MB/M/02/2010 final

MINUTES OF THE 18TH MEETING OF THE MANAGEMENT BOARD held on 22 and 23 June 2010

I. Documents submitted to the Management Board

Draft agenda	(MB/A/02/2010 rev.01)
Draft minutes	(MB/M/01/2010)
Multi-annual work programme 2011-2013	(MB/24/2010)
Opinion of the Agency's final accounts for 2009	(MB/25/2010)
Terms of reference of the working group on audit	(MB/26/2010)
Annual reports of IAS and IAC	(MB/27/2010)
Modification to the IAC Charter (MB/80/2008)	(MB/28/2010)
Draft decision on the classification of services and charges under the Fee Regulation	(MB/29/2010)
Review of the criteria for selecting stakeholder organisations (MB/05/2008)	(MB/30/2010)
Participation of stakeholder representatives at specific dossier related MSC debates	(MB/31/2010)
Consultation procedure for REACH-IT information requests	(MB/32/2010)
Code of Conduct for the members and alternates of the Board of Appeal	(MB/33/2010)
Amendment to the form "Declaration of interests of members and alternates of the Board of Appeal"	(MB/34/2010)
Appointment of Committee members	(MB/35/2010)
Revocation of Committee appointments (Risk Assessment Committee -Art. 5(3) RoP RAC)	(MB/36/2010)
Report from the Executive Director	(MB/37/2010)
Progress report on business continuity	(MB/38/2010)
Declarations of members pursuant to Art 88 REACH – corrigendum to the Annex of the Rules of Procedure	(MB/39/2010)
Establishment of a working group on the transfer of fees in the context of the authorisation procedure	(MB/40/2010)
Status of the preparedness for the 1st registration deadline	(MB/41/2010)

Report from the advisory group on dissemination (MB/42/2010)

Update on preparedness for the authorisation procedure (ECHA, Commission & Member State authorities)

Terms of Reference of the Security Officers Network (MB/43/2010)

Transfers within the budget 2010 (MB/44/2010)

II. Summary Record of the Proceedings

Introductory remarks

The Chair opened the meeting by referring to the 17th meeting of the Management Board which had to be cancelled due to European wide flight restrictions in April 2010. He informed the other Board members, that apart from the written procedures MB/01-04/2010¹, important agenda items from the cancelled meeting were dealt with by means of teleconferences of Management Board working groups.

He confirmed that by a Council Decision of 10 May 2010, Boyko MARINOV has been appointed as a Board member in place of Ekaterina ZAHARIEVA-GECHEVA. His mandate ends on 31 May 2011. By a decision of 12 May 2010, the European Commission has appointed Hubert MANDERY in place of Alain PERROY as a representative of interested parties. Mr MANDERY's appointment ends on 26 June 2011.

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

1. Agenda (MB/A/02/2010 rev.01)

The Chair indicated that several room documents had been made available for the meeting, in particular, proposals from the working group on audit matters regarding agenda items six and seven. The working group had met the day before the meeting in Helsinki to prepare these documents.

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/01/2010*)

The minutes of the meeting held on 04/05 Mach 2010 were approved with some modifications (see corrigendum in the annex).

¹ A full report of the written procedures MB/01-04/2010 was submitted to Board members on 28 April and is avalaible on CIRCA

4. Budget 2010 and 2011

The Executive Director informed the Board of the budget implementation for the current financial year and the state-of-play of the preparations for the budget 2011.

He explained that ECHA is presently reviewing the budget implementation for 2010. This may lead to the submission of an amending budget to the Management Board at its September meeting. With regard to the Agency's cash flow situation, the last estimates were that ECHA will be able to cover its running costs for September and October, even if the income from registrations fees does not increase substantially over the summer. However, if registration submissions will not pick up in September, this may require that the Commission makes available again the outturn of the Agency's budget for 2009 which ECHA plans to reimburse in July. A corresponding request will be sent to ECHA's parent Directorate General, if needed.

As regards the procedure for preparing the EU budget 2011, the Executive Director thanked all Board members who had intervened with their respective ministries or permanent representations to explain the atypical situation of ECHA in 2011 as a fee-financed Agency, meaning the requested additional staff would not result in additional EU expenditure. He acknowledged in particular the active support from ECHA's host country Finland for taking the initative for securing the establishment posts needed in 2011.

The Management Board took note of the information provided.

5. Multi-annual work programme 2011 - 2013 (*MB/24/2010*)

The Executive Director presented the final draft of the multi-annual work programme 2011-2013. The programme is updated on a yearly basis and a draft had been endorsed by the Management Board in March 2010 before being submitted for public consultation in March-May 2010. Seven comments were received from non-governmental organisations, companies, industry associations and private individuals. The final draft took these comments into account.

During a subsequent exchange of views, Board members referred to the impact of the Commissioners' agreement on the proposed schedule for the identification of substances of very high concern (SVHC). Further issues addressed were the use of REACH data for other regulatory purposes, the cumulative effects of chemical substances of concern, and the Agency's perspective for complying with the EMAS² standard.

The Executive Director answered these questions, explaining that the baseline figures for authorisation contained in the annex to the work programme are compatible with the agreement of the Commissioners. Furthermore, he acknowledged that the issue of the cumulative effects of chemicals requires close monitoring by ECHA in the future.

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² European Eco-Management and Audit Scheme.

The Management Board agreed to the Secretariat's proposal to take the outcome of the public consultation into account. In addition two minor changes were decided upon³.

The Management Board adopted the multi-annual work programme 2011-2013.

6. Opinion on the Agency's final accounts 2009 (*MB*/25/2010)

The Chair announced that ECHA's accounting officer, who is appointed by the Management Board, was participating in the meeting for this agenda item. He then informed the Board of a room document (MB/25/2010 Annex rev.01) which had been prepared by the working group on audit matters, the day before the meeting. As announced before the meeting, the room document contained a proposal for a Management Board opinion on the final accounts.

