Management Board (Dublin, 15-16 March 2011) *(Document MB22/4)*[2]

Following amendments from Germany, the draft minutes of the 21st meeting of the Management Board were unanimously adopted by the Management Board (Document MB22/4).

[1] Item for decision
[2] Item for decision

Item 23: Extraordinary oral report: update on outbreak of Shiga toxin producing E. coli centred on northern Germany

The Management Board took note of the updates from Germany, the European Commission and the ECDC. It was agreed that the Chair of the MB will prepare a reply to The Lancet with regards to ECDC's activities during the outbreak in collaboration with other agencies and organisations.

Item 10 - Director's briefing on ECDC's main activities since the last meeting of the Management Board

ECDC's Director presented a brief update on the main activities of the Centre since the previous MB meeting by highlighting some of the recent events and country visits, amongst other items.[3] He extended a special thanks to Alexandru Rafila for his excellent organisation and support provided during the visit to Romania. The Heads of Units followed with individual updates from their respective Units.[4]

Item 11 – Update on reorganising ECDC to enhance cohesion, responsiveness and excellence *(Document MB22/12 Rev.1)*

The Advisor from Germany proposed that ECDC carry out an evaluation of the reorganisation within one year's time and proposed that this could be combined with the external evaluation process. He also suggested that the MB and AF should be given the opportunity to comment on the reorganisation and that an opportunity should equally be granted to ECDC staff to actively provide their input. The Head of Resource Management and Coordination Unit responded that it would not be advisable to disseminate a staff survey in autumn 2011 since only less than half a year has passed since the reorganisation has been in place. She assured that the staff of ECDC, including the MB and AF, shall be consulted accordingly.

The MB took note of the update on reorganising ECDC to enhance cohesion, responsiveness and excellence (Document MB22/12 Rev.1).

Item 13 – Update on activity based budget in ECDC *(Document MB22/14 Rev.1)*

The Management Board took note of the update and strongly supported the development of the activity based budget in ECDC (Document MB22/14 Rev.1).

Item 8 – ECDC Multi-annual Staff Policy Plan 2012-2014 *(Document MB22/11 Rev.1)*[5]

The MB unanimously adopted the Multi-annual Staff Policy Plan 2012-2014 (Document MB22/11 Rev.1).

Item 5 – EU Reference Laboratory Networks – Position statement of the Commission and ECDC on human pathogen laboratories: a joint vision and strategy for the future *(Document MB22/8)*[6]

[3] Item 9 – Director's briefing on ECDC main activities (M Sprenger)
[4] *Ibid.*
[5] Item for decision
[6] Item for decision

ECDC's Director thanked the Board for their support and constructive questions. He highlighted that, in the light of any future crisis, it would be helpful to have a mapping of laboratory expertise and resources in Member States as a means to ensure effective control of infectious diseases, with more quality control and sharing of resources.

The MB endorsed the joint vision and strategy of the Commission and ECDC on human pathogen laboratories (Document MB22/8). A comprehensive progress report reflecting the requests of the Board shall be presented at the next meeting in November.

Item 4 – ECDC Management Board meeting dates for 2012 and 2013 *(Document MB22/7 Rev.1)*[7]

The Alternate of Cyprus expressed her gratitude for the opportunity to arrange the MB meeting in 2013.

The Member of Bulgaria also expressed his readiness to host a future Management Board meeting in his country.

The Management Board adopted its meeting dates for 2012 as follows (Document MB22/7 Rev.1):

MB24: 28-29 March 2012 (Stockholm)

MB25: 19-20 June 2012 (Stockholm)

MB26: 14-15 November 2012 (Stockholm)

The Management Board also provisionally took note of its provisional meeting dates for 2013:

MB27: 20-21 March 2013 (Cyprus)

MB28: 19-20 June 2012 (Stockholm)

MB29: 13-14 November 2013 (Stockholm)

Item 6 – Proposal: EU support for vigilance and traceability of tissues and cells *(Document MB22/9)*[8]

The Chair requested that ECDC draft a proposal considering all the comments from the Board and to finalise the discussion on the second day of the meeting.

Item 7 – Proposal from Management Board Working Group on the ECDC Language Regime *(Document MB22/10 Rev.1)*

The proposal on the language regime was put to a vote to the Board with the following caveats:

- The proposal is a temporary solution to follow the MBWG solution;
- The proposal refers exclusively to Management Board meetings and shall not extend to any other types of external communications from ECDC;
- The language regime of the Management Board will be formally taken up in the planned external evaluation and assessed accordingly.

Following its adoption, ECDC shall evaluate the new regime, and if necessary, request the European Commission to review the Founding Regulation.

The majority of the Management Board endorsed the proposed solution for the ECDC language regime, with three members against (Czech Republic, Greece and Portugal) and two abstentions (European Parliament and Italy).

[7] Item for decision
[8] Item for decision

Item 6 – Proposal: EU support for vigilance and traceability of tissues and cells *(Document MB22/9)* - ***Continued***[9]

The Chair informed the Board of the proposal on SoHO, which had been prepared the day before and sent out electronically to all members.[10] He recalled the basis of the proposal and that ECDC needs to initiate work therein, and that no decision is to be made with respect to collaboration between EMA and ECDC at this meeting. He also affirmed that EMA should carry out the leading role.

Item 3 – Summary of discussions held at the 17th meeting of the ECDC Audit Committee (14 June 2011), including its recommendations

Irene Nilsson-Carlsson, Chair, ECDC Audit Committee, briefed the MB on the items discussed and conclusions made at the 17th Audit Committee meeting.[11] Her presentation was supported by Anja Van Brabant who illustrated the improvements made within the budget execution during the last three years.

Final Annual Accounts 2010, including the Report on Budget and Financial Management *(Document MB22/5)*[12]

The Final Annual Accounts 2010, including the Report on Budget and Financial Management, were unanimously adopted (Document MB22/5).

Supplementary and Amending Budget *(Document MB22/6)*[13]

The Board unanimously approved the Supplementary and Amending Budget (Document MB22/6).

Item 12 - ECDC WP Priorities *(Document MB22/13 Rev.1)*

It was agreed that the MB would receive the written procedure via email with a deadline for a receipt of feedback from the Member States by 31 July 2011. The final version of the Work Programme 2012 will be presented to the MB in November (Document MB22/13 Rev.1).

Item 10a - Update from the Hungarian EU Presidency

Márta Melles, Alternate, Hungary, presented the main events and activities of the Hungarian EU Presidency.[14] She thanked the Member States as well as the ECDC for their participation.

Item 10b- Update from the Polish EU Presidency

Pawel Gorynski, Member, Poland, presented the main events and activities of the Polish EU Presidency.[15] He also agreed to share the calendar of events with the Management Board.[16]

[9] Item for decision
[10] "Draft Communication of MB on the EU support for traceability of tissues and cells" (paper tabled by the European Commission, 17 June 2011).
[11] Item 3 - Summary of 17th AC meeting (I Nilsson-Carlsson)
[12] Item for decision
[13] Item for decision
[14] Item 10a - Update regarding the Hungarian EU Presidency (M Melles)
[15] Item 10b - The Polish Presidency of the European Union (P Gorynski)
[16] Calendar of Events – Polish EU Presidency (refer to MB Extranet Handout documentation)

Item 14 - Planned External Evaluation of ECDC for 2012

Andrew Amato, Head of Surveillance, Surveillance and Response Support Unit, introduced the topic of the External Evaluation of ECDC, referring to the first one which was launched in 2007 and reported in 2008.[17] The Centre's Founding Regulation stipulates that ECDC needs to conduct these evaluations regularly and it was agreed to carry them out every five years. This means that in 2012, ECDC will need to contract out and conduct the next external evaluation. Prior to that, detailed terms of reference for this evaluation need to be drawn up and subsequently approved by the Management Board.

It was agreed that Andrew Amato, together with a small internal ECDC Evaluation Team that includes Jan Mos, Senior Advisor to Director, will support an MB Steering Sub-committee composed of the Management Board members from Belgium, Estonia, Romania, Slovenia and the United Kingdom, Jacques Scheres (European Parliament) and a Member of the European Commission (nominee to be confirmed shortly). The Belgian Board Member, Daniel Reynders, will chair the MB Steering Sub-committee.

The Management Board took note of the planned External Evaluation of ECDC for 2012.

Item 6 – Proposal: EU support for vigilance and traceability of tissues and cells *(Document MB22/9)* – ***Continued***[18]

The Chair recalled the two draft proposals that were tabled during the meeting.[19]

Given time constraints and the need to communicate with their countries' officials in order to receive clear instructions, France and Germany requested that this item be voted upon via written procedure. Both countries contended that clear positions are required in order to make consequential decisions. The MB Chair declined their request due to the urgency in advancing the proposal to the next steps. However, the Chair stated that all open questions can be addressed in the soon to be established Steering Group.

