MB/M/01/2011 final

MINUTES OF THE 21ST MEETING OF THE MANAGEMENT BOARD
24-25 March 2011

I. Documents submitted to the Management Board

Draft agenda	*(MB/A/01/2011rev02)*
Draft minutes of the 20th Management Board meeting	*(MB/M/04/2010)*
Draft Budget proposal and Work Programme outline 2012	
- Resources for preparing biocides related tasks in 2011/12	*(MB/01/2011)*
- Preliminary draft budget 2012 and establishment plan (accompanied by a preliminary Work Programme 2012)	*(MB/02/2011)*
General Report 2010	*(MB/03/2011rev01)*
Annual Activity Report of the Authorising Officer 2010	
- (Draft) Annual Activity Report 2010	*(MB/04/2011)*
- Analysis and Assessment of the Management Board	(MB*/05/2011rev01)*
Multi-annual dossier and substance evaluation planning	*(MB/06/2011)*
Multi-annual Work Programme 2012-14	*(MB/07/2011rev01)*
Multi-annual Staff Policy Plan (MASSP) 2012-2014	*(MB/08/2011rev01)*
Update of the IAS multi-annual strategic audit plan for 2011-2013	*(MB/09/2011)*
Appointment of reporting officers for the Executive Director and the members of the Board of Appeal	*(MB/10/2011)*
Appointment of Committees' members	*(MB/11/2011)*
Functioning of the Committees	*(MB/12/2011)*
Report of the Executive Director	*(MB/13/2011)*
Guidance update	
- Guidance for requirements of substances in articles	*(MB/14/2011rev01)*
- Review of the consultation procedure for Guidance update (MB/30/2007 final)	*(MB/15/2011rev01)*
Dissemination in accordance with Article 119 of the REACH Regulation	*(MB/16/2011)*
Amendment to Management Board Decision MB/17/2008 – Remedies for reviewing rejections of confidentiality claims	*(MB/17/2011)*
Update of the Management Board Rolling Plan	*(MB/18/2011)*
Transfers within the budget 2011	*(MB/19/2011)*

II. Summary Record of the Proceedings

Introductory remarks

The Chair opened the meeting and welcomed the participants.

He then made reference to the necessity of moving the meeting to Helsinki at short notice because of the unpredictable situation in the Mediterranean region, and noted that it was welcomed as a wise measure by the Board members. The moving of the venue was taken as a precautionary measure in order to ensure the Board's capability to take all necessary statutory decisions in time. The Chair expressed his sincere regret to the Maltese representative and pointed out that a future Board meeting could still be held in Malta.

He announced that Norway had appointed Mr Henrik Hallgrim ERIKSEN as an observer in place of Ms Anne Beate TANGEN.

The Chair introduced the other 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/01/2011 rev02*)**

The Chair proposed a change to the order of two items on the agenda: 'Issues on Guidance' was to be dealt with before the 'Report of the Executive Director'.

He mentioned that the following additional items were foreseen under "Any Other Business":
- Expiry of Management Board member mandates
- Report from the meeting of the Governing Board Chairs on 10 March
- Discharge procedure 2009 for the Executive Director
- Commission agreement on the revised ECHA stakeholder selection criteria.

The Chair indicated that several room documents had been made available for the meeting.

On this basis, the agenda was adopted.

2. Declaration of specific interests

None of the Board Members present declared a conflict of interest with regard to the agenda items.

3. Minutes
(MB/M/04/2010)

The minutes of the meeting on 16-17 December 2010 were approved with some modifications (see corrigendum in the annex).

4. Preliminary Draft Budget and Work Programme 2012 *(MB/01-02/2011)*

Resources for biocides related tasks in 2011-2012

The Director for Regulatory Affairs presented the planning regarding the future Biocidal Products Regulation which was foreseen to be adopted in early 2012 and enter into operation in January 2013. The estimated resource needs are 34 staff for 2012 and 80 in 2013, increasing to 132 for 2021. To launch the preparations, 5 full-time equivalents would need to start on 1 April 2011. To enable this, the Commission is preparing specific funding in the form of a Service Level Agreement with a budget of €500 000, which will allow ECHA to allocate 5 staff for preparatory work and to engage a business analysis to modify ECHA's IT systems for biocides related tasks. This is regarded as the minimum amount necessary to prepare ECHA in time for the new tasks. The revenue and expenditure for biocides, PIC (Prior Informed Consent) and REACH/CLP will be dealt with separately in the budget. Therefore, ECHA needs to prepare a cost accounting system which should be in place in 2012.

The Management Board held an extensive and fruitful exchange of views on the future tasks of ECHA under the revised EU biocides legislation. The need for sufficient resources for ECHA to comply with the tasks under a tight schedule was stressed by several Board members. Some Member State representatives highlighted the importance of cooperation with the Competent Authorities in preparing the implementation, profiting from their experience. Several Board members wished to gain more knowledge on biocides, and it was proposed that a training session on the occasion of the next Board meeting could be organised.

A Commission representative clarified that the Commission will put forward the 2012 budget with staff and budget requirements for biocides based on the original Commission proposal. It will later amend the budget proposal once the revised financial statement as part of the Commission communication on the Council common position is approved. He encouraged Board members to contact their national authorities about ECHA's future budgetary needs for biocides.