The Chair announced that, in accordance with the Financial Regulation of the Agency, the Executive Director had finalised the accounts and submitted them to the Management Board after having received the preliminary observations of the Court of Auditors on the provisional accounts.

The floor was then given to the Executive Director who explained the regulatory context of the required decision and gave an overview on the structure and content of the final accounts. He also outlined the draft reply of ECHA on the observation made by the Court of Auditors on the carry-over of budget appropriations from 2009 to 2010, agreeing that the figures indicate that the Agency was faced with some unforeseen delays in the implementation of some of its activities and contracting, resulting in the carry-over and some cancellations of appropriations. He assured the Board that ECHA would continue to further develop the planning and monitoring of its work and resources.

Subsequently, the floor was given to the Co-Chair of the working group on audit matters, Karel BLAHA, who presented the proposal for the opinion on the accounts prepared by the working group. He emphasised that the content of the preliminary observations by the Court of Auditors were highly appreciated by the working group and provide assurance as to the reliability of the annual accounts and the legality and regularity of the underlying transactions.

The Chair then opened the floor for comments. Board members agreed with the evaluation of the working group. With regard to the observation made by the Court of Auditors, it was acknowledged that the nature of ECHA's business makes it difficult to strictly adhere to the 'annuality' principle, for example due to the development of large IT applications. In order to highlight the Agency's intention to improve in this area, the Board agreed on an addition to the draft Management Board opinion⁴.

The Management Board took note of the ECHA final accounts for 2009 and adopted its opinion on them.

⁴ Adding "and also the Agency's intention to bring down the proportion of carry-over significantly in 2010." To the last paragraph on page 2 of room document MB/25/2010 Annex 1 rev.01.

³ On page 14: "minimise" was replaced with "avoid unnecessary"; on page 20: the number of substances on the candidate list was updated in the first paragraph (30 substances instead of 29).

7. Audit related agenda items (MB/26/2010; MB/27/2010; MB/28/2010)

The Chair informed the other Board members that the working group on audit matters had decided that he himself and Karel BLAHA shall act as co-chairmen of the group.

He then gave the floor to Karel BLAHA to present the draft Terms of Reference of the working group, agreed at the meeting the day before the Management Board. The draft was made available as a room document (MB/26/2010 Annex rev.01).

Subject to two editorial changes, the Management Board approved the Terms of Reference of its working group on audit matters.

Following this, Karel BLAHA informed the Board of the working group's findings on the two audit reports submitted to the Board for information: the annual report of the Commission's Internal Audit Service for ECHA and the annual report of ECHA's Internal Audit Capacity.

The Board took note of the information provided.

Furthermore, the Board approved an amendment to the Charter of the Internal Audit Capability, in order to align the Charter with the revised mission charter of the Commission's Internal Audit Service in relation to Agencies. The latter mission charter was endorsed by the Board at its meeting of December 2009.

8. Draft decision on the classification of services and charges under the Fee Regulation (MB/29/2010)

The agenda item was presented by the Executive Director.

He reminded Board members of the background of the requested decision which will impose an administrative charge if a company claims wrongly that it is entitled to the reduced fee applicable to smaller and medium sized companies (SMEs), or to a full fee waiver. An assessment of registration dossiers submitted in 2009 had shown the need to verify this aspect in more detail. As it is foreseen in the Fee Regulation (EC) No 340/2008, the workload resulting from this verification is to be compensated by an administrative charge. Moreover, the draft Decision would allow the levying of a service charge in situations where companies request certain services which are not foreseen in the REACH Regulation.

The underlying principles of the draft Decision were subject to a written procedure after the cancellation of the 17th meeting of the Management Board (MB/WP/04/2010). Based on the feedback received from Board members, the Secretariat finalised the draft decision and included a proposed scale of charges. The Executive Director recalled that during the written procedure, a majority of Board members supported the proposal, even though the necessary qualified majority was not attained due to concerns regarding whether the administrative charge may legitimately have a discouraging element. The proposal presented to the meeting was therefore based on the principle of full cost recovery for ECHA without an additional discouraging element.

The Executive Director clarified that the administrative charge would only be one part of a broader strategy to ensure that the SME rebate is claimed correctly by companies and a negative impact on Agency revenues avoided. In parallel to the administrative charge, ECHA will provide tools for self-verification of SME status and promote awareness amongst stakeholders. He further clarified that the draft Decision foresees that ECHA levies the administrative charge only once per legal entity, irrespective of the number of registrations submitted, and applies a reduced charge for SMEs⁵.

This was followed by an extensive exchange of views during which many Board members welcomed the proposal. With regard to the discouraging element of the administrative charge, the Board acknowledged that ECHA has no mandate in this regard. It was also noted that not all national penalty systems allow for a fine in cases of submission of false information on a company's status.

A discussion took place on the principle of full cost recovery upon which the draft Decision is based. As a result of the application of this principle, ECHA will recover the total (workload) costs incurred by the Agency related to the verification exercise from those companies identified as submitting false information. Whilst supporting ECHA's initiative, some Board members raised doubts about whether the resulting scale of charges would be in line with the principles set out in the Fee Regulation. Many other Board members supported the decision without this reservation.

A representative appointed by the Commission to represent interested parties raised doubts whether ECHA could apply a service charge in situations where a lead registrant is exchanged after a successful joint submission. In reply to this, the Executive Director pointed to the additional workload triggered by such a lead registrant exchange and emphasised that ECHA will always agree on the maximum amount of service charges before delivering the service.

Taking into account the discussions at the meeting, the Board agreed upon a change to the draft Decision in order to remove potentially misleading references to possible national fines⁶. Furthermore, it was concluded that the draft Decision should be forwarded to the Commission for its required opinion with explicit reference to the principle of full cost recovery. This shall allow the competent Commission services to assess this aspect in particular. It was also agreed that the review of the scale of charges should be done on a continuous basis.

