



MB/M/05/2008 final

**Minutes of the Meeting of ECHA's Management Board
17/18 December 2008**

I. Documents submitted to the Management Board

Draft agenda	MB/A/05/2008
Draft minutes	MB/M/04/2008
Final Budget 2009	MB/68/2008
Work Programme 2009 - Update of Annexes	MB/69/2008
Multi-Annual Staff Policy Plan	MB/70/2008
Budget Transfers 2008 (including report on written procedure MB/66/2008)	MB/71/2008
Appointment of Committee Members	MB/72/2008 MB/73/2008
Report from the Working Group on the Board of Appeal	MB/74/2008
Declarations of the members and alternates of the Board of Appeal	MB/75/2008
2 nd Interim report from the Working Group on Reimbursement of REACH tasks to Member States	MB/76/2008
Rules for the Remuneration of Experts	MB/77/2008
Amending the Guide for Reimbursement of travel, hotel and subsistence expenses (MB/25/2008) rev.01	MB/78/2008 MB/78/2008
Report on the REACH operations and the work of the Committees and the Forum	MB/RD/04/2008
Report on REACH-IT	MB/RD/05/2008
IAS Strategic Audit Plan 2009-2011	MB/79/2008
Internal Audit Charter	MB/80/2008
IAS Report on the Limited Review of the Implementation of the Internal Control Standards	MB/81/2008
Work Plan “International Activities”	MB/82/2008
Participation of third countries in the work of ECHA (Art 106 REACH Regulation)	MB/83/2008

II. Summary Record of the Proceedings

Introductory remarks

The Chair opened the meeting by congratulating the Executive Director and the staff of the Agency on successfully managing the workload associated with the pre-registration phase.

He then welcomed Ms KIVELÄ (FI) and Ms SANTIAGO (PT) as new representatives of their respective Member States and informed the Board that Mr PLATE (LT) had also been formally appointed. The new Members had previously participated at Board meetings as observers on behalf of Members.

Following this, the Chair introduced Mr FUEHR who had been invited to attend the meeting as the internal Commission procedure appointing him as representative of interested parties could not be finalised in time for the meeting¹. Mr. FUEHR briefly introduced himself.

As follow-up to his letter inviting EEA-EFTA countries to nominate observers to the Management Board, the Chair announced that Ms Anne Beate TANGEN had been nominated as observer for Norway. Ms TANGEN joined the meeting later in the morning. Liechtenstein had informed ECHA that, due to lack of human resources, its government would currently not be able to send an attendee to meetings but had asked to receive relevant meeting documentation. The Mission to Iceland had been contacted by the Secretariat at the beginning of December and replied that a nomination would follow soon².

The Chair informed the Board that on the second day two agenda items related to audit issues would be presented by Mr. Ignacio DE DIOS MORALES, Deputy Head of Unit from the Commission's Internal Audit Service.

The Chair introduced other observers attending the meeting and informed the Board members of the proxies that had been notified to him (Details are listed in Annex IV of these minutes).

1. Agenda
(*MB/A/04/2008*)

The Board took note of the draft agenda.

Three Board Members proposed additional items concerning the translation of EINECS in the context of the CLP Regulation³, substances imported from the United States and a conference on REACH in Malta. The Chair proposed that those aspects would either be included in agenda item 14, "report on operations", or dealt with under "any other business".

¹ The Commission decision appointing Mr FUEHR has been adopted on 18 December.

² A letter nominating Ms Kristín RANNVEIG SNORRADÓTTIR arrived at ECHA on 19 December.

³ Regulation (EC) No 1272/2008 on classification, labelling and packaging of chemical substances and mixtures

With regard to agenda item 7, the Chair informed the Board that item 7.2 “implementing rules for the Staff Regulations” would be postponed to the next meeting in February 2009.

On this basis, the agenda was adopted.

2. Declaration of specific interests

No Board Member declared a specific interest which could be considered to be prejudicial to his/her independence with respect to any points on the agenda.

3. Minutes
(*MB/M/04/2008*)

The minutes of the meeting on 24/25 September 2008 were approved with minor clarifications (see corrigendum in the annex).

The Board agreed that the names of the appointed alternates of the Board of Appeal should be deleted and the details related to discussions on the issue should be shortened in the public version of the minutes.

4. Final Budget 2009
(*MB/68/2008*)

The Executive Director was invited to present the budget 2009 that foresees financial appropriations amounting to 71.635.588 €.

He explained that Title 1 of the budget includes staff related costs, and would cover mainly salaries, recruitment, training, work related travel and external services amounting to a total of 38.134.000 €. Title 2 would include the rental cost for the building as well as basic infrastructure and information technology expenditures totalling 10.803.888 €. The operational Title 3 budget would directly support the implementation of the work plan and would have been aligned to the procurement plan which is presented to the Management Board as an annex to the work programme, an amount totalling 22.697.700 €. The establishment plan for 2009 foresees a total of 324 posts (temporary agents)

A room document was circulated containing a presentation of the budget that allowed for an easy comparison of the budget 2009 with the budget 2008 after the transfers made in 2008.

The Board adopted the Agency’s budget for 2009, including the establishment plan, with the understanding that the Community subsidy of 64.529.000 € for ECHA will be confirmed with the adoption of the general budget of the European Communities.

