



MINUTES OF THE 24th MEETING OF THE MANAGEMENT BOARD

15-16 December 2011

I. Documents submitted to the Management Board

Draft agenda	(MB/A/04/2011 <u>rev.01</u>)
Draft minutes of the 23 rd Management Board meeting	(MB/M/03/2011)
2 nd amending budget 2011	(MB/53/2011)
Transfers within the budget	(MB/54/2011)
Final budget and Establishment Plan for 2012	(MB/55/2011)
Work programme for 2012 – review and update of annexes	(MB/56/2011)
Update of work plan on international activities 2012	(MB/57/2011)
Future tasks and challenges of ECHA up to 2017	(MB/58/2011)
Third country participation in ECHA's work (Art 106 REACH)	(MB/59/2011 <u>rev.01</u>)
Update of the multi-annual strategic audit plan	(MB/60/2011)
Appointment of Committee members	(MB/61/2011)
ECHA's Assessment of the Need and Feasibility of Enhancing Multilingual Communication in the Agency's Operations	(MB/62/2011)
Report from the Executive Director	(MB/63/2011)
Multi-annual planning for IT systems	(MB/64/2011)
ECHA's approach towards accredited stakeholder organisations	(MB/65/2011)
External communications strategy	(MB/66/2011)
Reports from subgroups of the Management Board	(MB/67/2011)
Establishment of an Ethical Committee	(MB/68/2011)
Review of implementing rules for Article 9 of the EU Staff Regulation – Setting up of a Staff Committee	(MB/69/2011)
Review of the decision MB/77/2009(D) – payment of witnesses of the Board of Appeal	(MB/70/2011)
Update on the Agency's Work Plan on substances on nanoscale	(MB/71/2011)
Update on biocides / outcome of legislative process	(MB/72/2011)

II. Summary Record of the Proceedings

Introductory remarks

The Chair opened the meeting by welcoming the participants, in particular new members who were appointed by the Commission to represent interested parties without voting rights:

- For industry, Mr Hubert MANDERY (European Chemical Industry Council CEFIC).
- For trade unions, Ms Gertraud LAUBER (European Mine Chemicals and Energy Workers' Federation – EMCEF and European Trade Union Confederation - ETUC).
- For environment, health and consumer non-governmental organisations, Mr Martin FÜHR (European Environmental Bureau - EEB/University of Applied Sciences, Darmstadt)

Mr MANDERY and Mr FÜHR were appointed for a second term in office, Ms LAUBER for a first term. All three mandates run until December 2015. Ms LAUBER replaces Mr MUSU. The Board welcomed Ms LAUBER and thanked Tony MUSU for his work for ECHA since 2007.

The Chair also informed that Guido SACCONI and Eskil THUESEN had announced their resignation from the Management Board once new members have been appointed. Until these new appointments are finalised by the European Parliament and the Council respectively, Mr SACCONI designated Ms Christina RUDÉN, and Mr THUESEN Mr Peter ØSTERGAARD as their respective personnes de confiance.

The Chair introduced the observers attending the meeting and provided information on the proxy votes of which he had been notified (details are listed in section IV of these minutes).

1. Agenda (MB/A/02/2011 rev.01)

The Chair introduced the room documents that had been made available and announced that the Board's working group on the Board of Appeal will be report under the agenda item 18 on a matter related to "Board of Appeal selections performed by the Management Board".

On this basis, the agenda was adopted.

2. Declaration of specific interests

The Chair explained that the Secretariat had circulated new forms for the annual declarations of interest pursuant Article 88(3) of the REACH Regulation in November. All Board members were requested to complete these forms and return them to the Secretariat. The new forms had been approved as part of the ECHA policy on potential conflicts of interests.

It was reminded that the Secretariat had advised to declare a present employment in the field of activity of ECHA. This information should also include an employment in a public authority dealing with REACH or CLP, like ministries or Competent Authorities. The Chair explained that it would be important to make a differentiation between declaring interests on the one hand and classifying them as constituting (potential) conflicts of interest on the other. There would be no automatic link between declaring an interest and the existence of a potential conflict of interest.

It was agreed that the Secretariat would complete those declarations that nevertheless did not mention a relevant present employment known to ECHA. To this end, the employment

related information from the Board member contact list should be used. (A copy of this list was distributed for reference).

The Chair also encouraged the other members to submit an updated CV to the Secretariat for publication on the internet, if they had not done so yet.

On request, none of the Board members present declared a conflict of interest with regard to the agenda items of the meeting.

3. Minutes (MB/M/03/2011)

The minutes of the meeting on 29-30 September 2011 were approved with one modification (see corrigendum in the annex).

4. Budget 2011 (MB/53/2011, MB/54/2011)

The Director of Resources presented a proposal for a 2nd amending budget in 2011 and informed of the latest budget transfers carried out under the responsibility of the Executive Director. He explained that the regular review of the budget implementation resulted in a possibility to decrease the budgeted expenditure for 2011 by 7.143 MEUR to a total of 93.2 MEUR. This decrease was possible due to the postponement of several IT projects and infrastructure purchases as well as the reprioritising of some activities. Particular attention was also paid to adherence with the principle of annuality, an aspect that had been reminded regularly by the European Court of Auditors. Therefore, some projects that could have been started in 2011 were postponed.

The Management Board took note of the latest internal budget transfers and adopted the 2^{nd} amendment to the Agency's budget for 2011. The Executive Director was instructed to notify this decision to the Budgetary Authority, the Court of Auditors and the Commission, and to have the amending budget published.

