ECDC Management Board

Minutes of the Twentieth Meeting of the ECDC Management Board

Stockholm, 9-10 November 2010

Adopted by the Management Board at its Twenty-first meeting, 15-16 March 2011

Contents

Summary of Proceedings – ECDC Management Board Meeting

The Twentieth ECDC Management Board (MB) meeting convened in Stockholm, Sweden, on 9-10 November 2010.

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

Announcements

The following announcements were made:

The Chair announced that this would be the last meeting for the Members of Finland and the Netherlands, and he expressed his thanks and appreciation to each of them for their solid contributions to the Management Board.

The Chair further announced that ECDC has a brand new electronic voting system, and proposed that, given the possible margin for error in counting votes via a show of hands, it would be beneficial if the Board would to agree to vote using such technology. He then sought their formal consent via a show of hands. He also suggested that the Rules of Procedure could eventually be modified in order to reflect the use of this new technology. He indicated that while all electronic votes shall remain anonymous, during the plenary sessions, any points that are specifically raised by the Board will also be taken into account in the minutes. He then asked whether any Member objected to the idea of voting electronically in respect to certain decision items. The Board Members gave their unanimous consent to try out the electronic voting system.[1]

The Board gave their unanimous consent to try out the electronic voting system for certain decision items during the meeting. The Rules of Procedure of the Management Board will be revised and submitted to the Board for decision in a future meeting in order to reflect the use of this new technology.

Items for Decision

1. Adoption of the Draft Agenda (and noting the Declaration of Interest and proxy voting, if any) (Item 1 – MB20/2; MB20/3 Rev.2)

Proxy was given from Andrzej Ryś (European Commission) to John F Ryan (European Commission) for both days (8-9 November 2010). Proxies were given from Minerva-Melpomeni Malliori (European Parliament) to Greece, and Lithuania to Latvia for the second day (9 November 2010).

John F Ryan, European Commission, requested that Item 6 on the agenda (How to Manage Operational EU level Tasks related to Substances of Human Origin (SOHO): Joint proposal for a solution) be changed from a decision item to a discussion item. The European Parliament representative agreed with the Commission. The request was approved by the Board.

The Commission representative also requested that the language regime agenda point should be postponed until the new building issue had been investigated further. The representative of the European Parliament made no objections to postpone the decision on the language regime, but stressed that a practice nevertheless needed to be decided upon until unanimity could be reached. She also suggested establishing a working group to deal with the question. The Chair proposed that the agenda point concerning the language regime would be discussed in order to reach an interim decision.

Following the above-noted proposals, the Board unanimously adopted the Draft Agenda (Documents MB20/2; MB20/3 Rev.2)

[1] Due to some technical difficulties, the new electronic voting system was only used for the following decision items: 5, 7, 8, 9, 10, 12, 13, 14 and 15. In other cases, voting was conducted by a show of hands (Article 8(3) "Votes shall be taken by [a] show of hands unless a secret ballot is requested by at least one-third of the voting members present. A secret ballot is always used when electing persons").

2. Adoption of the Draft Minutes of the Nineteenth meeting of the Management Board (Menorca, 17-18 June 2010) (Item 2 – MB20/4)

The Board unanimously adopted the Draft Minutes of the Nineteenth meeting of the Management Board (Document MB20/4)

3. Election of the Chair and the Deputy Chair of the ECDC Management Board (Item 3)[2]

Hubert Hrabcik was re-elected Chair of the ECDC Management Board. 30 votes were collected and the candidate received 26 votes. Jacques Scheres was re-elected as the Deputy Chair. 30 votes were collected and 28 votes were received for this candidate.

With overwhelming support, the Board re-elected Hubert Hrabcik as Chair of the ECDC Management Board and Jacques Scheres as Deputy Chair of the ECDC Management Board.

4. Summary of discussions held at the 15th meeting of the ECDC Audit Committee (8 November 2010), including its recommendations (Item 4):

a. Update from the Audit Committee (Item 4a)

The Audit Committee encouraged ECDC to make a plan on how to improve the budget and payment execution for the coming years. The issue with the 2012 budget was brought to the Board's attention.

The Board Member from Germany requested to receive the conclusions of the update from the Audit Committee in writing. It was also noted by the MB Deputy Chair that SoHO already had a budget line in the Establishment Plan.

b. Budget and Establishment Table 2011 (Item 4b - MB20/5 Rev.2)

The cuts for 2012 were discussed. It was suggested to postpone the decision on the budget until after receiving the amended version of the budget excluding the SoHO item.

c. Second Supplementary and Amending Budget 2010 (Item 4c - MB20/6)

This item was presented for information.

d. Budget Execution 2010 (Item 4d - MB20/7)

The Board was informed that committed appropriations were higher in September 2010 compared to September 2009 for all three titles. This is also the case for payments executed. New figures for October 2009 and 2010 indicated the same trend.

16. Director's briefing on the main activities of the ECDC since the last meeting of the Management Board (Item 16)

The Director and the Head of Units updated the Board on major activities and developments since the last MB meeting in June 2010.

One Member raised a question whether data exists concerning the amount of visits on the ECDC website. It was agreed that this could be presented to the Board in the March 2011 meeting as it is one of the key performance indicators.

Prior to discussing the SoHO item below, the Member from Ireland informed about details of the next Management Board meeting in Dublin (15-16 March 2011). He recalled that 17 March will be St. Patrick's Day and that tickets will be organised for the St. Patrick's Day Parade in the centre of Dublin on that day, which is a highly worthwhile event to participate in. ECDC and the Irish authorities are currently working jointly on the next meeting, including the social programme.

[2] According to Article 2 of the rules of procedure of the Management Board, a two-thirds majority of the Management Board voting members present and secret ballot is required for adoption of this item.

6. How to Manage Operational EU Level Tasks Related to Substances of Human Origin (SoHO): joint proposal for a solution (Item 6 – MB20/9)[3]

As a result of the discussion, the MB requested to remove all SoHO related activities from the 2011 Work Programme and from the 2011 Budget prior to submitting them to the approval of the MB (voting procedures for both). The subsequent modified versions of the Work Programme and of the Budget were then approved by the MB.

The Board unanimously agreed to be consulted electronically via written procedure to provide their feedback on the excerpt of minutes stemming from this plenary session, which will be subsequently forwarded to the European Medicines Agency (EMA) for their Management Board meeting in December 2010.

5. ECDC Annual Work Programme 2011 (Item 5 – MB20/8 Rev.1)[4]

The Board unanimously approved the ECDC Annual Work Programme 2011 (Document MB20/8 Rev.1).

10. ECDC Work with the EU Member States (Item 10 – MB20/13 Rev.1)

The majority of the Board approved the ECDC Work with EU Member States (Document MB20/13 Rev.1).

9. ECDC Draft Policy for Collaboration with 'Third' Countries (Item 9 – MB20/12)

The majority of the Board approved the ECDC Draft Policy for Collaboration with 'Third' Countries (Document MB20/12).

7. Working Arrangement between the European Medicines Agency (EMA) and the ECDC (Item 7 – MB20/10)

Germany stated that the reference to cooperation with SoHO is assumed to refer to a possible cooperation and does not refer to the scope or extent of such cooperation.

The majority of the Board approved the Working Arrangement between the European Medicines Agency (EMA) and the ECDC (Document MB20/10).

8. Memorandum of Understanding between the European Food Safety Authority (EFSA) and the ECDC (renewal) (Item 8 – MB20/11)

The majority of the Board approved the Memorandum of Understanding between the European Food Safety Authority (EFSA) and the ECDC (renewal) (Document MB20/11).

12. Policy on Access and Use of Data from TESSy (Item 12 – MB20/15)

This topic will be revisited at a forthcoming Management Board meeting in 2011.

The majority of the Board approved the Policy on Access and Use of Data from TESSy (Document MB20/15).

[3] During discussions regarding the Draft Agenda, it was agreed that Item 6 would be amended from a decision to a discussion item. The excerpt in question reflects the feedback as received from Members of the ECDC Management Board. The written procedure terminated on 24 November 2010 and a final version of the text was circulated to the Board on 29 November 2010. Since then, the finalised text was duly transmitted to the Management Board of the European Medicines Agency (EMA) in order to advance discussions on this topic.

[4] According to Article 8 of the rules of procedure of the Management Board and Article 15 of the Founding Regulation, a two-thirds majority of all members is required for adoption of this item.

14. ECDC Draft Policy for Declarations of Interest and Handling of Potential Conflicts of Interest (Item 14 – MB20/17)

The majority of the Board approved the ECDC Draft Policy on Declarations of Interest and Handling of Potential Conflicts of Interest (Document MB20/17).

17. Development of a clear, long-term vision of the ECDC, including the financial perspective (2014-2020) (Item 17):

a. Briefing from the ECDC Director on the outcome of the Working Group (Item 17a)

b. Core values and related behaviours (Item 17b)

ECDC will send the MB a paper on the Centre's long-term vision and will hold further discussions on this item at MB21 in March 2011. The MB is invited to give the Director feedback on the long-term vision, and in particular, what adaptations are needed for the future, whether the timelines foreseen in the Working Group's roadmap are realistic and whether there are specific flaws in the Centre's relationships with its stakeholders.

11. EU Reference Laboratory Networks: a Vision to Strengthen Member State Capacity in Public Health Microbiology (Item 11 – MB20/14)

The Director presented ECDC's vision of how it should further develop its cooperation with Member States' laboratories. Many members contributed to a lively and wide-ranging debate on this item.

The MB welcomed ECDC's work on laboratories and gave the ECDC Director a mandate to:

- Explore with HPA and the Commission how ECDC could cooperate with the Commission's initiative on reference laboratories

- Contact WHO/Euro to discuss a common approach on laboratory quality issues and to avoid duplication

- Present further proposals to MB21 in March 2011

John F Ryan of the Commission undertook to prepare a written report for MB21 in March addressing the issues raised by members in relation to the Commission / HPA initiative on reference laboratories.

13. Proposal for the ECDC Language Regime (Item 13 – MB20/16)

The MB was invited to vote on two alternative proposals for a language regime for future meetings: 1) that the current language arrangements of having 4 active languages (English, French, German, Spanish) be adopted as a formal language regime; 2) that a one language regime (English only) be adopted.

Result of votes:

Proposal 1: 11 votes against proposal, 14 votes in favour and 3 abstentions.

Proposal 2: 10 votes against proposal, 17 votes in favour and 0 abstentions.

With neither proposal commanding unanimity, the MB was unable to decide on a language regime. This being the case, the MB decided to establish a Working Group tasked with developing a proposal capable of commanding unanimous support. The decision to establish this group could be made by simple majority (result of vote: 23 in favour, 3 against, 3 abstentions). Members wishing to be part of the Language Regime Working Group were asked to express their interest to the MB Secretariat by 26 November. It is hoped that this Working Group will have a proposal to present to MB21 in March 2011.

18. Establishment of a Sustainable System for Scientific Quality Assurance for ECDC's Scientific Products (Item 18 – MB20/19):

a. Quality assurance for ECDC's scientific products (Item 18a)

b. Working evidence based (Item 18b)

c. Review process (Item 18c)

It was agreed that the interim results of ECDC's pilot survey with the Advisory Forum on the impact of ECDC's scientific advice be presented at the June 2011 Board meeting.

20. ECDC Building Project: Current Status (Item 20 – MB20/20 Rev.1)

The MB unanimously agreed to suspend the building project and give the Director a mandate to explore options for alternative premises for ECDC, and to look for a new tenant for ECDC's current buildings. The MB established a Working Group to assist the Director if a decision on the new premises needs to be taken before the next MB meeting. The Working Group will be composed of: the MB Chair, the Vice Chair, the Director, and members from the Commission, Parliament, Germany and Sweden.

15. Future Management Board Meetings Hosted Outside Sweden (Item 15 – MB20/18)

The MB endorsed the proposal that its meetings should convene in locations outside Sweden once every two years. Ireland will host the next MB meeting in Dublin in March 2011. The next MB meeting will be hosted outside Sweden in 2013 (Document MB20/18).

Items for discussion and information and/or guidance

19. Update on progression of the Seat Agreement (Item 19)

The MB will be fully informed on the progression of the Seat Agreement at MB21 in March 2011.

21. Update on "External Evaluation of EPIET" and Presentation of a new EPIET Paradigm to Address Member State Needs (Item 21 – MB20/21)

The MB decided to postpone its debate on this item until MB21 in March 2011.