5. Work Programme 2009 – Update of Annexes
(MB/69/2008)

The Executive Director explained that following the adoption of ECHA's Work Programme 2009 at the Board's meeting of September 2008 (MB/59/2008), as an update the two Annexes to this document are submitted to the Board for adoption. Annex 1 would update the resources for 2009 in the Work Programme and align it to the budget as it is adopted by the Board under agenda item 4. Annex 2 would complete the Work Programme 2009 with a procurement plan. This would go back to a recommendation issued in the context of an audit performed by the Commission's Internal Audit Service to the Agency.

One Board Member requested receipt of information on the background to a substantial increase of budget appropriations for translations compared to the preliminary draft budget. Responding to this, Andreas HERDINA, Director of Cooperation, explained that the translation cost would mainly relate to REACH-IT and to Guidance documents. He also pointed out that the Communities Translation Centre (CdT) had recently decided to raise the fees in 2009.

With regard to Annex 2, a Board Member asked whether the development of an electronic exchange system for enforcement would be expected to be finalised in 2009. The Executive Director answered that the date of the conclusion of the project could not be confirmed yet as the procurement would only be scheduled to start in the 2nd quarter of 2009.

The Board adopted the revised Annexes 1 and 2 of the Work Programme 2009 as contained in meeting document MB/69/2008.

6. Reserve Fund

The Executive Director introduced this agenda item by outlining the Agency's estimates with regard to the availability of an adequate cash-flow in 2010, an aspect that concerns the financing of the Agency's activities but is not directly linked to the issue of a reserve fund for fee revenues.

The Executive Director explained that the cash flow for paying the Agency's running expenses in 2010 could become problematic insofar as the co-legislator has based the assumptions for Community grants to ECHA on a steady flow of fee income from the beginning of the year 2010. Experience gained in the meantime would however lead ECHA to the conclusion that the bulk of the income from registration fees will more likely be generated towards the end of the year and thus lead to a lack of synchronisation of revenues and expenditures over the months preceding the year end. He backed these estimates with detailed figures. A "temporary" Community subsidy in the form of an advance would therefore be a potential requirement to ensure the Agency's operation in 2010.

A Board Member representing ECHA's parent Directorate General later debriefed the Board on the discussions with the Commission's General Directorate for Budget (DG BUDG) regarding the establishment of a reserve fund for fee revenues. In the absence

of a legal base, derogation from the General Framework Financial Regulations would not be a viable option. He however indicated confidence that a solution would be found for carrying over unused fee revenues into the following financial year. Given the amount of fee income expected towards the closing of the registration deadlines, the Commission sees an obligation to support ECHA in the sound financial management of the fee income and proposed that the Agency present to the Board a set of draft rules on this aspect at the next meeting.

With regard to the cash flow situation in 2010, he noted that the reply from DG BUDG on a Community subsidy for 2010 would have been negative insofar as such a payment is not foreseen in the Communities financial planning. The Commission would nevertheless be willing to look into the figures provided by the Executive Director and discuss the issue further with DG BUDG, the Secretariat and the Management Board.

The Chair thanked the Executive Director and the Commission for the detailed information and concluded that ECHA should present a set of rules on the sound financial management of its income from fee revenues at the next Board meeting in February 2009.

7. Multi Annual Staff Policy Plan (MB/70/2008)

The Board heard Jef MAES, Director for Resources, who presented the draft Multi-Annual Staff Policy Plan. This plan is a regularly updated planning tool required by ECHA's Financial Regulation. He explained the further procedure which consists of a consultation of the Commission on the draft and a final approval at the next Board meeting.

Regarding the content he reported that the staff figures would correspond to the estimates communicated with the Multi-Annual Work Programme and thus be in line with the financial legislative statement for ECHA.

One Board Member asked for clarification on the staff needs for tasks deriving from the CLP Regulation that will enter into force in early 2009 and the general prospects of ECHA for achieving its recruitment targets in 2009-2011. In response to that, the Executive Director highlighted that ECHA had already in the past performed well in this respect, particularly in comparison with similar European bodies in the start-up phase. Additional tasks related to the CLP Regulation would already be foreseen in the Work Programme 2009. As soon as the new Regulation enters into force, the Commissions Fee Regulation⁴ would need an update and ECHA should be closely involved in this process.

The Board took note of the draft Multi-Annual Staff Policy Plan.

⁴ Commission Regulation No 340/2008

8. Budget Transfers 2008
(*MB/71/2008*)

As an initial remark, the Chair noted that the written procedure WP/01/2008 (MB/66/2008) on the budget transfer necessary for allowing ECHA to fund its share of the construction work on the Agency's conference centre was a first and successful practical test of the procedure provided for in Article 7 of the Board's Rules of Procedure (MB/02/2008). With reference to the discussions at the meeting of the Management Board of September 2008, he concluded that there would be no urgent need to revise these provisions. This was agreed.

The Executive Director asked the Secretariat of the Management Board to present the report on the written procedure on the budget transfer as contained in document MB/71/2008. The transfer was agreed by 27 positive replies from Members with voting rights by the deadline. No negative replies were received.

The Board was informed that a representative of the Commission has based its agreement on the following observations:

- the lump-sum payment of the renovation costs of the conference does not negatively affect the implementation of the work programme 2008;
- the transfers are made within the available budget appropriations for 2008;
- according to the background document the proposal is in line with the Agency's Financial Regulation;
- an early termination of the rental contract would not have negative implications for the Agency;
- the conditions proposed by the building owner for the calculation of the lump sum payment appear to be financially acceptable.