5. Final Budget and establishment plan for 2012 (MB/55/2011)

The Director of Resources introduced the proposal for ECHA's budget for 2012 and the establishment plan. The proposal amounted to a total of 103.2 MEUR, and was thus 10% higher than the total of the final budget for 2011 (i.e. after the decrease approved with the 2nd amending budget – see above). The whole of the Agency's budget necessary for carrying out tasks under the REACH and CLP Regulations in 2012 will be funded through own fee income. The primary source of revenue will be the cash reserve that was accumulated as a result of the first registration deadline in 2010.

The most significant increase in the operational expenditure is anticipated for the substance evaluation activity where approximately 40 service requests are foreseen to be extended to Member State Competent Authorities (MSCAs) in support of their tasks and for which $\[\in \] 2.8 \]$ MEUR have been budgeted. Other significant operational expenditure relates to communications and translations as there is a steady need for translation services primarily due to the need to support SMEs and to make more information available to the general public. The further development of the ECHA website and the awareness raising for the 2^{nd} registration deadline in May 2013 also require allocation of funds leading to a total of $\[\in \]$ MEUR designated for communications and translation. Moreover, resources ($\[\in \]$ 10.7 MEUR) have been budgeted to cover the needs for maintaining and further developing the specialised IT tools in support of the industry in preparation for the upcoming $\[\in \]$

registration deadline. Furthermore, funds have been foreseen for the procurement of services in support of the authorisation and risk management activities as well as the specialised consultancy services for the Agency's quality system.

The ECHA establishment plan, as adopted by the European Parliament and the Council (budgetary authority), remains at the level of 2011 (456 establishment plan posts). Thus, the budgetary authority eventually did not authorise any additional posts for REACH and CLP tasks, whereas the Management Board had requested for 20 new posts in March 2011 for substance evaluation and application authorisation purposes. It was noted that the budget proposal as presented included funds for financing 10 contract agents with which ECHA will try to - partly - compensate the resources shortfall. This was already discussed and agreed in the September 2011 meeting of the Management Board.

The Management Board was, furthermore, informed that the budgetary authority has reserved 14 new posts as well as EU subsidies for ECHA tasks under the pending Biocides and PIC Regulations. These resources will become available once the final legislative acts have been adopted. (It is noted that for Biocides, the budget proposal as presented foresaw a further amount of 0.5 MEUR for preparatory activities funded by the European Commission through a service level request for tasks under the upcoming Biocides Regulation).

The presentation was followed by an exchange of views.

A Commission representative highlighted the constraints for the EU budget under the next multi-annual financial framework 2014-2020 and the desire of EU Member States to reduce the number of staff working for EU institutions and decentralised EU bodies, like agencies. The Management Board should, therefore, be prepared for dealing with a difficult budgetary environment also in the coming years. Applying different scenarios with reduced staff numbers could be useful for future planning.

On request by a member, the Executive Director clarified that the 2012 budget would increase compared to 2011 as the Agency would factually still grow even if the number of authorised establishment posts remains at the same level. One reason for this is that many of the staff recruited in 2011 had only started the employment towards the end of the year and the average monthly expenditure related to salaries will accordingly increase in 2012. Also, the number of contract agents, which are not connected to establishment posts will increase. The Executive Director highlighted that the ongoing work on a revised staff model for REACH and CLP tasks will facilitate a flexible resource planning in the future, should the EU budgetary context oblige ECHA to reduce the number of staff.

The Management Board adopted the Agency's budget for 2012 as proposed. The budgetary decision will be notified to the Budgetary Authority, the Court of Auditors and the Commission, and be published.

6. Work programme for 2012 – review and update of annexes / Update of the work plan on international activities (MB/56/2011, MB/57/2011)

The Executive Director presented the draft for a revised work programme for 2012. The initial version of the work programme had been adopted by the Board in September 2011. The revision was needed to adapt the planning to the final number of establishment posts. By way of contrast to the Board's request to the Commission and the Budgetary Authority, 20 additionally needed establishment posts were not authorised for REACH and CLP related tasks and can only be partly compensated by non-statutory contractual staff (see above).

The Executive Director explained that the Secretariat together with the Management Board's working group on planning and reporting has elaborated a proposal that spreads minor reductions over several activities instead of cutting certain activities as such. Furthermore, a

number of activities will be postponed. The start of new activities for 2012, as authorisation applications and substance evaluation was not affected by this proposal. The Executive Director also reminded that ECHA has contacted the Commission and the Member State Competent Authorities (MSCA) to verify whether they would be interested to second senior experts to ECHA with full salary coverage by the Agency. Such secondees could enable ECHA to secure a higher completion of the 2012 work programme.

The Chair of the working group on planning and reporting, Mr Martin LYNCH, explained that the working group had met on 30 November to discuss the proposal for the reviewed work programme. The working group had proposed small modifications and approved the revised staff structure allocation. He recommended that the Board should consider the proposal with a favourable attitude.

The Board acknowledged that the amendments proposed focused on preserving the Agency's capability to deliver its core mandate in support of the aims of the REACH and CLP legislations. The approach of having several small reductions instead of activity cuts was welcomed. Many members regarded the revised work program as a well balanced proposal, leaving some flexibility for ECHA's management to react if needed.