The 'Draft Communication of MB on the EU support for traceability of tissues and cells'[20] was adopted by the Management Board, with two abstentions from France and Germany. Such conclusions are centred on the following: i) no change in legal mandate of ECDC; ii) tasks to support the European Commission in implementing the EU legislation; iii) tasks limited to rapid exchange of information and provision of scientific advice and the; iv) creation of a Steering Group,[21] which consists of ECDC, EMA, European Commission, MB members of both Agencies, including representatives of national competent authorities.

The 'Draft Communication of MB on the EU support for traceability of tissues and cells' was adopted by the Management Board, with abstentions from France, Germany and Spain. ECDC Director to implement the tasks as contained in the adopted Communication and to present a progress report in a forthcoming Management Board meeting.

Item 18 – Update from the European Commission: legal and financial aspects to be considered by ECDC prior to engaging in and/or responding to threat assessments

John F Ryan confirmed that the EC Legal Service considers the Commission not a competent body but a competent authority. Therefore, under the Founding Regulation, the Commission can ask ECDC for

[17] Item 14 - Planned External Evaluation of ECDC 2012 (A Amato)
[18] Item for decision
[19] See Annex I (Communication from Germany on the EU support of traceability of tissues and cells) and Annex II (Draft Communication of MB on the EU support for traceability of tissues and cells)
[20] See Annex II
[21] During this plenary session, Germany proposed to establish a working group.

risk assessments or activities in relation to that. Further, the Commission has been making such requests to ECDC since the latter's inception.

The Management Board took note of the update from the European Commission in respect to the legal and financial aspects to be considered by ECDC prior to engaging in and/or responding to threat assessments.

Item 15 – Organisational Excellence (Quality Assurance)

The Management Board took note of the update from Andrea Ammon on organisational excellence (Quality Assurance).

Item 16 – Interim results of ECDC's pilot survey with the Advisory Forum on the impact of ECDC's scientific advice

The Management Board took note of the Interim results of ECDC's pilot survey with the Advisory Forum on the impact of ECDC's scientific advice.

Item 17 – Strengthening Disease Prevention and Control capacity in the Mediterranean Region through Training ("Mediterranean EPIET")

The Management Board took note of the presentation, 'Strengthening Disease Prevention and Control capacity in the Mediterranean Region through Training' ("Mediterranean EPIET").

Item 19 – Interim report on improving communications between ECDC and the Management Board

The interim report on improving communications between ECDC and the Management Board was noted by the Board and feedback therein will be duly integrated into the planned external evaluation.

Item 20 – Update on status of alternative premises for ECDC

The Management Board took note of the Director's update on the status of alternative premises for ECDC.

Item 21 – Update on matters concerning the Seat Agreement

The Management Board took note of the update on matters concerning the Seat Agreement and look forward to receiving a more comprehensive report at the next meeting in November.

Opening and welcome by the Chair (and noting the Representatives)

1. The Chair, Hubert Hrabcik, opened the Twenty-second Meeting of the ECDC Management Board (MB) and welcomed all members to Stockholm. He also welcomed the following newly appointed individuals: Martin Seychell (Member, European Commission), Angel Kunchev (Member, Bulgaria), Anni Virolainen-Julkunen (Alternate, Finland), Dora Hennessy (Alternate, Ireland), Marianne Donker (Member, Netherlands), Carmen Amela Heras (Member, Spain). The Chair also welcomed Ioana Siska from the European Commission, who had been invited to present during the agenda item, 'EU support for vigilance and traceability of tissues and cells'.

2. Apologies were also noted from Line Matthiessen-Guyader (European Commission), Denmark, Germany, Iceland, Liechtenstein and Malta.

Introduction from Dr Marc Sprenger, Director, ECDC

3. Marc Sprenger, Director, ECDC, welcomed the members of the Management Board to Stockholm. He referred delegates to the brand new tabled ECDC brochure entitled "Excellence in prevention and control of infectious diseases", which includes the new internal ECDC Organisational chart. He also extended a special thank you to gv Gobec and her Slovenian colleagues for having hosted a highly successful joint meeting with the WHO Regional Office for Europe in Ljubljana the previous week.

Item 1: Adoption of the draft agenda (and noting the declarations of interest and proxy voting, if any) *(Documents MB22/2 Rev.2; MB22/3 Rev.1)*

4. The Chair informed the MB that it was not possible to present the Draft Memorandum of Understanding between the European Centre for Disease Prevention and Control (ECDC) and the Israel Center for Disease Control (ICDC), since ECDC was still awaiting final confirmation of the text from the Ministry of Health of Israel, including confirmation of a legal basis/mandate of the Israel CDC, which is needed for the finalisation of this draft MoU. Once completed, the draft MoU will be submitted for final comments to DG SANCO. He assured the MB will be duly updated on the progress of this important item.

5. The Director of ECDC informed the MB that, as a result of legal complications, the "Framework Partnership Agreement between the European Centre for Disease Prevention and Control (ECDC) and the coordinating Competent Bodies (CCBs): allocation and provision of grants" paper had been withdrawn from this meeting. ECDC will liaise further with the Commission on this matter and it is hoped that this item will be revisited in the forthcoming MB meeting.

6. During the previous MB meeting in Dublin, in respect to the item, "A sustainable Agenda for ECDC", it was agreed that document MB21/13 needs to be further developed and as such was not included in this meeting due to the existing highly ambitious programme. The Director of ECDC proposed to postpone this item to the November MB meeting.

7. Due to various last-minute changes in the draft agenda/programme, the Chair informed the MB that some document numbers are not aligned with the numbering on the agenda/programme. Documents with revised numbering will thus be made available on the Management Board Collaborative Workspace (Extranet) directly following the meeting.

8. Members were asked to declare any specific interests that could be considered to be prejudicial to their independence with respect to the items on the agenda. No conflict of interests was declared.

9. With reference to the Declarations of Interest, Martin Seychell and John F Ryan, Members, European Commission, declared under agenda item 3 (Summary of discussions held at the 17th meeting of the ECDC Audit Committee [14 June 2011], including its recommendations: a) Final Annual Accounts 2010, including the Report on Budget and Financial Management; b) Supplementary

and Amending Budget 2011) that they are Authorising Officers at DG Sanco. They are also responsible for laboratory issues within DG Sanco, and therefore declared their interests under item 5 (EU Reference Laboratory Networks - Position statement of the Commission and ECDC on human pathogen laboratories: a joint vision and strategy for the future). Under agenda item 6 (Proposal: EU support for vigilance and traceability of tissues and cells), they are responsible for implementation within DG Sanco. With respect to agenda item 12 (ECDC 2012 Work Programme Priorities), both Members are responsible for government policy in the area of public health. They declared under agenda item 13 (Update on activity based budget in ECDC) their roles as Authorising Officers for budget issues in DG Sanco. Under agenda item 17 (Strengthening Disease Prevention and Control capacity in the Mediterranean Region through training ["Mediterranean EPIET"]), they are responsible for government policy in the area of migrants and communicable disease issues in DG Sanco. Under item 18 (Update from the European Commission: legal and financial aspects to be considered by ECDC prior to engaging in and/or responding to threat assessments), they declared their status as members and their responsibility for government policy in the area of public health. Under agenda item 22 (Extraordinary oral report: update on outbreak of Shiga toxin producing E. coli centred on northern Germany: a) Germany; b) European Commission; c) ECDC.), they are responsible for government policy on health threats and health security. Iréne Nilsson-Carlsson, Member, Sweden, noted under item 21 (Update on matters concerning the Seat Agreement) that she represents Sweden.

10. It was announced that proxy had been given to John F Ryan on behalf of Line Matthiessen-Guyader from the European Commission; Denmark had given proxy to Sweden, Germany to France and Malta to Greece.

The Management Board unanimously adopted the Draft Agenda (Documents MB22/2 Rev.3; MB22/3 Rev.2).

Item 2: Adoption of the draft minutes of the 21st meeting of the Management Board (Dublin, 15-16 March 2011) *(Document MB22/4)*

11. Following some amendments from Germany, the draft minutes of the 21st meeting of the Management Board were adopted.

Following amendments from Germany, the draft minutes of the 21st meeting of the Management Board were unanimously adopted by the Management Board (Document MB22/4).

Item 23: Extraordinary oral report: update on outbreak of Shiga toxin producing E. coli centred on northern Germany

Germany

12. Johann Fontaine, Advisor, gave an oral update on the outbreak on behalf of Germany. He extended a thank you to both ECDC and EFSA for their good collaboration and support. He informed that the number of new infections is clearly decreasing. In total, thirteen people have died, over five hundred cases were confirmed and some additional cases suspected. He noted the geographical areas in Germany where the cases originated. The three first potential carriers of the infection indentified were tomatoes, cucumbers and lettuce. The origin of the infection was identified in bean sprouts.