22. ECDC's expertise and role concerning activities outside its mandate: *ECDC Threat Assessment - Russian Forest Fires* (12 August 2010) and *Interim Threat Assessment – Ash cloud following volcanic eruption in Iceland* (16 April 2010) (Item 22 – MB/Info Notes)

The MB decided to postpone discussion of this item until MB21 in March 2011.

23. Update regarding the EU Presidencies (Item 23):

a. **Belgian EU Presidency (July-December 2010) (Item 23a)**

The Belgian Representative presented the Public Health Agenda of the Belgian EU Presidency to the Board.

b. **Hungarian EU Presidency (January-June 2011) (Item 23b)**

The Hungarian Representative presented the Public Health Agenda of the Hungarian EU Presidency to the Board.

Other matters

24. Any other business (Item 24)

Renewal of ECDC Memorandum of Understanding with WHO/Euro

At the request of Germany, the Director gave an update on progress in renewing ECDC's Memorandum of Understanding (MoU) with WHO Euro. The EU's Lisbon Treaty has changed the EU's institutional arrangements in the area of external relations, including how the EU relates to UN bodies such as WHO. As a result of this, a new MoU between ECDC and WHO/Euro cannot be concluded until the newly created European External Action Service (EEAS) has commented on it. Nonetheless, the Director clarified that ECDC will continue to cooperate closely with WHO/Euro, with or without a MoU.

The MB asked John F Ryan of the Commission to communicate its concern to EEAS and the EU High Representative about the delay in concluding a new MoU between ECDC and WHO/Euro. Mr Ryan undertook to do so.

Farewell from Dirk Ruwaard of the Netherlands

Dirk Ruwaard, who has represented the Netherlands on the MB for the past four years, announced that this would be his last meeting. He gave thanks to the Chair, the Deputy Chair and the other MB members, saying that "it had been a privilege to work with you." He also expressed his appreciation of the dedication and hard work of the ECDC staff. Finally, he personally thanked the ECDC Director, Marc Sprenger, for his energy and enthusiasm. He wished Marc Sprenger and his family every success in their new life in Sweden.

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

1. The Chair, Hubert Hrabcik, opened the Twentieth Meeting of the ECDC Management Board (MB) and welcomed all members to Stockholm.

2. Apologies were received from Andrzej Ryś and Anna Lönnroth Sjödén of the European Commission. Apologies were also noted for Liechtenstein. Proxy for Andrzej Ryś was given to John F Ryan, European Commission. For the second day, 10 November, apologies were noted for Minerva-Melpomeni Malliori, European Parliament, and proxy during this day was given to Greece. Lithuania gave proxy to Latvia for 10 November 2010.

3. The Chair also announced that this would be the last meeting for the Finnish Member and the Dutch Member and extended his sincere thanks and appreciation to both of them on behalf of the Board.

4. The Chair further announced that ECDC has a brand new electronic voting system, and proposed that, given the possible margin for error in counting votes via a show of hands, it would be beneficial if the Board would to agree to vote using such technology. He then sought their formal consent via a show of hands. He also suggested that the Rules of Procedure could eventually be modified in order to reflect the use of this new technology. He indicated that while all electronic votes shall remain anonymous, during the plenary sessions, any points that are specifically raised by the Board will also be taken into account in the minutes. He then asked whether any Member objected to the idea of voting electronically in respect to certain decision items. The Board Members gave their unanimous consent to try out the electronic voting system.[5] Concerns regarding the voting system were discussed later (see item 10).

The Board gave their unanimous consent to try out the electronic voting system for certain decision items during the meeting. The Rules of Procedure of the Management Board will be revised and submitted to the Board for decision in a future meeting in order to reflect the use of this new technology.

Item 1: Adoption of the Draft Agenda (and noting the Declarations of Interest and proxy voting, if any) *(Documents MB20/2; MB20/3 Rev.2)*

5. John F Ryan, European Commission, requested that Item 6 on the agenda (How to Manage Operational EU level Tasks related to Substances of Human Origin (SOHO): Joint proposal for a solution) be changed from a decision to a discussion point. The European Parliament representative agreed with the Commission. The request was approved by the Board.

6. The European Commission also requested that the language regime agenda point should be postponed until the new building issue had been investigated further.

7. The European Parliament made no objections to postpone the decision on a language regime, but stressed that a practice nevertheless needs to be decided on until unanimity can be reached. She also suggested establishing a working group to deal with the question.

8. The Chair then proposed that the agenda point concerning the language regime should be discussed in order to reach an interim decision. The Board agreed with this proposal.

9. With reference to the Declarations of Interest, Françoise Weber, Member and Anne-Catherine Viso, Alternate, France, declared under the agenda item 9 (ECDC Draft Policy for Collaboration with 'Third' Countries), that EpiSouth, which is a PHP-funded project, is mentioned in the document. The contact was recently renewed and InVS is a partner. Both declared that their Annual Declaration of Interest will be updated. Else Smith, Member, Denmark, noted that under the item 5, ECDC Annual Work Programme 2011, her country hosts the network on vaccine-preventable diseases. In reference to item 19, Iréne Nilsson-Carlsson, Member, Sweden, remarked that Sweden has a vested interest in

[5] Due to some technical difficulties, the new electronic voting system was only used for the following decision items: 5, 7, 8, 9, 10, 12, 13, 14 and 15. In other cases, voting was conducted by a show of hands.

the Seat Agreement. The Alternate from the Czech Republic, Jan Kynčl, declared under item 10 (ECDC Work with the EU Member States) that he is a representative of one of ECDC's Competent Bodies. In reference to agenda item 1 (Adoption of the Draft Agenda), Ildefonso Hernández Aguado, Member, Spain, stated that he was a member of the MSD International Advisory Board on Health Policy between 2006-2008. John F Ryan, Member, European Commission, declared that he is a sub-delegated Authorising Officer for DG Sanco's public health budget lines, including ECDC's budget (Item 4 - Summary of discussions held at the 15th meeting of the ECDC Audit Committee [8 November 2010], including its recommendations). He also noted that he is the Head of Unit for Health Threats at the Commission, and therefore declared interests for: item 5 (ECDC Annual Work Programme 2011), where the Commission has corrected and commented on several points; item 6 (How to Manage Operational EU Level Tasks Related to Substances of Human Origin (SoHO): joint proposal for a solution); item 12 (Policy on Access and Use of Data from TESSy); items 17-20 (Development of a clear, long-term vision of the ECDC, including the financial perspective (2014-2020); Establishment of a Sustainable System for Scientific Quality Assurance for ECDC's Scientific Products; Update on progression of the Seat Agreement and ECDC Building Project: Current Status) as the Health Threat Unit is responsible for relations with ECDC, including the areas covered in the above-noted agenda points; item 21 (Update on "External Evaluation of EPIET" and presentation of a new EPIET paradigm to address Member State needs) and item 22 (ECDC's expertise and role concerning activities outside its mandate: ECDC Threat Assessment - Russian Forest Fires (12 August 2010) and Interim Threat Assessment – Ash cloud following volcanic eruption in Iceland (16 April 2010)) as the Health Threats Unit is responsible for risk management at the Commission. He then declared an interest with reference to agenda item 14 (ECDC Draft Policy for Declarations of Interest and Handling of Potential Conflicts of Interest) vis-à-vis DG Sanco.

Following the proposals noted above, the Board unanimously decided to adopt the Draft Agenda *(Documents MB20/2; MB20/3 Rev.2)*

Item 2: Adoption of the Draft Minutes of the Nineteenth Meeting of the Management Board (Menorca, 17-18 June 2010) *(Document MB20/4)*

10. The minutes of the 19th meeting were approved as presented in document MB20/4.

The Board unanimously adopted the Draft Minutes of the Nineteenth meeting of the Management Board (Document MB20/4)

Item 3: Election of the Chair and the Deputy Chair of the ECDC Management Board[6]

11. The Board approved for the current Chair to act as Chair during this agenda point.

12. The current Chair reminded the members of the election procedures and that the election of Chair and Deputy Chair of the ECDC Management Board shall be taken by two-thirds majority of the Management Board voting members present and would be carried out by secret ballot. He also reminded the Members of the nominations received for Chair and for Deputy Chair. The Board then reconvened to vote. The Chair informed that all the Board Members present would cast their votes and reminded the members of the duly signed proxy statements (see Opening and Welcome).

13. Iceland and Denmark acted as tellers to count the ballots.

14. Results from the secret ballot were as follows:

- Hubert Hrabcik was re-elected Chair of the ECDC Management Board. 30 votes were collected and the candidate received 26 votes.
- Jacques Scheres was re-elected as Deputy Chair. 30 votes were collected and 28 votes were received for this candidate.

[6] According to Article 2 of the rules of procedure of the Management Board, a two-thirds majority of the Management Board voting members present and secret ballot is required for adoption of this item.

With overwhelming support, the Board re-elected Hubert Hrabcik as Chair of the ECDC Management Board and Jacques Scheres as Deputy Chair of the ECDC Management Board.

Item 4: Summary of discussions held at the 15th meeting of the ECDC Audit Committee (8 November 2010), including its recommendations

Item 4a: Update from the Audit Committee

15. Iréne Nilsson-Carlsson, Chair of the Audit Committee and Stefan Sundbom, Internal Control Coordinator, Resource Management Unit, ECDC, updated the Board Members on the outcome of the Audit Committee meeting held the previous day.[7] The main conclusions were:

- The Audit Committee (AC) recommended approving the Budget and Establishment Table for 2011. However, the financial effects of the full establishment table and of a suitable building require close examination.
- The AC also noted that the 2010 Budget Execution was better than the previous year; however, there still exist problems with payment execution under Title 3.
- The AC encourages ECDC to formulate a plan in which to improve budget and payment execution for the coming years.
- The AC endorsed the new Annual Report template, albeit raised concerns on assessing the internal control system segment of the Annual Report.
- The AC welcomed ECDC's efforts to strengthen its Conflict of Interest policy.
- And finally, the AC noted that the recruitment of a new Head of Unit for the Resource Management Unit (RMU) would start within the coming months and that Andrea Ammon is currently the acting Head of Unit, RMU.

16. The Board Member from Germany requested to receive the above-noted conclusions in writing.

17. It was also noted by the MB Deputy Chair that SoHO already had a budget line in the Establishment Plan.

Item 4b: Budget and Establishment Table 2011 (Document MB20/5 Rev.2)

18. Anja Van Brabant, Head of Section, Finance and Accounting, RMU, ECDC, presented the Budget and Establishment Table for 2011, and gave a brief account of previous budgetary decisions taken by the Management Board.[8] The effects of the full Establishment Plan will only be seen in 2012.

19. The Board Member from Germany commented that while budget cuts are being faced by many at the national level, in the future, priorities should be made increasingly to strictly cut out that which is not firmly within the ECDC mandate. He added that in his opinion, SoHO is not part of ECDC's mandate.

20. The Director acknowledged that if the National Public Health Institutes in the Member States were facing budget cuts, this would be consequential for ECDC, too. He then informed the Board that although ECDC is also facing budget cuts, he has taken the decision to make EPIET a 'protected zone' and declared that the operational costs (Title 3) have reached a minimum of that which ECDC can operate with.

21. He then proposed that the Board approve the budget with the provision regarding SoHO and to come back to this issue after the discussions following that specific agenda item.

22. It was suggested by several members to have a final version of the budget prior to approving it.

[7] Item 4a - Update from the Audit Committee (I Nilsson-Carlsson).pdf

[8] Item 4b - Budget and Establishment Table 2011 (A Van Brabant).pdf

23. The Board agreed to postpone approval of the Budget and Establishment Table 2011 until the SoHO agenda item has been addressed.

Item 4c: Second Supplementary and Amending Budget 2010 (Document MB20/6)

24. Anja Van Brabant, ECDC, explained the procedures for the Second Supplementary and Amending Budget.[9]

Item 4d: Budget Execution 2010 (Document MB20/7)

25. The Board was informed that committed appropriations were higher in September 2010 compared to September 2009 for all three titles. This is the same for payments executed. New figures for the period between October 2009-2010 indicated the same trend.[10]

Item 16: Director's briefing on the main activities of the ECDC since the last meeting of the Management Board

26. The Director gave an update on major events since his appointment in May 2010, followed by all the Heads of Units who updated the Board on the major activities and developments in their respective units since the previous MB meeting in June.[11]

27. One Member asked whether data is available in respect to the amount of visits posted on the ECDC website.

28. Karl Ekdahl, Head of Communication and Country cooperation Unit, ECDC, confirmed that this is indeed one of the key performance indicators which could be presented at the March 2011 MB meeting.