The Executive Director clarified that ECHA had already recruited several experts on biocides who were currently working on REACH/CLP and who could put their biocides expertise into practice. They would be efficiently replaced by trained interim staff who had up to now been employed in the registration unit as part of the contingency measures put in place to deal with the 2010 REACH registration deadline. He emphasized the cooperation with both the Competent Authorities and the Joint Research Centre. However, the recruitment of further experts had to start quickly.

The Management Board endorsed the approach for compensating the resources used for biocides preparation through the specific Commission funding to avoid a negative impact upon REACH/CLP activities. The Board recommended that ECHA associate the biocides Competent Authorities in the implementation of the preparatory projects.

The Board agreed that, if needed, the Executive Director would present a corresponding amending budget 2011 to the Management Board as soon as possible. It took note of the need to accelerate and extend an envisaged cost accounting system which is required to separate the budget of REACH from those of Biocides and PIC.

Preliminary draft budget 2012

The Executive Director presented the proposal for the Agency's budget for the financial year 2012, together with the establishment plan and outline of the work programme. He highlighted some of the main challenges ahead such as the preparation of Agency tasks under the Biocides and PIC legislations, of the next REACH registration deadline in 2013, evaluation tasks and the handling of authorisation applications.

The total budget proposal for REACH/CLP 2012 amounts to €102 666 000. It will increase by €2.8 million but will be entirely financed by new fees and the cash reserve of fee revenue from the year 2010. The budget for staff for REACH and CLP activities is proposed to increase from €54.5 million in 2011 to €57.8 million in 2012 (i.e. by 6.1%). The additional 20 TA posts requested will mainly contribute to growing activities in the areas of evaluation and authorisation, and scientific advice in areas such as nanomaterials and endocrine disruptors.

For Biocides-related tasks, €1.9 million is budgeted to be entirely financed by subsidies, the main expenditure items being the development of IT tools for €1 million, and Communications and Translations for €400 000. Thirty TA posts are requested to build up capacity on all areas to be ready for the entry into operation of the Regulation by 1 January 2013. For PIC-related tasks, the budget foreseen is €1.4 million to be entirely financed by subsidies, the main item of which is development of IT tools consuming €1.3 million. Four TA posts are requested to undertake preparatory activities.

The floor was given to Martin LYNCH, Chair of the working group on Planning and Reporting. He informed the Board about the work of the group, which had met in Helsinki on 8 February and 2 March to discuss the proposal. He emphasised the increase in staffing for 2012, for both REACH/CLP and Biocides/PIC.

The Commission representatives reminded the Board that the financial situation for 2012 is very difficult for all EU Institutions and agencies. In the following discussion, Board members exchanged views about priorities in the Agency's activities and the division of work between scientific and administrative tasks. The Executive Director emphasised the high proportion of the Agency's staff already working with scientific tasks. He highlighted some savings foreseen for 2012, e.g. the use of webinars instead of meetings. The Board agreed on some amendments[1] to the outline of the work programme 2012.

The Management Board approved the draft estimate of revenue and expenditure for 2012, together with the establishment plan. It instructed the Executive Director to forward the estimate with the establishment plan to the Commission by 31 March 2011.

The Board agreed that the Executive Director should, in agreement with the Chair, take the necessary steps towards the Budgetary Authority in case the draft budget presented by the Commission were to show a significantly lower resource level than that proposed by the Board.

[1] P.8, ECHA's challenges and priorities, first sentence: deletion of "~~main~~" challenges;
p. 10, second bullet point, addition about ECHA's contribution to the reviews that the Commission is carrying out;
p. 26, sixth bullet point, addition about ECHA's contribution to the first review of the Agency

5. General Report 2010
(MB/03/2011rev01)

The Executive Director presented the draft General Report of the Agency, stating the main achievements of 2010, e.g. handling of the first REACH registration deadline; building up capacity for dossier evaluation; updates of the SVHC Candidate list; recommendations for the Authorisation list; as well as the successful recruitment of staff. This was the first systematic follow-up of the performance indicators defined in the Work Programme 2010.

The floor was given to Martin LYNCH, Chair of the working group on Planning and Reporting, who informed the Board about the modifications to the draft report suggested by the group.

The Board welcomed the quality and content of the report. In a short exchange of views, Board members discussed the indicators measuring the Agency's performance, especially regarding transparency towards different stakeholders. A Board member representing interested parties appointed by the Commission proposed that ECHA could assess different stakeholders' satisfaction separately in the future.

The Management Board adopted the General Report 2010 with some minor amendments[2]. It instructed the Executive Director to submit the document to the Member States, the European Parliament, the Council, the Commission, the European Economic and Social Committee and the Court of Auditors, and to have it published.

6. Authorising Officer's Annual Activity Report 2010
(MB/04/2011), (MB/05/2011rev01)

The Executive Director presented the Annual Activity Report 2010, consisting of the main priorities and achievements, accounts, staffing, control systems and risk management.

Following this, the Chair of the working group on Planning and Reporting, Martin LYNCH presented the draft analysis and assessment of the Authorising Officer's annual activity report. He pointed out that the assessment was very positive, as the Agency had managed the difficult challenges of 2010 extremely well. However, he was concerned about the high stress levels among the staff. The working group congratulated ECHA e.g. for the successful handling of the first registration deadline; developing IT and communication tools; providing support to registrants; and for building up dissemination and evaluation tasks. The group noted the high quality of the Agency's scientific advice and opinions as well as the efforts made in recruitment.

