

MB/M/04/2010 final

MINUTES OF THE 20TH MEETING OF THE MANAGEMENT BOARD held on 16-17 December 2010

I. Documents submitted to the Management Board

Draft agenda (MB/A/05/2010) Draft minutes of the 19th Management Board meeting (MB/M/03/2010) Second amending budget 2010 (MB/59/2010) **Budget transfers** (MB/60/2010) Final Budget and Establishment Plan 2011 (MB/61/2010) Management of the Agency's cash reserve (MB/62/2010) Work Programme 2011 – update of annexes (MB/63/2010 rev.01) **ECHA Corporate Identity** (MB/64/2010) Decision on the transfer of fees to Member States in the context (MB/65/2010 rev.01) of the authorisation procedure (rev. MB/20/2009) Review of the scale of remuneration provided in decision on (*MB*/66/2010 rev.01) MB/77/2008 (remuneration of experts / co-opted members) **ECHA Committees** (*MB*/67/2010 rev.01) Update on the functioning of the Committees (MB/68/2010 part 1) Appointment of Committee members (MB/68/2010 part 2 rev.01) Report from the Executive Director, including report on the outcome of the first registration deadline (MB/69/2010) Informative update from the Chairman of the Board of Appeal (MB/70/2010) Guidance on substances in articles (MB/71/2010) Report on Forum activities (MB/72/2010 Multi-annual Staff Policy Plan (MB/73/2010 rev.01) Implementing rules of the Staff Regulation (MB/74/2010) Work Programme of the Security Officers Network (MB/75/2010)Report from the advisory group on dissemination (MB/76/2010) Planning for the preparation of the Agency report pursuant to (MB/77/2010)Article 117(2) of the REACH Regulation

II. Summary Record of the Proceedings

Introductory remarks

The Chair opened the meeting by welcoming the participants.

He confirmed the appointment of the following new members: Mario GRACIO (PT), Eskil THUESEN (DK), Nina CROMNIER (SE) and Simona FAJFAR (SL), appointed in place of Fernanda SANTIAGO, Per NYLYKKE, Ethel FORSBERG and Marta CIRAJ, respectively.

The Chair also welcomed Leena YLÄ-MONONEN and Jack DE BRUIJN who participated for the first time as ECHA directors at a Management Board meeting.

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/04/2010)

The Chair proposed that the order of two items on the agenda be changed: "ECHA's future involvement in the Directors' Contact Group" should be dealt jointly with the Work Programme 2011. Furthermore, he proposed that, with regard to the resource implications for ECHA, the "status of the adoption of the biocides regulation" should be discussed in connection with the Multi-Annual Staff Policy Plan.

The Chair also announced two additional items under "Any Other Business": the updated list of Member State Authorities with REACH-IT access, and future vacancies at ECHA.

Finally, he noted the room documents that had been made available for the meeting.

Further to these changes, 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/02/2010)

The minutes of the 19th Management Board meeting were approved.

4. Second amending budget 2010 and transfers within the budget (MB/59/2010, MB/60/2010)

The Director for Resources presented the second amendment to the budget 2010 and referred to the latest budget transfers carried out under the responsibility of the Executive Director. He reported that the budget for 2010 could be further reduced by €4 million to a total of €75 481 700. The budget 2010 had been adopted by the Management Board at its meeting of 17 December 2009 (MB/69/2009 final) and initially amounted to a total of €86 481 700. A first budget decrease by €7 million had then been confirmed by the Board in September 2010.

The Director for Resources explained that the reduction was possible because throughout 2010 ECHA's budget implementation was characterised by caution in embarking on new projects and a focus on the first registration deadline, with priority for existing projects over new ones. There have also been significant savings due to automation in the registration process and the postponement of IT projects.

Mr. LYNCH, Chair of the Working Group on Planning and Reporting, which dealt with the issue at a meeting on 9 December, supported the proposed amendment.

The Management Board adopted the second amending budget for 2010 and took note of the latest budget transfers carried out under the responsibility of the Executive Director. The Board instructed the Executive Director to notify the amended budget to the Budgetary Authority, the Court of Auditors and the Commission, and to publish it on the Agency's web page and in the Official Journal of the European Union.

5. Final Budget and Establishment Plan for 2011 (*MB/61/2010*)

The Executive Director presented the final draft budget of the Agency for 2011, including the establishment plan. He explained that the total of the draft budget was 32% higher than the total of the budget for 2010 as amended and presented under agenda point 4.1, and amounted to €99.8 million. This amount is eventually €8 millionless than anticipated and approved by the Management Board in March 2010 in the context of the preliminary draft budget.

The whole of the Agency's expenditure in 2011 is funded through its own income. The primary source of revenue will be the cash reserve accumulated from fees paid for registrations submitted for the first registration deadline. At the end of 2010, the amount of this reserve was estimated to be €266 million. The Executive Director noted that the reserve is expected to generate interest income through which ECHA should be able to finance 2.6 % of its expenditure.

On the expenditure side, the Executive Director explained that an increase of 25% is foreseen in Title 1 for staff related costs, covering mainly salaries, recruitment, training, work related travel and external services. The increase reflects the projected growth of staff as depicted in the establishment plan (increase from 426 to 456 staff) and reflects the impact of the massive recruitment in 2010 which is now featured in the 2011 budget. Furthermore, ECHA faces increased costs for employer's staff social security contributions which burden the Agency in full due to its financial independence.

An increase of 36% compared to 2010 is anticipated for Title 2 covering rental costs for the premises as well as other basic infrastructure and information technology expenditure. The increase is also due to some high-value IT projects, such as development of an HR support system, an enterprise architecture project, and further development of the Agency's IT security system.