29. Clarification was requested from Andrea Ammon, Head of Surveillance Unit, ECDC, regarding the dedicated surveillance network while coping without an increase in staff. Andrea Ammon replied that, according to the Establishment Plan, two more persons will be recruited to work on the dedicated surveillance network.

30. The Member from Ireland informed about details of the next Management Board meeting in Dublin (15-16 March 2011). He recalled that 17 March will be St. Patrick's Day and that tickets will be organised for the St. Patrick's Day Parade in the centre of Dublin on that day, which is a highly worthwhile event to participate in. ECDC and the Irish authorities are currently working jointly on the next meeting, including the social programme.

Item 6: How to Manage Operational EU Level Tasks Related to Substances of Human Origin (SoHO): Joint proposal for a solution[12] *(Document MB20/9)*

31. The Chair opened the item with a short introduction and noted the developments since the last MB meeting in Menorca, Spain. He also welcomed Stefaan Van der Spiegel from the European Commission and Arielle North from the European Medicines Agency (EMA) to be updated about issues discussed within the ECDC MB in view of the upcoming Management Board meeting of EMA in mid-December 2010.

[9] Item 4c - Second Supplementary and Amending Budget 2010 (A Van Brabant).pdf

[10] Item 4d - Budget Execution 2010 (A Van Brabant).pdf

[11] Item 16 - Director's briefing_update from Units.pdf

[12] The Board unanimously agreed to be consulted electronically via written procedure to provide their feedback on the draft minutes stemming from this plenary session, which will be subsequently forwarded to the European Medicines Agency (EMA) for their Management Board meeting in December 2010. The excerpt in question reflects the feedback as received from Members of the ECDC Management Board. The written procedure terminated on 24 November 2010 and a final version of the text was circulated to the Board on 29 November 2010. Since then, the finalised text was duly transmitted to the Management Board of the European Medicines Agency (EMA) in order to advance discussions on this topic.

32. The floor was then given to John Ryan, Member, European Commission, who sought to clarify some technical points, namely, the scope for SoHO covers organs,[13] tissues, cells and blood.[14] The EU and Member States mainly have a mandate for tissues and cells and the entire document (MB20/9) has been drafted with this background in mind. It is clear that organs remain outside the scope of this paper and this initiative. The basic needs as contained in the paper have been defined and agreed with the Member States in the Tissues and Cells Competent Authority meetings.[15] The Commission would therefore examine the possibilities for involvement of a European Agency (EMA and/or ECDC) and report back to the Competent Authorities on Tissues and Cells.

33. Representatives of the Commission have thoroughly discussed this topic over the summer months with EMA and ECDC, and have also examined the paper in depth and are fully in line with it. For both agencies, it is technically feasible to take up each of the five operational initiatives in question, including the simple traceability system, since the two agencies clearly have all the necessary capacities. The Commission has therefore no preference as to which Agency should actually carry out these tasks.

34. While the SoHO item was presented as an item for decision in the agenda, John Ryan informed the MB that no decision has to be made today, but rather a discussion as the Commission is willing to consider comments from both EMA and ECDC Management Boards. All points of views expressed shall be carefully taken into consideration by the Commission. Notwithstanding a legal perspective, as the Commission does not have adequate resources, the Commission favours a pragmatic approach in determining which tasks should be implemented by both Agencies and which one is best suited to take the lead on each of the activities and coordinate.

35. Stefaan Van der Spiegel, European Commission, briefly took the floor to summarise progress that has been carried out to date and to clarify some technical questions. It was also clarified that both Agencies are expected to require overall a similar level of resources to undertake these five operational initiatives as an assessment of the required efforts was also done by SANCO C6.

36. Arielle North, EMA, informed that the next meeting of the EMA Management Board will take place on 16 December 2010, and that comments from today's plenary session should be integrated together with the comments of the EMA Management Board into a formal record for further discussion and decision by the European Commission.[16]

37. Thereafter, a short presentation was made by Andrea Ammon, Head of Surveillance Unit, ECDC.[17]

38. In referring to the Commission's introductory remarks above, the Member from France declared that the proposal as presented to the Management Board, that is, all tasks led by ECDC, is not acceptable. Moreover, as a matter of principle, it is not up to the ECDC MB to define the mandate of ECDC. She conceded that the Management Board discusses technical issues. ECDC may work in the field of SoHO for the tasks that remain within its mandate and for which ECDC has the resources and skills available. She proposed that a strictly technical debate should ensue in which a subsequent opinion could be made for the decision makers. In respect to the technical issues, she thanked EMA and ECDC for their collaborative work and replies to the majority of questions that arose from the MB, including the sharing of tasks between the two Agencies. As a caveat, however, while much work has been carried out to date, ECDC should not be responsible for the coordination of these activities for the following reasons:

[13] Spain affirms that SoHO does not cover organs as there is neither a legal nor a medical basis. Article 168 TFUE clearly separates organs from SoHO; thus they must not be mixed. Although in many cases donors are the same, solid organ donation and transplantation have peculiarities, which make them different from SoHO donation and transplantation.

[14] Due to the differences between the technical aspects of the substances of human origin, organs, blood, tissues and cells, Spain opines that it is of relevant importance that the technical aspects of the document should be widely discussed at national and European level by the competent authorities. Current approved legislation, the systems already established (at both national and European level), differences between Member States and their involvement should be carefully analysed and considered in the forthcoming proposal.

[15] As far as Spain is concerned, neither the working group on coding nor the group of competent authorities have decided yet to hand over the coding to ECDC or anyone else.

[16] Spain has indicated that both ideas should be reflected in the next paper released: cooperation between ECDC, EMA and Member States, including background legislation.

[17] Item 6 - How to manage operational EU level tasks related to SoHO (A Ammon).

- Notwithstanding additional resources, these are new work areas for the ECDC which are considered to be beyond its current mandate. Required skills and know-how are closer to those of EMA than to those of ECDC. For instance, in terms of traceability per se, work will be needed in establishing registers, coding, etc., which will require skilled experts. Therefore, traceability should be undertaken by EMA.
- Traceability of products and traceability of risks should be clearly distinguished.
- With regards to risk management, a risk/benefit analysis is required. ECDC is not well versed in this type of practice as compared to EMA; thus additional resources will necessarily be required at ECDC. It would be therefore far more efficient to give this responsibility to EMA.
- Risk assessment and exchange of information for infections: this is well covered by ECDC's mandate and ECDC has the required skills and tools. ECDC could provide support in this matter. For non-infectious threats, including alerts related to quality defects, EMA possesses the requisite technical skill set; thus it is reasonable to allocate the task of coordination in these areas to EMA.
- Overall, EMA should be the lead Agency, ECDC supporting EMA.

39. The Member from France also informed that a letter was sent by the Director General for Health to Mrs Testori to detail the French position on SoHO.

40. The Member from Germany complimented the Member from France for her analysis and recommendations. He then recalled the need for ECDC to realise and comply with its mandate, and also to exercise caution in respect to any kinds of proposals that could fundamentally alter the Centre's mandate and resources. He also expressed the need for a European solution in which ECDC can contribute productively and effectively, albeit not as the lead Agency.

41. While agreeing with the above-noted statements of France and Germany, in referring to the proposal, the Member from the Netherlands questioned the rationale of ECDC as the lead Agency for SoHO. He also stated that it was contradictory with the previous MB in Menorca where it was agreed that ECDC needs further consolidation. He also questioned the position of the EMA Management Board.

42. In referring to the inherent challenges of SoHO, the Member from Spain stated that the European added value needs to be assessed, and that once the issue is properly mapped, the resulting economic impact will need to be identified. Additional details will be required in terms of risk, economic costs and benefits. He also agreed that although EMA could take the lead, this still needs to be carefully considered.

43. The Member from Spain also highlighted that due to the highly technical nature of SoHO, he would need to analyse it further with experts from several Units within the Spanish Ministry of Health, as is probably the case in other Member States. Given that additional time will be required in which to build his position, he thereby requested that the new version of the Commission paper be circulated at least one month prior to the forthcoming 21st ECDC Management Board meeting.

44. The Member from the Czech Republic stated that pre-existing capacities at Member State level and feasibility need to be evaluated. EMA should be the institution in charge of activities related to SoHO.

45. Minerva-Melpomeni Malliori, Member, European Parliament, expressed her support for France and Germany. She pointed out that the external evaluation recommended a consolidation of existing tasks. She suggested that the legal service of the Commission or the Parliament could be involved. She also requested that the Board review and approve the minutes of this plenary session, and that they subsequently be circulated to EMA in a transparent way in order to be more constructive on this issue in future meetings. She also stated that if the required tasks are beyond the mandates of the Agencies, the mandates should be reviewed and a written request should be formulated. The issue of resources would therefore need to be adequately addressed by the European Parliament and the European Commission.

46. Arielle North, EMA, noted that while seeking a pragmatic solution, the fundamental principle of cooperation between the two Agencies must be kept and relevant legislation has to be taken into account in considering the organisation of the respective tasks.

47. The Member from the United Kingdom agreed that a pragmatic solution will be required in which both Agencies are fully involved. In addition, the two Agencies will need to consider the benefits of having one lead Agency, especially in relation to the role and added value to the existing work of the national competent authorities. Moreover, an inventory of past incidents should be provided. She noted the overall process will require clarity to avert duplication, particularly in the area of risk assessment.

48. The Member from Belgium agreed with France, Germany and the Netherlands, and questioned the priority for ECDC to be involved in SoHO while some dedicated surveillance networks, such as the one dedicated to Creutzfeld Jacob's disease, will remain outsourced in the coming years, given the lack of resources and skills within ECDC, while surveillance is within its core business. He therefore questioned ECDC's priorities.

49. In concurring with the UK Member, the Member from Finland added that a pragmatic, economic solution is needed in order to solve this issue. The national competent authorities in Finland are flexible and thus amenable to coordination conducted either by EMA or ECDC. Cooperation is essential at the EU and the national levels in order to progress in this area, while keeping in mind that the entire system cannot be built solely by one without the other. She then inquired whether the same level of resources would be required if EMA was designated as the coordinator, or whether this has been estimated thus far?

50. The Member from Germany urged the Commission to remain in contact with the two regulatory committees at the EU level since they possess the requisite expertise.

51. The Chair then requested that the European Commission draft a new paper, in cooperation with EMA and ECDC, which is to be circulated to the Board at least one month prior to the forthcoming 21st ECDC Management Board meeting. The Commission agreed with this proposal and promised to deliver a paper in time as per the Chair's instructions.

52. The Member from France suggested that a formal statement be sent on behalf of the ECDC MB to the EMA MB recognising the capacity of the latter in taking the lead.

53. The Deputy Chair suggested writing a letter to the Management Board of EMA with the minutes, including a short summary from the discussion.

54. While noting EMA's presence in the room, Minerva-Melpomeni Malliori, Member, European Parliament, advised against any undue complication for the ECDC MB, citing that only the excerpt of the minutes from this plenary session is distributed to EMA in time for circulation to their Management Board meeting.

55. The Director of ECDC thanked the members for their excellent feedback. He recalled that the proposal was developed at the request of the European Commission and nevertheless welcomes further discussions at the political level. He endeavours to opt for a pragmatic solution. He noted that the appropriate resources as specified in the paper should be re-evaluated in two years' time. He then stated that formal agreement of the Management Board is required in order to transmit the minutes of this plenary session to EMA's Board.

56. The Chair thanked all parties for a highly constructive discussion thus far and proposed the following summary points:

1. An agreement is needed for a European solution to the SoHO issue.
2. EMA and ECDC are clearly the two most suitable potential EU agencies.
3. While some diverse views were expressed in the MB as to which Agency should take the lead, the majority of delegates hold the view that EMA should take the lead and that ECDC should play a supporting role; and
4. The European Commission is asked to draft a paper on this topic, in cooperation with EMA and ECDC, and to prepare a final proposal, which is to be circulated to the Board at least one month prior to the 21st MB meeting. He also confirmed that the draft minutes on this sensitive topic will be finalised as quickly as possible and that written approval of the Board will be required in order to agree to and transmit the minutes of this plenary session to the EMA Management Board in time for their meeting in December 2010.