On this basis, the Management Board adopted the draft Decision on the classification of services and charges under the Fee Regulation subject to the favourable opinion of the Commission.

⁶ Recital ("Whereas") five of the intial draft Decision annexed to MB/29/2010 was removed and instead a reference to Recital 11 of the Fee Regulation (EC) No 340/2008 added to the introductory part.

⁵ The Executive Director introduced a room document with a new version of the annex to the Management Board draft Decision MB/29/2010 adding a reduced administrative charge also for micro-sized companies to cover cases of Article 74.2 of the REACH Regulation (EC) No 1907/2006.

9. Review of the criteria for selecting stakeholder organisations (*MB/30/2010*)

The Director for Cooperation presented several proposed amendments to the criteria for selecting stakeholder organisations to participate in ECHA's work. The initial criteria were approved by the Management Board in February 2008 and since then applied by the Secretariat. The main change to the initial criteria was to allow for more flexibility as regards the minimum number of Members States in which the organisations must be represented.

During an exchange of views, one Board member emphasised the importance of maintaining sufficiently high thresholds for the eligibility of stakeholder organisations. Other Board members asked for clarification as regards the consequences for organisations that have been identified as eligible.

In reply to this, the Executive Director emphasised that it is in the Committees' remit to decide which organisations are invited to meetings and presence on the list as such does not create any immediate rights for an organisation. ECHA would like to be able to distinguish between those stakeholder organisations that have a general interest in ECHA's work and those that are more specifically concerned by the Agency's work. As regards a sufficiently high threshold for eligibility, reference was made to the criterion of "legitimate interest in the areas of work of ECHA".

Two Board members appointed by the Commission to represent interested parties inquired about a specific non-governmental organisation which should, in their view, also become eligible when applying the revised criteria. The Director for Cooperation agreed to look into the matter. He clarified that, following the required agreement of the Commission to the new criteria, stakeholder organisations not considered eligible thus far will be invited to resubmit their applications.

The Board approved the revised criteria subject to the Commission's agreement⁷. The Chair invited the Secretariat to inform the Board at a future meeting on how the new criteria have been applied and what experiences have been noted.

10. Participation of stakeholder representatives at specific dossier related MSC debates (MB/31/2010)

The Director for Cooperation introduced the agenda item. Similar to the draft decision on the charges under the Fee Regulation (agenda item 8), an initial version of the meeting document had been subject to a written procedure after the cancellation of the April 2010 Management Board meeting, and had received the support of a majority of Management Board members – even though the required qualified majority of members with voting rights was not attained. The document presented to the meeting took account of the outcome of the written procedure.

The Director emphasised the importance of adequate stakeholder involvement for the credibility and accountability of the Agency's decision making process and referred to the safeguard measures in place to protect confidential information from inappropriate disclosure.

 $^{^{7}}$ A clarifying addition was still made to criterion 3 listed under heading 4 of meeting document MB/30/2010 by addding: "in the EU/EEA".

On the request of Board members, the members of the Member State Committee were consulted at the Committee meeting of June 2010 on their views regarding the participation of stakeholder representatives at Committee meetings. The Chair of this Committee gave a report to the Board on the outcome of the Committee's deliberations on this matter. The Committee's conclusions were also made available as a room document.

Following this introductory presentation, the Chair summarised the scope of the requested action by the Management Board. He emphasised that the proposals made would require changes to the Member State Committee's rules of procedure. The Board's involvement at this stage would thus mainly consist in providing guidance to the Committee as regards the attendance of stakeholder and case holder representatives at meetings, their right to intervene orally at the meetings, the admittance of accompanying experts, and the availability of meeting documents.

This was followed by an exchange of views during which numerous Board members intervened. Many members referred to the sensitive balance between the necessary protection of confidential business information and a transparent decision making process. In general, Board members expressed support for the approach taken by the Member State Committee which suggested certain modifications to the proposal by the ECHA Secretariat, for example the proposal to differentiate between a discussion stage and a decision making stage and admit stakeholders and case owners on equal terms for the first phase.

One Board member was of the view that an obligatory participation of stakeholders in the Committee's work was not intended by the legislator, arguing that the REACH Regulation provides only for the possibility to invite stakeholder representatives to Committee meetings.

Whilst agreeing in principle to the approach by the Member State Committee, representatives of the European Commission referred to Article 108 of the REACH Regulation as applicable for the general question of stakeholder participation in Committee meetings. This would not be in contradiction to Article 85(4). On this question, another Board member expressed a wish for further clarification.

Two Board members appointed by the Commission to represent interested parties referred to the positive experiences of stakeholder participation at Committee meetings thus far, and the efficient safeguard measures in place to protect confidential information. It was argued that the good experience and the trusting cooperation between the Committee and stakeholder observers would not require formalisation through a change to the rules of procedure.

Based on an intervention by a member, the Board took the view that case—owner representatives should also sign a confidentiality declaration in order to protect the secrecy of Committee deliberations as such.

The Chair of the Member State Committee agreed to this and explained that the Committee had already considered how confidential information can be systematically protected and what public information can be made available to observers in order to follow the deliberations.

With regard to the procedural question of whether Article 108 of the REACH Regulation would be applicable, the Board was informed that Article 85(4) of the Regulation would deal

specifically with the invitation of stakeholder observers by Committee members without requiring the Committee to seek the prior agreement of the Commission.

Following a proposal by the Chair of the Management Board, it was eventually agreed not to formally endorse a approach on stakeholder involvement in Committee meetings at this stage, but to invite the Member State Committee to provide the Board with a revised set of Rules of Procedure on the participation of stakeholder and case-owner representatives as observers, based on the Committee's conclusions on the matter. The following aspects should be taken into account when preparing the revised rules:

- protection of confidential business information shall be safeguarded while maintaining at the same time a high degree of transparency;
- experts shall accompany representatives only if that would add value to the procedure;
- the procedure shouldn't increase the workload of the Agency and the workability of the procedure should be borne in mind;
- the rules shall distinguish between a hearings phase and a decision-making phase.