European Commission

13. John F Ryan, representative of the European Commission, listed some of the main activities which had been carried out during the outbreak. He noted that the Early Warning and Response System (EWRS) and the Rapid Alert System for Feed and Food (RASFF) provided very good information. He mentioned that the Commission has been working with ECDC on the risk assessment report. The Commission has also requested ECDC to work with EFSA to develop advice for the general public, which has been translated and is available on both websites. Since public perception

has been paramount during the crisis, daily press updates have been submitted and the European Parliament has been consulted accordingly to inform people. He also noted that staff from the Commission, together with colleagues from ECDC and EFSA, were on site in Germany to assist accordingly. With regards to banning certain food products, the Commission's standpoint was that this was unjustified at the present time. The Commission has been communicating with Russia and Canada, amongst others, to eliminate the bans. John F Ryan concluded that the contribution from ECDC has been very important and valuable and he expressed the Commission's satisfaction with the rapid reaction and response from ECDC.

ECDC

14. The Director of ECDC recalled that on 31 May 2011, the Public Health Event (PHE) level 1 was activated. As a result of this, more than thirty staff members were actively involved. He made reference to the ECDC core values and noted that these were strongly reflected in the work during the crisis. Updates on the situation had been also forwarded to the Management Board via email. He also informed that the PHE level has since been lowered to zero.

15. Denis Coulombier, Head of Surveillance and Response Support Unit, ECDC, provided the MB with an overview of various activities taking place during the crisis.[22] Marc Struelens, Head of Section, Microbiology Coordination, Resource Management and Coordination Unit, ECDC, updated the MB on the laboratory support. Denis Coulombier referred to ECDC staff members on site and underlined the extreme usefulness of having such liaison.

16. The Director commented on the press coverage and was content that ECDC was cited quite often for facts and figures. However, he referred to an editorial in The Lancet[23] where it was stated that ECDC remained inactive throughout the crisis. He informed the MB that a reply[24] had been prepared by ECDC and that the Senior Editor of the journal has approved its publication.

17. The Chair supported the comments from the ECDC Director in The Lancet and declared that the criticism was not fair. Germany requested that the Chair of the ECDC Management Board should also react to the editorial as published in The Lancet.

18. The Member of Spain noted that contact with ECDC and EFSA has proven to be highly valuable. However, she pointed out the delay in reaction, i.e. referring to waiting until 22 May, and underlined that this should be avoided in future crisis situations. She also noted that this event has shown the need to improve the coordination mechanisms related to health crisis in the European Union. This should consider both, the alerts network and the coordination with Health Authorities. We should ensure that decisions are based on scientific evidence and that Health Authorities are rapidly informed when a health threat is suspected. She also commented on the lack of satisfactory communication and that we have to learn of this experience with the aim of improving communication and coordination to better handle crisis situations. She was supported by the Member of the European Commission who agreed that communication and overall coordination needs to be improved.

19. In referring to The Lancet editorial, one member suggested that ECDC should also consider improving its visibility and investing in better public relations.

20. The Director of ECDC pointed out that one of the major weaknesses is the microbiology function. He highlighted the importance of having a clear overview about where the laboratories are situated for necessary tests, etc. He also strongly supported the idea that the Chair formally reply to the editorial as published in The Lancet on the behalf of the Board.

---

[22] Item 22c - ECDC Update on outbreak of Shiga toxin producing E. coli (D Coulombier)

[23] Editorial, "Responding to disease outbreaks in Europe" in The Lancet, Volume 377, Issue 9782 (25 June 2011), p. 1978 http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2811%2960846-5/fulltext (a copy of this editorial was tabled during the MB22 meeting.

[24] Correspondence, Dr Marc Sprenger, "ECDC and the Escherichia coli outbreak in Germany" in The Lancet, Volume 377, Issue 9782 (25 June 2011), p. 2180 ("http://download.thelancet.com/pdfs/journals/lancet/PIIS014067361160963X.pdf?id=40bade4753939e7f:2efe163f:1311850e5de:6f2d1310381018251) (a copy of this correspondence was tabled during the MB22 meeting).

The Management Board took note of the updates from Germany, the European Commission and the ECDC. It was agreed that the Chair of the MB will prepare a reply to The Lancet with regards to ECDC's activities during the outbreak in collaboration with other agencies and organisations.

Item 10 - Director's briefing on ECDC's main activities since the last meeting of the Management Board

21. ECDC's Director presented a brief update on the main activities of the Centre since the previous MB meeting by highlighting some of the recent events and country visits, amongst other items.[25] He extended a special thanks to Alexandru Rafila for his excellent organisation and support provided during the visit to Romania.

22. The Heads of Units followed with individual updates from their respective Units.[26]

23. Minerva-Melpomeni Malliori, Member, European Parliament, extended her gratitude in respect to the updates and noted that they are quite useful. She continued by informing the MB of the increasing percentage of HIV infections in Greece resulting from the increasing number of injecting drug users. She stated that this issue is strongly related to migration and that similar patterns are noticeable in the case of tuberculosis. She requested that ECDC and the European Commission assess this matter.

24. The Director of ECDC confirmed that the staff of the Centre are highly aware of the current situation in Greece and closely collaborate with their Greek colleagues. Together with the World Health Organization (WHO), ECDC is working on guidance documents on TB screening. The Member of the European Commission added that the Commission will work closely together with ECDC on this and support the Member States involved.

Item 11 – Update on reorganising ECDC to enhance cohesion, responsiveness and excellence *(Document MB22/12 Rev.1)*

25. In referring to the document, as well as to the tabled brochure, ECDC's Director noted that the staff of the Centre is engaged in using the full names of the Units and Sections in order to avoid using acronyms. He also informed the MB of intensive management training, which will soon be provided to all Section Managers and Team Leaders, and that a kick-off seminar will convene directly following this meeting. Andrea Ammon, Head of Resource Management and Coordination Unit, noted that there have been no formal complaints received by the Joint Committee, including the Staff Committee members, which was set up specifically for giving staff a forum to voice their concerns regarding the reorganisation.

26. Johann Fontaine, Germany, asked on what basis the five different options/models for the Centre were developed by ECDC's consultant. Andrea Ammon responded that the contractor worked with ECDC during a shorter period of time and was supposed to use the information collected internally to develop the five options. It was clear at the time that not all of the suggestions from the ECDC staff could be addressed by organisational changes. The contractor therefore outlined different approaches of organisational set ups with both advantages as well as disadvantages of each option. In the end, it was a decision of the working group of ECDC to suggest the best option to the Senior Management Team (SMT), and the decision of the SMT to implement the current solution.

27. The Advisor from Germany also proposed that ECDC carry out an evaluation of the reorganisation within one year's time and proposed that this could be combined with the external evaluation process. He also suggested that the MB and AF should be given the opportunity to comment on the reorganisation and that an opportunity should equally be granted to ECDC staff to actively provide their input. The Head of Resource Management and Coordination Unit responded that it would not be advisable to disseminate a staff survey in autumn 2011 since only less than half a year has passed since the reorganisation has been in place. She assured that the staff of ECDC, including the MB and AF, shall be consulted accordingly.

[25] Item 9 – Director's briefing on ECDC main activities (M Sprenger)
[26] *Ibid.*

The MB took note of the update on reorganising ECDC to enhance cohesion, responsiveness and excellence (Document MB22/12 Rev.1).

Item 13 – Update on activity based budget in ECDC *(Document MB22/14 Rev.1)*

28. Philippe Harant, Head of Section, Quality Management, Resource Management and Coordination Unit, ECDC, gave a presentation on the current status of the activity based budget in ECDC, which is still in the form of a pilot exercise.[27]

29. Iréne Nilsson-Carlsson, Swedish Member and Chair of the ECDC Audit Committee, informed that this item was also discussed during the previous day's Audit Committee meeting and complimented ECDC on the work carried out in developing this useful tool.

30. While sharing Sweden's viewpoint, Martin Seychell, Member, European Commission, remarked on the need to integrate performance indicators in the model and to link the activities to each area.

31. In referring to some figures in the document, the Member of France suggested indicating the number of full posts for TP and also finding a way in which to define core functions.

The Management Board took note of the update and strongly supported the development of the activity based budget in ECDC (Document MB22/14 Rev.1).

Item 8 – ECDC Multi-annual Staff Policy Plan 2012-2014 *(Document MB22/11 Rev.1)*

32. Jessica Mannheim, Head of Section, Human Resources, Resource Management and Coordination Unit, ECDC, presented the Multi-annual Staff Policy Plan for 2012-2014.[28]

33. John F Ryan, European Commission, recalled the reserved position of the Commission due to an outstanding question in respect to entry grades for Heads of Unit posts, which is currently being discussed between ECDC and the Commission.