57. While the Member from Germany recognised that a solution at EU level is needed, the MB can contribute to this solution only within its area of responsibility. He cautioned that there can be no agreement in respect to the proposed conclusion that ECDC and EMA are deemed to be the two best agencies for solving this. He concluded that ECDC can contribute to the solution within its mandate, albeit not as the lead Agency.

58. Followed Germany's statement, the Chair proposed to cancel point two from the above-noted list of proposed summary points, and concluded that:

1. An agreement is needed for a European solution to the SoHO issue;
2. While some diverse views were expressed in the MB as to which Agency should take the lead, the majority of delegates hold the view that EMA should take the lead and that ECDC should play a supporting role; and
3. The European Commission is asked to draft a paper on this topic, in cooperation with EMA and ECDC, and to prepare a final proposal, which is to be circulated to the Board at least one month prior to the 21st MB meeting. He also confirmed that the draft minutes on this sensitive topic will be finalised as quickly as possible and that written approval of the Board will be required in order to agree to and transmit the minutes of this plenary session to the EMA Management Board in time for their meeting in December 2010.

59. As a result of the discussion, the MB requested to remove all SoHO related activities from the 2011 Work Programme and from the 2011 Budget prior to submitting them to the approval of the MB (voting procedures for both). The subsequent modified versions of the Work Programme and of the Budget were then approved by the MB.

The Board unanimously agreed to be consulted electronically via written procedure to provide their feedback on the excerpt of minutes stemming from this plenary session, which will be subsequently forwarded to the European Medicines Agency (EMA) for their Management Board meeting in December 2010.

Item 5: ECDC Annual Work Programme 2011[18] *(Document MB20/8 Rev.1)*

60. The amended version of the Annual Work Programme 2011 was circulated to all Members of the MB. This includes specific provisions further to the decision of the MB on SoHO (previous item). Following the presentation of the Director's item,[19] the Chair noted that the MB is requested to adopt the Annual Work Programme.

61. The Member from Finland inquired about the item of unforeseen needs on the wish list and precisely where they are included in the budget. The Director noted that this is not an easy issue to grapple with as the unforeseen needs cannot be integrated into the budget. However, it is a tentative way of solving this issue in respect to the A or B capacity levels, assigned to each activity in the document, which are aimed at providing some flexibility to initiate unforeseen projects.

62. The Member from Spain complimented the Director and his staff for the highly comprehensive and well prepared Work Programme. He was especially pleased to see a provision for social determinants, as well as the inclusion of vulnerable populations in the budget, which was examined by the Spanish Presidency. He expressed his positive support that climate change and the impact on health were included therein, and that H1N1 and views on the pandemic were also noted. Some markers would need to be set down for the European Health Policy to profile decisions taken in various EU Member States on morbidity and mortality, e.g. for Chlamydia. He also noted that ECDC needs to be increasingly engaged with the European Chemicals Agency (ECHA) as insufficient evidence often exist vis-à-vis biocides and available data, for instance. The prevention aspect should also be included. He then encouraged the Centre to broaden their definition of independence in this context.

[18] According to Article 8 of the rules of procedure of the Management Board and Article 15 of the Founding Regulation, a two-thirds majority of all members is required for adoption of this item.

[19] Item 5 - ECDC Annual Work Programme 2011 (M Sprenger).pdf

63. The Member from the Netherlands also complimented the Director and his staff on the document. He noted that the AMR should be more of a cross-cutting issue, citing a letter which was previously sent to the ECDC Director regarding an EU meeting on AMR on viruses and fungi. Surveillance is seen more as a goal in itself rather than as a tool linked with scientific advice.

64. The Member from Denmark also welcomed the document, which provides an interesting insight into how the money is spent, and suggested that ECDC should focus increasingly on the impact on health of climate change and the social determinants that WHO and the United Kingdom per se have already worked extensively with.

65. The Member from France also expressed her satisfaction that every forthcoming Work Programme is becoming clearer and easier to follow. As a caveat, however, she raised some concerns that the Programme is rather ambitious and that priorities should be set in order to avoid the risk of not realising plans in their entirety. The risk is to rely increasingly on external support, to the detriment of ECDC internal teams' experience. She asked whether the survey on health associated infections and antimicrobial use in the long-term care could be conducted every two years instead of annually. Regarding the development of molecular surveillance, she asked whether the objective is to develop a laboratory capacity within ECDC or simply to collect the data.

66. The Member from Sweden agreed with her French colleague and reiterated placing greater emphasis on priorities in the future. She also added that the forthcoming financial constraints should be considered. The public health functions of ECDC, such as the surveillance system, needs to be continuously improved and developed. While TESSy is very good, much work remains to be done with regards to quality assurance of the data.

67. The Alternate from the Czech Republic expressed his concern regarding the Missions and Meetings section of ECDC. He referred to the time it takes to acquire prepaid tickets and suggested that improved effectiveness in this area could save money.

68. The Director acknowledged all comments raised during the discussions. He remarked that more important priorities need to be identified and reordered. The Work Programme is the first step towards an increasingly planned approach. While it is not easy to change things, and requires some "out of the box" discussions, it is a first step in trying to better articulate priorities. He also assured the Board that ECDC will work on arranging cheaper airplane tickets. TESSy is a priority for ECDC and therefore needs constant attention. In referring to social determinants, while "the facts are known," he asked, "how can they be changed?" This is why the focus is set on the target level in which to reach a given population, e.g. the Roma. In respect to molecular biology, ECDC endeavours to invest in supporting existing laboratories in the EU in order to be prepared for dispersed epidemics. Moreover, we should reflect on how to better balance external/in-house expertise.

69. In agreeing with Sweden, the Member from Germany noted that it may be more difficult to assemble a wish list due to budgetary constraints. It is vital to assess the skills that can be used to save money. In particular, caution should be exercised regarding the division of labour between ECDC and EMA, for instance, on vaccination safety. The activities under the mandate of ECDC need to be prioritised. Regarding the exploration of the feasibility of a possible virtual stockpile of antitoxins, he mentioned that as a precaution, while ECDC could provide medical expertise, the administration of a stockpile should not be ECDC's responsibility. He also posed a question regarding the service contracts with the Competent Bodies which have increased and queried about the rationale.

70. The representative from the Parliament also extended his compliments in respect to the paper, and affirmed that the approach is very good. He continued that Molecular typing of host determinants is a growing area, e.g. HIV, Chlamydia, which could be integrated into the programme in two-three years. He also noted that the figures in the annexes do not correspond with the main paper and thus should either be corrected or dropped altogether.

71. While noting that vaccine-preventable diseases and narcolepsy remain the responsibility of ECDC and that side effects remain the responsibility of EMA, the Director informed that the relevant authorities have had lengthy discussions about this issue. ECDC has also increased the budget for this topic. He continued that ECDC should facilitate Member States given their high amount of requests for information. In responding to a previous query pertaining to country support, Karl Ekdahl, ECDC, informed about a pilot project on country information, including the provision of data to ECDC, in addition to quality control of translation in nine countries. The pilot project represents a highly

valuable project with money going to some of the Competent Bodies. Based on this experience, ECDC is proposing to extend the project to all Member States.

72. Philippe Harant, Senior Officer, Quality and Planning, Director's Office, ECDC, noted that the changes are highlighted in the revised document for easier reference. Adjustments are as follows: MRSA typing study – 175 000 €; Influenza information day 68,729 €; service contracts for Competent Bodies 300,000 €. This money will not be committed until a decision from the MB is made on the SoHO project.

73. Germany then asked whether the SoHO part is still included in the Work Programme to be approved by the Board. Philippe Harant affirmed that the SoHO text is no longer included in the amendment as presented to the MB with the Work Programme.

eVote:	**Does the Management Board approve the ECDC Annual Work Programme 2011?**	**Responses**	
	Yes	29	100%
	No	0	0%
	Abstain	0	0%
	Totals	**29**	**100%**

The Board unanimously approved the ECDC Annual Work Programme 2011 (Document MB20/8 Rev.1).

Item 10: ECDC Work with the EU Member States *(Item 10 – MB20/13 Rev.1)*

74. Johan Giesecke, Chief Scientist, ECDC, gave a short presentation.[20] He reiterated that the proposal is to have just one Competent Body (CB) for each Member State or, in case this is not possible, one coordinating CB per country. The focal point would be the national coordinator.

75. The proposal was welcomed by the Board members. Denmark remarked on the advantages of having one coordinating CB per country. The Member from France congratulated ECDC for the simplification, which would improve the coordination process as well as the responsibility, for example, in the nomination to participate in meetings. The new proposal would not allow for the experts themselves to decide which meetings they want to attend as this decision would be made by the CB. The Member from Poland noted that there is a long history behind the current situation. In Poland, the nomination process was carried out by the approval of the Minister (How some CB's accessed the list remains unknown). He added that the ECDC website should be internally consistent in this regard. The number of CB's has increased, albeit without control. The Member of the Czech Republic also welcomed the paper, and added two comments: firstly, he supports video and web conferences instead of actual physical meetings. However, some countries may lack the technology to do this. Secondly, the proposed system might become problematic if ECDC takes the lead on SoHO. In that case, an additional agency or CB would be needed. Austria suggested that due to different data sets that are sent to ECDC, perhaps more single contact points are needed for the single data set. She also supported the idea of videoconferencing. The Member from Belgium advised that ECDC needs to be clear between scientists, experts and national delegate representatives, each of whom has different roles that need to be clarified or specified. The workload of each group needs to be specified. Germany concluded that the Board should vote in favour of this proposal today, which is a starting point for further changes.

76. During the eVoting session, the question was raised regarding the anonymity of the system. Demetrio Barros, Audiovisual and Logistics Assistant, ECDC, who was managing the system, noted that the members' handsets had not been personalised. It was suggested by the Board that it would be useful to know who voted and how; however, it was also noted that sometimes secret ballots are required. It was also mentioned that there might be some conflicts of interest as regards to anonymous voting on tenders or decisions regarding tenders. Also, as some papers might be revised and the decisions might need to be amended, it was questioned whether it is possible to change the

[20] Item 10 - ECDC work with the EU Member States (J Giesecke).pdf

questions before voting. The Chair concluded this by confirming that in case of secret ballots, the handsets should not be personalised. The eVoting system can be further refined over time.

eVote:	Does the Management Board agree with the proposal for ECDC's Work with the EU Member States – one Competent Body per Member State?	Responses	
	Yes	25	86.21%
	No	1	3.45%
	Abstain	3	10.34%
	Totals	**29**	**100%**

The majority of the Board approved the ECDC Work with EU Member States (Document MB20/13 Rev.1).

Item 9: ECDC Draft Policy for Collaboration with 'Third' Countries *(Document MB20/12)*

77. The Chair introduced the item. ECDC collaboration with third countries is laid down in the Founding Regulation, in particular, in Articles 3, 9, and 30. Since the establishment of the ECDC, the role of the EU in health has been further specified in the EU Health Strategy, and in the recent Commission Communication on Global health, as well as in the new Lisbon treaty. There is a clear mandate to enable ECDC to act beyond EU borders to protect EU citizens in situations where communicable disease outbreaks may threaten the health of EU populations. ECDC policy development should be congruent with the strong global outlook of recent Communications from the Commission on the EU role in global health.

78. Following a brief presentation from Karl Ekdahl, ECDC,[21] the Member from Belgium noted that in the activity report, the amount set aside for coordination, trips abroad and conferences is visible. He queried whether it would be possible to see the actual percentage of staffing resources given to 'third' countries. He also added that the annex to the budget programme should identify the 'third' countries. Germany supported this statement and recalled that ECDC policy development should be taken into account. The Member from Spain wondered about the relations with other agencies, for instance, US CDC, and whether there exists a budget for areas of common interest? He emphasised the need to prioritise and examine the work done by other agencies.