Based on the experiences noted, the Committee should then be invited to re-evaluate the approach after one year.

11. Consultation and referral procedure for REACH-IT data information requests (MB/32/2010)

The Management Board received a presentation from the Secretariat of the Management Board on a consultation and referral procedure for requests for access to environmental information or access to documents or other information contained in REACH-IT.

The procedure laid out a structured application of the relevant provision described in the Security Declaration signed by the legal representatives of each entity with access to REACH-IT.

The Management Board agreed on some modifications to the proposed procedure annexed to the meeting document, namely: an explicit reference to the Member State's competence to eventually reply to requests after consultation with the Agency; the replacement of the words "right of access" with "procedure" at the beginning of the second paragraph of Article 1; and the addition of a new fourth paragraph in Article four, regarding situations in which a decision on a confidentiality claim is pending⁸.

On that basis, the Management Board adopted the consultation and referral procedure for REACH-IT data information requests.

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⁸ The new paragraph reads: "4. If a request covers information where a decision under Article 119(2) of the Regulation (EC) 1907/2006 is pending, the Agency will inform the requesting authority accordingly and strive to take the decision as soon as possible."

12. Code of conduct for the members (regular/alternates/additional) members of the Board of Appeal (MB/33/2009; MB/34/2010)

The Management Board heard from the Chair of the Board of Appeal who presented a code of conduct for the members of the Board of Appeal and their alternates/additional members. The development of this code stemmed from a request from the Management Board in September 2009 when it was felt necessary to provide guidance on potential conflicts of interests to the alternate/additional members of the Board of Appeal who do not pursue this function as their main occupation⁹. Linked to the establishment of this code of conduct, the Chair of the Board of Appeal presented a proposal for amending the form for declarations of interest by members and alternates of the Board of Appeal.

The Chair of the Management Board thanked the Chair of the Board of Appeal for the presentation and the open manner of interaction with the Management Board.

In a subsequent exchange of views, a Management Board member inquired whether information according to Article 5 of the code should not always be provided on a mandatory basis and in written form. The Board member also proposed the establishment of a stronger link between the code of conduct and the declaration of interest signed by all members of the Board of Appeal¹⁰.

Another Board member referred more generally to the working methods of the Board of Appeal and the cooperation with the Secretariat and Committees. Other aspects addressed included the workload of the Board of Appeal and the budgetary implications of the appeal procedure.

A representative of the Commission noted a rising public interest in the work of the Board of Appeal. With regard to cooperation with the Committees, he asked for careful consideration of this option which would serve as only one of many ways to achieve effective information exchange and which involves fundamental aspects of the status of the Board of Appeal.

In reply to this, the Chairwoman of the Board of Appeal thanked the Board for the useful comments and indicated that these will be carefully considered by the Board of Appeal during the next revision of the code of conduct. With regard to the information referred to in Article 5, she mentioned that it was the intention to avoid unnecessary formalities. Written information would in practice be most likely the standard. Referring to the cooperation with the Secretariat and the Committees, she emphasised the need for the Board of Appeal to understand ECHA's processes in order to be able to exercise the full range of decisions in its legal remit and to prepare itself.

The Executive Director outlined the resource planning for Registry of the Board of Appeal as it is contained in the multi-annual work programme. In the light of the factual number of appeals in the coming years, this planning would be adjusted. With the presently planned fitting of the Registry and the Board of Appeal, it is estimated that a maximum of 65 appeals per year could be handled.

of minutes of the meeting of the Management Roard of 29/30 Sentember

⁹ Cf minutes of the meeting of the Management Board of 29/30 September 2009 (MB/M/04/2009 final), point 7. ¹⁰ It was proposed to delete paragraph 2 of Article 1 of the code of conduct. With regard to the declarations it was clarified that they are available for the public in a register at the Agency's premises, as foreseen in the REACH Regulation.

The Chair concluded that the Management Boards remarks on the code of conduct should be taken into consideration during its next revision. He emphasised, however, that the Board encourages the members and alternates of the Board of Appeal to document any possible conflict of interest in writing to the Chairman of the Board of Appeal, even in cases when this is not explicitly foreseen in the code.

With regard to the cooperation between the Secretariat, the Committees and the Board of Appeal, the Chair agreed with the representative of the Commission and concluded that further reflection on the matter would be needed. He invited the Secretariat to look into the issue with a positive attitude and equip the Board at one of its future meetings with a background documents on the consequences and implications of the involvement of the Board of Appeal in the daily work of the ECHA Secretariat and the Committees.

The Management Board endorsed the code of conduct for the members and alternates of the Board of Appeal and approved the amended version of the annual declaration of interests for the regular and alternate / additional members of the Board of Appeal.

13. Appointment of Committee members (*MB/35/2010*)

Following nominations from Romania, Italy and Ireland on 20 May, 25 May and 4 June, the Management Board appointed

- Ms. Maria OLTEANU as a member of the Risk Assessment Committee and
- Ms. Silvia GRANDI and Ms. Marie DALTON as members of the Socio-Economic Analysis Committee.

14. Revocation of a Committee appointment for the Risk Assessment Committee (*MB/36/2010*)

In agreement with the nominating Member State authority and the Board member representing the respective Member State, the Management Board revoked the appointment of Mr. Milan PAULOVIC as a member of the Committee for Risk Assessment in accordance with the Committees Rules of Procedure.

15. Report of the Executive Director (*MB/37/2010*)

The Board took note of the report of the Executive Director on the Agency's activities in April and May 2010. Board members thanked the Executive Director for the report and the assurance it provides in a crucial phase of the implementation of REACH.

Several Board members used the following exchange of views to report on issues of concern related to REACH and CLP implementation from the point of view of national authorities and industry. Aspects addressed from an authority point of view included the Member States access to REACH registration data, the moratorium for registration related Guidance

documents, the scope of dossier evaluation decisions, the lessons learned from the "borates" opinion of RAC, and the resource implications of the potential biocides tasks for ECHA.