In the exchange of views, several members expressed concerns in relation to a proposed postponement of a Guidance document for downstream users. Downstream users would face considerable challenges related to their legal obligations, and therefore require effective support from ECHA. Some Board members also emphasised that the proposed downscaling of ECHA's work related to restriction proposals on behalf of the Commission could be wrongly perceived by the general public. Board members also intervened with regard to the target for the assessment of confidentiality claims and the dissemination target of publishing information as such. Furthermore, a Board member asked for an overview of all the tasks that the Commission requested from ECHA under Article 77 of the REACH Regulation, for example on international activities. Attention was also paid to the reduced operational budget of the Board of Appeal.

Overall, a need to further increase the efficiency in all processes was highlighted by several Board members.

A Commission representative emphasised that it would be important to provide distinction between the core responsibilities of ECHA, which are tasks defined in the legislation, important activities, and those activities that are helpful and useful, but not essential. He clarified that the discussion was about 10 senior expert posts out of a total of approximately 500 agency employees. For the Commission, it was also emphasised that the staffing would not allow supporting ECHA with seconded officials from its own staff.

The Executive Director replied to the remarks and questions, reminding that ECHA is already continuously improving its efficiency in all processes. He confirmed that all confidentiality claims will be examined and that the proposal put forward with the revised work programme was merely to lower the pace compared to the original planning. He also reminded that for evaluation activities, no cuts were foreseen for 2012 and that more work was foreseen for Substances of Very High Concern (SVHCs). Therefore the work on restrictions would have to be scaled down as it factually depends on the availability of the same senior scientific experts. Concerning support for downstream users, he clarified that the planned Guidance document does not constitute ECHA's only support tool for this stakeholder group. As regards the reduced expenditure for the Board of Appeal he clarified that the budget foreseen for 2011 was largely underspent due to the low number of appeals and that the forecast was adapted accordingly. Should more funds than currently anticipated be required for the Board of Appeal, this could be accommodated by internal budget transfers.

Furthermore, the Executive Director highlighted that ECHA can meet its targets in 2012 on the basis of the revised work programme and that no performance indicators were changed.

However, future planning would be even more difficult in the light of the EU budgetary situation and the work on the revised staff model would therefore be even more important.

The Executive Director's interventions were supplemented by explanations from the Directors for Registration and Risk Management.

The Chair summarised the discussion and proposed two specific changes to the work programme that related to the targets for assessing confidentiality claims and the preparation of restriction proposals on behalf of the Commission¹.

The Board agreed to the Chair's proposal, and adopted the revised work programme for 2012 and its annexes. As part of this decision, the Board also endorsed an updated ECHA work plan on international activities for 2012, which describes in more detail the respective parts of the overall work programme of the Agency. The Executive Director was instructed to have these documents published and to forward the work programme for 2012 as amended to the Member States, the European Parliament, the Council and the Commission.

7. Future tasks and challenges of ECHA up to 2017 (MB/58/2011)

The discussion was initiated by an intervention of a Commission representative who provided an insight view into the current perspective for the budgetary and staff situation of EU institutions and decentralised agencies. He highlighted that national governments are advocating substantial further reductions to the Commission proposals for the next multiannual financial framework and the revision of the EU Staff Regulations. As the Management Board composition includes representatives from all Member States, these members would have a dedicated responsibility in defending the Agency's interests in their respective administrations. However, even in optimistic scenarios, in the future, ECHA would have to manage its tasks with lower resources and require flexible management in order to address unexpected shortfalls while at the same time maintaining the Agency's ability to fulfil its mandate. The Commission representative advised the other members that the Management Board should be conscious of these circumstances when defining tasks and challenges for the future and either strive to further increase efficiencies, if possible, or set priorities accordingly and distinguish essential core tasks from less important activities.

Afterwards, the Chair presented the agenda item and the corresponding background document which aimed to facilitate, as a thought starter, the discussion and definition of ECHA's future tasks and challenges up to 2017. This had been agreed in September 2011 in the context of the prolongation procedure for the Executive Director's mandate. The background document had been prepared by the Management Board working group on planning and reporting supported by the Secretariat. The challenges identified therein were also based on the dedicated work of the ECHA management team on the future strategic objectives of ECHA, done in the context of the preparation of the multi-annual work programme.

The Chair outlined the main strategic challenges ahead in achieving ECHA's vision to become the world's leading authority in the field of chemical safety. Central elements for this would be to maximise the quality and public availability of scientific data, to tackle the right chemicals and focus on the best regulatory action, to respond to increasing scientific

¹ P. 13, third bullet point, addition: **at least** 160 new claims.

p. 20, third paragraph, addition: Upon the Commission's request, ECHA will prepare or finalise the preparation of **at least** one Annex XV restriction dossier in 2012.

p. 22, fifth bullet point, addition: At the request of the Commission, *at least* one Annex XV restriction dossier prepared and submitted to the Committees for the formulation of the opinion and consequential adaption of the annex containing the base line figures for 2012.

challenges and operate as openly as possible, and to manage its resources efficiently while tasks continue to increase.

This was followed by an exchange of views.

Board members thanked for the work done and the background document. As regards the level of ambition and the visionary aspects outlined in the document, some members pointed out that regular operational challenges, like the management of the 2nd registration deadline, deserve more emphasis. ECHA should indeed be the leading regulatory authority for the safety of chemicals but this should be done by being instrumental in making the REACH Regulation deliver its expected benefits. It was also noted that innovation and competitiveness – which includes substitution aspects – should be more visible. Further elements highlighted included the cooperation with different stakeholders and the use of various networks. The Board also discussed whether it would still be too early to confirm that the REACH Regulation as such functions as intended. The registration deadlines 2013 and 2018 would still be ahead, and SMEs would have dedicated challenges. A further proposal related to seeking further synergies by looking for interlinks of REACH with other environmental legislations.