79. Following an inquiry from the representative of the Parliament, the Commission responded by noting that Switzerland is omitted from the document due to the sensitive and complicated nature of international relations. He then continued by agreeing with Belgium and affirmed the need to be more precise about investing in activities with 'third' countries. This should be specified in the Annual Work Programme, if funds are emanating from other parts of the Community budget, including the number of ECDC staff involved and how ECDC fits into international representation. This is very much up in the air following the setting up of the External Action Service as a result of the Lisbon Treaty.[22]

80. Karl Ekdahl confirmed that the resources are in place and that in the majority of projects, Candidate and Potential Candidate Countries are invited to meetings in ECDC. During the March MB meeting in 2011, ECDC will also provide further details on the number of ECDC experts that are invited to these countries. Recently, ECDC held a two-day meeting in Brussels with various Commission DG's on international relations. He noted that ECDC is working closely with Commission, on a weekly basis. He then informed that the Standard Operating Procedures (SOP) for work data for 'third' countries will be developed and presented to the Management Board meeting in March 2011. With regards to Switzerland, Commission is in the lead and besides one proposed country visit there is nothing further envisaged.

[21] Item 9 - ECDC Draft Policy for Collaboration with 'Third' Countries (K Ekdahl).pdf

[22] He also commented on the Paragraph 16 of page 3: 'act beyond the EU borders to protect EU citizens'. Mandate may not be clear and we should seek a legal clarification of the wording. New institutional arrangements have been set up through Lisbon Treaty.

eVote:	Does the Management Board approve the ECDC Draft Policy for Collaboration with 'Third' Countries?	Responses	
	Yes	27	93.10%
	No	0	0%
	Abstain	2	6.90%
	Totals	**29**	**100%**

The majority of the Board approved the ECDC Draft Policy for Collaboration with 'Third' Countries (Document MB20/12).

Item 7: Working Arrangement between the European Medicines Agency (EMA) and the ECDC *(Document MB20/10)*

81. Johan Giesecke gave a combined presentation.[23] ECDC and EMA have agreed to sign an overarching Working Arrangement as a framework for joint activities. For the implementation of mutually agreed activities, Technical Annexes, laying down responsibilities, timelines, and expected outcomes, will be developed in the future, and annexed in the Working Arrangement document.

82. In order to enhance cooperation on issues of common interest, ECDC and EFSA signed a Memorandum of Understanding (MoU) in April 2008. Since that time, the two Agencies have completed several joint projects in accordance with their respective mandates under their Founding Regulations, such as assessment of public health significance of Methicillin resistant *Staphylococcus aureus* (MRSA) in animals and food; annual joint reports on zoonoses and food-borne outbreaks in the European Union; and several scientific opinions.

83. There are also many ongoing joint long-term activities, in particular, supporting the European Commission with scientific advice and risk assessments in areas covering human, animal or food aspects of communicable diseases, introducing a common approach to data collection on human and animal surveillance, including the provision of exchange of surveillance data on communicable diseases for risk assessment purposes.

84. Based on satisfactory experiences on the exchange of expertise, information, and joint projects, both ECDC and EFSA are willing to continue, improve, and further strengthen this collaboration with a renewed MoU, which is now presented to the Board for approval.

eVote:	Does the Management Board approve of the Working Agreement between the European Medicines Agency (EMA) and the ECDC?	Responses	
	Yes	28	93.33%
	No	1	3.33%
	Abstain	1	3.33%
	Totals	**30**	**100%**

85. Germany stated that the reference to cooperation with SoHO in the paper is assumed to refer to a possible cooperation and does not refer to the scope or extent of such cooperation.

The majority of the Board approved the Working Arrangement between the European Medicines Agency (EMA) and the ECDC (Document MB20/10).

[23] Items 7 and 8 - Cooperation with EFSA and EMA (J Giesecke).pdf

Item 8: Memorandum of Understanding between the European Food Safety Authority (EFSA) and the ECDC (renewal) *(Document MB20/11)*

eVote:	Does the Management Board approve the Memorandum of Understanding between the European Food Safety Authority (EFSA) and the ECDC (renewal)?	Responses	
	Yes	27	90%
	No	1	3.33%
	Abstain	2	6.67%
	Totals	**30**	**100%**

The majority of the Board approved the Memorandum of Understanding between the European Food Safety Authority (EFSA) and the ECDC (renewal) (Document MB20/11).

86. Following the vote, due to time constraints, it was agreed to postpone item 11 (EU Reference Laboratory Networks: a Vision to Strengthen Member State Capacity in Public Health Microbiology) to the second day of the meeting.

Item 12: Policy on Access and Use of Data from TESSy *(Document MB20/15)*

87. Andrea Ammon, Head of Surveillance Unit, gave a presentation.[24]

88. The Member from the Netherlands sought to confirm whether the fee was actually abandoned. He imagined that several Non-governmental organisations are seeking data that would normally cost a lot of money.

89. The Member from Sweden was very much in favour of this policy. Confidentiality of data provisions could be in conflict with potential legislation and therefore it should be kept in mind.

90. The Member from Denmark questioned the publication of data covered in this procedure and inquired how it will work in practice.

91. The Member from Belgium conveyed that Member States should have priority preference for using the Member States' data. He also inquired about the interpretation of data, citing that comparisons between Member States differ, that "once you have given them the data, it remains a mystery what happens to the data thereafter."

92. The Commission representative noted that all procedures are legally compliant and authorised via the European Data Protection Supervisor. He cautioned, however, about retrospective problems with the EWRS.

93. Andrea Ammon reflected on the feedback from the Management Board. With regards to the fee – the effort in collecting the fee is actually larger than the fee itself – but this will be reviewed in the future depending on the amount of requests from these third parties in the future. Currently, the procedure represents an attempt to standardise this practise. In response to Belgium's question, ECDC is trying to take this into account in a SOP that has been developed. In terms of interpretation, Andrea Ammon maintained that there exists a step before publication in order to comment on the text. With respect to legal compliance, the implemented procedures are compliant with the European Data Protection Supervisor; however, this has not been verified formally.

94. Following a comment from the Member of Finland, Andrea Ammon confirmed that a request to withhold the data until the countries themselves have published it refers to case-based routine surveillance data.

95. The Chair informed that this issue will be revisited in a meeting next year.

[24] Item 12 - Policy on Access and Use of Data from TESSy (A Ammon).pdf

eVote:	Does the Management Board approve of the Policy on Access and Use of Data from TESSy?	Responses	
	Yes	23	79.31%
	No	2	6.90%
	Abstain	4	13.79%
	Totals	**29**	**100%**

The majority of the Board approved the Policy on Access and Use of Data from TESSy (Document MB20/15).

Item 14: ECDC Draft Policy for Declarations of Interest and Handling of Potential Conflicts of Interest *(Document MB20/17)*

96. The Director introduced this item and gave a short presentation.[25] Potential conflicts of interest were a very hot topic during the influenza epidemic. A working group was established under the leadership of Andrew Amato, Deputy Head of Surveillance Unit, ECDC. This has also been discussed with the European Parliament. A new page on transparency is situated on the ECDC website. The Director also informed that ECDC is one of the forerunners in the EU with respect to transparency. The Chair added that ECDC staff members and the Board should operate under the same rules.

97. While noting that all experts working with ECDC should be covered, the Member from Belgium questioned whether different rules of conflict of interest exist and pointed out that a uniform basis for all EU agencies is needed.

98. In agreeing with Belgium, Denmark advised that a cross EU approach is needed; however, it remains a very delicate and sensitive area.

99. Spain agreed that it is a good idea to move forward with this issue, and warned that not having a policy may result in a loss of image.

100. The representative from the Commission asked that the data protection aspects of this policy be clarified. He noted the importance of recognising the revision and step forward made by the ECDC on DoI/CoI: "It is clear that in revising ECDC's policies on DoI/CoI", he said, "attention has been paid to other agencies' policy, particularly to EFSA in order to ensure consistency." He informed that the Commission has set up an internal task force with participation from four agencies under SANCO. He also recommended not adopting the policy today as the matter is still subject to possible recommendations from the European Data Protection Supervisor (EDPS).

101. The Member from France agreed that the opinion of the EDPS is necessary.

102. The Director noted that he would like to publicly inform the public that ECDC has strict policies on Conflicts of Interest and thus he is seeking the support and approval of the MB on this policy.

103. The Member from Belgium expressed that the MB welcomes and supports this initiative to improve the procedures on Conflicts of Interest, and stressed that it should be in line with other agencies.

104. The Deputy Chair supported Belgium and the Director's statements and added that the MB should not await the decision of the European Data Protection Supervisor.

105. The Senior Legal Adviser of ECDC, Elisabeth Robino, explained that EFSA, EMA, as well as the Commission had been consulted and the opinion of the European Data Protection Supervision on EFSA's policy was taken into consideration. There are differences between agencies as for example declarations of interest of EFSA staff are not systematically published on the website. Contrary to EFSA, ECDC does not have specific scientific panels, scientific opinions are issued by ECDC, which is why the increased transparency as described in the policy paper is necessary. The draft policy may be adjusted depending on possible recommendations of the EDPS and will enter into force thereafter. The MB shall be informed thereof.

[25] Item 14 - Policy on DoI and handling of potential conflict of interest (M Sprenger).pdf

eVote:	Does the Management Board approve the ECDC Draft Policy on Declarations of Interest and Handling of Potential Conflicts of Interest?	Responses	
	Yes	25	83.33%
	No	2	6.67%
	Abstain	3	10%
	Totals	**30**	**100%**

The majority of the Board approved the ECDC Draft Policy on Declarations of Interest and Handling of Potential Conflicts of Interest (Document MB20/17).

Item 17: Development of a clear, long-term vision of the ECDC, including the financial perspective (2014-2020)

Item 17a: Briefing from the ECDC Director on the outcome of the Working Group

106. The Director recalled that during the summer, he had set up 15 internal Working Groups (WGs) in ECDC in order to help define a Sustainable Agenda for ECDC for the coming years.[26] The MB had already heard reports from most of these WGs during the first day of its meeting, most notably ECDC's Work Programme for 2011. WG outcomes were also discussed by the MB vis-à-vis ECDC Collaboration with 'Third' Countries (item 9), EU level tasks on substances of human origin (SoHO) (item 6), Budget Execution (item 4d), ECDC Work with the Member States (item 10) and Draft Policy on Declarations of Interest (item 14). On the second day, WG outcomes would form the basis for discussions on EU reference Laboratory networks (item 11) and Scientific Quality Assurance (item 18).

107. The Director then took the opportunity to present the initial outcome of WG1 on developing a clear long-term vision of ECDC.[27] He proceeded by asking Andrea Ammon, Head of Surveillance Unit, to present the outcome of WG11 on ECDC core values. These two items are very much linked, as ECDC's vision and its values need to support each other.

108. The scope of WG1's task was to develop a roadmap to take ECDC from being a 'good organisation', as it currently is, to being an 'excellent organisation'. The roadmap is still under development and as such was not up for decision at the current meeting. There would be a further discussion, and a decision at the next MB meeting in March 2011. The Director clarified that WG1 developed its vision within the remit of ECDC's current mandate. While there may well be discussions in the coming years on broadening the scope of ECDC's mandate, they will remain political discussions between the European Commission, the European Parliament and the European Council.

109. WG1's method of working was to interview more than 30 ECDC staff members about their vision for the organisation, and to screen the documents produced by the Advisory Forum and the Management Board. Essentially, WG1 was tasked with analysing significant amounts of information.

110. The outcome of WG1's discussions was that the mission as defined for ECDC in its Founding Regulation remains valid. Indeed, it had become even more relevant in the past seven years than at the time ECDC was created. Nonetheless, WG1 wanted to increase the impact of ECDC, with a renewed vision statement:

> *ECDC works on communicable diseases as part of public health and contributes to better health, reducing health inequalities and improving quality of life of the EU population.*

111. The Director stated that the MB would note from this statement that ECDC wishes to work on reducing health inequalities and improving the quality of life in the EU. These two priorities were already reflected in ECDC's Work Programme for 2011, which the MB adopted on 9 November 2010. The vision links across to the three core ECDC values that Andrea Ammon was due to talk about as the next item: ECDC being quality driven, service orientated and acting as "one team". The mission

[26] See Annex I.