Reporting on industry feedback, Board members mentioned requests to include a Business Rule checking routine into the – much welcomed – Technical Completeness Check (TCC) tool, or to enlarge the business hours for REACH-IT. Other issues addressed were compatibility questions linked to new versions of IUCLID 5, and Helpdesk support in general and for IUCLID and SMEs in particular. The still not fully satisfactory situation in SIEFs was also mentioned by a Board member.

The Executive Director and ECHA directors replied to the interventions. With regard to registration data, it was clarified that all MSCAs have access to it with the exception of PPORD notifications from other Member States. ECHA operates a Helpdesk for Member States for the use of REACH-IT which can be contacted if the data cannot be retrieved properly. On the Business Rules check inclusion into the TCC tool, it was announced that the next release will include part but not all Business Rule routines. This will be complemented by manuals and webinars available on the ECHA website.

Clarification was also provided on the future compatibility of earlier versions of IUCLID 5 – in particular assurance was provided that ECHA will strive to avoid any difficulties for companies – and on the business hours of REACH-IT. The latter are currently 24h during weekdays and will be expanded to weekends if the need arises.

With regard to Helpdesk support to industry, the Executive Director informed the Board that ECHA has taken up a telephone service for lead registrants and will accelerate the response time before the November deadline, as was done during pre-registration. He emphasised the crucial role of national helpdesks, also for enquires on REACH-IT by SIEF members.

The Management Board took note of the information provided.

16. Progress report on business continuity (*MB/38/2010*)

The Head of the Executive Office and Security Manager at ECHA provided an update on the progress made by ECHA in implementing a business continuity concept which ensures the continuity of operations and availability of data in the event of a crisis.

On the request of Board members, it was explained that a Security Committee exists at ECHA which is in charge of the coordination of business continuity.

The Management Board took note of the information provided.

17. Declaration of members pursuant to Article 88 of REACH – corrigendum to the annex of the rules of procedure (*MB/39/2010*)

The Board adopted a corrigendum to the annex of its rules of procedure containing the form for the annual declaration of interest according to Article 88 of the REACH Regulation (EC) No 1907/2006. The corrigendum brought the annex in line with the provision in the enacting terms of the rules which foresee the publication of the declarations on the internet.

18. Establishment of a Management Board working group on the transfer of fees in the context of the authorisation procedure (*MB/40/2010*)

The Director for Assessment introduced a proposal to establish a Management Board working group on the transfer of fees in the context of the authorisation procedure. He explained the task of this temporary working group which will consist of preparing a proposal for including the reimbursement of rapporteurs from the Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) Committees for authorisation applications, in the existing Management Board decision on the transfer of fees for restriction and substance evaluation tasks (MB/20/2009 final). Pursuant to the Fee Regulation, the decision by the Management Board will be taken in agreement with the Commission.

The Chair thanked the Director for Assessment for the introduction and proposed to reestablish the former working group that had prepared the existing decision on the transfer of fees. This was agreed with the modification that the representative of Italy offered to join the group.

The Board established a working group on the transfer of fees to Member States composed of the representatives from DE, IT, SE, UK, the Commission (Mr ZOUREK) and the Executive Director (chair). The mandate of the group is to develop a proposal for the Management Board on how the existing decision on the transfer of fees (MB/20/20009 final) should be amended in order to integrate the remuneration of RAC and SEAC rapporteurs for their work on delivering draft opinions on applications for authorisation (and respective reviews) for these Committees.

19. Status of the preparedness for the first registration deadline (MB/41/2010)

The Management Board heard a report by the Executive Director on the status of the preparedness for the first registration deadline and the progress made by the Directors' Contact Group (DCG) for the first registration deadline, in which he participates on behalf of ECHA.

The subsequent exchange of views centred on the need to coordinate the work of the DCG more closely with Member States, and to consult national authorities appropriately. While appreciating the work of the DCG as a significant contribution to making the first registration deadline a success, it was stressed that the conclusions reached should not try to influence decisions lying within the responsibility of Member States.

In reply to a remark from a Board member, the Executive Director confirmed that ECHA will enhance its interface and coordination with Member State authorities. In addition to the Secretariats of the Committees, the Forum and the Management Board, the Executive Office will in future provide a focal point for Member State Competent Authority relations. In this context, the Executive Director mentioned the difficulties experienced by the Secretariat in establishing a list of nominated competent authorities and their contact points.

The Chair concluded that the meeting of the Competent Authorities for REACH and CLP (CARACAL) would be the right forum in which to discuss the details of the work of the DCG. The Management Board would continue to monitor and to develop guidance on ECHA's role in the group which would in particular consist of a strong coordinating role and in spreading information on the relevant conclusions reached. Overall, the Chair noted that the Management Board appreciated the progress made by the group.

The Management Board took note of the information provided.

20. Report from the advisory group on dissemination of information to the public (MB/42/2010)

Ethel FORSBERG, Chair of the advisory group on dissemination of information to the public informed the other Board members of the recent activities of the group and the progress made by ECHA with the dissemination project. The group met in February for a meeting in Helsinki and held a teleconference in April. In addition, the Deputy Chair of the Management Board participated as a member of the group at a panel on dissemination at the ECHA Stakeholder Day on 19 May¹¹.

Ms FORSBERG reported that information on approximately 170 substances is currently disseminated on the ECHA webpage and new substances added regularly. An important development which will in future facilitate the faster addition of new substances was the publication of a practical guide for companies on 20 April, explaining what information from registration dossiers is disseminated. Based on a draft policy developed in cooperation with the advisory group, ECHA will launch the assessment of confidentiality claims and report back on the experiences made.

Ms FORSBERG mentioned that her mandate as a Board member will soon cease and she will thus not be able to continue her function as chair of the advisory group.