Following a request by the Chair, the Management Board then heard the Executive Director's view on the issues discussed. The Executive Director expressed support for the identified tasks and challenges and the additional issues brought up in the discussion, such as the need to maintain dedicated attention to SMEs, the importance of substitution for the innovation aims of REACH or the links between REACH and other EU legislation. He also informed that the draft multi-annual work programme for 2013-2015, which will be submitted to the Board still in December, will contain strategic objectives and explain how ECHA can achieve them.

A procedural discussion took place in relation to the link with the prolongation procedure for the Executive Director's mandate. The Chair clarified that the determination of the future tasks and challenges should be the last step for finalising the prolongation procedure. A Board member designated as reporting officer for the Executive Director mentioned in this regard that the definition of future tasks and challenges will be an essential source for preparing the objectives for the Executive Director's future annual appraisal exercises.

With regard to the procedural aspects at Commission level, a Commission representative emphasised that the authority responsible for the appointment and prolongation of the mandate is the Management Board. The Commission representatives in the Management Board would depend on an internal procedure for which an evaluation of the first mandate of the Executive Director would be required to be submitted by the Board.

In the light of the discussion, the Chair was of the view that sufficient clarity on the future tasks and challenges of ECHA had been provided and that no formal agreement on a document would be necessary, especially with view to the ongoing preparation of the multi-annual work programme. A Member State representative expressed, however, preference for a formally agreed view of the Management Board.

The Chair concluded that further written contributions to the background document should be submitted until mid January 2012. The working group on planning and reporting would review these comments in February 2012. On the basis of a revised document, the issue would be brought to the March 2012 Board meeting for conclusion.

8. Third country participation in ECHA's work (MB/59/2011)

The agenda item followed discussions at the September 2011 Management Board meeting.

The Director of Cooperation presented background information on the criteria for third country participation in ECHA's work, which had been established by the Management Board in 2008 (MB/83/2008 final). He then referred to the pending request of the Chemicals Agency of the Republic of Serbia that had applied to become an observer in HelpNet, the network of national helpdesks established under the REACH and CLP Regulations and recommended the Management Board to decide favourably on this request.

One Member State representative referred to a scheduled Council decision in spring 2012 in relation to the status of Serbia as an EU candidate country and proposed to wait for this decision before deciding on any involvement of Serbia in ECHA's work. A number of other Board members argued in favour of the participation in HelpNet activities, highlighting the mutual benefits of the cooperation and the fact that the HelpNet is an information exchange platform and not engaged in regulatory decision making nor dealing with confidential information.

The Management Board agreed by majority decision to invite the Serbian Chemicals Agency to participate in the work of the ECHA HelpNet. The Board also took note of the established criteria for third party participation in ECHA's work and decided that there is no imminent need to revise these. Any future decision for the participation of third countries pursuant to Article 106 of the REACH Regulation will, however, be taken on a case-by-case basis and may thus be based on different criteria.

9. Update of the multi-annual strategic audit plan (MB/60/2011)

The Executive Director presented an update of the multi-annual strategic audit plan as provided by the Commission's Internal Audit Service (IAS). The conclusion of the IAS was that the multi-annual planning for 2011-2013 as endorsed by the Management Board on 24 March 2011 is still to be considered valid. For 2012, a new audit assignment on stakeholders and external communication had been proposed.

The Board took note of the IAS strategic audit plan for 2011-2013 and the planned assignments for 2013 that was proposed in the audit plan for 2011-2013.

10. Appointment of Committee members (MB/61/2011)

The Management Board appointed Ms Jolanta STAŠKO as a member of the Committee for Risk Assessment (RAC) as well as Mr João ALEXANDRE and Mr Robert CSERGO as members of the Committee for Socio-economic Analysis (SEAC). The RAC membership of Dr Marian RUCKI was renewed to take effect from 26 June 2012.

11. ECHA's Assessment of the Need and Feasibility of Enhancing Multilingual Communication in the Agency's Operations (MB/62/2011 & addendum)

The Director of Cooperation presented an assessment of the need and feasibility of enhancing multilingual communication in the Agency's operations to the Board. One important aspect mentioned was the enhancement of small and medium sized enterprises' accessibility to communication with the Agency, including via REACH-IT, in different

languages. The needs and feasibility would be reviewed on the basis of language practice of 2013 registrants.

The Board members thanked for the report and agreed with its conclusions. The importance of translations especially for small and medium sized enterprises was highlighted by a Board member appointed by the Commission to represent interested parties.

The Board took note of the information.

12. Report from the Executive Director (MB/63/2011)

The Executive Director informed the Board about the Agency's activities since the last meeting. Board members thanked him for the comprehensive report and congratulated for the excellent achievements.

Various topics were raised in the following exchange of views. Several members were interested in the number and assessment of confidentiality claims and the dissemination progress in general. Further questions concerned the quality of registration dossiers and how it can be improved; personnel changes taking place in RAC and SEAC; the number of testing proposals; the progress with service contracts for substance evaluation and the state of play with the candidate list against the policy target for 2012. A Member State representative reminded that he had at an earlier occasion requested a breakdown of confidentiality claims filed by SMEs which would be important to have as soon as possible.