Title 3, which directly supports the implementation of the work programme, increases by 45% compared to 2010, thereby covering for example an increased need for translation services - primarily due to the need to translate various documents to support small and medium sized companies (SMEs), the re-build of the Agency's website and the desire to make it available in 22 EU languages, as well as several scientific IT projects which were postponed to 2011 and are now included in the budget together with their ownership and maintenance costs. Furthermore, the authorisation and restriction processes require increased resources on the basis of the expected higher number of REACH Annex XV proposals.

The ECHA establishment plan for 2011 foresees 30 new temporary agent positions.

The Chair of the Working Group on Planning and Reporting, Mr. LYNCH, highlighted the budget increase from 2010 to 2011. Overall he recommended the adoption of the budget.

In an exchange of views, Board members asked for clarification on the precise purpose of different budget lines. One Member State representative noted that the registration numbers were lower than expected while at the same time the budget was increasing as planned. There were also questions regarding the staffing of different activities, for example for the dissemination or registration activities.

The Executive Director replied to the questions and explained that the budget for 2011 is close to the original forecast. The resource needs will be monitored and adjusted for each activity as needed.

The Management Board adopted the budget of the Agency for 2011 including the establishment plan.

6. Management of the Agency's cash reserve (*MB/62/2010*)

The Executive Director reported on the management of the Agency's cash reserve deriving from fees and charges.

He reminded Board members that ECHA has negotiated a contract with the Central Bank of Finland aimed at short-term cash management which entered into force on 1 December 2010. For the mid-term management, ECHA is in negotiation with the European Investment Bank (EIB) in view of possible co-operation. The arrangement with the EIB could serve the Agency's investment and risk diversification needs with regard to longer maturities covering up to two years.

The fee revenue generated by the first registration deadline will be partly used for securing the Agency's short term cash flow needs and partly invested on a medium term basis in line with the principles approved by the Management Board in June 2009 for managing the cash reserve (MB/42/2009 final).

The Chair thanked the Executive Director for his report and emphasised that the financial management of the cash reserve requires an expertise which is not part of ECHA's core mandate. The issue would therefore be of high sensitivity for the Agency.

During an exchange of views, Board members welcomed the conservative approach of the Executive Director's proposal and emphasised the importance of long-term security. The Board expressed the wish to be kept regularly informed on the status of the cash management.

The Management Board supported the Executive Director and the accountant continuing negotiations with the European Investment Bank with a view to establishing an agreement on cash management based on the principles approved by the Management Board in June 2009. It was agreed that ECHA will regularly report on cash management at future Management Board meetings. After two years of experience, the Executive Director shall also report on the opportunity for continuing the mid-term cash management agreement ultimately established, with regard to the fee revenue generated in the context of the second registration deadline in 2013.

7.1 Future involvement in the Directors' Contact Group¹

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. It was argued that the DCG should have no formal outward appearance and the ECHA website is consequently not to publish DCG documents. Furthermore, an involvement of Management Board or Member State representatives was not deemed appropriate as this would inadequately distort the relationship of institutions: representatives of institutions established to implement the REACH legislation should not be observing an informal and *ad hoc* information-exchange forum of the Commission, ECHA and industry associations.

¹ Originally placed under "Any Other Business", Agenda item 23 of the draft agenda MB/04/2010

Board members acknowledged, however, the importance of informal contacts and networks between regulators and stakeholders as a tool for gathering intelligence from the market and identifying potential problems in due time to find appropriate regulatory responses. The achievements of the DCG were generally considered as having been useful for the successful management of the challenges linked to the first registration deadline.

Overall, the Management Board took a critical view of prolonging the work of the DCG under the current mandate and spelled out a number of limiting conditions for any future involvement of the ECHA Executive Director. The Board also wished to be informed regularly about the resource implications of ECHA's participation in the Group.

It was the view of the Board that as the DCG has no legal basis, it can only be an informal and ad hoc platform for exchanging information and views and has to respect the decision-making institutions under the REACH Regulation. Furthermore, the DCG shall not establish "solutions" with binding effect for the Agency, and ECHA is not to make DCG documents available on its webpage. The ECHA management was asked to seek corresponding changes to the revised mandate. With regard to the update of the Work Programme for 2011, it was agreed to adapt the relevant passages accordingly. To this end, the Working Group on Planning and Reporting was mandated to convene and present a proposal.

7.2 Work Programme 2011 – update of annexes (*MB/63/2010 rev.01*)

As foreseen in September 2010, at the time of the adoption of the initial version of the document (MB/48/2010 final), the Executive Director presented a revised proposal for an updated ECHA Work Programme 2011 to the Management Board.

He emphasised that 2010 had been a special year for the Agency because of the first registration deadline on 30 November, and that the results were decisive for the Agency's future activities, in particular with regard to dossier evaluation, assessment of confidentiality claims and estimated appeals. Hence, the ECHA Secretariat had reviewed the baseline figures in the annex of the work programme, which provide the estimates of the main workload drivers for the Agency, and the relevant parts in the text as appropriate. Following the Commission's agreement on the Management Board decision on the classification of charges under the Fee Regulation an explicit reference to the verification of the SME status of companies would still be added to the draft as an additional update.

The Chair of the Working Group on Planning and Reporting, Mr LYNCH reported from the meeting of the Working Group on 9 December. On that occasion, the updated Work Programme in the version provided by the Secretariat on 7 December, had been reviewed. The Working Group agreed to limit the updates to the text of the programme to the extent necessary in order to reflect changes directly resulting from the outcome of the registration deadline. A revised version was submitted to the Management Board after the Working Group meeting (MB/63/2010 rev.1 of 10 December 2010). On behalf of the Working Group, Mr LYNCH recommended the adoption of this new version.