[27] Item 17a - Outcome of the WG (M Sprenger).pdf

defined in Article 3 of the Founding Regulation was still central to the new vision statement, but there was a stronger role for prevention. ECDC's products would be characterised by their speed, quality and cost effectiveness. An example of how ECDC already applies these values is daily roundtable meetings on Health Threats, in which new threats are identified and initial threat assessments produced within a matter of minutes. The Director then presented the main elements of WG1s roadmap for achieving its vision over the next five years (Table 1):

Table 1: Main Elements of Roadmap in achieving vision over the next five years:

N°	Adaptations	Timeframe
1	Organise systematic feedback on ECDC's performance	1-2 years
2	Subsequently set goals to differentiate ECDC's support to Member States	1-2 years
3	Increase quality of epidemiological data and strengthen simultaneously the link with laboratory networks	2-5 years
4	Move from reactive to proactive analysis	2-10 years
5	Improve health communication (empower communicators, target groups /risk communication)	~ 5 years
6	Achieve strong voice in public health	~ 5 years
7	Strengthen (inter-sectoral) networks and partnerships	~ 5 years
8	Promote coherent efforts in health determinants and prevention	> 5 years
9	Increase visibility in society and strive for 'OECD' like reputation	> 5 years

112. Another crucial factor in achieving this long-term vision is the need to re-analyse ECDC's relationship with its numerous stakeholders and partners. For example, ECDC's relationship with WHO is of crucial importance (WHO Headquarters in Geneva and WHO/Euro in Copenhagen). ECDC has relations with many Third Countries. But in dealing with countries in Africa, the Centre also comes into contact with the WHO Afro or WHO Eastern Mediterranean Region. ECDC needs to analyse and prioritise its various relations, and invest in the ones that are of critical importance.

113. Recruiting and retaining excellent staff will also be of central importance in achieving ECDC's vision. This means finding the right balance between competition and collaboration among staff, and also addressing the balance between the use of in-house and external expertise. The Director expressed his personal preference for collaboration over competition, and for in-house expertise in preference to using external experts.

114. The Director stated he would create a Task Force to further elaborate on the provisional analysis prepared by WG1 and on the upcoming challenges for ECDC. This Task Force would also support preparations for the next external evaluation of ECDC, due in 2011-2012, and help prepare the upcoming comprehensive Multi-annual Strategic Plan 2014-2020.

115. The Director promised to send MB members a paper on ECDC's long-term vision, inviting them to provide comments. The revised version of the paper will be sent to the MB together with other meeting documentation to be discussed further during the MB21 in March. Finally, he thanked the members of WG1: Svetla Tsolova (Secretary of the WG) (SAU), Irina Dinca (CCU), Ülla-Karin Nurm (CCU), Modris Stasuls (PRU), Kathryn Edwards (DIR) and Jan Mos (external expert, RIVM).

116. The Director invited feedback from the MB on the long-term vision and, in particular, what adaptations are needed for the future, whether the timelines foreseen in the Working Group's roadmap are realistic, and whether there are specific flaws in the Centre's relationships with its stakeholders.

117. During the debate, MB members welcomed the new long-term vision and generally felt that ECDC was on the right track of becoming an excellent organisation. Various members endorsed the importance of some of the specific priorities set out by the Director: the need to make ECDC better known among health policy makers, the importance of gathering systematic feedback, the importance of retaining and motivating excellent staff and the importance of finding the right balance between

internal and external expertise. One member commented that, while continuing to focus on individual diseases, starting to look at health determinants could make sense for ECDC – especially with a view to the Centre's longer term development. Another member opined that the discussion on internal versus external expertise should also look at the division of advisory tasks between ECDC and Member States.

118. The Board Member from Germany noted that the third priority in WG1's roadmap – "Increase quality of epidemiological data and strengthen simultaneously the link with laboratory networks" – was already a core ECDC task of vital importance. He would like to see progress even more quickly than the two-five years indicated in the roadmap. He noted the need for ECDC to work with other organisations, and in particular WHO/Euro, to increase the quality of epidemiological data and strengthen links with laboratory networks. In this regard, he expressed his concern that the Memorandum of Understanding (MoU) between ECDC and WHO/Euro was due to expire at the end of November, and that no new MoU had been agreed upon. He asked for a discussion on this matter under 'Any Other Business'.

119. The Director concluded by thanking the Board for their support and promising to discuss the item further at the Board meeting in March 2011.

Item 17b: Core values and related behaviours

120. Andrea Ammon, Head of Surveillance Unit, presented this item in her capacity as Chair of the internal ECDC working group on this topic.[28] The vision as outlined by the Director is what ECDC aims for. The values are about how ECDC and its staff behave. The three core values are:

1. Service Minded – we act on the needs of others.
2. Quality Driven – everything we deliver is useful.
3. One Team – we value the contribution from everyone.

121. What is critical is that the values are used to build trust both within the Organisation and externally. ECDC's management needs to "walk the talk". Therefore, the Centre is starting to train their managers about what these values mean, and how to implement them.

122. The values apply to ECDC's relationship with its partners and stakeholders. This should bring direct benefits to the MB members and their organisations. ECDC pledges to be service minded. It will be conscious of delivering quality in deciding how to use its time and money. And the "one team" approach should be applied to ECDC's relations with colleagues in the Member States and the European Commission. In closing, Andrea Ammon affirmed that "as the values get rolled out in early 2011, we hope you will already notice a positive impact by MB21 in March."

ECDC will send the MB a paper on the Centre's long-term vision and hold further discussions on this item at MB21 in March 2011. The MB is invited to give the Director feedback on the long-term vision, and in particular, what adaptations are needed for the future, whether the timelines foreseen in the Working Group's roadmap are realistic and whether there are specific flaws in the Centre's relationships with its stakeholders.

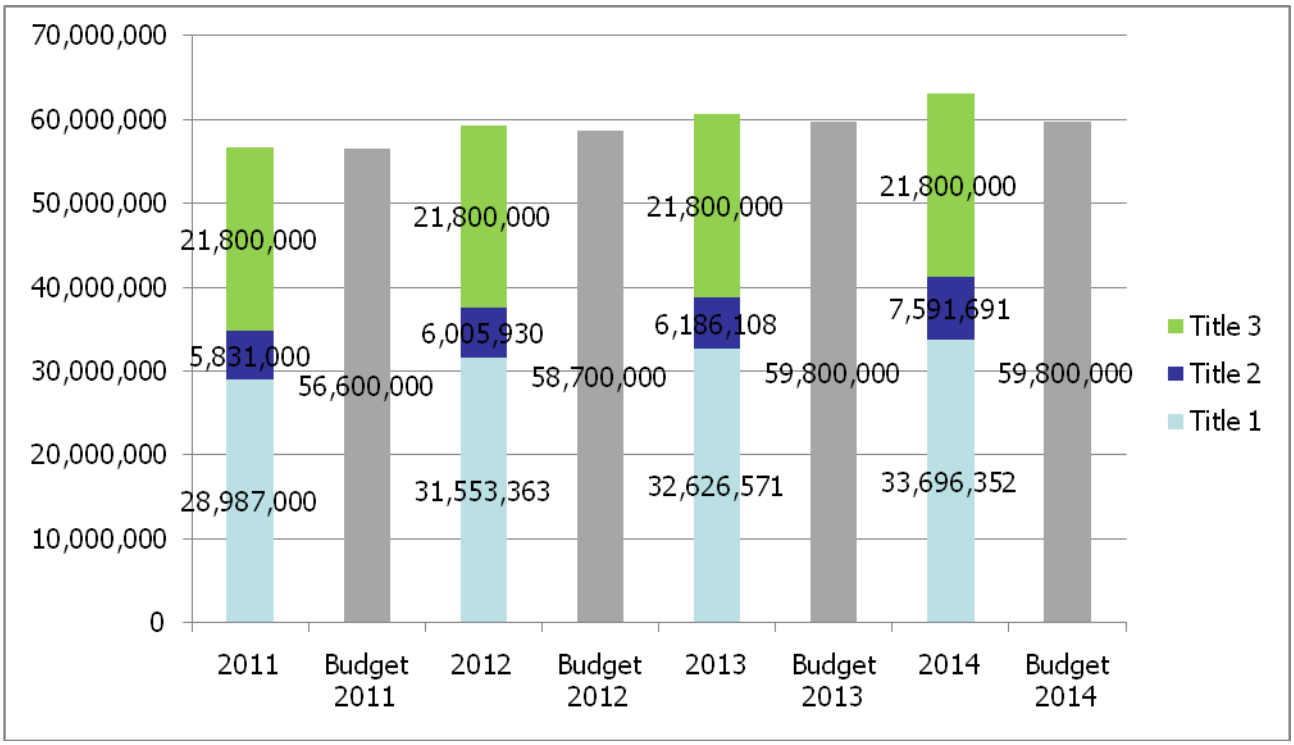
Item 16: Update from Resource Management Unit on financial situation (Continued)

123. Andrea Ammon presented this item in her capacity as Acting Head of the Resource Management Unit (RMU).[29] At the request of the Audit Committee on the first day of the meeting, RMU had produced an analysis of the expected financial shortfall in ECDC in the coming years. This was illustrated in a bar chart (Figure 1) showing projections of ECDC's budget in 2012, 2013 and 2014 (gray columns) against expected expenditures under the three strands of ECDC's budget – Title I (light blue), being staff salaries and related costs, Title II (dark blue) being the cost of ECDC's building and ITC systems and Title III (green) being operational expenditure. The graph assumes that ECDC

[28] Item 17b - Core values and related behaviours (A Ammon).pdf
[29] Budget forecast 2012 - 2014 (A Ammon).pdf

receives the full budget it is promised for the remaining years of the 2007-2013 EU Financial Perspective. For 2014, it assumes 0% budget growth.

Figure 1: Projections of ECDC's Budget in 2012, 2013 and 2014:



124. Expenditure on staff (Title I – light blue) will be around € 3 million higher in 2011 to 2012 than in 2010. This is because, from 2011 onwards, ECDC will start the year with a full, or nearly full, Establishment Plan. In addition, some of the existing staff will be reclassified to higher grades, thus their salaries will increase. ECDC is trying to minimise its ITC costs, but these will still rise slightly between now and 2013.

125. If ECDC wishes to maintain its current level of operational expenditure (Title 3 – green) over the coming years then, due to unavoidable rising costs under Title I and Title II, it will be faced with a financial shortfall of € 0.5 million in 2012, rising to € 0.8 million in 2013 and € 3.3 million in 2014.

126. The Director recalled that ECDC faces an extremely serious situation. There is no flexibility to reduce costs much more than is already being done. To make matters worse, ECDC has been "fined" around € 2 million for the year 2011 as a result of not having implemented its entire budget in 2009. If ECDC loses € 1 or 2 million in 2012, this will create enormous challenges.

127. MB members agreed that ECDC faces a serious situation and pledged their support to the Director in finding viable solutions. Nonetheless, one member characterised the situation as "serious but not impossible". The need to prioritise and look for savings was stressed. Various cost savings ideas were put forward, including replacing some face-to-face meetings of networks with audio conferences and limiting the use of external contractors.

128. On behalf of the Audit Committee, the Board Member from Sweden thanked Andrea Ammon and RMU for having produced such a satisfactory analysis so quickly.

Item 11: EU Reference Laboratory Networks: a Vision to Strengthen Member State Capacity in Public Health Microbiology *(Document MB20/14)*

129. The Director briefly introduced the item. Laboratories are extremely important for ECDC. Prior to becoming Director, while the epidemiological aspect of ECDC was in place, the microbiology at ECDC needed to be strengthened. ECDC was created without its own laboratories. This was a good idea as there are many fine national laboratories, and there is no need to duplicate them in

Stockholm. But currently there is no formal relationship between ECDC and these national laboratories. This is something that needs to change.

130. All EU Member States are signatories of the new International Health Regulations (IHR), which commits them to have in place by 2012 the capacities needed to deal with health emergencies. Do the EU Member States have these capacities? What precisely are the capacities needed? It is difficult to control communicable diseases without laboratories. Yet when one talks to experts, there is currently no clear view of the minimum laboratory capacity needed by Member States.

131. The Director's proposal was that in 2011, ECDC should focus on defining these basic requirements for laboratory capacity. It should then look at whether Member States have this capacity available, and how access to this capacity can be organised in an efficient way. Greater EU cooperation on laboratory resources is not necessarily a radically new idea. For some diseases, this capacity sharing already happens. For example, the Robert Koch Institute in Germany is a *de facto* European reference centre on testing for West Nile Virus, and has played a key role in the response to outbreaks in Greece, Portugal and Romania. ECDC endeavours to see this sort of cooperation in relation to other diseases.