The Executive Director and ECHA's senior management replied to the interventions. They referred to ECHA's achievements so far with the dissemination of information on chemicals and the assessment of confidentiality claims. Information from over 24 000 registration dossiers had already been published and more than 1 000 confidentiality claims assessed, half of which were evaluated as unsatisfactory.

Regarding the Committees, the recruitment process of a new chair for SEAC was almost finalised. For RAC, the Executive Director explained that it has been agreed that the current Chair will take a new challenge on the more scientific tasks of ECHA and that it is planned to publish the post shortly.

The Executive Director referred to the number of substances on the candidate list noting that not all Member States were active yet in the preparatory work. He informed that the Commission intended to raise the issue at a competitiveness Council meeting. ECHA would support the Member States with different measures, such as risk management workshops. Regarding substance evaluation, a workshop was planned for the end of January.

The Board took note of the information.

13. Multi-annual planning for IT systems (MB/64/2011)

The Board received an update from the Director of Information systems on the Agency's multi-annual IT priorities, challenges, resources and future direction. The Director also presented the state of play in relation to REACH-IT access for Member States and the IUCLID Member Sate database development.

Several Board members expressed thanks for being provided with a comprehensive planning in a central field of ECHA's functioning. Questions were raised about the data centres, the fragmentation of the databases and the role of IT systems in the preparation for tasks under the upcoming Biocides and PIC Regulations. It was stressed that for IT applications, usability should remain a high priority.

The Director of Information systems clarified that ECHA's data centres would be located in the Helsinki area but with external back-up centres in another EU Member State. Usability would be an important criterion in the development of all IT portals. The Member States would be invited to participate in working groups for further development discussions on the dashboard and to test the systems. Other feedback would also be welcome.

The Board took note of the information.

14. Prolongation of the mandate of the Executive Director – next step

As part of the prolongation procedure for the mandate of the Executive Director, the Management Board formally concluded its evaluation of the first mandate. It instructed the Chair to inform the Commission in form of an agreed letter of the positive outcome of this evaluation in order to allow the Commission representatives in the Management Board to proceed with the internal procedure applied by the Commission in the context of the prolongation of mandates of Heads of Agencies.

The final decision on the prolongation of the Executive Director's mandate is scheduled to take place at the next meeting of the Management Board in March 2012, after the final discussion on the future tasks and challenges of ECHA (See above heading 7). The conclusions were taken unanimously.

15. ECHA's approach towards accredited stakeholder organisations (MB/65/2011)

The Director of Cooperation introduced the agenda item. ECHA's stakeholder policy dated from 2008, and eligibility criteria for Accredited Stakeholder Organisations had been developed since then in agreement with the Commission. Currently, 51 stakeholder organisations are accredited with ECHA. Systematic procedures had been created for registration and cooperation.

On request, the Executive Director and the Director of Cooperation explained the accreditation procedure and the criteria for participation in Committees' meetings in more detail. Stakeholder organisations have to fulfil the criteria set by the Management Board to be able to participate in ECHA's work and it regularly occurs that an application has to be refused for not meeting these criteria. As regards the participation in Committee meetings as observers, it was clarified that status as an Accredited Stakeholder Organisation qualifies them to be invited by the Committee but constitutes no right in itself to participate. It remains in the responsibility of each Committee to decide on the meeting composition.

The Board endorsed ECHA's updated approach towards involving accredited stakeholder organisations in the Agency's work.

16. External communications strategy (MB/66/2011)

Subsequently, a revised external communication strategy was presented by the Director of Cooperation. It will replace ECHA's present strategy, which was adopted in 2008. The new strategy focuses on target audiences and communication vehicles, defining communication objectives per ECHA service.

Board members welcomed the clear document. One member representing interested parties proposed to add one more target audience to the strategy: non-accredited stakeholders or third parties, which are often mentioned in REACH with public consultations. He also

suggested that third parties might need to be contacted in order to receive feedback for ECHA.

A representative of the Commission mentioned that in the present as well as all other documentation of ECHA, it would be appropriate to clarify that ECHA is an "Agency of the European Union". He also pointed out that the vision chapter of the document should put less emphasis on ECHA's "commitment to well-being" which would be difficult to understand in the context of ECHA's mandate.

A Member State representative highlighted the importance of competitiveness and innovation, which should be more visible in the strategy. When addressing the industry, also sustainability issues could be included.

The Director of Cooperation replied to the comments made. He agreed to the proposal to add "third parties" in general as a target group.

The Executive Director concurred that it should be clear from all documentation that ECHA is an Agency of the European Union. As regards the reference to being "committed to well being" he reminded that this wording is part of the vision statement of ECHA as adopted in September 2011 together with the work programme for 2012 and that it refers to improved wellbeing of citizens through the safe and sustainable use of chemicals.

The Board endorsed ECHA's updated External communications strategy, including the adjustments outlined above. The Chair concluded that the status of ECHA as an Agency of the European Union should be visible in external communications of the Agency.

17. Reports from subgroups of the Management Board (MB/67/2011)

The Board received activity reports from its subgroups: on audit matters, transfer of fees and dissemination.

Dissemination

The Chair of the advisory group on dissemination, Helmut DE VOS, informed of the outcome of the group's last meeting, which was held on 1 December in Helsinki. As part of this report, he submitted a proposal for a revised mandate of the advisory group.