The Management Board thanked the Working Group for the thorough preparation of the decision and held an exchange of views. In the course of the discussion, several Board

members proposed changes to the document regarding REACH IT, the work of the DCG, dossier evaluation, and cash reserve management.

At a separate meeting, the Working Group on Planning and Reporting reviewed document MB/63/2010 rev.1 in the light of the discussions under agenda points 7.1. and 7.2. and proposed modifications on the second meeting day².

The Management Board adopted document MB/63/2010 rev.01 with the revisions proposed by the Working Group, and instructed the Executive Director to forward the Work Programme for 2011, as amended, to the Member States, the European Parliament, the Council and the Commission and to have it published.

8. ECHA Corporate Identity (*MB/64/2010*)

The Executive Director presented the ECHA Corporate Identity project, including the timeframe for its implementation and the resource implications, and revised Agency mission, vision and values statements.

The aim of the Corporate Identity project is to create a consistent overall image of ECHA in line with the expectations of its stakeholders and staff. The visual identity of ECHA would also change later in 2011 on the occasion of the launch of the new website which is under development. The current mission, vision and values of ECHA have been reviewed to reflect the changes and the wish to have more concise texts. Corresponding amendments were proposed in document MB/64/2010. The Executive Director presented some further amendments which took into account the comments made by the Working Group on Planning and Reporting.

Board members actively discussed the project and welcomed the initiative, and in particular the objective of becoming a more proactive and easy-to-approach Agency.

As regards the revised mission, vision, and value statements, several suggestions were made. On the one hand, the brevity of the new statements was appreciated. On the other hand, several Board members expressed the wish to see further elements (such as "international" or REACH-related issues) included.

The Management Board agreed that the Secretariat should further improve the mission, vision and values statements in the light of the discussion and present revised versions in March 2011 in the context of the update of the multi-annual work programme.

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

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² Page 8, first paragraph: deletion of a reference to the DCG; page 10, 2nd and 3rd paragraph: modification to take account of the discussions under agenda item 7.1; page 14, 4th paragraph: change related to testing proposals / compliance checks; page 27, last paragraph: addition related to the accesibility of REACH-IT; page 44, 2nd paragraph, addition for the work on SME checks; page 45: addition of an indicator for the management of the cash reserve.

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 fee that would be payable in case such a dossier is submitted by large companies only) irrespective of the size of the company. A proportion of the derived "size neutral fee" is transferred to Member State Competent Authorities for the work of RAC and SEAC rapporteurs based on available workload distribution between rapporteurs and ECHA of 25%:75%. The rest of the fee will remain with ECHA. The Executive Director pointed out that the proposal ensures the transfer of a predictable fee, independent of company size, to Member States but could potentially lead to income fluctuations for the Agency.

The Management Board thanked the working group for the proposal and held an exchange of views during which the proposal was generally welcomed as being well elaborated.

A discussion also took place on the appropriateness of the correction coefficients set out in the current decision on the transfer of fees in order to take account of the different costs of work in the EU Member States. Several Member State representatives expressed concerns whether these provisions - which were not subject to the revision done by the Working Group for the purpose of including authorisation aspects - would discourage the participation of rapporteurs from Member States with lower than average labour costs.

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 cost levels in the Member States. He added that salaries were converging in the European Union and that Member States authorities should provide Eurostat with the latest salary information. The decision also provides that ECHA will collect data on actual expert salary costs directly from the Member State Competent Authorities and will investigate the feasibility of an approach based directly on these figures.

The Management Board adopted the proposed draft decision on the transfer of fees to Member States as contained in annex document MB/65/2010 rev.01 with one amendment³ and subject to a required favourable opinion of the Commission. The amended draft decision will be submitted to the Commission with a view to putting the final rules in place in the first half of 2011.

The Latvian Board member expressed a reservation with reference to the concerns regarding the application of correction coefficients. It was agreed that he will join the Working Group on the Transfer of Fees for its future work.

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³ The review foreseen in Article 7 shall take place "at the latest" on 31 March 2013

10. Review of the scale of remuneration of experts/co-opted members provided in decision on MB/77/2008 (MB/66/2010 rev.01)

The Director for Cooperation presented the agenda item. The scale of remuneration for coopted members and experts (€300 per day of attendance in a meeting or other service) was established by a decision of the Management Board in 2008, and scheduled for review by the end of 2010. Taking into account the Annual Inflation Rate (EU area) in October 2010 it was proposed to adjust the daily rate to €310.

After a short discussion on the effective use of these remunerations and the general need for adapting the decision to the development of the Consumer Price Index the item was postponed to a future meeting of the Management Board.

11.1. Update on the functioning of the Committees - Renewal of the Committees and Forum

(MB/67/2010 rev.01)

The Director for Cooperation presented an update on the functioning of the Committees.

It was explained that the document presented to the meeting for this purpose focused on the renewal procedure for Committee appointments but was not intended to follow-up the broader discussion on the functioning of Committees which started in September 2010. The continuation of this process is planned for the March 2011 meeting. He also mentioned that several Member States were still considering nominating Committee members for RAC and SEAC over the coming months.

During an exchange of views, Management Board members stressed the need for further discussions on the functioning of the Committees as well as the Forum. For example, it was mentioned that the Forum should consider using alternates in order to fulfil its role in the most efficient manner. The Director for Cooperation undertook to bring this proposal to the attention of the Forum Chair. Other Members expressed concern that the number of members in the RAC and SEAC would decrease instead of increasing as proposed by the Secretariat in September 2010. Against this backdrop, Member State representatives were invited to encourage further nominations.