The Director for Resources explained the recovery of the valued added tax (VAT) for the renovation works of the ECHA conference centre in 2009. As the renovation was carried out by the landlord of the building, the VAT exception did not apply automatically. During 2010 it proved impossible to recover the remaining part of the above VAT and consequently it was charged to the 2010 budget.

Mr LYNCH proposed one amendment[3] to the draft analysis and assessment prepared by the Board's working group on Planning and Reporting.

[2] p. 6, second paragraph, addition of two sentences on dissemination; p. 29, first sentence, addition about information from stakeholders

[3] Under point 8, a removal of a reference to the recruitment target of staff members for 2010.

The Board took note of the Annual Activity Report for 2010, and adopted, subject to the signature of the Executive Director's declaration of assurance for 2010, the analysis and assessment thereof. The Executive Director was instructed to send the Annual Assessment Report and the Analysis and Assessment thereof before 15 June 2011 to the Budgetary Authority and the Court of Auditors, and to include it into the General Report for 2010.

7. Multi-annual dossier and substance evaluation planning *(MB/06/2011)*

The Director for Evaluation presented the Agency's planning on dossier and substance evaluation for 2011-2014. The Agency is facing several challenges such as the high number and complexity of the dossiers, the long training time for staff, the complexity of the process and possible legal challenges. The multi-annual plan entails a high work load for both the Agency and the Competent Authorities. Therefore, a change of approach is necessary to gain efficiency and to achieve a higher number of dossiers throughout the process. ECHA will constantly monitor progress and take appropriate measures to ensure that the multi-annual targets are met. A workshop on substance evaluation will be held in May, back-to-back with the Member States Committee meeting.

The Board discussed the heavy workload ahead. For ECHA, the number of compliance checks was, in particular, seen as a tremendous work. A Commission representative was interested in getting more detailed information on compliance check plans.

The Member State representatives commented on the plans for substance evaluation. It was stated that ECHA had very ambitious targets on substance evaluation numbers. However, this might not follow at the cost of quality. It was important to have the right selection criteria for the substances evaluated to be able to prioritise effectively. There were concerns about the share of dossiers possibly to be dealt with by the Member States Committee.

One Board member stated that the Member States were now nominating their candidates for the CoRAP[4] . However, it would be difficult to extract data from REACH IT. The Member States would need further selection tools to be able to prioritise substances and asked ECHA for help on this.

Several members requested clarification about the consequences necessary if ECHA did not get enough information from a registrant and whether a withdrawal of the registration number could be possible in the case that the quality of a dossier was not satisfactory. They highlighted the roles of the national enforcement authorities. These issues should also be discussed in the Forum. One member representing interested parties appointed by the Commission highlighted the role of ECHA in this situation: Taking into account the "respice finem" perspective, ECHA should consider legal consequences based on the general administrative procedure rule, which allows for revocation of decision of a public authority in cases where the conditions under which the decision has been taken were not met in the moment of the decision ("revocation of the administrative act"), thus allowing to withdraw a registration number.

[4] Community rolling action plan

One member representing interested parties appointed by the Commission emphasised the need for transparency in communicating with the stakeholders. The stakeholders should be more involved in the evaluation process and participate in the workshop on substance evaluation, if feasible. One Member State representative pointed out that a closed session workshop amongst authorities might still be needed at this stage.

The Director for Evaluation replied that where registrants were not responding to ECHA's requests, national enforcement authorities would have to enforce the cases on the national level. The Management Board would have the next report on substance evaluation at a subsequent meeting. The issue would also be discussed at the CARACAL meeting in June.

The Executive Director took the floor, stating that ECHA needs information on substance evaluation from all Member States for its planning – the latter all need to foresee sufficient resources for their legal obligations. The figures on evaluation plans will be reviewed every year. He confirmed that REACH-IT will be further improved to work in the best possible way for searches. ECHA will also examine whether it can open the May workshop for stakeholders or consult stakeholders otherwise. He continued by stating that stakeholder involvement adds to ECHA's transparency. However, the balance between different interests should be taken into account.

The Executive Director also emphasised that the quality observation letters were important, allowing companies to improve their dossiers. With the compliance checks, the Agency needs to maintain the possibility for random checks. Internal policy lines are currently being prepared for evaluation to ensure the effectiveness of the decision-making. The Executive Director stated that the possibility to withdraw a registration based on general administrative procedure rules needs further reflections, in order to take a more ambitious approach.

The Chair thanked the Board members for the productive discussion. He concluded that a structured follow-up of evaluation issues was needed at a subsequent Board meeting, focusing also on sanction and enforcement issues.

The Management Board took note of the information provided.

8. Multi-annual Work Programme 2012-14
(MB/07/2011rev01)

The Executive Director presented the Multi-annual Work Programme 2012-14 to the Board. He reported on the revised mission, vision and values as part of ECHA's corporate identity project. He listed some of the main challenges for 2012-2014, such as the next REACH registration deadline; dissemination goals; plans on dossier evaluation; updates of the candidate and authorisation lists; the process for authorisation applications; and managing the classification and labelling proposals. The importance of ECHA's scientific knowledge and expertise, as well as enhanced communication with stakeholders, was also highlighted.

To improve the accuracy of the baseline estimates, good communication and coordination with the Commission and the Member States is essential. Therefore, the Executive Director proposed to organise annual planning meetings with the Directors of the Competent Authorities. The first meeting would be in December 2011, back-to-back with the Management Board meeting.