34. Minerva-Melpomeni Malliori, Member, European Parliament, questioned whether ECDC is aware of the number of turnover of staff since the establishment of the Centre. The Head of Section, Human Resources, responded that the annual turnover rate is approximately 5-6%.

35. Germany sought clarification with regard to posts omitted from the document, such as staff for SoHO. The Director of ECDC noted that ECDC is anticipating resource requirements for SoHO, as well as other potential tasks, and due to this some posts remain unfilled. Currently, there are eight posts which are not filled, and even though these are not particularly reserved for SoHO, it guarantees flexibility.

36. In response to a question from Germany, Jessica Mannheim clarified that while the statutory staff is 300 persons (200 TAs and 100 CAs), ECDC also has external staff, such as interims, consultants and SNEs, and therefore the total overall staff is 350.

The MB unanimously adopted the Multi-annual Staff Policy Plan 2012-2014 (Document MB22/11 Rev.1).

Item 5 – EU Reference Laboratory Networks – Position statement of the Commission and ECDC on human pathogen laboratories: a joint vision and strategy for the future *(Document MB22/8)*

37. The European Commission expressed their support to the Director of ECDC for his continued focus on the laboratory networks. The Commission is working together with the ECDC in order to

[27] Item 13 - ECDC Activity Based Budget (P Harant)
[28] Item 8 - ECDC Multi-annual Staff Policy Plan 2012-2014 (J Mannheim)

increase the capacity. The recent outbreak has shown the necessity for a well coordinated laboratory network. The goal is to add value and avoid any duplication of work.

38. During a presentation given by Marc Struelens on behalf of ECDC,[29] the lessons learnt from the recent Escherichia coli outbreak were highlighted and the role of the Commission as well as of ECDC was further clarified.

39. The Member of France thanked ECDC for this clear vision, and also brought out a few observations and questions. She remarked that further information would be needed prior to approval by the Management Board. She suggested that there are two different possible paths, namely, to have the Member States, together with the Commission, designate the laboratories, in which case the issue is how to coordinate the National Reference Laboratories and the European Reference Laboratories. She also asked whether the Commission would base its actions on the existing list of national laboratories. She also sought information on how the WHO reference laboratories system works. Who would be triggering the laboratory activities once the time has come remains unclear. The outcome of the ongoing Eurolop project also needs to be taken into account

40. The Member of the Netherlands strongly supported the vision and strategy, and welcomed any plans that result from this strategy in the future.

41. The Alternate of the United Kingdom agreed with the previous speakers and highlighted the importance of the joint vision and strategy. While the Swedish Member also shared the view that the vision and strategy would provide added value, she cautioned that the concept of "reference laboratories" remains unclear as ECDC uses the term in different contexts, which creates confusion. She continued by noting the importance of defining the legal basis and proposed that the Commission and the Council elaborate further in this respect. She also pointed out the difference between the veterinarian and food safety sides, including the different public health regulations in place, which should also be considered. She also noted that Sweden supports a gap analysis in which further clarification will be made in respect to necessary areas for collaboration.

42. The Member of Spain expressed that it is not necessary for reference laboratories to proceed further to the EU level. Rather, the Member States require a mechanism in which to increase their response to public health. The role of ECDC and the Commission should be complementary and clarification is needed in terms of 'who does what' and 'how' prior to having a system in place.

43. In agreeing with France, the Romanian Member stated that there are two different components to this issue, namely, the Commission should ask the Member States to define the reference laboratories, based on Terms of Reference and considering the financial situation and possibilities, to establish a common structure of criteria for each Member State. Otherwise, the differences between various laboratories will be sizeable and coordination between countries would need to be enforced due to these differences. Secondly, the role of ECDC should be strengthened in terms of coordination.

44. While noting that the present document represents an important step forward, Germany conceded that clarification is still needed and the structure could be further improved. The concept of the reference laboratories is missing and needs to be worked on. The issue of leadership and who is responsible for what was also questioned.

45. The Member of Belgium asked that clear objectives for the reference laboratories be better defined.

46. Martin Seychell, Member, European Commission, presented his initial reactions to the questions posed by the Management Board. He explained that as there was a sense of lack in transparency, it was the objective this time to unveil the work of the Commission and the ECDC. He recalled that what was presented at this point was the vision for the future and that the actual results have to wait until the ongoing processes have been completed. The Commission is finalising a proposal on the legal basis. In terms of the work of WHO, it is vital to ensure that they would not be duplicating any of the activities and therefore further discussions with WHO are necessary. The aim is to conduct a gap analysis to ascertain what needs to be improved.

[29] Item 5 - EU Reference Laboratory Networks (M Struelens)

47. ECDC's Director thanked the Board for their support and constructive questions. He highlighted that, in the light of any future crisis, it would be helpful to have a mapping of laboratory expertise and resources in Member States as a means to ensure effective control of infectious diseases, with more quality control and sharing of resources.

48. Martin Seychell, Member, European Commission, agreed that much can be done despite the absence of a strong legal basis. He reiterated the earlier statement of John F Ryan, namely, that this strategy is only the first step in the process and it is aimed at maximising transparency. He agreed that some laboratories might be less strong than others, but the main effect of the entire network can still be very relevant. He stressed the importance of knowing how to utilise the best expertise in the best possible way and also decreasing the reaction time in the event of a crisis. It is alarming that ECDC does not possess a basic list of the laboratories. He also reflected on earlier comments and stated that the aim is not to duplicate any activities from other sectors, but to learn from them. The MB needs to decide upon the next steps and what is expected from the reference laboratories.

49. Marc Struelens reflected on the comments made and thanked the MB for their support. He accepted defining the roles and functions of the reference laboratories and opined that clarification still needs to be reviewed. He pointed out that ECDC has held many consultations with the MFPs and one result has been to define the five core public health functions which should define the reference laboratories. He referred to the technical report on the core functions of microbiology reference laboratories for communicable diseases. He also agreed that the legal basis needs to be further clarified. Regarding more concrete examples of tasks and outputs to be delivered according to the strategic objectives, he invited the Members to consult the description of ongoing ECDC microbiology projects in the annex to the paper.

50. The Chair concluded by calling for a comprehensive progress report for the next Management Board meeting in November.

The MB endorsed the joint vision and strategy of the Commission and ECDC on human pathogen laboratories (Document MB22/8). A comprehensive progress report reflecting the requests of the Board shall be presented at the next meeting in November.

Item 4 – ECDC Management Board meeting dates for 2012 and 2013 *(Document MB22/7 Rev.1)*

51. Iréne Nilsson-Carlsson, Chair of the ECDC Audit Committee, informed the MB that a suggestion was made at the previous day's Audit Committee meeting to postpone its meetings, as well as MB meetings in June, due to the potential delay in preparing the financial documents. The Audit Committee accepted this proposal, with a caveat that some documents may not be submitted to the AC and the Board within the statutory ten working day in advance rule. The Chair added that the delays in submission of documents are usually caused by third parties from which ECDC needs to collect additional information.

52. In referring to financial documents, Andrea Ammon confirmed that if the meetings are due to take place around the second week of June, it will not be possible to deliver them on time.

53. Germany proposed to postpone the meetings in June by one additional week, namely, to convene the meetings during the last week of June. This was opposed by ECDC and supported by the Chair as this would have serious implications on the follow-up of meetings due to holiday season. The Chair asked the Board to accept the proposal supported by the Audit Committee and convene the meetings on 19-20 June in 2012. He recalled that the MB is asked to approve the dates for 2012, and provisionally approve the dates for 2013.

54. The Alternate of Cyprus expressed her gratitude for the opportunity to arrange the MB meeting in 2013.

55. The Member of Bulgaria also expressed his readiness to host a future Management Board meeting in his country.

The Management Board adopted its meeting dates for 2012 as follows (Document MB22/7 Rev.1):

MB24: 28-29 March 2012 (Stockholm)

MB25: 19-20 June 2012 (Stockholm)

MB26: 14-15 November 2012 (Stockholm)

The Management Board also provisionally took note of its provisional meeting dates for 2013:

MB27: 20-21 March 2013 (Cyprus)

MB28: 19-20 June 2012 (Stockholm)

MB29: 13-14 November 2013 (Stockholm)

Item 6 – Proposal: EU support for vigilance and traceability of tissues and cells *(Document MB22/9)*

56. Martin Seychell, Member, European Commission, highlighted the urgency of setting up the support system for the vigilance and traceability of tissues and cells of human origin in order to comply with the directive. He noted that the Commission concurs that ECDC and EMA should play both an EU supporting role for Member States and collaborate together. He affirmed that endorsement from both Management Boards is vital.