A Member State representative informed the Board that, due to lack of national resources, her Competent Authority has approached the Competent Authority of another Member State with the request to nominate an expert from this Member State as a Committee member. Several Board members explicitly welcomed such arrangements as a signal of good cooperation between European Union Member States and as a useful tool for capacity building in countries with less experience in the regulatory field of chemicals risk management. Two Board members emphasised that their Member States have nominated experts from another Member State as Committee members and had very positive experiences with these arrangements. One Board member, however, raised doubts whether the nomination of a national expert of another Member State as Committee member is compliant with the REACH Regulation. It was agreed that the issue should be clarified by the Secretariat in the context of the ongoing discussion on the functioning of the Committees.

The Board agreed to continue the discussion in March 2011.

11.2. Appointment of Committee members (*MB/68/2010 part 1, MB/68/2010 part 2 rev.01*)

The Board received information on the anticipated composition of the Committee for Risk Assessment (RAC) and the Socio-Economic Analysis Committee (SEAC) based on the results of the call for nomination and appointments of 15 September 2010.

Based on the nominations received, the Management Board appointed four new members to the Risk Assessment Committee: Dr. Robert WINKLER (AT), Mr. Pietro PARIS (IT), Ms Elodie PASQUIER (FR) and Dr. Benjamin PIÑA (ES). Furthermore, the Board renewed the membership of 21 RAC members⁴.: Annemarie LOSERT (AT), Karen VAN MALDEREN (BE), Maria ORPHANOU (CY), Paola DI PROSPERO FANGHELLA (IT), Riitta LEINONEN (FI), Annick PICHARD (FR), Helmut GREIM (DE), Norbert RUPPRICH (DE), Katalin GRUIZ (HU), Yvonne MULLOOLY (IE), Normunds KADIKIS (LV), Lina DUNAUSKIENE (LT), Hans-Christian STOLZENBERG (LU), Marja PRONK (NL), Maria Teresa BORGES (PT), Céu NUNES (PT), Agnes SCHULTE (SL),Helena POLAKOVICOVA (SK), Bert-Ove LUND (SE), Stephen DUNGEY (UK), and Andrew SMITH (UK).

The Board also appointed five new members for the Committee for Socio-economic Analysis: Ms Johanna KIISKI (FI), Ms Karine FIORE-TARDIEU (FR), Ms Federica CECCARELLI (IT), Mr Vitalius SKARŽINSKAS (LT) and Ms Åsa THORS (SE). The Management Board renewed the membership of ten members whose three-year term will expire by mid February 2011: Simone FANKHAUSER (AT), Catheline DANTINNE (BE), Jean-Pierre FEYAERTS (BE), Franz-George SIMON (DE), Lars FOCK (DK), Jean-Marc BRIGNON (FR), Endre SCHUCHTÁR (HU), Cees LUTTIKHUIZEN (NL), Mats FORKMAN (SE) and Stavros GEORGIOU (UK).

The ECHA Secretariat will introduce the new members to their tasks, working procedures and other key documents as appropriate without delay. To integrate the new members efficiently to the Committees, the MSCAs were invited to help the process by supporting the effective handover between former and new Committee members.

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

The floor was given to Executive Director, who reported on relevant developments related to the different Agency activities, including the results on work programme indicators. He pointed out that the first registration deadline for CMRs was completed successfully on 30 November 2010 with 24 675 registration dossiers accepted for processing and thanked the ECHA staff for their efforts. He also reported that the staff stress levels are high and that the management have agreed to tackle that issue.

This was followed by an exchange of views.

Board members congratulated the Executive Director and ECHA staff for the successful work done to make the first registration deadline a success. At the same time, many members were

⁴ The new term of office of these members will start when the current three-year membership term expires.

concerned about the high level of exhaustion amongst Agency staff and emphasised the importance of staff wellbeing and the need to arrive at a more stable workload in the future as well as to discontinue the regular opening hours during public holidays. Many members agreed with the management on the need to take appropriate actions.

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

With regard to the new Management Board decision on the classification of charges under the Fee Regulation, a Board member pointed out that ECHA should inform Member States of the results of the SME status check for companies from their countries, as well as of the registration dossiers that arrived after the registration deadline.

A short discussion also took place on REACH-IT functionalities for Member States. On this it was agreed that the issue should be addressed in more detail at the next Management Board meeting.

Referring to proceedings at the CARACAL, several members requested a more proactive approach by the Commission services when providing legal interpretations on REACH implementation questions. In reply to this, a Commission representative reminded the meeting that a legal consultation is only part of the Commission decision making process and that the need for legal consultations would underline the complexity of the underlying questions. A representative of interested parties appointed by the Commission mentioned in this context that ECHA as independent Agency is also in the position to decide on legal questions without consulting the Commission.

The Executive Director thanked the Board members for their feedback and replied to specific comments. He concurred with the Board's concern with regard to the exhaustion and stress levels of ECHA staff and detailed the initiatives already taken by the management in response to this. He stressed that REACH is a demanding legislation and that ECHA needs to act carefully to keep staff on board for upcoming challenges. The re-organisation of the Agency which takes effect on 1 January 2011 is expected to support a more balanced workload.

With regard to the result of the stakeholder survey, the Executive Director confirmed that ECHA has already addressed many aspects raised in the feedback received from stakeholders. On the request to submit information on late registrants and SME checks to Member States, he undertook to look into the issue and verify how this information is planned to be communicated. He informed that national registration data is by default submitted to the Member State concerned. The Director for Registration and IT Tools explained that ECHA will soon start to analyse the registration data in depth.

The Management Board took note of the report and concluded that ECHA has managed its challenging mandate so far in a very satisfactory manner. It would now be the time to come to cruising speed which would also put less stress on staff. This should be taken into account by Member States and stakeholders, for example when raising expectations regarding new Agency projects.