Mr DE VOS confirmed that in 2011, 89.3% of registration dossiers had been disseminated and the target set had been reached. However, changes in legal interpretation and technical issues would still pose challenges. The planning for 2012 should substantially improve the situation. New legal interpretations would have to be implemented as speedily as possible and the outstanding issue in relation to the dissemination of the tonnage band would need an urgent resolution.

In a discussion, Board members reminded that user needs would need to be taken into account when further developing the dissemination portal. Some members requested whether the time table of dissemination would be ambitious enough or if it could be accelerated. Regarding the dissemination of the tonnage band, several members were of the view that a solution should be found without delay. It was mentioned that if there would be no advice from the Commission, ECHA should take a decision.

One Member State representative reminded that ECHA had already published over 20 000 dossiers and congratulated ECHA for the tremendous work that had already been done. Some time would still be needed to accomplish the task.

On request, it was clarified by members of the advisory group and the Executive Director that ECHA operates in compliance with the REACH Regulation in the field of public

dissemination of information on chemicals, even though the known constraints, like the need for legal interpretation, as well as the technical and legal complexity of the activity lead to delays in specific areas. Members of the advisory group also emphasised that the ECHA Secretariat was making strong efforts to bring the dissemination activity to full speed but that there were still issues which needed to be addressed.

The Executive Director emphasised that ECHA had already examined a high number of confidentiality claims and that information from Safety Data Sheets, such as company names, will be published in 2012. The Director of Registration gave a more detailed background of the dissemination progress. She highlighted that stakeholder participation would be one focus area in 2012, with a user needs survey being planned.

The Chair concluded that the question on advice concerning the tonnage band should be discussed in the next meeting of the advisory group. Ms Getraud LAUBER was invited to join the group which comprises all three Board members appointed by the Commission to represent interested parties.

Subject to one editorial change², the Board also agreed on a revised mandate of the advisory group on dissemination.

Transfer of fees

The Executive Director informed the Board of the outcome of the last meeting of the working group. The MB Decision 65/2010 shall be revised by March 2013, and several options for an update were presented.

Some Member State representatives stated that current differences between the payments to the different Member States would be too large, and that the current decision should be updated already before 2013, if possible. Some of the options presented could be quickly implemented, whereas others would require more data. Other Board members stated that regardless of the different options, the salaries as well as the price levels in the Member States would still remain very different. To ensure a balanced view on the matter, the working group on the transfer of fees should have members from both new and old Member States.

Several members asked for a revision of the decision already in 2012, at the September Board meeting, to then be adopted after the Commission's agreement in the December meeting.

A Commission representative reminded that the transfer of fees was no subsidy to the Member States, but a compensation, which should reflect the real costs of the work. The data gathered should be comparable and the system should not be too complex.

The Executive Director explained that ECHA would contact the Directors of Member State Competent Authorities to provide salary data to the Agency. Board members were asked to support ECHA with this request. In order to prepare for the 2013 service contracts for substance evaluation, the item should be discussed in September and December 2012. The working group will continue to discuss the update options with the new data available.

The Board invited the Bulgarian Board member, Mr Boiko MALINOV, to join the working group on transfer of fees. The Swedish member, Ms Nina CROMNIER, will be the new Chair of the group.

² Decision, text: (...) to monitor the progress made on **the** dissemination and other publication on the Agency's website of information on chemical substances – the full text of the revised mandate is repeated in section III of these minutes.

<u>Audit</u>

The Board received an update on audit matters from the Co-Chair of the group, Karel BLAHA. He reported on outsourcing of the data centre, audit plans for 2012 and on two audit reports.

18. Designation of a MB member for ECHA Ethical Committee (MB/68/2011)

The Executive Director informed the Board of the progress made with the implementation of ECHA's Policy on potential conflicts of interest, which was endorsed in September 2011. He explained the implementation of the new forms for declarations of interest, an ongoing internal awareness campaign and other implementation steps. The establishment of an Ethical Committee was a further part of the policy. The Committee would have a consultative function, be chaired by the Head of ECHA's Legal Affairs Unit and also comprise an external expert. Once established, the Committee would agree on a proposal for its Terms of Reference.

Several Board members suggested a different name for the Committee taking into account that it should deal exclusively with potential conflict of interest situations, not general ethical questions, e.g. Advisory Committee for the Management of Potential Conflict of Interests. The Committee was asked to assess its naming when discussing its Terms of Reference and submit a proposal to the Management Board.

The Board appointed Mr Antonello LAPALORCIA as its member for the Ethical Committee.

19. Review of implementing rule for Article 9 of the EU Staff Regulation – Setting up of a Staff Committee (MB/69/2011)

The Director of Resources presented proposed amendments to the implementing rule for Article 9 of the EU Staff Regulation – Setting up of a Staff Committee. He clarified that the proposal was presented in agreement with the Agency's Staff Committee of which a representative was present for the agenda item.

One Board member requested whether an annual report of staff committee activities was foreseen in the rules. The Director of Resources replied that the Staff Committee formally reports to ECHA staff at each staff assembly.

The Board adopted the amendment to the Implementing Rules for Article 9 of the EU Staff Regulation. The amendment will be submitted to the European Commission for the required agreement and subsequently formalised by the Chair under the usual procedure.

20. Review of the decision MB/77/2009(D) – payment of witnesses BoA (MB/70/2011)

The Chair presented the agenda item.

The Board reviewed its decision on the payment of witnesses in Board of Appeal proceedings. It was decided that no amendments are necessary. The Board of Appeal should report back to the working group on the Board of Appeal if it would later identify the need for future adaptations to be made.