The floor was then given to the Executive Director to provide more detailed information on the current status and planning for the dissemination project and the start of the confidentiality claim assessment. He announced that ECHA will soon make an IT tool available which will allow registrants to easily verify what information from their dossiers will be made public 12.

The floor was then opened for contributions from members of the advisory group. All members acknowledged the good progress made with the dissemination project and the constructive working atmosphere.

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¹¹ Video of the session available at http://echa.europa.eu/news/events/4th_stakeholders_day_en.asp.

 $^{^{12}}$ NB: The IT tool was made avaiable on 30 June 2010.

With regard to Ms FORSBERG's reference to open discussions on the scope of the dissemination project, two members appointed by the Commission to represent interested parties referred to discussions in the group on the dissemination of the name of the registrant and voiced doubts regarding the position of the ECHA Secretariat to disseminate information on substances only, not on registrants. Other members of the working group, including a Commission representative agreed that further discussion on this and other aspects of a principle nature will be needed while noting the constructive and promising developments of the working group's deliberations.

On behalf of the Management Board, the Chair thanked the advisory group, in particular Ms FORSBERG, for the work done and the quality of reporting back to the full Board.

It was clarified that the advisory group will select a new chair at its next meeting. As regards the composition of the group, it was concluded that Sweden will continue contributing to the work through its incoming new Board member. Mr MANDERY will take over the position of Mr PERROY.

The Management Board took note of the information provided.

21. Update on the preparedness for the authorisation procedure (MB/RD/02/2010)

The Chair informed the other members that the agenda item was proposed by a Board member representing a Member State. The Secretariat had prepared a room document for this purpose which took into account the discussions at the CARACAL meeting of June 2010.

The Director for Assessment presented the state of preparedness at ECHA for the authorisation procedure. ECHA's activities are focused on actions in terms of advice to potential applicants, tools for the development and submission of applications to ECHA, internal and Committee procedures, fee collection and the transfer of a proportion of the fees for the work of Committee rapporteurs (see point 18 above), and communication on the authorisation process.

The Director reported also on other developments linked to the authorisation process, such as the announcement by the responsible European Commissioners of the reinforcement of their commitment to the implementation of REACH, with special focus on the authorisation procedure, and the endorsement of the Guidance document on authorisation applications by CARACAL which will now be published in the Official Journal of the European Union and subsequently handed over to ECHA. It was emphasised that the potential impact of this development needs to be considered by ECHA when planning the workload and resource needs related to authorisation. As regards the identification of SVHCs, the Commissioners have agreed on a roadmap for the inclusion of 106 priority substances by 2012. ECHA has resources to prepare dossiers for 15 of these substances and expects a request, before the summer, by the Commission to develop dossiers for five substances.

The following discussion centred on the potential for reinforced ECHA and Member State contributions in the identification of SVHC, including through partnerships and best practice exchange.

The Executive Director informed the Board that the ECHA resource planning for SVHC identification on behalf of the Commission is in line with the Commissioners' approach, but does not allow for more engagement without negatively affecting other core processes.

The Chair proposed that ECHA should consider functioning as a clearing house to support Member State activities on SVHC identification, in particular by contributing to a newly established CARACAL working group.

It was concluded that continued efforts on the identification of SVHCs need to be jointly undertaken by ECHA and Member State authorities. The Management Board invited the Secretariat to play an active role in this field and noted the willingness of several Member States to share their experiences and to provide support to other authorities.

22. Terms of Reference of the Security Officers Network (*MB/43/2010*)

The Board was informed by the Head of the Executive Office about Terms of Reference agreed upon by the Security Officers Network (SON). The SON was originally created by the Commission as a subgroup of the REACH Competent Authorities meeting and handed over to ECHA in November 2007.

One Board member referred to the lack of clarity about the tasks and the role of the SON. Subsequently several board members expressed their wish to revisit the Terms of Reference and verify if the level of detail of the procedural provisions shall be maintained. It was also questioned whether the Management Board should formally adopt the Terms of Reference.

The Executive Director replied to these remarks. He highlighted that ECHA operates other networks, including the HelpNet which are not formally created by the Management Board. Even though the SON is giving advice on important security matters, including on deviations from the REACH-IT Standard Security Requirements, the eventual decision will always be taken by himself and under his responsibility as Executive Director. The reason for creating the formalised Terms of Reference for the SON and bringing them to the attention of the Management Board was the specific role which was assigned to the network by decision of the Management Board when endorsing the REACH-IT Security Declaration in November 2009.

A discussion took place on whether the Management Board needs to formally adopt the Terms of Reference. In this context it was stated that the ongoing technical work of the SON is important for Member State authorities that have access to REACH-IT. A Board member noted the very positive experiences in his national authority of cooperation with the SON. It was concluded that the SON should continue to operate for a period of 2 years based on the present Terms of Reference. For the December Board meeting , the Secretariat was asked to prepare at the occasion of its next meeting a two-year work programme for the SON and possibly an improved set of operating rules.

23. Transfers within budget (*MB/44/2010*)

The Management Board took note of a budget transfer carried out under the responsibility of the Executive Director.

24. Any other business

Report from the 2nd meeting of the Chairs of the Management Boards

The Deputy Chair gave a report from the 2nd meeting of the Chairs of Management Boards of European Union agencies which took place on 29 May 2010 in Amsterdam. The main topic on the agenda was the evaluation study on agencies which is done under the responsibility of the Commission. The next meeting will take place on 5 October 2010.

Annual appraisal of the members of the Board of Appeal and the Executive Director
The Chair mentioned that he has duly received the positive annual appraisal reports 2009 for
the members of the Board of Appeal and the Executive Director signed by the reporting
officers designated by the Management Board

Shortlists for a technically qualified member and an alternate chair of the Board of Appeal The Chair informed the Board that he has received shortlists from the Commission for the position of a technically qualified member and an alternate Chair of the Board of Appeal. As in the past, a selection group composed of three Management Board members will be mandated to assess the candidates and make a proposal for appointments. It was agreed that the interviews shall be performed by the same group that did the selection of the present members and alternates / additional members (Deputy Chair, DE, and Commission ENV). Thereby, only one of the reporting officers for the Board of Appeal, who are responsible for the probationary reports and regular annual appraisals, will be involved in the selection procedure. As in the past this was deemed appropriate for facilitating the objectivity of the appraisal exercise.