13. Update from the Chair of the Board of Appeal (MB/70/2010)

The floor was given to the Chair of the Board of Appeal who provided an update on relevant developments, including information related to the first appeal, on implementing decisions adopted by the Board of Appeal, on the framework for working with alternate and additional members, on networking with other boards of appeal and on communication with stakeholders.

The Chair of the Board of Appeal also provided some personal reflections to the Board, such as on the reasons for the low number of appeals so far received.

Questions raised during a subsequent discussion included the involvement of alternates in the daily work of the Board of Appeal and the working relations with the General Court. One Board member stressed that the Board of Appeal needs to be clearly recognised by stakeholders as independent from the ECHA Secretariat.

The Chair of the Board of Appeal reacted to questions. She indicated that the Board of Appeal held good relations with the General Court and with the boards of appeal of other agencies and expressed satisfaction that an agreement was reached with the Secretariat on access for Board of Appeal members to relevant ECHA decisions under the REACH processes.

The Management Board took note of the information provided and thanked the Chair of the Board of Appeal for the work done in 2010.

14. Report from the Working Group on Audit matters

The Co-Chair of the Working Group on Audit matters, Mr. BLAHA, reported from the last meeting of the group on 15 December 2010.

Among the topics discussed were the preliminary Internal Audit Service (IAS) Strategic Audit plan 2011-2013, the Internal Audit Capability (IAC) audit plan for 2011 and several other audit reports.

Mr BLAHA informed the Board that the final updated IAS Strategic Audit plan will be presented to the Management Board for endorsement at the March 2011 meeting.

Furthermore, he informed the other Board members that as the Agency will be self-financing in 2011-2013, the mandate of the IAS to continue internal audits at the Agency deserves clarification. To this end, the Executive Director was asked to write to the IAS in order to agree on the continuation of the IAS work at ECHA during the self-financed period.

The Management Board took note of the report.

Report on Forum activities (*MB/72/2010*)

The Director for Cooperation gave a report on the operation of the Forum between 2007 and 2010 and on the state of play of the RIPE project.

The report on the Forum activities - which was not presented in detail due to time constraints - was prepared by the Chair, Richard BISHOP (whose mandate as Chair recently ended), the Forum's Vice-Chair Nikolay SAVOV and the first Forum Chair Ulrike KOWALSKI. The report came to positive conclusions with regard to the establishment of the Forum as the first formal enforcement network at the EU level, which could serve as a model for other legislation.

This was followed by a short exchange of views.

The Management Board warmly thanked the former Forum Chair, Mr. Richard BISHOP, for his contributions. Mr BISHOP could not participate at the meeting.

With regard to RIPE, Board members discussed security aspects and the relation between the respective arrangements put in place and the Standard Security Requirements for access to REACH-IT for Member State Competent Authorities or mandated national institutions. One Board member was of the opinion that the security recommendations for RIPE require a similar high standard and deserve in depth deliberations at the Management Board level. Other Board members welcomed the progress with RIPE and emphasised that a good balance had been found between providing an adequate security level and ensuring the needed access for enforcers to the relevant information. The Director for Cooperation pointed out that the national RIPE databases will include only a limited amount of the non-public data contained in the full REACH-IT database and, moreover, only data from dossiers submitted by registrants from the respective Member State. Furthermore, the organisation of enforcement activities varies considerably between Member States and this aspect needs to be taken into account when designing efficient information exchange procedures and tools for enforcers.

The Management Board took note of the information provided.

16. Guidance on substances in articles (*MB/71/2010*)

The Executive Director reported on latest developments regarding the revision of the Guidance document on the requirements for substances in articles under the REACH Regulation. This included a report on the advice received from Board members following a request by the Executive Director in accordance with the consultation procedure on Guidance update. The consultation procedure was endorsed by the Management Board in February 2008 (MB/30/2007 final). In the light of the advice received, and since a new legal opinion by the Commission services on the crucial issue of the application of the 0.1% threshold for substances in articles is foreseeable, ECHA decided in early December to postpone the publication of the revised Guidance.

The Executive Director confirmed that ECHA will continue working together with Member States and the Commission on a common interpretation of the application of the 0.1% threshold. To this end, ECHA will host a technical workshop on its premises on 3-4 February

2011. The intention is to bring together experts to analyse and discuss the consequences that the different interpretations have for obtaining adequate information for substances in articles, technical implementation issues, and difficulties that enforcement authorities may encounter. Furthermore, the Executive Director clarified that ECHA will seek means by which the uncontroversial parts of the draft Guidance can be communicated so that they can be of immediate use to industry.

The Board held an extensive discussion on the role of the Commission Legal Service in the Guidance development process during which Board members referred to the importance of making updated Guidance available to stakeholders as soon as possible. Several Board members expressed their concern with the time needed to come to conclusion on the specific matter.

The Executive Director and the Secretariat were thanked for the transparent way of dealing with the Guidance issue since the October meeting of CARACAL.

The Executive Director thanked the Management Board members for their contributions. He recalled that there is an existing Commission legal service opinion on the application of the 0.1% threshold and stressed the wish of the Agency to deliver the best possible service to its stakeholders. Moreover, he clarified that ECHA does not systematically depend upon Commission legal advice on REACH implementation issues but that certain horizontal questions deserve a harmonised approach at EU level. As Guardian of the Treaties, the Commission has a specific role in this regard. The placement of footnotes in Guidance documents, however, should be re-considered and the Guidance consultation procedure be revised in order to avoid similar situations in future.

In order to further facilitate a swift and informed decision-making process on the issue, the Board concluded that the Chair should send a letter to the responsible Commissioners. In the letter, the Chair should propose to share with Member States the expected opinion of the Commission's Legal Service with regard to the alternative interpretation of the definition of articles as proposed by seven Member States in good time before the ECHA workshop in February. The shared information should include not only the reasoning of the legal opinion but also the wording of the questions raised.