The floor was given to Martin LYNCH, Chair of the working group on planning and reporting, to present the group's findings. The group had met on 8 February to analyse the comments received from Board members during an initial consultation round on a first draft of the programme. ECHA then agreed to significantly revise the document for the second meeting on 2 March, during which the working group welcomed the new draft and provided advice for its finalisation. The comments of the members and the replies from the ECHA Secretariat were made available to the Board as a room document. Mr LYNCH thanked all Board members who had submitted contributions during the internal consultation, and concluded that the programme could be endorsed for public consultation.

The Board welcomed the ambitious programme with its five key challenges and many other priorities and appreciated the work done by the working group in improving its quality. In a following exchange of views, Board members discussed the mission, vision and values and proposed slight changes to them. Some other minor changes were also suggested by different members.

The Commission representative stated that the Commission could endorse the document in principal but that it reserved the position on the Forum activities due to the Forum's new forthcoming (multi-annual) work program expected to be adopted by June 2011.

A member state representative raised the question of the specific needs of small and medium-sized enterprises (SME) as to the 2013 REACH registration deadline. One member representing interested parties appointed by the Commission was concerned about public access to ECHA's databases and proposed that a Chief Inclusive Governance Officer post could be created. Another member representing interested parties supported this idea and highlighted the increasing need for emphasis to be placed on synthetic nanomaterials.

The Executive Director thanked the Board members for the diverse modification proposals to the multi-annual work programme and the vision, mission and values[5]. He stated that most SMEs were expected to register only for the 2018 REACH registration deadline. However, the Agency would already start to enhance its communication activities to smaller companies. He will consider the idea of having a Chief Inclusive Governance Officer at the Agency although the specific concern could also be addressed by all directors.

Subject to agreed text amendments[6], the Board endorsed the submission of the draft Multi-annual Work Programme 2012-14 for public consultation, including the multi-annual staffing plan and revised mission, vision and values statements.

---

[5] Changes:
Mission: ECHA is the driving force among regulatory authorities in implementing the EU's groundbreaking chemicals legislation for the benefit of human health and the environment as well as ***for*** innovation and competitiveness. (…)
Values:
Trustworthy
Our decisions are science based ***and*** consistent ~~(and impartial).~~ Accountability and the security of confidential information are cornerstones of all our actions.
Committed to well-being
We stimulate the safe and sustainable use of chemicals to improve the quality of ***human*** ~~(of all citizens)~~ life in Europe ***and to protect and improve the quality of*** the environment.

[6] P. 6, third paragraph, editorial modifications; p. 6, last paragraph, addition of a reference to ECHA's appropriate financial and staffing means and deletion of a reference to the Budgetary Authority and the Commission; p. 10, first and second paragraph added on the background to Mission, vision and values; p.11, first and third sentence: modifications in values; p. 29, fifth bullet point, addition of MSCAs; p. 30, last paragraph, modification on products;

The draft document would be put on ECHA's webpage with the possibility for the general public to provide comments. Final adoption by the Board was foreseen for June 2011.

The Board approved the proposal to organise a first planning meeting with the Directors of the Member States Competent Authorities before the end of 2011.

9. Multi-annual Staff Policy Plan (MASPP) 2012-2014 *(MB/08/2011rev01)*

The Director for Resources presented the multi-annual staff policy plan 2012-2014, which represents a rolling multi-annual planning for the recruitment of staff and is based upon a common template used by all EU agencies. The draft was approved by the Board in December 2010. As stipulated in the Financial Regulation, the Commission services had been consulted on the draft, prior to its submission to the Management Board. The Commission had only provided its comments on March 22. A revised version of the plan, taking account these comments, was thus presented at the meeting as a room document. The Director for Resources explained the Commission's comments and the associated changes to the draft.

A representative of the Commission clarified that its opinion will also be transmitted to the budgetary authority and reminded the meeting that the budgetary negotiations will be difficult in the current financial situation, especially when discussing new posts for the Agency. On request from other members, he also clarified that some of the comments were consistent with similar opinions on the MASPP of other agencies. The Executive Director informed the Board that some of these comments were being discussed in the context of the inter-institutional working group on agencies.

The Management Board adopted the multi-annual staff policy plan 2012-2014 with two modifications[7]. The Executive Director was instructed to forward the estimate with the establishment plan to the Commission by 31 March 2011.

10. Update of the IAS multi-annual strategic audit plan for 2011-2013 *(MB/09/2011)*

The Executive Director presented the plan of the Internal Audit Service, which had conducted a risk assessment at ECHA in December 2010. The multi-annual audit plan 2011-2013 was revised based on that assessment. In 2011, an IT Risk assessment and an IT audit would be taking place.

The Board endorsed the updated IAS multi-annual strategic audit plan for 2011-2013.

---

p. 35, second and third paragraph, addition about PICs; Annex 3, p. 2, first row: addition of number of RAC and SEAC meetings..

[7] P. 2: the mission, vision and values added; p. 3, last paragraph: addition about the start of biocides related tasks.

11. Appointment of reporting officers ED/BoA
(MB/10/2011)

Based on a proposal by the Chair, the Management Board appointed Ms Simona FAJFAR to the working group on Reporting officers for the Executive Director. Mr Jan Karel KWISTHOUT was appointed to be a future member of the working group on Reporting Officers for the members of the Board of Appeal as a replacement for Ms KITAJEWSKA, whose mandate as Board member was to end on 30 May 2011.