Another representative of the Commission and a Board Member had affiliated themselves with these comments.

Following this report, the Director for Resources notified some other budget transfers carried out in the remit of the Executive Director and contained in document MB/71/2008. He informed the Board that contrary to a more moderate budget consumption that had been reported to the Management Board in September 2008, ECHA would eventually have achieved a rate of 80% consumption. The remaining 20% could possibly be reused in 2010 as assigned revenue. To this end, ECHA would enter into discussion with its parent Directorate General.

The Management Board took note of the information provided.

9. Appointment of Committee Members
(*MB/72/2008 and MB/73/2008*)

On the basis of meeting documents MB/72/2008 and MB/73/2008, as well as an additional nomination that had arrived on 10 December and was presented as a room document, the Management Board decided to appoint Mr. Aristodemos

ECONOMIDES, nominated by Cyprus, as Member of the Committee for Socio-Economic Analysis and Mr. Milan PAULOVIC, nominated by Czech Republic and Ms Tomasina BARRON, nominated by Ireland, as Members of the Committee for Risk Assessment.

10. Report from the Working Group on the Board of Appeal/
Declarations of the members and alternates of the Board of Appeal
(*MB/74/2008 and MB/75/2008*)

The Board heard the Vice-Chair and chair of the Working Group on the Board of Appeal who presented the findings of this Group.

The Chair thanked the Working Group and the Registrar of the Board of Appeal who has provided the Group's secretariat for the work done.

The Management Board endorsed the timetable for the appointment of the open positions at the Board of Appeal as set out in document MB/74/2008 and empowered the alternate legal member placed first on the list of merit, or if the latter refuses his appointment, the subsequent alternate legal member, to act on designation by the Chair of the MB as an interim Chairman if appeals are lodged before a permanent Chair (or his or her alternate) assumes functions. Members agreed that letters by the Chair to those person(s) explaining the situations and asking for their acceptance should be sent in due course.

The Board came to the understanding that a high degree of transparency towards appellants is required in order to duly inform them of the circumstances in the event that appeals need to be processed before a regular Board of Appeal could be established

It was also decided that the members and alternates of the Board of Appeal should be requested to make a declaration of commitment and confidentiality and an annual declaration of interests in accordance with the models contained in the Annexes of document MB/75/2008⁵.

11. 2nd Interim report from Working Group on reimbursement of REACH tasks to Member States
(*MB/76/2008*)

The Board heard a report of the Executive Director on the progress made in the Working Group on reimbursement of Member States for REACH tasks. The Group consists of representatives from Germany, UK, Sweden, the Commission and ECHA. The report followed a first report given at the meeting of the Management Board of June 2008.

At a meeting on 23 September 2008 the Working Group discussed the pilot project for transitional restriction dossiers, the terms of reference for rapporteur work, the

⁵ Subject to a linguistic correction to the templates for the declarations

coefficients to be used for reimbursement, the maximum proportion of the reimbursement to be established and the contractual arrangements.

The Executive Director presented the conclusions reached by the Working Group and contained in meeting document MB/76/2008. He highlighted an important development with regard to the planned test cases for restriction dossiers. The working group had originally supported the idea of such a pilot project on transitional cases to reassess the time assumptions for rapporteurs. However, the Executive Director indicated that ECHA had received no “transitional” restriction dossiers⁶ by the deadline of 1 December. The pilot project could therefore not be realised. Against this background, he proposed that the Board entrust the Working Group with finalising a proposal for approval at the Board’s April 2009 meeting which would allow adoption in Q3/2009, i.e. earlier than initially planned (Q4/2009).

The Chair thanked the Working Group for the report. He reminded the other Board Members that the Group would so far only be concerned with substance evaluation and rapporteur work on restrictions.

The following exchange of views centred on the need of securing confidential business information to which Member States will get access, the payment modalities and the use of the coefficient based on figures published by Eurostat. It was clarified that the modalities will be adjusted according to the most recent figures, values and coefficients available.

The Board agreed that a special emphasis should be put on confidentiality aspects during the further work of the Working Group.

With regard to the test cases on restriction dossiers, it was clarified that the evaluation of 25 transitional dossiers for 26 substances received by the deadline have not indicated the need for a Community-wide restriction proposal. One dossier was nevertheless still under closer scrutiny.

As far as the national law does not allow for transferring payments to private contractors via the competent authorities, it was clarified that this would potentially need adaptation of national legislation.

The Management Board noted the report and agreed to the conclusions as presented by the Executive Director. Different from the proposed commitment foreseen to be given by Board Members in document MB/76/2008 aimed at informing on behalf of the Member States to which instances the framework contract can be sent, it was agreed that ECHA will instead address this issue separately vis-à-vis the Member States.

12. Rules for the remuneration of experts - Art 88(3) REACH (MB/77/2008)

The agenda item was presented by the Executive Director who explained that by setting up a scale of fees the remuneration of experts, the Management Board would implement Article 87(3) of the REACH Regulation and Article 15 of the

⁶ see Art. 136(3) of the REACH Regulation (EC) 1907/2006

Commission's Fee Regulation⁷. ECHA would propose a conservative approach with regard to the scope and magnitude of remuneration of experts and co-opted members, i.e. the recipients of the remuneration should be restricted and the magnitude of the fees should be set at the lower end of the range of fees paid by other EU institutions in comparable circumstances.