The Management Board agreed to continue discussing the subject at its meeting in March 2011.

17.1 Status of the adoption of the biocides regulation⁵

The Belgian Board member, Mr. DE VOS, presented an overview of the legislative procedure on the proposed new regulation concerning the placing on the market and use of biocidal products. He informed the Management Board that COREPER supported a political agreement based on a compromise text proposed by the Belgian Presidency on 8 December. The Environmental Council will conclude on the Council's political agreement on 20 December and the Council activities during the second reading of the European Parliament will be coordinated by the forthcoming Polish Presidency. The entry into force of the new regulation is still foreseen for 2013.

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⁵ The order of agenda items in these minutes follows the order at the day of the meeting

Following this, a Commission representative reiterated that the legislative process is not concluded with the Council vote and that there is indeed a clear tendency to enlarge ECHA's mandate compared to the Commission's original proposal. In the further process the Commission will continue to put emphasis on resource implications for the Agency. This will be underlined by a Commission declaration at the Council meeting on 20 December.

The Director for Assessment confirmed that the resource implications of an enlarged mandate for ECHA are a concern for the Agency's management. The present text of the draft regulation could lead to considerably higher numbers of applications (up to 10 times) being handled by the Agency.

In a subsequent exchange of views, Management Board members underlined the need for adequate resources for the Agency to implement any new tasks, as well as for sufficient time for preparation. A Board member appointed by the Commission to represent interested parties highlighted that industry looks forward to ECHA taking on the new biocides tasks as the newly proposed regulation contains considerable improvements compared to the existing legislation.

A Commission representative appealed to Board members to also address the resource implications of the new legislation with their national Finance Ministries.

The Board agreed that it should receive regular reports on the preparations for ECHA's mandate under a future Biocides regulation.

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

The Director for Resources presented the updated multi-annual staff policy plan for 2012-2014, including the staffing evolution, the policy developments that took place in 2010 and the staffing outlook for 2011 and beyond.

The Chair of the Working Group on Planning and Reporting, Mr. LYNCH, reported from the discussions of the group on the issue. He highlighted the development of the staff level between 2011 and 2014 which is proposed to be stable from 2013 onwards.

This was followed by an exchange of views during which several Board members pointed to the need for an (updated) legislative financial statement for the draft biocides regulation as well as for the foreseen recast of the PIC Regulation at each important step in the legislative process.

With reference to specific operational tasks, such as evaluation or dissemination, it was mentioned that adequate resources must be available.

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. Moreover, factual developments need to be taken into account, such as the evaluation tasks which started later than originally anticipated due to the later arrival of registration dossiers and will, thus, require more staff in the time after 2011.

The Board endorsed the draft Multi-Annual Staff Policy Plan for the period 2012-2014 and instructed the Executive Director to consult the Commission on the draft. The final plan will then be submitted to the Management Board for approval in March 2011.

18. Implementing Rules of the Staff Regulations (*MB*/74/2010)

The Director for Resources presented the agenda item.

The ECHA implementing rules for the EU Staff Regulation were adopted by the Management Board in agreement with the Commission. The implementing rule on the policy and procedure for reclassification of temporary agents, implementing Article 10 of the Conditions of Employment of other Servants, was adopted by the Board in April 2009 and subsequently forwarded to the Commission. On 28 October 2010, the Commission's Secretariat General informed the Agency of its agreement with some modifications to the text that were explained to the Board.

The Board adopted the decision on the policy and procedure for reclassification of temporary agents, implementing Article 10 of the Conditions of Employment of other Servants, as submitted by the Commission on 28 October 2010.

19. Report from the Advisory Group on Dissemination (*MB*/76/2010)

The newly appointed Chair of the Advisory Group on Dissemination, Mr DE VOS, provided a report on the work of the Group since June 2010. He warmly thanked the dissemination project team in ECHA for the efficient support and the work on dissemination undertaken so far.

The Group met on 30 September and 2 December and mainly discussed the scope of the information to be disseminated in accordance with Article 119 of the REACH Regulation, in particular the question of whether Article 119(2)(d) of the REACH Regulation includes the dissemination of the identity of the registrant as part of the information in the Safety Data Sheet. A written consultation on the dissemination of information contained in the Safety Data Sheet was performed in October. As a follow-up, the opinion of the Commission Legal Service has been sought by the Commission representative participating in the Advisory Group.

Mr DE VOS reported that the advisory group was also informed about a foreseen adaptation of the workflow for assessment of confidentiality claims for cases where a registrant claims the IUPAC name of a substance as confidential. In this case a public name is needed to enhance the usefulness of the dissemination website and the functioning of other processes under REACH, such as consultations on testing proposals. Up to now, registrants were only asked to provide such a name on a voluntary basis. The respective manual was updated in order to make the

public name mandatory. A further manual on masked names was developed and published, providing advice on how to derive to a public name.

The Chair thanked Mr DE VOS for the report and referred to recent media reports related to confidential issues discussed in the Advisory Group. He reminded all Management Board members in this context of their duty of professional secrecy⁶.

Following this, a representative of the Commission confirmed that the Commission's Legal Service has provided an opinion which favours an affirmative reply to the question of whether the name of the registrant should be considered part of the information to be disseminated in accordance with Article 119(2) of the REACH Regulation, i.e. unless a confidentiality claim is made. It was, however, clarified that the Agency is still to receive a formal notification of the view of the Commission as such.