57. The Irish and Polish Members of the Board expressed their full support for the proposal.

58. The Alternate of Italy stated that the national position of her country is that EMA maintains the regulatory mandate, which is closer to handling tissues and cells, and therefore it does not seem reasonable that both agencies work equally. Essentially, EMA should play the leading role.

59. France noted that it is still premature to adopt this proposal, at least when considering the current document. Notwithstanding existing reservations regarding the legal basis, the roles of both ECDC and EMA should be further clarified. Bearing in mind the finalisation of the health threat package, SoHO must be well thought out and not hastily carried out.

60. Spain concurred with France and referred to implications to staff and financing.

61. While agreeing with the Commission that some kind of a system needs to be in place, the UK Alternate stated that the role of ECDC should be further clarified. She also noted that as the document does not refer to any specially skilled experts working on SoHO, ECDC's capability of carrying out risk assessments *per se* could be questioned.

62. In agreeing with France and Italy, Germany pointed out that carrying out risk assessments for infectious diseases is clearly within ECDC's mandate. However, the running of an overarching information platform by ECDC has to be questioned. He noted that additional tasks in the context of SoHO would be at the expense of other ECDC activities as no additional budget, especially for staff, is available.

63. The Netherlands agreed with the Commission in respect to the urgency of the issue. It was suggested to approve this proposal while considering and solving the issues raised by some of the countries. She also proposed to give EMA the leading role.

64. The Member of the Czech Republic stated that his Ministry is unable to support this proposal. It has been suggested to take into consideration the comments previously raised by other members of the Board.

65. Minerva-Melpomeni Malliori, Member, European Parliament, questioned why the ECDC Management Board should approve this kind of collaboration and suggested that primary responsibility should always rest with one agency. She also sought clarification on page 4 (Table 1, first column) of the document in respect to the rationale for the differentiation and how it would work in reality.

66. The European Commission clarified that the aim of the proposal is not to divide the tasks, but rather to recognise the existing capabilities of both agencies, while keeping in mind their existing mandates. It was clarified that, anyhow, the primary responsibility rests with the Member States. The

EU roles are supportive and the EU mandate is not so centralised, in contrast to the field of pharmaceuticals.

67. ECDC's Director stated that ECDC has discussed this matter extensively with EMA and is fully prepared to take this on board. ECDC also has an AD8 Senior Expert post available for recruitment purposes. He also called on the Member States to send the Seconded National Experts from their respective countries to the Centre.

68. The Chair requested that ECDC draft a proposal considering all the comments from the Board and to finalise the discussion on the second day of the meeting.

Item 7 – Proposal from Management Board Working Group on the ECDC Language Regime *(Document MB22/10 Rev.1)*

69. Alexandru Rafila, Member, Romania, presented the proposal of the Management Board Working Group on the ECDC Language Regime.[30]

70. Following Romania's presentation, the Deputy Chair recalled that this agenda item is for endorsement and not for decision.

71. ECDC's Director recalled that there exist four booths for interpreters and that staff are currently verifying whether two additional booths will fit into the room. He also informed that he is checking whether interpreters are willing to carry out their jobs remotely (outside the room). He then advised that, in accordance with the proposal of the MB Working Group on the ECDC Language Regime, new premises will be required with adequate interpretation facilities.

72. Minerva-Melpomeni Malliori, Member, European Parliament, stated that after consulting with the EP ENVI Committee, ECDC's contact MEP Marina Yannakoudakis had instructed her to support the Working Group's proposal, notwithstanding the latter's preferred regime of maintaining one language.

73. The Director commented on the proposal and referred to spacing issues in the Board room and informed that ECDC is looking into finding possible solutions.

74. The Member representing the Czech Republic expressed his dissent in respect to the proposal. He recalled this discussion has been ongoing for five years and that there are additional burdens and costs. He expressed his preference for English plus three languages on a rotational basis as per the original proposal.

75. The Alternate representing Greece referred to the practical shortcomings of the proposed solution and stated that it is deeply unfair. He also argued that it would lead to additional expenditure. All documents are in English and nobody has complained to date. Convening meetings in Greek every five or ten years would not augur well. It is unclear on which basis these languages were chosen. For instance, why Spanish and not Italian? Why Spanish and not Polish, the latter of which is a sizeable Member State. It is certainly unjust that some delegates speak in their native language while others speak a foreign language. He then expressed that he is in favour of meetings being held in one language, i.e. English.

76. The Member representing Sweden expressed the view that she did not see any genuine improvements in the Board meetings arising from applying this proposal. She also sought more details on the financial consequences for additional translation booths.

77. Notwithstanding the importance of monetary issues, Germany conveyed that the EU is a political and symbolic entity and that multilingualism represents an important manifestation of that. Germany favoured the compromise proposal set forth in Document 22/10 Rev.1 as presented to the Board.

78. The Alternate of Cyprus expressed support for the Working Group's proposal as it increases the possibility of communication. She also asked that a needs assessment be carried out. She also referred to the costs involved and suggested that the Commission investigate the situation in other EU Agencies to perhaps come up with a solution that fits all.

[30] Item 7 - Proposal on the ECDC Language Regime (A Rafila)

79. The Member of the Netherlands favoured the proposal, notwithstanding her preferred solution for a one language (English) regime. As a caveat, however, the proposal should only be endorsed while confirming that it has no implications for any other type of communication in ECDC, i.e. reports, publications, etc.

80. Alexandru Rafila, Member, Romania, confirmed that the proposal was intended for the meetings of the Management Board.

81. The Member of Spain supported the proposal while noting her Foreign Ministry's opposition to a one language regime.

82. The Member of France stated that the existing working languages need to be adopted and that a one language regime would not provide any benefit to the MB. She also thanked the Working Group for their work and their proposal for a reasonable and open solution.

83. John F Ryan, Member, European Commission, informed that he had participated in the Working Group and in the MB on this issue for five years. He referred to proposed solution and noted that the Working Group tried to find a viable solution that could be acceptable overall for all members. The solution put forward by the Working Group of the existing regime and the Presidencies does not impose a sizeable supplementary requirement as it gives the possibility of rotation. As several languages are used by various delegates in the MB, the possibility of bringing in new languages increases the potential for participation, which augurs well with the Commission's policy of multiculturalism and multilingualism and the Commission has written to the previous ECDC Director highlighting the importance of these policies. While multiculturalism is the most preferred approach, the Commission has also looked into other agencies and one of the tasks is to harmonise the various language regimes. In terms of existing agencies, eight require unanimity and 15 have different rules based on the subject matter. He also noted that this solution could be further reformed in the future. He then stressed the importance of finding a compromise on this topic rather than maintaining the discussion. He stated that the Commission is in favour of the proposal of the Working Group as it has taken fellowship and communication into account.

84. Jacques Scheres, Member, European Parliament and Deputy Chair of the Board, advised that the Board should endorse this proposal in order to finalise discussions on this item and devise a workable solution at a later stage. He also referred to the costs of the Working Group and that, despite existing differences in opinion, the Board needs to come to a conclusion.

85. The Member of the Commission suggested that the Board adopt the proposed solution with the current status quo, plus two rotating languages, while keeping in mind that this does not need to be the final solution. He also referred to the planned external evaluation and noted that this issue could be taken up therein. Therefore, the current proposal would serve as a transitional arrangement. He added that following its adoption, ECDC should evaluate the new regime, and if necessary, request the Commission to review the Founding Regulation.

86. The proposal on the language regime was put to a vote to the Board with the following caveats:

- The proposal is a temporary solution to follow the MBWG solution;
- The proposal refers exclusively to Management Board meetings and shall not extend to any other types of external communications from ECDC;
- The language regime of the Management Board will be formally taken up in the planned external evaluation and assessed accordingly.

87. Following its adoption, ECDC shall evaluate the new regime, and if necessary, request the European Commission to review the Founding Regulation.

The majority of the Management Board endorsed the proposed solution for the ECDC language regime, with three members against (Czech Republic, Greece and Portugal) and two abstentions (European Parliament and Italy).

Item 6 – Proposal: EU support for vigilance and traceability of tissues and cells *(Document MB22/9)* - *Continued*

88. The Chair welcomed the Management Board to the second day of the meeting and extended a warm thanks to the Director of ECDC, as well as other staff, for having made excellent arrangements for the boat excursion and the dinner. He also thanked Johan Giesecke for having guided the Board members about the history of Stockholm.

89. The Chair informed the Board of the proposal on SoHO, which had been prepared the day before and sent out electronically to all members.[31] He recalled the basis of the proposal and that ECDC needs to initiate work therein, and that no decision is to be made with respect to collaboration between EMA and ECDC at this meeting. He also affirmed that EMA should carry out the leading role.