According to the Secretariat's proposal, remuneration would be paid to co-opted members of the ECHA Committees and to experts invited to the Committees to contribute to their work as a whole. The Forum would not be included as it was concerned with enforcement in the Member States and ECHA was already providing substantial support to it. The scale of fees should be set uniformly to EUR 300 per day and a review foreseen by the end of 2010.

The Chair summarised the proposal and invited the other Members to express their views.

Many Board Members were of the opinion that the Forum should not be generally excluded from the scope of the decision. Some Members also questioned the attractiveness of the fees paid considering that the Agency if it wants to attract highly skilled experts.

In response to this, the Executive Director clarified that the Forum has a special role within the Agency and the numerous working groups it has established have quite different mandates than those of the Committees. Expertise needed also come rather from the public than the private sector. In addition, ECHA already supported the Forum activities considerably, for example through connections to REACH-IT for enforcement authorities. Regarding the magnitude of remuneration, the Executive Director stressed that the non pecuniary aspects of serving as experts for the Agency must also be taken into account.

The Chair summarised the discussion and proposed, as a compromise, to include co-opted members of the Forum into the scope of the decision. In addition, the role of the Forum should be particularly focused on during the review of the decision in 2010.

The Board agreed to this and adopted the decision on the remuneration of experts with that change.

13. Amending the Guide for Reimbursement (*MB/78/2008; MB/78/2008 rev.01*)

The Board heard the Director for Resources who presented some amendments to the Guide for reimbursement which provides the basis for the reimbursement of expenses to participants at meetings organised by ECHA.

The Guide needed some adjustments, namely with regard to remarks received from the Court of Auditors, the reimbursement of stakeholder organisations in justified cases and the administrative procedures involved in the reimbursement.

⁷ Regulation of the EP and the Council No (EC) 1907/2008 and Commission Regulation (EC) 1907/2008

As far as the reimbursement of stakeholder organisation observers is concerned, the Director informed the Board that this originates in the discussion at the April and June 2008 Board meetings. The reason for the reimbursement of stakeholders would be that some stakeholder organisations may not have the funding necessary to permit the participation of their experts at ECHA meetings. As it would be in the Agency's interest to have a balanced participation of observers from different interest groups at meetings, provisions have been included to allow their reimbursement. However, in order to keep the financial and administrative implications of the reimbursement of stakeholder organisations within a reasonable spectrum, the scope should be limited to a contribution to the travel expenses. To this end, stakeholder organisations wishing to receive reimbursement should be asked to sign a declaration (annexed to document MB/78/2008) stating that they do not have sufficient financial means to fund the attendance of an observer.

The Chair summarised the proposal and informed the Board that a written amendment had been distributed as room document on the request of Mr. FUEHR. He invited Mr. FUEHR to present the proposal which mainly aimed at reducing the bureaucratic burden for non-governmental organisations caused by the proposed text. Mr. FUEHR also argued in favour of aligning the scope of the payment to the one applicable to members and other invited participants. In the following exchange of views, many Members representing Member States, interested parties and an independent person appointed by the European Parliament supported an equal reimbursement of persons invited to meetings and highlighted the importance of stakeholder representation. In particular, a Board Member appointed by the Commission to represent workers' interest stressed that the contributions from stakeholder organisations are an added-value to ECHA's meetings and their presence as observers is necessary to ensure a degree of transparency in the Agency's work

A representative of the Commission stressed that steps need to be taken to avoid any double funding of stakeholder organisations through European funds.

The Executive Director justified ECHA's proposal by pointing out the difference between participants invited to a meeting for providing expert input and those invited as part of the Agency's transparency policy. He also noted that there is no legal obligation to provide for any reimbursement of stakeholder observers. He proposed however to present a compromise proposal to the Board.

The Chair invited the Executive Director and the Board's secretariat to accommodate the comments made and to table a revised document

Document MB/78/2008 rev.01 was presented containing a revised proposal allowing for the reimbursement of public interest non-governmental organisations, workers organisations and organisations representing the interest of smaller and medium sized companies that fulfil the eligibility criteria approved by the Management Board⁸ without asking for a signed declaration. This reimbursement would cover the travel costs and an additional lump sum of 100 EUR per diem. In future, the lump sum payment and travel cost reimbursements may be replaced by vouchers for hotel and lunch and by pre-paid tickets.

⁸ See Annex to MB/05/2008 final

The Management Board agreed to this proposal and decided on some additional technical amendments⁹ to the Guide on Reimbursement.

14. Work Plan International Activities 2009¹⁰
(MB/82/2008)

The floor was given to Leena YLÄ-MONONEN, Head of Unit Committees & International Relations, who presented the Work Plan on International Activities of ECHA (document MB/82/2008). The document had been agreed with the Commission following an earlier request of the Commission in accordance with Article 77(2) of the REACH Regulation.

Members were informed that the work related to OECD activities has the most prominent role in the Work Plan. Following discussions at the meeting of the Management Board of June 2008, ECHA has also found an agreement with the Commission regarding the special case of SAICM (support to side events organised by COM). Other areas of activity will be the Stockholm Convention on Persistent Organic Pollutants or scientific and technical work of the UNECE Subcommittee on the Globally Harmonised System (GHS).

The overall resources foreseen for international activities account for four FTE¹¹ and 550.000 €. The Work Plan will be reviewed in 2009 and the reporting included in the Agency's General Report.