12. Appointment of Committees' members
(MB/11/2011)

After a Board member representing interested parties appointed by the Commission questioned the qualifications of one of the candidates for the Socio-Economic Analysis Committee, the Board held an exchange of views on its role in assessing the suitability of the Committees' members. It was stressed that a broad representation of different disciplines was important for the functioning of the Committees.

Based on the nominations received, the Board appointed the following members to the Risk Assessment Committee: Dr. Urs SCHLUETER (EE), Dr. Christina TSITSIMPIKOU (EL), Dr. Nikolaos SPETSERIS (EL) and Mr Radu BRANISTEANU (RO).

The following members were appointed to the Committee for Socio-Economic Analysis: Ms Elina Velinova STOYANOVA-LAZAROVA (BG), Ms Angela LADOPOULOU (EL) and Mr Zbigniew ŚLĘZAK (PL).

The mandate of the following RAC members would be renewed after their current three year term expires on 20.6.2011: Ms Zhivka HALKOVA (BG), Mr Boguslaw BARANSKI (PL), Ms Alicja ANDERSSON (SE).

The mandate of the following SEAC member would be renewed after his current regular three year term expires on 13.2.2011: Mr Dimosthenis VOIVONTAS (EL).

13. Functioning of the Committees
(MB/12/2011)

The Director of Regulatory Affairs gave an overview of the increasing work load in the Committees as a follow-up to the discussions of the September and December 2010 Board meetings. The Member State Committee would be dealing with a high number of draft decisions, draft recommendations and SVHC dossiers; while the RAC and SEAC would face an increase in authorisation applications and restriction proposals. For the RAC, the number of opinions was expected to grow from 90 in 2012 to 480 in 2015. He proposed several measures to tackle this work load, in order to increase efficiency and strengthen support for the Committees, and to aim at a more equal sharing of work. The structure and procedures of the Committees and the capacity of the ECHA Secretariat needed to be reviewed and good cooperation with the Competent Authorities was crucial.

The Board members thanked him for the good analysis and held an exchange of views on the measures proposed. They discussed whether the involvement of additional Committee members

should be encouraged. Smaller Member States in particular pointed out the lack of resources when nominating any members to the Committees. However, some members supported the continuation of the current practice of using co-rapporteurs, as this allowed more flexibility and expertise in the process. One Board member stated that more radical structural changes were needed to improve the situation. Both initial support and caution were expressed towards the idea of splitting the RAC into two separate Committees. The cooperation between the RAC and SEAC was also highlighted. There was a consensus on the need for a strict quality-check for dossiers which were brought to the Committees. One member pointed out that while on the one hand the work load was increasing, on the other the experience of the Committee members and rapporteurs was increasing as well. A Commission representative viewed the improvement of existing working methods as preferable to creating new procedures or structures.

The Executive Director thanked the Board members for the feedback. The relevant, new elements of the discussion, such as the maturity of the dossiers reaching the Committees, would be added to a first package of improvement measures. This package would be brought to the immediate attention of the Committees. With regard to the more structural proposals, further reflection was needed and the effect of the first package would need to be assessed beforehand. The Board should return to the issue at a later meeting.

The Management Board took note of the information provided.

14. Guidance update[8]

(MB/14/2011rev01) (MB/15/2011rev01)

Review of the consultation procedure for Guidance update

The Director of Regulatory Affairs presented the state of play as to the revision of the Guidance Consultation Procedure, which was initially endorsed in February 2008. Guidance should provide a common understanding on how to comply with obligations under REACH. The purpose of the revision is to strengthen ECHA's autonomy to publish its own guidance and delete the possibility to include footnotes referring to dissenting positions. The involvement of the Committees, Forum and Partner Expert Groups would follow in a more flexible way. This would lead to a faster adoption of guidance and more certainty on timelines for stakeholders, especially industry.

A revised version of the Guidance Consultation Procedure in track changes was presented to the Board as a room document.

An extensive exchange of views took place on the handling of guidance which does not find consensus at the meeting of Competent Authorities for REACH and CLP (CARACAL). The Board members highlighted the need for clear guidance with regard to industry, but had different views on how to implement this in practice.

Several Board members representing Member States highlighted that dissenting views have to be mentioned in the guidance to avoid uncertainty about national enforcement practice. There would be no reason to hide the dissent among the Member States and it would be transparent to make the different views visible in the guidance. Ultimately, the responsibility to solve the matter would lie with the courts.

[8] Originally agenda item 15

Other Board members pointed out that the guidance should rather harmonise the enforcement in Europe and reflect a common understanding. They supported ECHA's autonomy and stronger role in this matter. In addition, the timely delivery of the guidance should be taken into account.

The Commission representatives reminded the Board of the role of the Commission as Guardian of the Treaties in case of different interpretations of European law. They emphasised that the legal opinion of the Commission should be respected and that no mention of any dissenting views should be published in the guidance. At the end, a court decision might be needed to regulate the matter.

Finally, a compromise was reached which foresees that in circumstances where a piece of guidance does not find consensus at CARACAL, a separate note from the Executive Director will make readers specifically aware of this lack of consensus and provide a cross-reference to the respective CARACAL minutes. This note to the reader will be printed/downloaded automatically whenever the guidance document is printed/downloaded.

Several Board members agreed with the compromise proposed. However, one Board member explicitly disapproved of the conclusion while another member announced the possible submission of a declaration. The Commission representatives also issued a declaration in relation to this compromise.