132. The Director noted that the European Commission and the UK Health Protection Agency (HPA) are running a project to create an EU inventory of the "high end" labs. ECDC is starting to cooperate and coordinate closely with this project, which will be very important over the coming years. However, the ECDC network would be wider than just "high end" laboratories.

133. The Deputy Chair opened the debate by stating that the issues set out in the paper are clear. Based on its mandate, ECDC relies on Member States' laboratories, albeit it has not yet fully substantiated how this relationship is to work.

134. In the debate that ensued, there was recognition that ECDC's proposed strategy built on the work on microbiology undertaken by ECDC since 2007 as part of its Multi-annual Strategic Programme. There was consensus on the need for ECDC to network with national public health laboratories and that this cooperation falls squarely within ECDC's mandate. Nonetheless, many members wanted further clarification as to how the work being undertaken by ECDC related to the initiative on EU reference laboratories launched by the Commission and the UK Health Protection Agency (HPA). Several members expressed unease about a questionnaire to national labs circulated by HPA as part of this project. The questionnaire was very long and asked some sensitive questions concerning laboratories' activities. Some of the national laboratories compete for business against HPA, and therefore regard HPA as having a potential conflict of interest. Two members complained about what they perceived to be a threatening remark from an HPA official about what would happen if their Member States did not respond to the questionnaire. There was a call for clarification as to the relationship between ECDC and WHO/Euro's Collaborating Laboratories. Several members expressed discomfort with the term "reference laboratories". Some regarded the creation of "reference laboratories" as a quasi-regulatory action requiring a specific EU legal base, while others cautioned against concentrating all the recognition and expertise on one laboratory: a network of several laboratories would be more appropriate. It was asked on what basis, and under what criteria, would reference laboratories be appointed.

135. The Deputy Chair asked the Commission to respond to concerns raised about its initiative with HPA.

136. The representative of the Commission stated that he undertook to investigate in cooperation with ECDC and HPA and to submit a written report to MB21 in March. He took very seriously the issues raised about perceptions of a conflict of interest and the perceived threatening remark. By way of clarification of the origin of the Commission's initiative with HPA, he recalled that the EU Health Action Programme endorsed by the Council of Ministers called for the creation of a system of EU reference laboratories. DG Sanco had launched a call for tender, and then appointed HPA as a contractor to produce a study on how this action could be implemented.

137. The Director clarified that at the heart of his vision was the development of a common understanding of quality. ECDC does not use the term 'reference laboratories' in a regulatory sense. Rather, ECDC wants to find out which laboratories are deemed by their peers to be the best for specific tests and diagnostics. ECDC is willing to explore different possibilities. It is not of central importance whether there is one EU reference laboratory for one test or three, or five. What matters is a (shared) common understanding of quality. This means that the laboratories in the network must

share their protocols and demonstrate that their quality assurance systems are in line with the EU consensus on quality. ECDC wants to develop a common EU vision on laboratory quality, ascertain tests Member States need to be able to run for effective disease control, the quality standards for those tests and EU solidarity to ensure all Member States have access to the testing capacity they need, either in their country or another Member State. The Director sought a mandate from the MB to meet with HPA and discuss collaboration with the Commission/HPA initiative.

138. The Deputy Chair summed up the conclusions of the MB on this item. There is support for further steps by ECDC. The Director should be given a mandate to discuss with HPA and the Commission about their reference laboratory initiative. The Director should also contact WHO/Euro to see if they can agree a similar approach to quality and to avoid duplication. The MB welcomed ECDC's work with laboratories and await a further proposal from ECDC at MB21 in March.

The MB welcomed ECDC's work on laboratories and gave the ECDC Director a mandate to:

- Explore with HPA and the Commission how ECDC could cooperate with the Commission's initiative on reference laboratories

- Contact WHO/Euro to discuss a common approach on laboratory quality issues and to avoid duplication

- Present further proposals to MB21 in March 2011

John F Ryan of the Commission undertook to prepare a written report for MB21 in March addressing the issues raised by members in relation to the Commission/HPA initiative on reference laboratories.

Item 13: Proposal for the ECDC Language Regime *(Document MB20/16)*

139. The Chair recalled that in the MB19 in June, the Board concluded that it had never taken a decision on the language regime during any of its meetings.

140. Elisabeth Robino further recalled that MB19 had concluded that the language regime for future meetings of the MB should be voted on at the November meeting.

141. Based on the discussions at MB19, the MB was invited to vote on two alternative proposals for a language regime for its future meetings: 1) that the current language arrangements of having four active languages (English, French, German, Spanish) be adopted as a formal language regime; or, if proposal 1) could not command unanimous support, 2) that a one language regime (English only) be adopted.

142. Neither proposal received unanimous support. The results of the votes are given below. The MB therefore decided to set up a Working Group tasked with developing a proposal for a language regime for future MB meetings capable of achieving unanimous support.

143. The Chair clarified that, in the absence of unanimity, the MB had not decided on its language regime for future meetings. In the meantime, until the MB is able to make a decision, ECDC will continue to facilitate MB meetings by making available the same four active languages as at previous meetings.

eVote:	**1.) Does the Management Board formally adopt the current language regime of ECDC?**	**Responses**	
	Yes	14	50%
	No	11	39.29%
	Abstain	3	10.71%
	Totals	**28**	**100%**

eVote:	**2.) Does the Management Board formally adopt a one language (English) regime?**	**Responses**	
	Yes	17	62.96%
	No	10	37.04%
	Abstain	0	0%
	Totals	**27**	**100%**

eVote:	3.) Does the Management Board approve of setting up an MB working group on the ECDC Language Regime?	Responses	
	Yes	23	79.31%
	No	3	10.34%
	Abstain	3	10.34%
	Totals	**29**	**100%**

Result of votes:

Proposal 1: 11 votes against proposal, 14 votes in favour and 3 abstentions.

Proposal 2: 10 votes against proposal, 17 votes in favour and 0 abstentions.

With neither proposal commanding unanimity, the MB was unable to decide on a language regime. This being the case, the MB decided to establish a Working Group tasked with developing a proposal capable of commanding unanimous support. The decision to establish this group could be made by simple majority (result of vote: 23 in favour, 3 against, 3 abstentions). Members wishing to be part of the Language Regime Working Group were asked to express their interest to the MB Secretariat by 26 November. It is hoped that this Working Group will have a proposal to present to MB21 in March.

Item 18: Establishment of a Sustainable System for Scientific Quality Assurance for ECDC's Scientific Products *(Document MB20/19)*

144. Johan Giesecke informed that two ECDC internal working groups worked this autumn on quality issues.[30] One group examined quality in terms of organisational performance, while the other assessed the quality of ECDC's scientific output.[31]

145. ECDC's Chief Scientist then identified three key elements to be examined in ECDC's scientific quality assurance system. Firstly, the process of priority setting for the topics on which ECDC is to deliver scientific advice, secondly, the process for producing scientific advice, and thirdly, systems for measuring the impact of scientific advice.

146. Responding to Johan Giesecke's presentation, the Chair asked that the interim results of this survey be presented at the June 2011 MB. Johan Giesecke agreed to this. The Chair then opened the floor.

147. Several members emphasised the importance of assessing the impact of ECDC's advice. Even the process of asking Member States what they had done with the advice could have a positive effect, encouraging more consideration and analysis of the advice at Member State level. One member suggested adding a question in the Advisory Forum survey to the effect "Has ECDC's advice influenced your thinking?" It is possible that the advice has had some influence, even if it has not been implemented 100%. Other issues raised in the discussion were the difficulty of finding experts with no conflicts on some topics. The view was expressed by one member that, as long as the interest is declared, a certain level of conflict could be acceptable. There was a discussion on the criteria for selecting experts and a note of caution from one member as to the need to avoid giving opinions that could be perceived as firm recommendations.

148. Responding to the debate, Johan Giesecke happily agreed to add the additional question proposed to the survey on the impact of ECDC's advice. He agreed that finding experts with no conflict at all could sometimes be difficult. Regarding the selection of experts, ECDC often asks the Advisory Forum for suggestions; however, the decision as to who is selected to sit on a scientific panel lies with ECDC. Experts are solely chosen in their personal capacity. They do not represent their Member State, but rather the "Country of Science". He recalled that ECDC produces guidance and advice, but never recommendations. This policy had been decided after a lengthy discussion at MB11. ECDC is well aware of the sensitivities in this area.

[30] Item 18 - Scientific Quality Assurance (J Giesecke).pdf

[31] Item 18 refers only to this latter topic.

It was agreed that the interim results of ECDC's pilot survey with the Advisory Forum on the impact of ECDC's scientific advice be presented at the June 2011 Board meeting.

Item 20: ECDC Building Project: Current Status *(Document MB20/20 Rev.1)*

149. The Director thanked the MB for its support for the building project at MB19 in June.[32] Following the MB's vote in favour of the project, ECDC had formally notified the project to the EU's Budget Authority – the Council of Ministers and the European Parliament. Parliament had made some serious comments about the project, despite having issued a favourable opinion on it. In particular, Parliament's Budget Committee had insisted that there should be an opt-out clause in ECDC's lease on the new building.

150. The Director had restarted negotiations with Akademiska Hus, the Organisation that rents ECDC its current buildings and which was meant to deliver the building project. The Director wanted Akademiska Hus to agree to an opt-out clause, and also meet other value for money criteria as laid down by Parliament's Budget Committee. On 9 November 2010, the Director convened a meeting with the Director of Akademiska Hus. Akademiska Hus is unable to accept an opt-out clause in ECDC's 12-year lease on the new building. It is also unable to meet other value for money criteria relating to the rental cost per square metre.

151. Given the refusal of Akademiska Hus to meet the conditions required by the European Parliament, the financial risks involved in the building project, and the fact that it will incur ECDC staff having a building site outside their offices for three years, the Director felt he had no alternative but to recommend to the MB that it suspend the building project.

152. The Director asked for a mandate to seek alternative office space for ECDC. He was confident it would be possible to find a new office space in the Stockholm area suitable for the expanded ECDC staff for a lower cost than the current ECDC buildings. This would avoid ECDC staff having to work at a building site for three years, and it would also reduce ECDC's rental expenses. Nonetheless, he observed that there was no opt out clause in ECDC's current lease. ECDC would also need to explore finding a new tenant for its current buildings.

153. The Chair summed up the proposal from the Director and supported the creation of a small Working Group to assist the Director. The Chair stated it was impossible to know how quickly a new building might come available. The Working Group would be able to give the Director approval to sign a new lease, in case a decision was needed ahead of MB21 in March.

154. In the subsequent discussion, one Board member expressed his surprise at this development. One member emphasised that in order to improve the staff's situation, it is necessary to find a solution very fast and a deadline should be set for this. Nonetheless, there was consensus that it was not possible to accept Akademiska Hus's refusal to meet the conditions as laid down by the Parliament's Budget Committee. The MB therefore unanimously supported the course of action proposed by the Director and the Chair.

155. The member from the European Commission suggested that the Staff Committee will be informed about this process.

The MB unanimously agreed to suspend the building project and give the Director a mandate to explore options for alternative premises for ECDC, and to look for a new tenant for ECDC's current buildings. The MB established a Working Group to assist the Director if a decision on the new premises needs to be taken before the next MB meeting. The Working Group will be composed of: the MB Chair, the Vice Chair, the Director, and members from the Commission, Parliament, Germany and Sweden.

[32] Item 20 - ECDC Building Project - Current status (M Sprenger).pdf

Item 15: Future Management Board Meetings Hosted Outside Sweden *(Document MB20/18)*

156. Corinne Skarstedt, Senior Officer, Corporate Governance, Director's Office, ECDC, recalled that this item, and a paper accompanying it, had been on the agenda of MB19 in June and postponed to today. There had been much discussion about budget constraints when the MB had debated ECDC's Work Programme for 2011. This consideration was also pertinent when looking at the convening of MB meetings outside Sweden. Such meetings represent an additional financial cost both to ECDC and the Member State hosting them. She presented an analysis of the cost of the various meetings held outside Sweden.[33] On top of this financial cost, such meetings consume more ECDC person days than ones held in Sweden as ECDC staff spend time travelling. Corinne Skarstedt noted that some EU agencies, such as the European Medicines Agency (EMA) and the European Aviation Safety Agency (EASA), never convene Board meetings outside their host country. The European Maritime Safety Agency (EMSA) and the European Centre for the Monitoring of Drugs and Drug Addiction (ECMDDA) hold external meetings only once every two years.