Several Board Members pointed out the importance of focusing on the potential benefits to promote the aims of the REACH Regulation when deciding on international activities. One Board Member representing interested parties added that this would be particularly important as far as fee income is used for these activities. In response to the comments made by Board Members, the Head of Unit laid out the links between the international activities of ECHA and the implementation of the REACH legislation.

The Chair concluded that the Board acknowledges that the Agency's involvement in international activities will be advantageous for an effective REACH implementation but that ECHA should stay focused on core REACH tasks and thus keep the resources for international activities strictly within the presented scope.

On this basis, the Work Plan International Activities 2009 was endorsed.

⁹ The amendments concern page 3, point 2.5 (addition of the words "and the details of the calculation" at the end of the section and page 6, point 3.3.2 adding "in Helsinki" after the word "allowance")

¹⁰ The order of the agenda items presented in these minutes follows the order in which the items were ultimately dealt with at the meeting on 17/18 December 2008.

¹¹ Full Time Employees

15. Report on the REACH operations and the work of the Committees and the Forum (*MB/RD/04/2008*)

Jukka MALM, Director of Assessment, presented a detailed report on the REACH operations and the work of the Committees and the Forum.

He informed Members that the pre-registration phase ended on 1 December 2008 with more than 2.7 Mio pre-registrations submitted by more than 65.000 companies. Based on the information submitted, ECHA would refine the estimates for the number of registrations that will arrive at the deadlines provided for in the REACH Regulation. He noted that this would be a highly complex and difficult undertaking. A current focus of ECHA's substance identification specialists would be to clean the pre-registration list by removing invalid entries.

The report also covered the number of dossiers submitted for inquiries, registrations and PPORD notifications¹² and an assessment of the reasons for dossier rejections. The Board was also debriefed on the assignment of registration numbers to notifiers under the previous legislation. Importantly, ECHA informed participants that REACH-IT had been closed for practical reasons as of 17 December and will be re-started after the Christmas break on 5 January 2008. Submissions via the temporary submission procedures stopped on 15 December to enable the handling of the dossiers before the system had been closed

With regard to the authorisation procedure, the Board was briefed on the latest meeting of the REACH Competent Authorities of December 2008 at which ECHA had announced the timetable for the update of the candidate list. Member States were invited to submit any new proposals for SVHC identification at the same time (mid May 2008) as ECHA plans to be ready with the finalisation of the proposals for the five substances requested by the Commission. An update was also given on the proceedings in the Member State Committee that took place in parallel to the Board meeting. The Committee had agreed on the criteria for the first recommendations for inclusion of substances in Annex XIV. The Board was informed that 7 out of the 15 substances on the first candidate list meet the criteria and will thus be included in the recommendations. In January 2009, ECHA will host a workshop in Helsinki for Member State representatives on the use of the authorisation and restriction procedure.

Turning to classification & labelling, the Director of Assessment reported on the number of notifications from Member States in the Registry of Intentions and the status of submitted dossiers. He also announced that a full report on the implications from the CLP-Regulation that is expected to enter into force in January 2009 will be given at the next Board meeting.

With regard to the issue on the translation of substance names in Annex VI of the CLP Regulation which had been raised at the beginning of the meeting by a Board Member to be treated under "any other business", the Director mentioned that this aspect has been discussed in the Council Working Group during the finalisation of the co-decision procedure and a statement was issued by the three Institutions. According

¹² Product and Process orientated Research and Development

to this statement, ECHA will make available over the internet the chemical names contained in Annex VI in Community languages on the basis of substantive input from Member States and the Commission. In preparation of this statement it had been agreed with the Commission, that ECHA would be required itself to prepare translations.

Finally, the report turned to the proceedings, number of meetings and experiences made so far in the ECHA Committees and the Forum.

The Chair thanked ECHA for this detailed update and invited the other Board Members to hold an exchange of views.

Board Members congratulated and thanked ECHA for accomplishing the pre-registration period successfully. A representative of interested parties mentioned that industry had also heavily underestimated the number of pre-registrations. He reminded that it will be crucial to learn lessons from the experiences gained for the future and pointed to the difficulties that will derive from the high number of pre-registrations for the discussions in the SIEFs. To this end, he announced that industry associations would like to enter into talks with ECHA.

Regarding invalid or fake pre-registrations, it was generally felt that enforcement activities will be of high importance, as ECHA has only limited possibilities in this respect. The importance of an effective enforcement policy was also stressed by a Board Member representing interested parties who mentioned that industry would welcome a strong level of enforcement at the national level as this would efficiently back the efforts of those companies complying with the high REACH standards.

Two Members referred to the fact that the first Agency recommendations for inclusion in Annex XIV will probably comprise half of the substances on the candidate list and expressed their concern. In response to this, the Executive Director admitted that the number would indeed be low and ECHA would need to focus on a clear communication on the background of the criteria for selection the substances. These general criteria were unanimously agreed by the Member State Committee and are based on sound science. The scientific and technical justification was provided for all individual substances on the candidate list when considering their possible inclusion. Furthermore, the recommendation of substances on the candidate list can be reconsidered at a later stage, e.g. on the basis of new information.

Concerning the work of the Committees, some Members expressed concerns about the fact that Committee members sporadically show a rather passive participation at the meetings. With respect to difficulties identified by ECHA to find volunteers for rapporteurship in the Committees it was noted that this is a serious issue that deserves high attention by the Secretariat which was asked to render rapporteurships more attractive and to provide sufficient support.