The Board agreed on a number of clarifications and improvements to the proposal of the Secretariat. The revised procedure will streamline and accelerate the process for developing and updating technical guidance for industry and authorities whilst duly involving ECHA partners in the process.

The Board endorsed the revised Guidance Consultation Procedure.

Guidance for requirements for substances in Articles

The Board noted that the Guidance for requirements for substances in articles under REACH – which was discussed in October 2010 and February 2011 at the CARACAL meeting and where no consensus was achieved on its content – will be published by 1 April in accordance with the agreed procedure as outlined above.

It was understood that the Commission services will display dissenting Member States' views in the CARACAL October 2010 minutes. The Board also welcomed the proposal of ECHA to improve the guidance in two aspects which take account of the conclusions of the technical meeting organised by ECHA in February on the topic.

15. Report of the Executive Director *(MB/13/2011)*

The Management Board heard the regular report from the Executive Director on the activities of ECHA since the last Board meeting. Board members thanked the Executive Director for the report and the various achievements.

The subsequent discussion focussed on Member States' access to REACH-IT and registration dossiers, information from the Director's Contact Group and its dissemination to the Member States, security issues, nanomaterials, and the issue of the translation of documents. One Board

member was interested in seeing the preliminary results of the latest Eurobarometer study on CLP. Another member was interested in knowing the number of self-classified CMR 1 & 2 registered by the first registration deadline. The Executive Director confirmed that these would be uploaded to CIRCA shortly.

The Management Board took note of the information provided.

16. Dissemination in accordance with Article 119 of REACH
(MB/16/2011)

Mr Helmut DE VOS, Chair of the advisory group on dissemination, reported on the conclusions of the advisory group following the legal opinion of the European Commission on the registrant's name. According to the opinion, the name of the registrant, captured under Article 119(2)(d) of the REACH Regulation via the safety data sheet, should be part of the disseminated information. The group had met in Helsinki on 17 February to discuss the issue. The working group members were informed that technical changes would be needed in IUCLID, REACH-IT and the dissemination portal. The technical work should be finalised by the end of 2011 and the dissemination should start in early 2012 after giving companies a chance to update their dossiers with possible new confidentiality claims.

The Director for Registration introduced the state of play regarding dissemination issues. Currently, information for 1 400 substances had been disseminated. The aim was to publish all dossiers submitted individually or by lead registrants, by the Stakeholders' day in May. Moreover, the workflow system supporting the assessment of confidentiality claims would be put in production in April which should enable ECHA to process a large number of these claims in 2011. She presented the necessary changes to IT systems to accommodate the legal opinion and advice from the advisory group regarding the disseminated data from registration dossiers.

In the following discussion, further clarification on the conclusions reached by the advisory group was requested by one Board member in particular. The Secretariat was also reminded that the timely preparation of working group documents was crucial.

The Chairman concluded that the advisory group should reconvene and discuss the way forward. The group was asked to continue to refine its advice on the consequential questions resulting from the new opinion. The Management Board would return to the issue at a later meeting.

The Management Board took note of the information provided.

17. Amendment to Decision MB/17/2008 on reviewing rejections of confidentiality claims
(MB/17/2011)

The Director of Regulatory Affairs presented the existing decision, which establishes remedies when ECHA has rejected a confidentiality request made in a registration dossier. The purpose of the update was to implement the reference in Article 24 of the CLP Regulation (requests for use of an alternative chemical name) to the remedies of Article 118(3) REACH.

One Board member representing interested parties appointed by the Commission proposed a different legal basis to the item, which provoked a discussion on legal issues.

The Management Board decided to postpone and, if needed, continue via written procedure to amend the Management Board decision MB/17/2008.

18. Update of the Management Board Rolling Plan
(MB/18/2011)

The Management Board took note of an update of the rolling plan, specifying the main agenda items for future meetings. A proposal for 2012 meetings was also distributed: these would take place on 22-23 March, 19-20 June, 27-28 September and 13-14 December.

19. Transfer within the budget 2011
(MB/19/2011)

The Management Board took note of the latest budget transfers under the responsibility of the Executive Director.

20. Any other business

- *Renewal of mandates of Member State Representatives*

The Chair informed the Board that there were two Member States which still needed to renew the mandates of their Board members. These Member States were invited to submit the relevant files to the Council Secretariat as soon as possible.

- *Report from the meeting of Chairs of Governing Boards of EU Agencies*

The Chair reported from the meeting that he had attended in Amsterdam on 10 March.

- *REACH-IT functionalities for Member States*

The Director for Information Systems presented the current developments of the REACH-IT functionalities for the Member States. A short discussion took place on whether a working group should be established to further elaborate the functionalities.

- *Report in accordance with Article 117(2) of the REACH Regulation*

The Director of Regulatory Affairs reported the current state of play.

- *Discharge 2009*

The Executive Director informed the Board that the European Parliament Committee on Budgetary Control had adopted a favourable discharge report for him for 2009. The report was expected to be confirmed by the Parliament on 7 April and would be subsequently made available to Board members by the Secretariat.

- *Commission agreement to the revised criteria for selecting stakeholder organisations*

The Board was informed that the Commission was expected to agree to the revised ECHA stakeholder selection criteria subject to the requirement that any stakeholder organisation must be included in the Commission's Register of Interest before a Committee or the Forum could invite them to attend meetings. Due to concerns raised against this requirement, it was concluded that ECHA would not automatically apply the revised criteria, once formally received, but bring the matter to the June Board meeting.