90. Martin Seychell, European Commission, recalled that ECDC's aim is to take this on based on the existing mandate and expertise to be able to guarantee that the Member States would have the opportunity to request expert advice. He stated that at this point, there is no coverage in respect to the issue of tissues and cells. A suggestion was also made to conduct a trial period.

91. Johann Fontaine shared the German comments and amendments to the Commission's proposal with the Board.[32] In referring to the Commission's proposal, he expressed that "the wording is unclear and that the running of technical platforms for non-communicable diseases has not actually been decided upon by the Management Board."

92. The Member of France expressed that improvement needs to be consistent and that a clear framework is necessary in order to make the necessary reforms.

Item 3 – Summary of discussions held at the 17th meeting of the ECDC Audit Committee (14 June 2011), including its recommendations

93. Iréne Nilsson-Carlsson, Chair, ECDC Audit Committee, briefed the MB on the items discussed and conclusions made at the 17th Audit Committee meeting.[33] Her presentation was supported by Anja Van Brabant who illustrated the improvements made within the budget execution during the last three years.

Final Annual Accounts 2010, including the Report on Budget and Financial Management *(Document MB22/5)*

94. Anja Van Brabant, ECDC, presented the final accounts 2010.[34] Irene Nilsson-Carlsson added the conclusions on the Audit Committee.

The Final Annual Accounts 2010, including the Report on Budget and Financial Management, were unanimously adopted (Document MB22/5).

Supplementary and Amending Budget *(Document MB22/6)*

95. Anja Van Brabant presented this item.[35] She was followed by Iréne Nilsson-Carlsson who noted that the Audit Committee proposed that the MB to adopt this document.

96. Andrea Ammon informed the Board that ECDC is currently in the process of recruiting a Senior Legal Advisor and Head of the Legal and Procurement Section/Resource Management Unit, in

[31] "Draft Communication of MB on the EU support for traceability of tissues and cells" (paper tabled by the European Commission, 17 June 2011).
[32] Communication of the Management Board of ECDC on the EU support for traceability of tissues and cells (paper tabled by Germany on 17 June 2011)
[33] Item 3 - Summary of 17th AC meeting (I Nilsson-Carlsson)
[34] Item 3a Final Annual Accounts 2010 (A Van Brabant)
[35] Item 3b - 1st Supplementary Amending Budget 2011 (A Van Brabant)

addition to the existing expert. She also announced that during the early autumn, a written procedure and approval for budget transfers may be sent to the Board for their approval.

The Board unanimously approved the Supplementary and Amending Budget (Document MB22/6).

Item 12 - ECDC WP Priorities *(Document MB22/13 Rev.1)*

97. ECDC's Director gave a presentation on the planning process for the Work Programme 2012.[36] Notwithstanding the Centre's core work, ECDC proposes to have a number of cross-cutting themes for 2012, namely: elimination of measles, migrant health, support for EU Candidate Countries, health inequalities, identification, together with the Member States, reference laboratories to support molecular surveillance and typing.

98. The German advisor acknowledged that the Centre's values are important paradigms for ECDC. He suggested, however, not using them for this planning process. In his view, the corresponding headings in the draft proposal are not coherent. Fitting the structure of the Work Programme to the value concept would complicate the planning process. Currently, it would be more important for ECDC to focus on the internal implementation of the values. The German advisor also remarked that the planning for activities in respect to Substances of Human Origin is to be considered under reserve, pending the outcome of the upcoming discussions.

99. France and Spain supported the idea of the eradication of measles. The Member of France expressed that it would be apt to see more emphasis placed on the exploitation of data collected previously, and in particular, for HAI-Net. With regards to vaccine preventable diseases, it would be more relevant to focus on the surveillance of pneumococci rather than undertaking a feasibility study for rotavirus, for example (for which vaccination programmes do not exist in all Member States of the European Union).

100. The Netherlands proposed that more attention could also be paid to collaboration with the other EU agencies on various topics.

101. ECDC's Director asked the Management Board to provide their comments on ECDC's proposed priorities for 2012 by 31 July 2011.

It was agreed that the MB would receive the written procedure via email with a deadline for a receipt of feedback from the Member States by 31 July 2011. The final version of the Work Programme 2012 will be presented to the MB in November (Document MB22/13 Rev.1).

Item 10a - Update of Hungarian Presidency

102. Márta Melles, Alternate, Hungary, presented the main events and activities of the Hungarian EU Presidency.[37] She thanked the Member States as well as the ECDC for their participation.

Item 10b- Update from the Polish EU Presidency

103. Pawel Gorynski, Member, Poland, presented the main events and activities of the Polish EU Presidency.[38] He also agreed to share the calendar of events with the Management Board.[39]

Item 14 - Planned External Evaluation of ECDC for 2012

104. Andrew Amato, Head of Surveillance, Surveillance and Response Support Unit, introduced the topic of the External Evaluation of ECDC, referring to the first one which was launched in 2007 and reported in 2008.[40] The Centre's Founding Regulation stipulates that ECDC needs to conduct these evaluations regularly and it was agreed to carry them out every five years. This means that in 2012, ECDC will need to contract out and conduct the next external evaluation. Prior to that, detailed terms

[36] Item 12 - ECDC WP priorities for 2012 (M Sprenger)
[37] Item 10a - Update regarding the Hungarian EU Presidency (M Melles)
[38] Item 10b - The Polish Presidency of the European Union (P Gorynski)
[39] Calendar of Events – Polish EU Presidency (refer to MB Extranet Handout documentation)
[40] Item 14 - Planned External Evaluation of ECDC for 2012 (A Amato)

of reference for this evaluation need to be drawn up and subsequently approved by the Management Board.

105. Following the proposal of ECDC and the Chair of the Management Board, it was agreed that Andrew Amato, together with a small internal ECDC Evaluation Team that includes Jan Mos, Senior Advisor to Director, will support an MB Steering Sub-committee composed of the Management Board members from Belgium, Estonia, Romania, Slovenia and the United Kingdom, Jacques Scheres (European Parliament) and a member of the European Commission (nominee to be confirmed shortly). The Belgian Board Member, Daniel Reynders, will chair the MB Steering Sub-committee.

106. The Member of Sweden emphasised the importance that the aims of the evaluation are made very clear.

107. The Advisor from Germany agreed with the proposal of an MB Steering Sub-committee. He suggested the evaluation of the reorganisation to be combined with the external evaluation. He stated the importance of ECDC staff participating in the preparation and conception of these evaluations and that the staff committee remains closely involved. He also remarked that there is much internal expertise available among ECDC staff in respect to designing and performing evaluations and they should be approached accordingly.

108. The Chair of the Management Board opined that there is probably no need for a separate evaluation of the impact of the reorganisation. He agreed that there should be interviews with the staff committee representatives, similar to what was done the previous time.

109. Minerva-Melpomeni Malliori, European Parliament, recalled that the first external evaluation was held too close to the start of the ECDC. Expectations from this external evaluation are much higher now as a few years' work can be evaluated. She remarked on the importance of "finding out quickly what the European Parliament expects from the results and to gather their thoughts on what should be included so that the evaluation can be designed accordingly to anticipate the ENVI Committee's expectations." She also called on the Commission to produce a standard method to evaluate the agencies in order that procedures are adhered to impartially and uniformly.

110. The MB Chair suggested a web-based consultation, with analysis by end July, to ascertain what should be included in the evaluation – and during this consultation the EP members could bring their ideas forward.

111. ECDC's Director affirmed that this work has to be carried out in close collaboration with the European Commission. He added that ECDC is also aware that the European Parliament has a working party that is looking at the evaluation of all agencies and their work should also be taken into account.

112. The results of this evaluation will be of vital importance for the future of ECDC, and everyone wished Andrew Amato and Daniel Reynders every success in leading this process.

The Management Board took note of the planned External Evaluation of ECDC for 2012.

Item 6 – Proposal: EU support for vigilance and traceability of tissues and cells *(Document MB22/9)* – ***Continued***

113. The Chair recalled the two draft proposals that were tabled during the meeting.[41]

114. Finland sought confirmation that the European Commission is expecting ECDC to provide only scientific advice.

115. The Member of France recalled the earlier comments from the Commission and questioned the necessity of these discussions in the light of ECDC already carrying out various tasks in this field during its daily work. She thereby requested that the Commission clarify whether the work of the Centre will be broadened further, on top of what is already being carried out by ECDC.