This was followed by an exchange of views during which several Member State representatives were of the view that the identity of the registrant should indeed be part of the disseminated information as long as the possibility exists to protect the information with confidentiality claims. Board members wished, however, to be informed of details of the opinion of the Commission Legal Service on the matter, also for further deliberations at the CARACAL meeting.

A Board member appointed by the Commission to represent interested parties expressed deep dissatisfaction with the fact that internal information from proceedings of the Management Board were communicated to external parties. The Board member confirmed that industry would adapt to any solution found on the controversial aspects and called for timely communication to stakeholders.

Another Board member appointed by the Commission to represent interested parties proposed that the Secretariat should start preparing the implementation of changes to the dissemination process. This would in any case be needed for the amended information requirements in relation to PBT properties in the Safety Data Sheet.

On request, the Secretariat explained that the result of the PBT analysis for individual substances is already now disseminated in accordance with Article 119(1) of the REACH Regulation. The underlying studies can, however, be claimed confidential. A recent change with regard to the dissemination of PBT relevant information is linked to an amendment adopted by the Commission to Annex II of the REACH Regulation. The amendment entered into force on 1 December 2010 and makes the outcome of the PBT studies part of the information to be disseminated. The implementation of this change requires technical adaptations, including to the IUCLID application, which are ongoing.

The Executive Director proposed that the legal opinion of the Commission should be made available for further discussions at CARACAL level and in the Forum. The issue should then be brought back to the Management Board in March 2011. He confirmed that ECHA will implement any changes needed to the present procedures once a final conclusion is reached but that the resources required to realise such changes are not yet covered by the current work programme.

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⁶ Art. 105 of the REACH Regulation

The Management Board took note of the information provided. The Chair expressed the hope that the outstanding issues could be concluded at one of the next meetings.

20. Work Programme of the Security Officers Network (*MB/75/2010*)

As requested by the Management Board in June 2010, the Head of the Executive Office presented the the work programme of the Security Officers' Network for 2011-2012.

The Security Officers' Network (SON) was established in 2007 as a sub-group of the former Commission Working Group on the Practical Preparations for REACH. The role of the SON is vital in the establishment of secure network connections between the Member State Competent Authorities, Mandated National Institutions, the European Commission and ECHA.

The Management Board took note of the information.

21. Planning for the preparation of the Agency report pursuant to Article 117(2) of the REACH Regulation (MB/77/2010)

The Director for Assessment informed the Board about the planning for the first Agency report for the Commission under Article 117(2) of the REACH Regulation.

22. Any other business

Resources on PIC – information from the European Commission

A Commission representative informed the Board of the planned recast of the PIC Regulation (Prior Informed Consent concerning the export and import of dangerous chemicals) which would result in additional tasks for ECHA. The Executive Director clarified that the work done by ECHA depends on the availability of sufficient resources and staff, and called on Member States to support this request.

Mandates of Management Board members

The mandate of a number of Management Board members will expire on 31 May 2011 and renewals or new appointments are needed in due time. The procedure is handled by the Council Secretariat and is initiated by the Permanent Representations to the EU. As this process requires some time, the Chair will write to the Permanent Representations in order to kindly remind of the need for timely action to ensure the continuity of the Management Board. A draft of the template for this letter was presented as a room document for information.

Member State Access to REACH-IT

An update was provided and it was agreed that reports on the status of the access to the REACH-IT system will be provided at future Board meetings. A room document listing the 19 Member States that are connected to REACH-IT was distributed and the Board took note that a solution has been found for concerns raised by Sweden, Denmark and Finland. The Secretariat strongly encouraged Member States Authorities to implement the requirements for REACH-IT access to be able to contribute to REACH related activities.

Job vacancies at ECHA

The Agency will publish two scientific profiles for a high number of posts in December 2010. The Chair asked Board members to actively promote these opportunities in their Member States.

Preparation of the multi-annual work programme 2013-2014 and work programme 2012. The Chair informed the Board about the timeline for preparing the document.

23. Next meeting and closure

The Chair reminded members that the next meeting of the Management Board would be held in Gozo/Malta on March 24-25, 2011.

III. Decisions taken/ Conclusions reached by the Management Board

The Management Board

- approved the minutes of its 19th meeting (MB/M/03/2010).
- adopted the agenda for the 20th meeting (MB/A/05/2010).
- adopted the second amending budget for 2010 (MB/59/2010) and instructed the Executive Director to notify this decision to the Budgetary Authority, the Court of Auditors and the Commission. The amended budget will be published on the Agency's website and in the Official Journal of the European Union.
- took note of the budgetary transfers indicated in document MB/60/2010.
- adopted the updated Work Programme for 2011 (MB/63/2010 rev.01⁷) and instructed the Executive Director to forward it, as amended, to the Member States, the European Parliament, the Council and the Commission and to have it published.
- adopted a revised decision on the financial arrangements for transfer of a proportion of fees to Member States in order to include fee transfers in the context of the authorisation process (Annex 1 to document MB/65/2010⁸), subject to a favourable opinion of the Commission; and instructed the Executive Director to forward the draft decision to the Commission for its opinion.
- appointed the following persons as members of the Committee for Risk Assessment:

Dr. Robert WINKER Mr Pietro PARIS Ms Elodie PASQUIER

Ms Elodie PASQUIER Dr. Benjamin PIÑA

- appointed the following persons as members of the Committee for Socio-economic Analysis with effect from 14 February 2011:

Johanna KIISKI Karine FIORE-TARDIEU Federica CECCARELLI, Vitalius SKARŽINSKAS Åsa THORS

- renewed the mandate of the following members of the Risk Assessment Committee after their current, regular three-year term expires, as indicated below:

Annemarie LOSERT	18 Dec 2010
Karen VAN MALDEREN	18 Dec 2010
Maria ORPHANOU	18 Dec 2010
Riitta LEINONEN	18 Dec 2010

⁷ Subject to additional amendments as indicated in these minutes under agenda item 7.2.