Readiness of the national REACH and CLP Helpdesks

With regard to the upcoming regulatory deadlines under REACH and CLP, the Executive Director mentioned that ECHA would like to review the readiness of the national REACH and CLP Helpdesks together with the Member States. He invited Board members to liaise within their Member States and report on the status in their country to ECHA for a meeting of the HelpNet in September. ECHA will provide a questionnaire for the national helpdesks. The matter will then be included in the agenda for the September Management Board meeting.

In this context, reference was made to the Member State reports on the implementation of REACH in their territory which were to be submitted to the Commission by 1 June 2010¹³. Commission representatives explained that, once the complete set has reached the Commission and has been evaluated, the results will be shared with CARACAL.

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¹³ Article 117(1) of the REACH Regulation (EC) No 1907/2006.

Renewal of Committee appointments / future workload of Committees

The Director for Cooperation announced that the Executive Director will send letters to the Member State Competent Authorities on the need for more engagement in the increasing work of the Committees, in particular the Risk Assessment Committee.

A letter will also be sent to the Permanent Representations on the need to renew the first Committee appointments in 2010 / 2011. On this, a Board member raised the question of implications of the exchange of a Committee member who is a rapporteur for a pending procedure. The Director for Cooperation undertook to bring this question to the attention of the Chairs of the Committees.

Participation of Board members in Quality Steering Committee

It was noted that Francis FARRUGIA (MT) will replace Alain PERROY in the ECHA Quality Steering Committee which will report to the next Management Board meeting.

Discharge 2008

The Chair could announce that the European Parliament has granted a discharge to the Executive Director for the financial year 2008.

Follow-up of the visit from the European Parliament Committee for Environment Public Health and Food Safety (ENVI) in April 2010

The Board was informed in the context of the report of the Executive Director of a request from the Committee for technical advice related to the Commission proposal for a regulation on the placing on the market of biocidal products.

The Executive Director informed the Board of another issue that was followed up by MEPs after a visit from the ENVI Committee to Helsinki. MEPs were surprised that no permanent subsidy is foreseen for ECHA, despite uncertainties, and contacted the Commissioners responsible for REACH and CLP accordingly. Following this, an exchange of letters between ECHA and its parent Directorate General took place; these were made available as room documents for internal information.

Potential future tasks for ECHA

A Commission representative provided an update on recent developments on the legislative procedure on the new EU biocides regulation where discussions in Council and Parliament tend towards enlarging the scope of the centralised authorisation procedure for which ECHA is foreseen to be in a coordinating role.

The Board was informed that the Commission services are also looking into the future responsibility for notifications under the PIC Convention¹⁴. The Joint Research Centre will discontinue this activity. ECHA could be charged with this task. This would, however, require a formal Commission proposal under the ordinary legislative procedure and a financial statement with resource estimates.

Meeting dates in 2010 / 2011

The Chair reminded Board members that the December meeting will take place one week later than originally foreseen, 16-17 December 2010. He also informed that the Board has been invited by the Maltese authorities for the March 2011 meeting.

¹⁴ Prior Informed Consent (PIC) procedure under the Rotterdam Convention

25. Next meeting and closure

The Chair reminded members that the next meeting of the Management Board would be held in Helsinki on 30 September and 1 October 2010.

The Management Board bid farewell to Ms FORSBERG who will be replaced as a Board member and thanked her for the active contribution she had made to the building up of the Agency.

III. Decisions taken/ Conclusions reached by the Management Board

The Management Board

- approved the minutes of its 16th meeting contained in document MB/M/01/2010, subject to the amendments indicated in the corrigendum attached to the present minutes.
- adopted the agenda for the 18th meeting as contained in MB/A/03/2010 rev.01.
- adopted the multi-annual work programme of the Agency for 2011-2013 as contained in MB/24/2010 subject to the modifications indicted in these minutes, and instructed the Executive Director to forward the multi-annual work programme to the Member States, the European Parliament, the Council and the Commission and to have it published on the ECHA web site.
- adopted its opinion on ECHA's final accounts for the financial year 2009, as contained in document MB/25/2010 Annex <u>rev.01</u>, subject to a modification indicated in these minutes, and instructed the Executive Director to forward the accounts and the opinion by 1 July 2010, at the latest, to the European Parliament, the Council, the Commission, and the Court of Auditors.
- approved the Terms of Reference of the working group on audit as contained in document MB/26/2010 Annex rev. 01.
- approved the revised Charter of the ECHA Internal Audit Capability (MB/80/2008) as contained in document MB/28/2010.
- adopted subject to a favourable opinion of the Commission a draft decision in accordance with Article 11(5) of the Fee Regulation (MB/29/2010 Annex 1 with a modification agreed at the meeting and indicated in these minutes.); and instructed the Executive Director to forward the draft decision to the Commission for its opinion.
- approved the changes to the criteria for selecting stakeholder organisations to participate in ECHA's work as contained in document MB/31/2010 subject to the agreement of the Commission, and instructed the Executive Director to forward the revised criteria to the European Commission for agreement.
- adopted a procedure for consulting on and referring requests for access to data contained in REACH-IT as annexed to document MB/32/2010, subject to the modifications indicated in these minutes.
- endorsed the Code of Conduct as adopted by the Board of Appeal and annexed to document MB33/2010.
- approved the amended version of the annual declaration of interests of regular members and alternate/additional members of the Board of Appeal of ECHA as annexed to document MB/34/2010.