16. Report on REACH-IT
(MB/RD/05/2008)

The Board received a detailed report on the state of play of REACH-IT by Christel MUSSET, Director of Registration and IT-tools. This included information on the REACH-IT Benchmark study, the current status of the Security Officers Network (SON) and other security topics. Members were informed that REACH-IT was shut down on 17 December 2008 to integrate a new release of the software which covers, amongst other things, the electronic submission of dossiers. It was also shut down to allow for the migration of all temporary databases to the updated version and will be re-started on 5 January 2009 with the online submission functionality. The migration of data from the temporary submission pipeline to REACH-IT will include all supporting documents, like letters from and to companies, decisions made on dossiers, invoices etc.

Since October 2008, ECHA had put emphasis on securing pre-registration by increasing the system's performance and capacity with the aim of ensuring ECHA meets its legal obligations. At the same time, the assignment of registration numbers for substances considered as registered had to be managed by 1 December 2008.

Further it was noted that REACH-IT will be ready for Member State Competent Authorities access by the end of Q1/2009. Currently, the implementation of secure network connections to ECHA is being finalised.

As the first dossiers containing significant quantities of confidential business information are expected from 2009, ECHA will put high priority on IT security aspects.

The specifications of the classification and labelling inventory will need some revision after the adoption of the CLP Regulation and the first part of the dissemination module is expected in summer 2009.

In the following discussion, Members showed high interest in the progress of the connection of national authorities to REACH-IT and IT-security aspects. In particular the connection of enforcement authorities to REACH-IT proved to be a complex matter as it not only constitutes technical challenges, but also significantly raises the number of system users and thus has security implications. The Executive Director explained in this context that ECHA has developed a specific proposal to establish access to enforcers and by training national officers by 1 December 2010. In order to contain the risks, not all enforcement authorities would have direct access to the full ECHA systems; instead regional databases with selected information could be consulted.

A representative of the Commission emphasised that, especially due to the Agency's efforts, REACH-IT performed quite well under the given circumstances. He was however anxious whether the closing of the system by 17 December would give the wrong picture to companies. Regarding the security aspects, he appreciated the progress ECHA had made but reminded nevertheless that some aspects raised by the Commission still need to be addressed. Responding to this, the Executive Director outlined the timeline for migrating the data from the temporary dossier submission

procedure to the next REACH-IT release that forces ECHA to shut down the systems over a certain period. The Christmas break would be a good opportunity for this project. Referring to the IT-security aspects, the Executive Director reported that the next steps foreseen by ECHA include reducing the opening hours of the IT-system from 24/7 to extended working hours in order facilitate the monitoring of intrusions and the dislocation of the backup centre from ECHA's premises.

The Chair thanked the Executive Director and the Secretariat for this comprehensive report.

17. IAS Strategic Audit Plan 2009-2011
(MB/79/2008)

The Executive Director introduced the agenda items related to audit aspects by providing an overview of the internal and external audit aspects that apply to ECHA and put the subsequent agenda items into the broader context.

The European Court of Auditors (ECA) is ECHA's external Auditor and it reports to the Authority of Discharge (EP). A first visit to ECHA took place in September 2008 a second visit being planned in March/April 2009. The first annual accounts of ECHA would be submitted to the Management Board together with the Court's observations before 1 July 2009.

The Internal Audit Service of the European Commission (IAS) is the Internal Auditor of ECHA and reports to the Management Board. According to the Financial Regulations, the IAS assumes this function at least as long as the Agency receives grants from the Community budget¹³. The IAS has prepared a risk-based strategic audit plan for the 3 years to come which is established on a rolling basis. The Service has also performed a "Limited Review of the Implementation of Internal Control Standards" in July 2008.

Finally, the Agency also decided to establish the function of an Internal Audit Capability (IAC) which is a resident Internal Auditor set up to respond to the needs of the Executive Director (ED) for assurance and consulting. The IAC reports to the ED.

Following this, the floor was given to Ignacio DE DIOS MORALES to present on behalf of the IAS the Strategic Audit Plan 2009-2011. He thanked the Chair and the Executive Director for the invitation to explain the findings and the work of his service. He pointed out the advantages that go along with the fact that the IAS has a horizontal view over almost all Agencies. He then explained the different steps involved in the assessment business risks of the Agency and the identified risk areas as provided to the Board in document MB/79/2008.

The Chair thanked Mr DE DIOS MORALES for his comprehensive and helpful explanations.

¹³ Reference was made to Art. 185 General Financial Regulation (Council Regulation (EC) 1605/2002), Art. 71(2) and 72(3) of ECHA Financial Regulation (MB/53/2008)

He clarified that even though the IAS is also the internal auditor of the Commission, the service would act as independent auditor from the Agency's perspective.

The Board endorsed the IAS strategic audit plan for ECHA 2009-2011.

18. Internal Audit Charter
(MB/80/2008)

The floor was given to the Executive Director who provided background to the Agency's "Internal Audit capability" (IAC) and to the charter governing the future activities of this function as detailed in document MB/80/2008. He outlined that the IAC provides an assurance and consulting function explicitly for the Executive Director and supports the issuance of his annual declaration of assurance. The IAC also serves as a link between the internal control and quality system and coordinates the assurance work with the IAS.