Subsequently, the Chair referred to a draft letter to the Court of Auditors regarding a selection procedure for a function at the Board of Appeal. The draft had been agreed by the working group on the Board of Appeal after analysis of the procedure. It was agreed that the Chair should send the letter on behalf of the Management Board to the Court of Auditors.

21. Update on the Agency's Work Plan on substances on nanoscale (MB/71/2011)

The Director of Regulatory Affairs provided an update on the work plan on substances on nanoscale. A first planning in this area had been presented to the Management Board in 2009 (MB/84/2009 final). The updated plan included four pillars to support ECHA's activities related to substances on nanoscale:

- Internal and external capacity building;
- sharing experience with and generate consensus among MSCA, MSC and RAC members on safety information on nanomaterials in REACH registration dossiers;
- feedback and advice to registrants that wish to register nanomaterials at the 2013 registration deadline; and
- contribution to ongoing international regulatory activities.

The previous planning covering 2010-2011 was supported by 2.5 full time equivalents (fte); an increase of 2.5 fte was foreseen for 2012-2013 to support all planned activities on nanomaterials.

The Board held an exchange of views which emphasised the importance for ECHA to closely follow and actively contribute to developments in this area, by implementing the already existing REACH and CLP instruments. Further areas mentioned were one Member State's national database plans on nanomaterials, the wish for ECHA to involve the Member States in examining dossiers, a request about guidance, training possibilities and sharing experience on nanomaterials as well as the importance of international cooperation, especially within the OECD. It was also stated that the "no data, no market" principle should also be applied to nanomaterials, and that the legal uncertainty in this area has to be reduced.

The Director of Regulatory Affairs pointed out that ECHA's annual work programmes would be its framework for activities on nanomaterials. There would be further updates of guidance in 2012. It would be up to the Commission to publish the next communication on regulatory aspects of nanomaterials.

The Board took note of the information.

22. Update on biocides / outcome of legislative process (MB/72/2011)

The Director of Regulatory Affairs continued with the presentation of the outcome of the legislative procedure and ECHA's preparatory activities related to the EU Biocidal Products Regulation, which was expected to enter into force in mid-2012. Operational activities at ECHA would start from September 2013.

With regard to ECHA's preparatory work, the Board was informed that the scoping phase on planning of operational processes was nearly finished, and hand-over arrangements with the Joint Research Centre had started. A new Biocides unit was foreseen to be established in ECHA in February 2012.

The Board took note of the information.

23. Any other business

- Review of ECHA (Art. 75 REACH)

A Commission representative informed the Board on the review of ECHA under Article 75 of the REACH Regulation, for which an external study is about to be finalised. The Board would receive a copy of the final study report.

MSCA Directors Planning meeting

The Executive Director informed the Board of the first MSCA Directors planning meeting, which took place on 14 December. Directors from almost all Member States discussed a variety of items related to the planning of work on REACH and CLP and the resource needs in 2012-2015. First feedback from the participants was positive and most of them wanted to continue with this informal meeting annually. Participants suggested distributing the meeting documents earlier in order to facilitate their preparations for the meeting.

- C&L inventory - state of play

The Director of Risk Management explained the state of play on Classification & Labelling inventory to the Board. Due to technical difficulties related to data transfers, the launch of the inventory was delayed until the first quarter of 2012.

24. Next meeting and closure

The Chair reminded members that the next meeting of the Management Board would be held in Helsinki on **22-23 March 2012**.

III. Decisions taken / Conclusions reached by the Management Board

The Management Board

- adopted the agenda for its 24th meeting as contained in MB/A/04/2011 rev.01.
- approved the minutes of its 23rd meeting, subject to the amendments indicated in the corrigendum attached to the present minutes. (MB/M/03/2011).
- adopted a 2nd amendment to the Agency's budget for 2011 as contained in document MB/53/2011 and instructed the Executive Director to notify this decision to the Budgetary Authority, the Court of Auditors and the Commission, and to have it published on the Agency's website and in the Official Journal of the European Union.
- adopted the Agency's budget for 2012 as contained in document MB/55/2011, and instructed the Executive Director to notify this decision to the Budgetary Authority, the Court of Auditors and the Commission, and to publish it on ECHA's website.
- adopted a revised work programme for 2012, including the annexes as contained in document MB/56/2011, subject to the modifications indicated in these minutes, and instructed the Executive Director to forward the Work Programme as amended to the Member States, the European Parliament, the Council and the Commission, and to have it published on ECHA's website.
- endorsed an updated work plan on international activities for 2012 as contained in MB/57/2011.
- decided to invite the Serbian Chemicals Agency to participate in the work of the ECHA HelpNet.
- appointed Ms Jolanta STAŠKO as a member of the Committee for Risk Assessment.
- appointed Mr João ALEXANDRE and Mr Robert CSERGO as members of the Committee for Socio-economic Analysis.
- renewed the membership of Dr Marian RUCKI in the Committee for Risk Assessment to take effect from 26 June 2012.
- concluded the evaluation of the first mandate of the Executive Director and instructed the Chair to inform the Commission accordingly.
- endorsed an updated approach of ECHA towards involving accredited stakeholder organisations in the Agency's work as contained in document MB/65/2011.
- endorsed the revision of ECHA's External communications strategy as contained in document MB/56/2011, subject to the modifications indicated in these minutes.
- agreed on a revised mandate of the advisory group on dissemination as follows:
 - to monitor the progress made on dissemination and other publication on the Agency's website of information on chemical substances
 - to assist the ECHA management by giving advice when needed
 - to act as "ambassadors" to civil society, in particular by reporting back to their respective stakeholders (and raising awareness)
 - to report to the Management Board on its activities