[41] See Annex I (Communication from Germany on the EU support of traceability of tissues and cells) and Annex II (Draft Communication of MB on the EU support for traceability of tissues and cells)

116. John F Ryan, European Commission, expressed that it is foreseen that ECDC will take part in two activities: the platform for rapid exchange of information, similar to the EWRS, and the provision of adequate scientific advice, upon request of the national authorities. He assured that this work would fall within the current mandate of ECDC. Transparency is essential and therefore this needs to be reflected accordingly in the Work Programme. Martin Seychell added that, in respect to collaboration between ECDC and EMA, the suggestion is to have a Steering Group composed of SANCO, ECDC, EMA and perhaps national authorities as well. The Commission is willing to set up this group and coordinate its work. Clarification on the legal text and link to definitions can be prepared via the Steering Group in order to ensure full transparency.

117. The Chair referred to an updated proposal from ECDC and the Commission wherein comments from the MB have been taken into consideration. The updated proposal notes the Steering Group and clarifies the definitions, which are referenced in the footnotes. He suggested that the Board endorse this proposal as the role of ECDC has been clarified therein.

118. The German Advisor sought to make additional adjustments with regards to the title of the proposal, as well as adding further explanations based on the recent discussions. He stated that the communication is not satisfying and needed clarification. He noted that his proposal has been to establish a (temporary) working group tasked with distributing the work and not simply coordinating the work. He welcomed the removal of the text on the trial period.

119. The Member of France sought clarification vis-à-vis the platform issue and whether it is solely about the risks or the products. If it is simply all about risks, ECDC would then be working beyond its mandate. Otherwise, if it is the early warning system for the products alone, the EWRS can then be broadened a bit more. She then referred to point 3 of the proposal and suggested that the text should indicate "should be limited", otherwise the document contains a possibly erroneous statement.

120. While the Alternate of Finland acknowledged that the proposal stipulates that it would be an extension of the workload and not the mandate, she questioned how the EWRS could be broadened without the coding system. In this case, the workload for ECDC would be enormous.

121. The Alternate of the United Kingdom supported the proposal, while noting that ECDC had replaced the trial period with the Steering Group. She also concurred with Germany's points.

122. In agreeing with the United Kingdom, the Member of Sweden expressed the importance of facilitating collaboration between the agencies due to practical and cost effective reasons. She then cautioned about the composition of the Steering Group and the potential complication in the selection process. She suggested that relevant stakeholders must be included in the composition include ECDC, EMA and the European Commission.

123. The Chair thanked Sweden, but acknowledged his doubts about omitting the national authorities. He stated his preference to include the national authorities in the development process.

124. While welcoming the proposal, in referring to point 3, the Dutch Member suggested limiting the platform to communicable diseases. She also agreed that various agencies should collaborate together, learn from one another, while remaining within their mandate.

125. The Advisor from Germany clarified that the idea is not only to limit this, but also to know who will provide input on which platform and who is going to receive the information. He conceded that the EWRS is a good system, which could be adjusted for this specific purpose. These types of issues can be discussed in the group to be established.

126. The Member of France acknowledged that while work is improving in this area, a clear and coherent framework is needed. If the framework covers risks in its entirety, ECDC is going beyond its mandate. She then advised of the importance of agencies remaining within their respective mandates and avoiding veering towards the unknown.

127. John F Ryan, European Commission, pointed out that during the first meeting day, as ECDC highlighted some of the main events and activities which had been carried out since the last MB meeting, parts of the presentation indicated that ECDC is working on SoHO as a normal everyday activity. He also recalled discussions on the E.coli outbreak whereby cooperation between the food and human factors were brought out, and noted that there was no mention about either mandate or legislation changes. He agreed that collaboration with EMA might incur some complications, yet this

has been clarified in the document provided to the Board, and there is no intention to change any of the mandates. He summarised that success can be guaranteed for this project if ECDC works in the same way on this as it collaborates with EFSA. He stated that the conclusions as circulated the previous evening via email accurately reflect the facts of the situation. He recalled that there is no extension of ECDC's mandate and then asked the Management Board to agree to a trial period until the end of 2013 in order to ascertain the actual volume of work entailed. Such a period will thus enable the Commission to revisit this matter with more permanent solutions.

128. Given time constraints and the need to communicate with their countries' officials in order to receive clear instructions, France and Germany requested that this item be voted upon via written procedure. Both countries contended that clear positions are required in order to make consequential decisions. The MB Chair declined their request due to the urgency in advancing the proposal to the next steps. He added that all open questions can be addressed in the group to be established.

129. The 'Draft Communication of MB on the EU support for traceability of tissues and cells'[42] was adopted by the Management Board, with two abstentions from France and Germany. Such conclusions are centred on the following: i) no change in legal mandate of ECDC; ii) tasks to support the European Commission in implementing the EU legislation; iii) tasks limited to rapid exchange of information and provision of scientific advice and the; iv) creation of a Steering Group,[43] which consists of ECDC, EMA, European Commission, MB members of both Agencies, including representatives of national competent authorities.

The 'Draft Communication of MB on the EU support for traceability of tissues and cells' was adopted by the Management Board, with abstentions from France, Germany and Spain. ECDC Director to implement the tasks as contained in the adopted Communication and to present a progress report in a forthcoming Management Board meeting.

Item 18 – Update from the European Commission: legal and financial aspects to be considered by ECDC prior to engaging in and/or responding to threat assessments

130. At previous Board meetings there had been some discussion on the legality of the Commission requesting ECDC to produce rapid risk assessments on health threats such as the Icelandic Ash Cloud or the Russian Forest fires (i.e. threats not caused by infectious diseases). During the 21st Management Board meeting in Dublin, the European Commission was requested to update the Board in June "about the legal and financial aspects to be considered by ECDC prior to engaging in and/or responding to threat assessments." John F Ryan reported on the findings from the Commission's Legal Services.[44]

131. In closing, John F Ryan confirmed that the EC Legal Service considers the Commission not a competent body but a competent authority. Therefore, under the Founding Regulation, the Commission can ask ECDC for risk assessments or activities in relation to that. Further, the Commission has been making such requests to ECDC since the latter's inception.

The Management Board took note of the update from the European Commission in respect to the legal and financial aspects to be considered by ECDC prior to engaging in and/or responding to threat assessments.

Item 15 – Organisational Excellence (Quality Assurance)

132. Andrea Ammon gave a presentation on organisational excellence (quality assurance).[45] She then informed the following three requirements for ECDC Quality Management: i) add value, not burden; ii) light and practical; iii) ensure efficiency of operations and organisational performance. She also informed about the Common Assessment Framework (CAF), which is used in EU Agencies,

[42] See Annex II
[43] During this plenary session, Germany proposed to establish a working group.
[44] See Annex III
[45] Item 15 - Quality Management in ECDC (A Ammon)

Institutions and ongoing in public health institutions. ECDC will continue to progress in its implementation of a quality management system.

The Management Board took note of the update from Andrea Ammon on organisational excellence (Quality Assurance).

Item 16 – Interim results of ECDC's pilot survey with the Advisory Forum on the impact of ECDC's scientific advice

133. Johan Giesecke, Chief Scientist, presented the interim results of ECDC's pilot survey with the Advisory Forum on the impact of ECDC's scientific advice to the MB.[46]

134. The Member of the Netherlands asked that the survey be targeted more specifically according to the nature of guidelines. Finland also conceded that it would be interesting to view the guideline.

135. The Member of Belgium questioned why the guidance on risk groups on influenza was not distributed. He also asked which kind of advice is translated into decisions or policies.

The Management Board took note of the Interim results of ECDC's pilot survey with the Advisory Forum on the impact of ECDC's scientific advice.

Item 17 – Strengthening Disease Prevention and Control capacity in the Mediterranean Region through Training ("Mediterranean EPIET")

136. In response to a request from the European Commission and Germany, Arnold Bosman, Head of Section, Public Health Training, Public Health Capacity and Communication Unit, informed the Board that ECDC has developed a proposal. The Commission stated that corresponding activities would be covered by ECDC's mandate, and is now considering whether it can find funding to implement this programme.[47]

The Management Board took note of the presentation, 'Strengthening Disease Prevention and Control capacity in the Mediterranean Region through Training' ("Mediterranean EPIET").

Item 19 – Interim report on improving communications between ECDC and the Management Board

137. Irina Dinca, Senior Expert Communicable Diseases, Public Health Development section, Public Health Capacity and Communication Unit (PHC), presented an interim report on improving communications between ECDC and the Management Board.[48] She explained the results from the interviews she and Arnold Bosman Head of Public Health Training Section, Public Health Capacity and Communication Unit, conducted with Board members at the Management Board meeting in Dublin in March 2011.

138. Following her presentation, the Chair of the Management Board thanked Irina and Arnold for their work and suggested that their input be integrated into the aims of the planned external evaluation.

The interim report on improving communications between ECDC and the Management Board was noted by the Board and feedback therein will be duly integrated into the planned external evaluation.