He then introduced Régis DURAND to the Board who has worked with ECHA since 2007 as seconded official of the Commission's Internal Audit Service on audit, quality control and general coordination. He will be made available full time for audit issues from this date forward. A vacancy for the IAC post was published on the 12th December 2008.

The Chair thanked the Executive Director and invited the other Board Members to consult the updated ECHA organigramme. This was presented alongside the Multi-Annual Staff Policy Plan earlier in the meeting (MB/70/2008) in order to understand where exactly the internal audit capability is located within ECHA. He also informed the Board that a decision could be made at a later stage to create an audit committee of the Management Board in order to assist the Board in its audit related duties. He proposed that this aspect be revisited after initial experience had been gained.

The following exchange of views centred on the relationship between ECHA's internal audit capability and the Commission's Internal Audit Service as well as the situation from 2010 onwards where ECHA is expected to receive no Community subsidy. One Board Member inquired as to whether the IAC can efficiently assume its function whilst reporting directly to the Executive Director.

The Executive Director clarified that the Charter of the IAC would only be valid as long as the IAS assumes its role towards ECHA as Internal auditor. He pointed out that through its Charter, the IAC would have guarantees of independence within the Agency and necessary access to all staff, documents and other relevant information. The IAC would report directly to the Executive Director.

The Chair concluded that the IAC Charter would be reviewed as appropriate. He emphasised the unchanged statutory role of the Court of Auditors (as external auditor) with a focus on financial ex post audit.

The Management Board approved the Charter of the Internal Audit Capability.

19. IAS Report on the Limited Review of the Implementation of Internal Control Standards in ECHA
(MB/81/2008)

The Board heard from Mr DE DIOS MORALES who gave a debrief on the IAS limited review of ECHA that took place during July 2008. The corresponding report was presented to the Board alongside meeting document MB/81/2008. The objective of this review was to get an overview of ECHA's internal management system and in particular the recruitment of staff, procurement procedures and financial circuits. He reported that his review came to the conclusion that in respect to the recent setting up of the Agency, the procedures would be well developed and could mostly be considered as "best practice" or "well under way". Priority should be given to those recommendations that have been marked as "Very Important".

The Chair then gave the floor to the Director for Resources, who presented the action plan devised by ECHA in response to the IAS recommendations and submitted to Members with document MB/81/2008. He expressed his satisfaction with the fact that no critical issues have been identified by the IAS. ECHA has focused on the important points raised in the IAS report and all issues have already been addressed, some of them with action still to be on-going in 2009. For example, ECHA has held elections for a Staff Committee on 5 November 2008 and the Committee is in the process of establishing itself.

This was followed by an exchange of views.

On request by a Board Member representing interested parties, the Director of Resources outlined the role and function of the Staff Committee and the meaning of a "negotiated procedure", a procurement procedure where ECHA can consult economic operators of its choice and negotiate the terms of contract with one or more of them. This procedure should be reserved for exceptional cases. Two Board Members stressed that ECHA should use exceptional procurement procedures with due care and should consider to inform the Management Board of important cases.

A representative of interested parties emphasised the high risks involved for ECHA with respect to confidential business information. In this context he inquired to know the extent to which the IAS addresses aspects like the access of national officials to the ECHA databases or ECHA's handling of access to document requests. The Commission's Internal Audit Service replied that the scope of the audit is defined in a stepwise procedure and it could not be predicted at this point in time on what precisely upcoming audits will focus. The IAS would however most probably not examine the content of decisions taken by ECHA but rather focus on systems and procedural aspects.

The Chair concluded the discussion by emphasising that the Board is pleased by the IAS statement that "the overall process, structure and management of the setting-up of the Agency can be considered as best practice". The observations submitted should nevertheless be taken carefully into account. ECHA had shown its commitment in this respect by drawing-up and closely following-up the presented action plan.

The Board took note of the first IAS report and ECHA's action plan and agreed that it should be continuously informed of areas which are of concern from an audit perspective.

20. Participation of third countries in the work of ECHA
(MB/83/2008)

The floor was given to the Director of Co-operation who presented meeting document MB/83/2008. He began by giving a thorough background analysis of the legal basis in the REACH Regulation as well as the institutional and EU external policy context of the participation of representatives from third countries in the work of ECHA. Based on this assessment ECHA has elaborated a general orientation for "international relations" with individual third countries. The trigger for this exercise was the receipt of the first formal requests by Turkey and Switzerland to participate in the work of the Agency.

The Secretariat suggested that, as a general approach, third countries on a path towards aligning with the EU chemicals *acquis* should be treated on the basis of the principle of gradual intensification of relations, synchronised with their progress in actual alignment. At this juncture, neither Turkey nor Switzerland has yet begun such a process. Therefore, it would still be premature to respond favourably to these two countries' requests to be involved in the work of the Agency in accordance with Article 106 REACH Regulation¹⁴.

Other third countries should be approached in accordance with the Community's trade and global normative interests and, with regard to participation in regulatory work, on the basis of reciprocity.

The Chair thanked the Secretariat for the precise analysis and proposals and opened the floor for discussion.

Some Board Members expressed their support for cooperating closer with Switzerland and Turkey, in particular as both countries have either a well established or fast growing chemical industry with close links to European companies. As Switzerland runs for example a national REACH helpdesk, cooperation within the REHCORN network would be useful for both sides.

Regarding more direct involvement in ECHA's work, Members pointed out that it might be difficult to define concrete criteria for ECHA's minimum requirements, for instance in terms of confidentiality or the level of alignment with REACH. The Board should base any invitation to third countries on the factual progress towards an alignment with REACH.