157. The Chair observed that it was still possible to hold meetings outside Sweden, but in view of the costs, the MB ought to limit them. The proposal was then put to a vote.

eVote:	**Does the Management Board endorse the convening of meetings held outside Sweden every two years?**	**Responses**	
	Yes	23	79.31%
	No	4	13.79%
	Abstain	2	6.90%
	Totals	**29**	**100%**

The MB endorsed the proposal that its meetings should convene in locations outside Sweden once every two years. Ireland will host the next MB meeting in Dublin in March 2011. The next MB meeting will be hosted outside Sweden in 2013 (Document MB20/18).

Item 19: Update on progression of the Seat Agreement

158. Elisabeth Robino recalled that at MB19 in June, the Board had given the Chair a mandate to sign a Seat Agreement with ECDC's host country, Sweden.[34] The MB felt that the package presented by Sweden in June met the demands the MB had made at MB18 in March regarding the rights of working spouses, entering ECDC staff and their families into the Swedish population register and functioning contact points.

159. On 30 June 2010, the Chair and the Swedish Minister for Elderly Care and Public Health, Maria Larsson, had duly signed a Seat Agreement.

160. Following this, there were just two outstanding issues. Firstly, ratification of the Seat Agreement by the Swedish Parliament. Secondly, amendment of the Swedish population register legislation to allow ECDC staff and families to appear in this register.

161. The Director reported that the Swedish government had just presented a draft law to ratify the Seat Agreement which should be adopted imminently by the Swedish Parliament.

162. A draft law to amend the Population Register Act had been presented by the Swedish Government on 23 June 2010 and following a positive opinion of Sweden's Council of Legislation on 8 September it has been submitted to Parliament, which is expected to vote on the new law on 9 December, and it will then come into force on 1 January 2011. Hence from January 2011 onward, ECDC staff and families should have the same rights as local residents.

The MB will be fully informed on the progression of the Seat Agreement at MB21 in March 2011.

[33] Item 15 - Future MB meetings hosted outside Sweden.pdf

[34] Item 19 - Update on progress of Seat Agreement (E Robino).pdf

Item 21: Update on "External Evaluation of EPIET" and Presentation of a new EPIET Paradigm to Address Member State Needs *(Document MB20/21)*

163. Denis Coulombier, Head of Preparedness and Response Unit, ECDC presented the results of the evaluation, and how ECDC intends to take account of them.[35]

164. The External Evaluation of the European Programme for Intervention Epidemiology (EPIET) was initiated by ECDC in 2009 in a call for tender. Following this public procurement, the Dutch Royal Institute for the Tropics (KIT), as successful tenderer, performed the evaluation between September 2009 and June 2010.

165. A Steering Committee for this External Evaluation was installed by the Director of ECDC and consisted of Heads of Units of ECDC (5), the Head of Section for Training, the chief EPIET coordinator, representatives of EPIET training site forum (2), and competent bodies for training (2). The steering committee followed the progress of the evaluation, and gave advice on the plan of approach and the first draft report.

166. This evaluation has led to a final draft report that was sent to the Director of ECDC on 26 June 2010, and the report currently undergoes a minor editorial step to correct some factual errors. This editorial step, however, does not influence the main findings and recommendations, which is why at this stage ECDC can already express the plan of the general approach towards using the report for further planning and operations of the EPIET programme.

167. The overall conclusion is that the EPIET programme is seen to be of satisfactory quality and is generally very well regarded across stakeholders. However, Member States do not benefit equitably from the present EPIET programme in relation with selection mechanism and brain drain issues. There is general agreement amongst the respondents that the ECDC is the appropriate agency for facilitating a common EU-level communicable disease field epidemiology and control training.

168. The key conclusions and recommendations of the evaluation are:

1. Increase programme 'ownership' of Member States equitably (selecting fellows, addressing country specific needs).
2. Increase the amount of fellows trained (to address the needs more adequately).
3. Address brain-drain issues and develop a strategy for "repatriation" of fellows.
4. Expand the scope to a broader public health approach: Disease Prevention and Control.

169. In order to respond to these recommendations, ECDC is proposing a "new paradigm" for the EPIET programme. It should continue as one programme but with a national track as well as an EU track. Trainees on the national track would follow the same syllabus and get training developed and quality controlled by ECDC. However, these national trainees would stay in their home countries and have their salaries paid by their home countries. This paradigm would address the issue of repatriation (national trainees would stay in their national public health systems), as well as allowing an expansion of the number of professionals trained.

170. The EUPHEM programme for training public health microbiologists should be integrated into EPIET and expanded. EPIET would then be a programme with a public health microbiology career pathway as well as an applied epidemiology pathway.

171. In addition to having the new "national track" EPIET trainees, EPIET would continue to work with the national Field Epidemiology Training Programmes that are currently associated with the programme.

[35] Item 21 - Update on External evaluation of EPIET (D Coulombier).pdf

172. ECDC proposes that in 2011, the number of EU track EPIET fellows be expanded to 22 (there were 20 fellows admitted in 2010), and that 10 new national track EPIET fellowships be created. Of the 22 EU track fellows 4 would be on the public health microbiology pathway (compared to 2 in 2010).

173. ECDC would eventually like to see as many as 40 EPIET fellows on the national track. However, this will require the identification of enough suitable training sites and local supervisors.

174. The final report of the External Evaluation of EPIET will be published on ECDC's website shortly, once the editing process has finished.

175. Following Denis Coulombier's presentation, the German Board Member stated that EPIET is a highly important programme and the Management Board should take time to debate it properly. Given that time in the present MB meeting was short, he proposed that the MB postpone this debate until MB21 in March. This proposal was accepted by the Chair and subsequently the Board.

The MB decided to postpone its debate on this item until MB21 in March 2011.

Item 22: ECDC's expertise and role concerning activities outside its mandate: ECDC Threat Assessment - Russian Forest Fires (12 August 2010) and Interim Threat Assessment – Ash cloud following volcanic eruption in Iceland (16 April 2010) *(Documents MB/Info Notes)*

176. In order to allow for more time to discuss the slow progress in concluding a new MoU between ECDC and WHO/Euro, the German Board member proposed to postpone item 22 until MB21 in March 2011. The Board agreed with this proposal.

The MB decided to postpone its discussion on this item until MB21 in March 2011.

Item 23: Update regarding the EU Presidencies

Item 23a: Belgian EU Presidency (July-December 2010)

177. The Belgian Board Member recalled the public health priorities for the Presidency that he had outlined at MB19 in June 2010: 1) Health security: 1-2 July 2010 conference on lessons learned from the 2009 influenza A (H1N1) pandemic, followed by Informal Health Council on 5-6 July; 2) Health systems: a high-level ministerial conference with experts will be held on 9-10 September 2010, including an expert conference on dementia on 25–26 November; 3) Pharmaceutical products: a high-level conference will convene on 23–24 September 2010 and; 4) Chronic disease: a conference will be held on 19-20 October 2010.

178. He also briefly updated the MB that the outcome of the 1-2 July conference and the 5-6 July Informal Health Council had formed the basis for Council of Ministers' Conclusions, adopted in September, on Lessons Learned from the A/H1N1 Pandemic. Conclusions based on the outcome of the other conferences will be adopted by the Employment, Social Policy, Health and Consumer Affairs Council on 6-7 December 2010.

Item 23b: Hungarian EU Presidency (January-June 2011)

179. The Member from Hungary informed about her country's priorities for its EU Presidency, which starts on 1 January 2011. "Patients and Professionals" will be the theme for the Hungarian EU Presidency in the area of health. Specific topics the Presidency will be working on under this theme will include: 1) Patients' rights under the Cross-border Healthcare Directive, building on the work on this topic done by the Belgian EU Presidency; 2) The legislative package on the supply of medicines; 3) Safety in healthcare and; 4) How to increase EU level cooperation on childhood vaccination.

180. On this last topic (childhood vaccination), there would be an examination of how to increase cooperation on data collection and surveillance. There would also be an examination of vaccine strategies for specific target groups, including, in particular, the children of migrants. There will be discussion on the growing resistance to vaccination in Europe, and how this links to the problem of antimicrobial resistance. There will be a meeting on this topic in Budapest with ECDC, and also a joint EU/US meeting in Budapest.

181. Other health topics that the Hungarian EU Presidency will work on include: 1) National public health programmes; 2) Physical wellbeing and protection against accidents and injury. There will be a conference on this topic in June 2011; 3) Healthcare systems and the rational use of resources; and 4) eHealth and cross-border healthcare. This will be the theme of a Presidency eHealth Conference in May 2011 to which health ministers will be invited.

Item 24: Any other business

Renewal of ECDC Memorandum of Understanding with WHO/Euro

182. At the request of Germany, the Director gave an update on progress in renewing ECDC's Memorandum of Understanding (MoU) with WHO/Euro. The EU's Lisbon Treaty has changed the EU's institutional arrangements in the area of external relations, including how the EU relates to UN bodies such as WHO. As a result of this, a new MoU between ECDC and WHO/Euro cannot be concluded until the newly created European External Action Service (EEAS) has commented on it. Nonetheless, the Director clarified that ECDC will continue to cooperate closely with WHO/Euro, with or without a MoU.

183. The representative of the Commission pointed out that EEAS and Baroness Ashton, the EU High Representative for Foreign Affairs and Security Policy, come under the auspices of the Council rather than the Commission. It is therefore not within the remit of the Commission to compel the EEAS to deliver its opinion.

184. The Board Member from Germany expressed his concern and frustration that the internal politics of the EU in Brussels is blocking cooperation for the benefit of EU citizen's health. From the point of view of EU citizens, this is very difficult to understand. He asked that this view be passed on to Baroness Ashton and the EEAS.

185. On behalf of the MB, the Chair concurred with the comments from Germany. He asked the Commission to communicate the MB's view to the powers that be in Brussels. The Commission representative accepted to do this, while noting once again that the hoped for solution lay with the Council rather than the Commission.

The MB asked John F Ryan of the Commission to communicate its concern to EEAS and the EU High Representative about the delay in concluding a new MoU between ECDC and WHO/Euro. Mr Ryan undertook to do so.

Farewell from Dirk Ruwaard of the Netherlands

186. Dirk Ruwaard, who has represented the Netherlands on the MB for the past four years, announced that this would be his last meeting. He gave thanks to the Chair, the deputy Chair and the other MB members, saying that "it had been a privilege to work with you." He also expressed his appreciation of the dedication and hard work of the ECDC staff. Finally, he personally thanked the ECDC Director, Marc Sprenger, for his energy and enthusiasm. He wished Marc Sprenger and his family every success in their new life in Sweden.

Closing comments from the Chair

187. The Chair thanked the MB members for a truly rewarding meeting. The Board had made decisions on many important issues. The Chair thanked the interpreters, the Director and the ECDC staff for their hard work and professionalism. He then reminded everyone that the next Board meeting will convene during 15-16 March 2011 in Dublin, Ireland.

Closing comments from the Director

188. The Director thanked the Management Board for their continued support. He thanked the ECDC staff, but wanted to pay specific tribute to two individuals who had played an especially important role in MB20: Philippe Harant, who had prepared the excellent Work Programme that was so highly appreciated by the MB; and Corinne Skarstedt, who with her team had been working late into the evenings to make this meeting a success.

Annex I: ECDC Sustainable Agenda Working Groups

ECDC Sustainable Agenda Working Groups
WG 1. Develop a clear long-term vision of ECDC, including the financial perspective (2014-2020)
WG 2. Develop the 2011 Work Programme and determine the themes for 2011 and 2012
WG 3. Develop an ECDC policy paper for collaboration with 'third' countries
WG 4. Develop a clear approach for efficient customer relationships with Member States via Competent Bodies
WG 5. Develop a clear vision on collaboration with Public Health Microbiological Laboratories, including a network of reference laboratories
WG 6. Update and broaden ECDC policy on Conflict of Interest
WG 7. Set up a sustainable system for Scientific Quality Assurance for ECDC scientific products
WG 8. Develop a plan to integrate SoHO in the Work Programme
WG 9. Develop a New Building
WG 10: Review of the matrix organisation
WG 11. Develop ECDC values
WG 12. Introduce an Activity Based Budget system to ascertain the costs of the different products
WG 13. Develop Key Performance Indicators
WG 14. Action plan for Budget Execution
WG 15. Organisational Excellence -> Quality Assurance