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⁸ The review foreseen in Article 7 shall take place "at the latest" on 31 March 2013

Annick PICHARD	18 Dec 2010
Helmut GREIM	18 Dec 2010
Norbert RUPPRICH	18 Dec 2010
Katalin GRUIZ	18 Dec 2010
Yvonne MULLOOLY	18 Dec 2010
Paola DI PROSPERO FANGHELLA	24 Apr 2011
Normunds KADIKIS	18 Dec 2010
Lina DAUNASKIENE	18 Dec 2010
Hans-Christian STOLZENBERG	18 Dec 2010
Marja PRONK	18 Dec 2010
Maria Teresa BORGES	18 Dec 2010
Céu NUNES	18 Dec 2010
Agnes SCHULTE	18 Dec 2010
Helena POLAKOVICOVA	18 Dec 2010
Bert-Ove LUND	18 Dec 2010
Stephen DUNGEY	18 Dec 2010
Andrew SMITH	18 Dec 2010

- renewed the mandate of the following members of the Committee for Socio-Economic Analysis after their current, regular three-year term expires, as indicated below:

Simone FANKHAUSER	14 Feb 2011
Catheline DANTINNE	14 Feb 2011
Jean-Pierre FEYAERTS	14 Feb 2011
Franz-George SIMON	14 Feb 2011
Lars FOCK	14 Feb 2011
Jean-Marc BRIGNON	14 Feb 2011
Endre SCHUCHTÁR	14 Feb 2011
Cees LUTTIKHUIZEN	14 Feb 2011
Mats FORKMAN	14 Feb 2011
Stavros GEORGIOU	14 Feb 2011

- endorsed the draft multi-annual staff policy plan for the period 2012-2014 as contained in document MB/73/2010 rev.01, and instructed the Executive Director to seek the opinion of the Commission on it.
- adopted the Staff Regulation implementing rule on the performance appraisal of temporary and contract staff as submitted by the Commission on 28 October 2010.

List of agreed follow-up actions

- The Chair of the Board will send a letter to the responsible Commissioners and detailed information on the questions asked and the legal reasoning of the expected new opinion of the Commission Legal Service on the definition of an article under the REACH Regulation.
- The Secretariat will identify the best way of communicating the results of SME status verifications to the Member States concerned.

IV. List of Attendees

Representatives of the Member States

Zoltán ADAMIS (HU)

Maria ALAJÕE (EE)

Aurelija BAJORAITIENÉ (LT)

Karel BLAHA (CZ)

Nina CROMNIER (SE)

Simona FAJFAR (SL)

Arwyn DAVIES (UK)

Helmut DE VOS (BE)

Francis E. FARRUGIA (MT)

Ana FRESNO (ES)

Claude GEIMER (LU)

Mario GRACIO (PT)

Thomas JAKL (AT)

Katarzyna KITAJEWSKA (PL)

Pirkko KIVELA (FI)

Jan Karel KWISTHOUT (NL)

Antonello LAPALORCIA (IT)

Martin LYNCH (IE)

Boyko MALINOV (BG)

Catherine MIR (FR)

Leandros NICOLAIDES (CY)

also acting as proxy of Ms XEPAPADAKI (EL)

Alexander NIES (DE)

Edita NOVÁKOVÁ (SK)

Teodor OGNEAN (RO)

Armands PLATE (LV)

Eskil THUESEN (DK)

Representatives of the Commission

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

(for the second meeting day)

Elke ANKLAM

Independent persons appointed by the European Parliament

Guido SACCONI Hartmut NASSAUER

<u>Individuals from interested parties appointed by the Commission</u>

Martin FUEHR Hubert MANDERY Tony MUSU

Other Observers

Henrik ERIKSEN on behalf of Ms Anne Beate TANGEN (NO)
Ionut GEORGESCU (Expert accompanying Teodor OGNEAN)

Gwenole COZIGOU (European Commission)
Astrid BARTELS (European Commission)
Astrid SCHOMAKER (European Commission)

ECHA staff

Geert DANCET (Executive Director)
Andreas HERDINA (Director of Cooperation)
Jef MAES (Director of Resources)
Jukka MALM (Director of Assessment)

Christel MUSSET (Director of Registration and IT Tools)
Luisa CONSOLINI (Director of Information Systems)

Leena YLÄ-MONONEN (Director of Evaluation)

Jack DE BRUIJN (Director of Risk Management)

Lindsay JACKSON (Head of Unit, Communications)

Pilar RODRIGUEZ IGLESIAS (Head of Unit, Committees and International Relations) for

agenda items 10, 11

Tuula HAKALA (Head of Unit, Finance) for agenda items 4, 5, 6 Mercedes ORTUNO (Chair of the Board of Appeal) for agenda item 13

Ivar LUNDBERGH (Senior Scientific Officer) for agenda item 9

Sari HAUKKA (Registrar of the Board of Appeal) for agenda item 13

Johan NOUWEN (Senior Scientific Officer) for agenda item 16

Minna STROMBERG (Internal audit) for agenda item 14 Ulrike KOWALSKI (Forum team leader) for agenda item 15

Jens DEBUS (Head of Unit, Human Resources) for agenda item 17 Kari KLEMETTI (Information Security Officer) for agenda item 21

Catherine CORNU (Scientific Officer) for agenda item 20 Andrea IBER (Legal Advisor) for agenda item 20

Dana DVORAKOVA (Junior Scientific Officer) for agenda item 22 Erik VAN DE PLASSCHE (Senior Scientific Officer) for agenda item 17

Olli MÄNTYRANTA (Staff Committee) for agenda item 18

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)