- agreed that all three Board members, which are appointed by the Commission to represent interested parties, shall remain members of the advisory group on dissemination and, consequently, Ms LAUBER will take over the position of Mr MUSU.
- designated Mr Antonello LAPALORCIA as member for the ECHA Ethical Committee.
- adopted an amendment to the Implementing Rules for Article 9 of the EU Staff Regulation as contained in document MB/69/2011, subject to the agreement of the Commission. Upon the agreement of the Commission, the Chair is authorised to formalise the adoption of the implementing rule. For practical reasons, the Chair is authorised a strictly limited discretion to accept minor technical or linguistic changes proposed by the Commission, provided that these changes do not alter the content of the Board's decision. Any other changes require re-submission to the Board, possibly by written procedure.
- reviewed its decision on the payment of witnesses in Board of Appeal proceedings and concluded to that no changes are currently required.

List of agreed follow-up actions

- A breakdown of confidentiality claims filed by SMEs will be forwarded to Board members
- Comments on document MB/58/2011 should be submitted until mid January 2012 for review by the working group on planning and reporting
- ECHA will forward the confidential version of the report prepared by JRC under the administrative agreement on the assessment of nanomaterials in REACH registrations to MSCAs. (cf. Doc.: MB/71/2011, pg. 4, 2.4. Administrative Agreement on the assessment of nanomaterials in REACH registrations, 3rd paragraph).

IV. List of Attendees

Representatives of the Member States

Zoltan ADAMIS (HU) Karel BLAHA (CZ) Nina CROMNIER (SE) Arwyn DAVIES (UK) Helmut DE VOS (BE)

Kassandra DIMITRIOU (EL) also acting as proxy of Mr NICOLAIDES

Simona FAJFAR (SL)

Ana FRESNO (ES) also acting as proxy of Mr GRACIO (2nd day)

Claude GEIMER (LU) Mario GRACIO (PT) Ionut GEORGESCU (RO)

Thomas JAKL (AT) also acting as proxy of Mr SACCONI Jan Karel KWISTHOUT (NL) also acting as proxy of Mr THUESEN Antonello LAPALORCIA (IT) also acting as proxy of Mr FARRUGIA

Martin LYNCH (IE)
Boyko MALINOV (BG)
Edyta MIEGOC (PL)
Catherine MIR (FR)
Pirkko KIVELA (FI)
Alexander NIES (DE)
Edita NOVÁKOVÁ (SK)
Armands PLATE (LV)
Aive TELLING (EE)
Marija TERIOSINA (LT)

Representatives of the Commission

Gustaaf BORCHARDT Heinz ZOUREK Elke ANKLAM

Representatives from interested parties appointed by the Commission

Martin FÜHR (EEA/University of Darmstadt) Hubert MANDERY (CEFIC) Gertraud LAUBER (EMCEF/ETUC)

Observers from EEA/EFTA countries

Henrik ERIKSEN (NO)

Other Observers

Peter OSTERGAARD HAVE (DK)

Björn HANSEN (European Commission) Elena PASCUAL JIMÉNEZ (European Commission)

Tony MUSU (ETUC)

ECHA staff

Geert DANCET (Executive Director)

Jukka MALM (Director of Regulatory Affairs)

Leena YLÄ-MONONEN (Director of Evaluation)

Jack DE BRUIJN (Director of Risk Management)

Andreas HERDINA (Director of Cooperation)
Christel MUSSET (Director of Registration)

Luisa CONSOLINI (Director of Information Systems)

Jef MAES (Director of Resources)

Alain LEFEBVRE (Head of Unit, Executive Office) Frank BÜCHLER (Legal Officer, Executive Office)

Mervi MUSTAKALLIO (Planning and Monitoring Officer, Executive Office)
Tiiu BRÄUTIGAM (Member States Relations Officer, Executive Office)

Mira BANERJEE-RANTALA (Communications Officer) for agenda item 13 Claudio CARLON (Head of Unit, Evaluation) for agenda item 19

Catherine CORNU (Scientific Officer) for agenda item 15

Tuula HAKALA (Head of unit, Finance) for agenda items 4 and 5

Sari HAUKKA (Registrar, Board of Appeal) for agenda items 4, 5, 6, 18 and 20

Erik VAN DER PLASSCHE
Nathalie ALT-ANTSKOG
Mercedes ORTUNO
Eva SANDBERG

(Senior Scientific Officer) for agenda item 20
(ECHA Staff Committee) for agenda item 16 and 17
(Chair of Board of Appeal) for agenda item 18
(Senior Scientific Officer) for agenda item 7

Minna STRÖMBERG (Internal Audit Capability) for agenda item 8 and 15

Corrigendum to the minutes of the 23rd Management Board

III. Decisions taken / Conclusions reached by the Management Board

[...]

Pending agreed follow-up actions

- The Secretariat will assess different stakeholders' satisfaction separately in the future annual General Reports of the Agency.
- The Secretariat will provide to the Board a short analysis on the number of phase-in and non phase-in self-classified CMR 1 & 2 registered by the first registration deadline.
- The Secretariat will ensure a structured follow-up of evaluation issues for a subsequent Board meeting, focusing also on sanction and enforcement issues.