- appointed Ms. Maria OLTEANU as a member of the Risk Assessment Committee and Ms. Silvia GRANDI and Ms. Marie DALTON as members of the Socio-Economic Analysis Committee.
- revoked the appointment of Mr. Milan PAULOVIC as a member of the Committee for Risk Assessment in accordance with Article 5(3) of the Committees Rules of Procedures
- adopted the proposed corrigendum to its Rules of Procedure as annexed to document MB/39/2010.
- established a working group on the transfer of fees to Member States composed of the representatives from DE, IT, SE, UK, the Commission (Mr ZOUREK) and the Executive Director (chair). The mandate of the group is to develop a proposal for the Management Board on how the existing decision on the transfer of fees (MB/20/20009 final) should be amended in order to integrate the remuneration of RAC and SEAC rapporteurs for their work on delivering draft opinions on applications for authorisation (and respective reviews) for these Committees.

List of agreed follow-up actions¹⁵

- Any interpretations of the REACH-IT Security Declaration which may result from bilateral discussions with Member States will be shared with the entire Board.
- The Secretariat will continue to report regularly on the progress of IT system development.
- The Secretariat will regularly inform the Board about the progress achieved in the various fora dealing with nano-materials at the EU level.

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¹⁵ also from previous meetings if pending.

- IV. List of Attendees

Representatives of the Member States

Zoltán ADAMIS (HU)

Maria ALAJÕE (EE)

Aurelija BAJORAITIENÉ (LT)

Karel BLAHA (CZ)

Marta CIRAJ (SI)

Arwyn DAVIES (UK)

Helmut DE VOS (BE)

Francis E. FARRUGIA (MT)

Ethel FORSBERG (SE)

Ana FRESNO RUIZ (ES) also acting as proxy of Fernanda SANTIAGO (PT)

Claude GEIMER (LU)

Thomas JAKL (AT) also acting as proxy of Per NYLYKKE (DK)

and Guido SACCONI (EP)

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)

Alexander NIES (DE)

Edita NOVÁKOVÁ (SK)

Teodor OGNEAN (RO)

Armands PLATE (LV)

Maria-Miranda XEPAPADAKI-TOMARA (EL)

Representatives of the Commission

Elke ANKLAM

Gustaaf BORCHARDT also acting as proxy for Heinz ZOUREK on the 2nd day

Heinz ZOUREK

Representatives of the Parliament

Hartmut NASSAUER

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

Martin FUEHR

Tony MUSU

Hubert MANDERY

Observers

Eskil THUESEN on behalf of Per NYLYKKE

Mario GRACIO on behalf of Fernanda SANTIAGO (PT) Gwenole COZIGOU on behalf of Heinz ZOUREK (2nd day)

Astrid SCHOMAKER (European Commission)
Astrid BARTELS (European Commission)

Parvoleta LULEVA expert accompanying Mr Boyko MALINOV (BG)

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)

Minna HEIKKILÄ (Head of Unit, Legal Affairs)

Anna-Liisa SUNDQUIST (Chair of the Member State Committee)

Jose TARAZONA (Chair of the Committee for Risk Assessment)

Ann THUVANDER (Chair of the Committee for Socio-economic Analysis)

Lindsay JACKSON (Head of Unit, Communications)

Helene LILLGALS (Accounting Officer) for agenda item 6

Minna STROMBERG (ECHA Internal Audit Capability) for agenda item 7

Matti VAINIO (Team Leader, Socio-Economic Analysis) for agenda point 9 Sari HAUKKA (Registrar of the Board of Appeal) for agenda item 12

Mercedes ORTUNO (Registrar of the Board of Appeal) for agenda item 12

Catherine CORNU (Scientific Officer) for agenda item 20

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

Mervi MUSTAKALLIO (Planning and Monitoring Officer, Executive Office)

Bo BALDUYCK (Junior Legal Officer, Executive Office)

Annex

Corrigendum to Document: MB/M/01/2010

(Agreed at the Management Board meeting on 22 June 2010)

Minutes of the Meeting of ECHA's Management Board held on 04/05 March 2010 4. Preliminary draft budget proposal and establishment plan for 2011, accompanied by a preliminary work programme 2011

MB/01/2010

[...]

With reference to the upcoming negotiations in the European Council and Parliament on the EU budget for 2011, the Executive Director stressed that it is crucial to understand that ECHA will be self financed in 2011 and thus in a different situation in comparison to other Agencies. To this end, it would be important to communicate the atypical financing structure to the Budgetary Authority, especially the Council. The Executive Director explained that ECHA will, despite being self financed, depend on the authorisation of sufficient establishment posts by the Budgetary Authority. The requested amount for 2011 has been foreseen in the planning for the REACH Regulation (thirty new posts in 2011, mainly *for evaluation tasks* and authorisation and restriction purposes). Differently from other agencies, these new posts would be neutral for the 2011 budget, i.e. they would not require any expenditure by the European Union. However, the Budgetary Authority still needs to decide on these establishment posts.

A representative of the European Commission underlined this appeal to undertake necessary steps within Member States, in order to avoid the Agency being affected by possible horizontal cuts in staffing to agencies - without any benefit for the EU budget as such.

[...]

5. Multi-annual staff policy plan 2011 - 2013 (*MB/02/2010 rev.01*)

The Director for Resources presented the draft multi-annual staff policy plan of ECHA for 2011-2013 which represents a rolling multi-annual planning for the recruitment of staff and is based upon a common template used by all EU agencies. As stipulated in the Financial Regulation, the Commission services had been consulted on the draft, prior to its submission to the Management Board. The document will be updated in 2011.

A total of 50 new establishment posts are foreseen for 2011-2013, of which 30 for 2011 and 20 for 2012.

[...]

15. Any other business

[...]

Calendar for future Board of Appeal selections

A Commission representative informed the Board about the calendar for Board of Appeal selection procedures in 2010. New vacancies for alternate chairs and a technically qualified member will be published on 6 March with a view to submitting a shortlist to the Board by mid-June.

[...]