21. Next meeting and closure

The Chair reminded members that the next meeting of the Management Board would be held in Helsinki on 21-22 June 2011.

III. Decisions taken / Conclusions reached by the Management Board

The Management Board

- approved the minutes of its 20th meeting, subject to some modifications (see corrigendum in the annex) (MB/M/04/2010).

- adopted the agenda for the 21st meeting (MB/A/01/2011 rev02)

- endorsed the approach for compensating the resources used for biocides preparation through specific Commission funding to avoid a negative impact upon REACH/CLP activities as contained in document MB/01/2011.

- agreed that, if needed, the Executive Director would present a corresponding amending budget 2011 to the Management Board as soon as possible.

- approved the draft estimate of revenue and expenditure for 2012, together with the establishment plan (MB/02/2011rev01). The Board instructed the Executive Director to forward the estimate with the establishment plan to the Commission by 31 March 2011.

- agreed that the Executive Director should, in agreement with the Chair, take the necessary steps towards the Budgetary Authority in case the draft budget presented by the Commission will show a significantly lower resource level than proposed by the Board.

- adopted the General Report 2010 (MB/03/2011rev01) and instructed the Executive Director to submit the document to the Member States, the European Parliament, the Council, the Commission, the European Economic and Social Committee and the Court of Auditors, and to have it published.

- took note of the Annual Activity Report for 2010, as contained in document MB/04/2011. The Board adopted, subject to the signature of the Executive Director's declaration of assurance for 2010, the analysis and assessment thereof (MB/05/2011rev01). The Executive Director was instructed to send before 15 June 2011 the Annual Assessment Report and the Analysis and Assessment thereof, to the Budgetary Authority and the Court of Auditors, and to include it into the General Report for 2010.

- endorsed the submission of the draft Multi-annual Work Programme 2012-14 (MB/07/2011rev01) for public consultation, including the multi-annual staffing plan and revised mission, vision and values statements.

- approved the proposal to organise a first planning meeting with the Directors of the Member State Competent Authorities before the end of 2011.

- adopted the multi-annual staff policy plan 2012-2014, as contained in document MB/08/2011rev01.

- endorsed the updated IAS multi-annual strategic audit plan for 2011-2013 (MB/09/2011).

- appointed Ms Simona FAJFAR to the working group on Reporting officers for the Executive Director and Mr Jan Karel KWISTHOUT to the working group on Reporting Officers for the members of the Board of Appeal.

- appointed Dr. Urs SCHLUETER (EE), Dr. Christina TSITSIMPIKOU (EL), Dr. Nikolaos SPETSERIS (EL) and Mr Radu BRANISTEANU (RO) to the Risk Assessment Committee.

- appointed Ms Elina Velinova STOYANOVA-LAZAROVA (BG), Ms Angela LADOPOULOU (EL) and Mr Zbigniew ŚLĘZAK (PL) to the Committee for Socio-Economic Analysis.

- renewed the mandate of the following RAC members: Ms Zhivka HALKOVA (BG), Mr Boguslaw BARANSKI (PL), and Ms Alicja ANDERSSON (SE).

- renewed the mandate of the following SEAC member: Mr Dimosthenis VOIVONTAS (EL).

- endorsed a revised Guidance Consultation Procedure (MB/14/2011rev01). The Commission representatives issued the following declaration in relation to this decision:

  The Commission representatives in the Management Board take note of the compromise in relation to the revised consultation procedure on guidance and regret that a common interpretation could not be agreed. The Commission representatives wish to point out that the compromise may help to resolve the difficulties that have been faced in adopting the guidance over the past years. However, the principle remains that EU regulations should be enforced in a uniform manner throughout the EU. Economic operators have legitimate expectations in this sense. The Commission reserves the right to take legal steps.

- noted that the Guidance for requirements for substances in articles under REACH would be published by 1 April in accordance with the agreed procedure as outlined above.

- decided to postpone and, if needed, to continue via written procedure to amend the Management Board decision MB/17/2008.

- took note of the latest budget transfers under the responsibility of the Executive Director, indicated in document MB/19/2011.

<u>List of agreed follow-up actions</u>

- The Secretariat will upload the latest Eurobarometer survey results on CLP to CIRCA.

- The Secretariat will request whether the biocides staff model can be made available to Board members and Competent Authorities.

- The draft Multi-Annual Work Program will be uploaded to ECHA's website to allow the general public to provide comments on the draft.

- 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.

IV. List of Attendees

Representatives of the Member States

Maria ALAJÕE (EE)
Aurelija BAJORAITIENÉ (LT)
Karel BLAHA (CZ)
Nina CROMNIER (SE)
Simona FAJFAR (SL)
Arwyn DAVIES (UK)
Helmut DE VOS (BE)
Ana FRESNO (ES)
Claude GEIMER (LU)
Mario GRACIO (PT)
Thomas JAKL (AT) also acting as proxy of Mr ADAMIS and Mr SACCONI
Katarzyna KITAJEWSKA (PL)
Pirkko KIVELA (FI)
Jan Karel KWISTHOUT (NL)
Antonello LAPALORCIA (IT)
Martin LYNCH (IE) also acting as proxy of Mr FARRUGIA
Boyko MALINOV (BG) also acting as proxy of Mr OGNEAN
Catherine MIR (FR)
Leandros NICOLAIDES (CY)
Alexander NIES (DE) also acting as proxy of Mr NASSAUER
Edita NOVÁKOVÁ (SK)
Armands PLATE (LV)
Eskil THUESEN (DK)
Maria-Miranda XEPAPADAKI-TOMARA (EL)