[46] Item 16 - Interim results of ECDC's pilot survey on the impact of our scientific advice (J Giesecke)
[47] Arnold Bosman PowerPoint
[48] Item 19 - Improving communication between ECDC and the Management Board (A Bosman, I Dinca)

Item 20 – Update on status of alternative premises for ECDC

139. ECDC's Director provided a brief update on the status of alternative premises for ECDC. He reported that ECDC has closely scrutinised the lease on its current buildings and concluded it will be very difficult, from a legal standpoint, to get out of the lease before 2018. Nonetheless, examination of various solutions is continuing.

The Management Board took note of the Director's update on the status of alternative premises for ECDC.

Item 21 – Update on matters concerning the Seat Agreement

140. Andrea Ammon reported that most ECDC staff are now on the Swedish population register, and that the situation appears to be satisfactory. A more comprehensive report on the Seat Agreement will be presented to the Board at its meeting in November.

The Management Board took note of the update on matters concerning the Seat Agreement and look forward to receiving a more comprehensive report at the next meeting in November.

Item 22: Any other business

141. There was no other business.

Closing comments from the Director

142. The Director expressed his thanks and appreciation to the Management Board for their fruitful discussions and continued support.

Closing comments from the Chair

143. The Chair adjourned the meeting and thanked Management Board for their meaningful contributions, the interpreters for their flexibility and professionalism, and ECDC staff for their excellent contributions and support. He then reminded everyone that the next Board meeting will convene during 9-10 November 2011 in Stockholm, Sweden.

Annex I: Communication from Germany on the EU support of traceability of tissues and cells

Communication from Germany on the EU support of traceability of tissues and cells

1. The Management Board of ECDC has examined the analysis contained in the Document MB 22/9. Unfortunately, the Management Board of ECDC has no written minutes of the discussions during the EMA-MB meeting that took place on June 9.

   The Management Board of ECDC therefore asks the Director for reasons of transparency and good communication to facilitate a direct exchange between the members of the Management Boards of ECDC and EMA, either to plan a joint meeting or to give the EMA Management Board members enough time to exchange on national level by giving the members several weeks time in-between the meetings.

2. The new proposal now refers to "tissues and cells" and not to "SoHO". Unfortunately, it does not give exact definitions on what is meant by "tissues and cells".

   Therefore, the Management Board kindly asks the Director to add the legal definition of tissues and cells.

3. In the whole document there is no reference to the relevant legislation concerning "tissues and cells". (Dir. 2004/23/EG, Dir. 2002/98/EG, Dir. 2001/83/EG, etc.).

   The Management Board asks to add the legal background, especially concerning the legislation on "tissues and cells" and the paragraphs that are relevant for the new tasks of ECDC.

3. On the first view, the proposed tasks for ECDC do not affect existing legal responsibilities of Member States under the existing tissues and cells legislation, but are intended to support national activities, particularly in respect of cross border aspects. But indirectly, the document refers to tasks of the Member States.

   The safety regulations for tissues and cells should be the same as for medical products or ATMP.

3. The tasks envisaged for the ECDC have to be limited to those falling under the existing mandate concerning communicable diseases of the ECDC under its Founding Regulation and do not imply new competencies for ECDC. Communicable diseases are the categories of disease listed in the Annex to Decision No 2119/98/EC (see legal definition of the Founding Regulation).

   The Management Board asks to clarify the document in this respect.

   Furthermore, the Management Board asks the Director to present comparable data on how many serious adverse reactions will fall within the mandate of ECDC that means that they concern communicable diseases and how many serious adverse reactions per year will not concern communicable diseases.

   The Management Board asks the Commission to clarify the difference between its own statements:

   a) ECDC could not have the task to run a communication platform between MS concerning for 70% chemical and radio-nuclear threats and threats from biological toxins and for 30% threats from communicable diseases. This is not possible without changing the mandate of ECDC.

b) ECDC could have the task to run a communication platform between MS concerning for 70% other serious adverse reactions and for 30% serious adverse reactions from communicable diseases. This is possible without changing the mandate of ECDC

4. The tasks envisaged relate to support for rapid exchange of information concerning communicable diseases, and support for risk assessment concerning communicable diseases and scientific advice concerning communicable diseases, only upon request of Members States national competent authorities, and within the framework of the ECDC Founding Regulation.

   The Founding Regulation of ECDC dates from April 2004; the directive concerning tissues and cells dates from March 2004.

   The Founding Regulation gives ECDC explicitly the big task to support the implementation of the decision 2119/98. This is a big task.

   The Founding Regulation does not give ECDC the task to support the implementation of the legislation of tissues and cells. (Dir. 2004/23/EG, Dir. 2002/98/EG, Dir. 2001/83/EG, etc.). This is also a big task.

   In the parallel legislative process to establish the directive on tissues and cells and the Founding Regulation of ECDC, there was no political decision to put this additional big task on the shoulders of ECDC. The Management Boards of the two independent European Agencies cannot overrule this decision. It should at least be discussed in the Council working group.

5. A formal, independent and scientific excellent European Agency cannot follow the principle "learning by doing" or "trial and error". It should develop its core capacities and – if the mandate is changed – develop new capacities. Therefore, the Management Board strongly suggests to ECDC to provide scientific advice for communicable diseases for tissues and cells and wait for a political decision.

6. Based on the above, the Director of ECDC is asked to further improve the paper, engage discussions between the stakeholders of EMA and ECDC, wait for the reviews and evaluations of agencies and of legislation and engage in a possible long-term decision.

Annex II: Draft Communication of MB on the EU support for traceability of tissues and cells (final version)

Draft Communication of MB on the EU support for traceability of tissues and cells

1. The Management Board of ECDC has examined the analysis contained in the Document MB 22/9.
2. The proposed tasks for ECDC do not affect existing legal responsibilities of Member States under the existing tissues and cells legislation,49 but are intended to **support national traceability systems for tissues and cells** in respect of cross border aspects. **The beneficiaries of this EU support are National Competent Authorities for Tissues and Cells in all Member States.**
3. The tasks envisaged for the ECDC in this document should be limited to those falling under the existing mandate of the ECDC under its Founding Regulation50 and do not imply new legal competencies for ECDC.
4. The tasks envisaged relate **to support the Commission** in the rapid exchange of information, and support for risk assessment and scientific advice, only upon request of Members States national competent authorities, and within the framework of the ECDC Founding Regulation.
5. The Commission will establish a Steering Group to help **to further develop** this EU support system for traceability of tissues and cells, and oversee its progress and functioning. This Steering Group will consist of EC SANCO, ECDC, EMA, MB members of both Agencies, and representatives of National Competent Authorities on Tissues and Cells as appropriate.
6. Based on the above, the Director of ECDC is asked to implement these tasks and to present a progress report in a forthcoming Management Board meeting.

==========

Note

a. Safety requirements for tissues and cells for transplantations purposes are subject to the EU Directives on tissues and cells.

b. Safety requirements from Advanced Therapeutical Medicinal Products (ATMPs) are subject to

- EU Directives on tissues and cells as raw materials for ATMPs (procurement, testing, storage, and distribution)
- Pharma legislation (tissue engineering, market authorisation etc.).

[49] Article 8, 11, 25 of Directive 2004/23/EC (O.J. L 102; 7.4.2004; p. 57); Article 8 of Directive 2006/86/EC (O.J. L 294; 25.10.2006; p.35)

[50] REGULATION (EC) No 851/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 April 2004 establishing a European centre for disease prevention and control and DECISION No 2119/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community

Annex III: Speaking Points from European Commission

The notion of "competent body" refers to bodies recognised by a Member State. It is used on several occasions in the Regulation. However, the notion used in Article 3(1) is not that of "competent body" but that of "competent authority". This should be seen as the deliberate intention of the legislators and the two notions cannot be considered as equivalent or interchangeable.

The notion of "competent authority" is not defined in the Regulation but it is also used in recital 7 of the Regulation, where it explicitly encompasses both the national and EU level.

Moreover, the *rationale* of this whole Regulation is to reinforce coordination at EU level between the Member States. It would go against this rationale to interpret Article 3(1) in a way that would deprive the main player of this coordination, e.g. the Commission, of the right to request the ECDC to act in case of an outbreak not caused by a communicable disease.

Excluding the Commission from the notion of competent authority would also be incompatible with Article 168(2) of the Treaty on the Functioning of the European Union, which prevails over the regulation and under which:

"The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action."

"Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination (…)"

There is therefore *a priori* no reason to consider that the Commission could not be considered as a competent authority within the meaning of Article 3(1) of this Regulation.

Given the budgetary envelop in which the ECDC has to operate, ECDC needs to have a task allocation mechanism for its staff to deal with unexpected or new threats. Therefore, requests for threat assessments in the case of an outbreak which clearly is not caused by a communicable disease should be made judiciously. From the Commission's side, the two threats mentioned warranted the requests to be made to ECDC.