Representatives of the Commission

Gustaaf BORCHARDT also acting as proxy of Mr ZOUREK and Ms ANKLAM

Individuals from interested parties (appointed by the Commission)

Martin FUEHR
Hubert MANDERY
Tony MUSU

Observers from EEA/EFTA countries

Henrik ERIKSEN (NO)

Other Observers

Graham WILLMOTT (on behalf of Heinz ZOUREK, European Commission)
Astrid BARTELS (European Commission)
Cristina DE AVILA (European Commission)
Astrid SCHOMAKER (European Commission)
Katja VOM HOFE (expert accompanying Alexander NIES)

ECHA staff

Geert DANCET	(Executive Director)
Jef MAES	(Director of Resources)
Jukka MALM	(Director of Assessment)
Christel MUSSET	(Director of Registration and IT Tools)
Luisa CONSOLINI	(Director of IT systems)
Leena YLÄ-MONONEN	(Director of Evaluation)
Jack DE BRUIJN	(Director of Risk management)
Andreas HERDINA	(Director of Cooperation)
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)
Lindsay JACKSON	(Head of Unit, Communications)
Pilar RODRIGUEZ IGLESIAS	(Head of Unit, Committees Secretariat) for agenda item 13
Tuula HAKALA	(Head of Unit, Finance) for agenda items 4, 5
Helene LILLGÄLS	(Accounting Officer) for agenda item 6
Sari HAUKKA	(Registrar of the Board of Appeal) for agenda items 4, 6, 8, 9, 14
Shay O'MALLEY	(Head of Unit, Human Resources) for agenda item 9
Catherine CORNU	(Scientific Officer) for agenda item 16
Andrea IBER	(Legal Advisor) for agenda item 16
Minna STRÖMBERG	(Internal Audit) for agenda item 10

Annex

Corrigendum to Document: **MB/M/04/2010**

(Agreed at the Management Board meeting on 24-25 March 2011)

Minutes of the Meeting of ECHA's Management Board held on

16/17 December 2010

7.1 Future involvement in the Directors' Contact Group

The Executive Director outlined the foreseen continued involvement of the Agency in the Directors' Contact Group (DCG) under a revised mandate. He made reference to a background note with information on a draft extended mandate for the DCG which was submitted to the Management Board on 10 December 2010. Appreciating the work of this Group in 2010 as a positive experience, the Commission has proposed to continue the DCG after its present mandate ends in March 2011. The main focus of the future work of this informal group, now meeting less frequently, is to be downstream user issues and the preparation of the second registration deadline in 2013 with special attention given to the situation of SMEs. ***The Commission representative chairing the DCG highlighted the usefulness of continued contacts with industry to monitor preparedness and difficulties encountered not least in view of the 2013 deadline; while meetings should become less frequent in the future, the DCG provided an informal framework for doing so.***

This was followed by an extensive exchange of views.

A number of Member State representatives ***and a board member representing interested parties appointed by the Commission*** emphasised the importance of the DCG having an informal and *ad hoc* character and expressed the view that the Group should no longer establish solutions but rather focus on identifying issues that may affect registration, and monitoring their follow-up.

[…]

9. Decision on the transfer of fees to Member States in the context of the authorisation procedure (revision of MB/20/2009)
(MB/65/2010 rev.01)

[…]

The floor was given to the Executive Director who chairs the Working Group on the Transfer of Fees in the context of the Authorisation procedure. The Working Group met in September and December and agreed on a proposal for an amendment to the existing Management Board decision on the transfer of fees (MB/20/2009 D final). The proposal for a new decision was presented as an annex to document MB/65/2010 rev.01.

The Working Group proposed a system which converts the actual fee received into a "size-neutral fee" (~~*76.6% of the base fee of a large company of € 50,000*"~~) ***(76.6% of the fee that would be payable in case such a dossier is submitted by large companies only)*** irrespective of the size of the company.

[…]

The Executive Director replied to the comments made and explained that a report on the experiences with the decision on the transfer of fees to Member States will be provided to the Management Board in March 2012. With regard to the correction coefficients foreseen in the decision already in place, the Executive Director clarified that ECHA will adapt the annex at the latest on 31 March 2011 based on the latest Eurostat data. Addressing the concerns raised, he

clarified that it was a request from the Court of Auditors that agencies take account of the different ~~*costs of labour*~~ ***cost levels*** in the Member States.

12. Report from the Executive Director, including report on the outcome of the first registration deadline
(MB/69/2010)

[…]

A Board member appointed by the Commission to represent interested parties pointed out that the availability of the results from the first registration deadline ***for CMRs*** should be used for analysing whether REACH delivers the intended results.

[…]

17.2. Multi-annual staff policy plan 2012-2014
(*MB/73/2010 rev.01*)

[…]

The Executive Director replied to the comments made. He confirmed that the staff levels indicated in the draft plan as from 2013 onwards deviate from the Commission estimates that were established in 2006 before the adoption of the final REACH Regulation. New ***working*** estimates made by ***some*** Commission ***departments*** in 2007, after the adoption of the REACH Regulation, would, however, not foresee a similar reduction of staff. ***In the views of the Executive Director*** these estimates could not be translated any more into a newly revised financial legislative statement but should now be taken into account.

[…]