Other Board Members argued that any invitation, in accordance with Art. 106 of the REACH Regulation, should primarily be issued when in the interests of the Agency, particularly when it comes to the work of the Committees. It was also flagged that confidential business information must be strictly protected.

¹⁴ Regulation (EC) 1907/2006

In general, the ECHA approach was considered as reasonable and well balanced.

The Executive Director confirmed that ECHA would carefully communicate with third countries approaching the Agency for participation in its work and focus on giving incentives for seeking alignment with REACH. So far, the Committees or the Forum have not been concerned with the matter. He agreed that Switzerland could be invited to join REHCORN and mentioned that it could be worthwhile to consider using the REACH Competent Authorities meeting as a platform for exchanging experience with third countries that have not yet aligned with REACH.

Equipped with these comments, the Management Board endorsed the proposed approach towards the participation of third countries in the work of ECHA.

21. Any Other Business

Revision of the EC Biocides legislation

As follow-up of the meeting of the Management Board of September 2008, the Director of Assessment gave an update on the developments with regard to ECHA's involvement in the revision of the Biocide legislation. Members were informed that ECHA has put priority on achieving maximum synergies with the scientific and technical tasks under the REACH and CLP Regulation and on guaranteeing sufficient resources for any additional tasks. The Commission proposal for a new biocide regulation would currently be in inter-service consultation between the Commission Directorate Generals. Depending on the outcome of the co-decision procedure between the European Parliament and the Council, the entry into force could be during 2013.

It was agreed that an agenda point on ECHA's role in a revised EC biocides legislation would be part of the next meeting and supporting information would be prepared by the Secretariat.

Update on Guidance

The Executive Director gave an update on guidance development and explained the progress made on the update of the Guidance on Substances in Articles. ECHA would have tendered a study that will be coordinated with a study initiated by the group of Member States that have announced not to support the Commission's approach on the 0.1% threshold. In this context, the Executive Director mentioned that ECHA would have received information on the enforcement implications of this alternative interpretation by those Member States but without the required details

Risk Communicators Network

The Director of Co-operation debriefed the Board on the outcome of a meeting of the Working Group of the Risk Communicators Network (RCN) that took place on the 3rd December in a very positive atmosphere. The main outcome was that the role of the

Network should be to assist the Competent Authorities of the Member States to meet their obligations and to closely follow and contribute to the Guidance on Risk Communication that is currently under development. A report was also given to the REACH Competent Authorities meeting of December 2008.

National exemptions from the REACH Regulation in the interests of defence

The Board agreed that the coordination of national exemptions from the REACH Regulation in the interests of defence should be part of the agenda for the next meeting and prepared by the Secretariat. The matter would also be of high relevance to the Forum.

ECHA Management Seminar

The Executive Director briefly informed members of a seminar that took place in November 2008 involving the new ECHA management team. From January onwards, ECHA would have the assistance from an experienced organisational advisor who has previously worked in other Agencies and will stay for 12 months with ECHA. More information can be found in the regular ECHA Newsletter that is distributed via the news alert and available on ECHA's web page.

REACH debate in the European Parliament

The Chair informed the Board of an oral question submitted by all political groups of the European Parliament to the Commission on the number of pre-registrations received. The question was discussed on 3 December during a plenary session of the Parliament in Brussels. Commissioner Verheugen responded on behalf of the Commission.

Imported Substances

On the initiative of a Board Member, the Board briefly discussed the issue of imported substances from the United States but concluded that more detailed information would be needed on the background to allow for closer analysis.

Conference in Malta

A Board Member indicated that a well attended conference entitled "REACH reaching industry" took place in Malta on 27 November 2008.

Management Board meetings in 2009

The Board agreed that in 2009 it will hold 1 ½ day meetings and asked the Board's Secretariat to circulate a timetable.

20. Next meeting and closure

The Chair reminded Members that the next meeting of the Management Board would be held in Helsinki on 26/27 February 2009 in the Agency's conference centre, meeting room "Margot Wallström".

On behalf of the Board the Chair reiterated his thanks to ECHA's staff for the efforts put into successfully finalising the pre-registration phase. He also thanked the Board's secretariat for the well prepared meeting.



III. Decisions taken/ Conclusions reached by the Management Board

The Management Board

- approved the minutes contained in document MB/M/04/2008. This is subject to the amendments indicated in the corrigendum attached to the present minutes, and with the proviso that the names of the appointed alternate members of the Board of Appeal and the text on agenda items 4 and 5 of the meeting be shortened in the public version of the minutes.
- adopted the agenda as contained in MB/A/05/2008 with the understanding that some specific points raised by members will be discussed agenda item 20 (any other business).
- adopted the Agency's budget for 2009 with the understanding that the Community subsidy of 64.529.000 € for ECHA will be confirmed with the adoption of the general budget of the European Communities.
- adopted Annexes 1 and 2 of the Work Programme 2009 as attached to document MB/69/2008 and instructed the Executive Director to forward the Work Programme, as amended, to the Member States, the European Parliament, the Council and the Commission and to have it published.
- requested the Executive Director to present a proposal for rules on the sound financial management of fee revenues at the Board's next meeting.
- took note of the Multi-Annual Staff Policy Plan 2010-2013 as contained in document MB/70/2008 before it is forwarded to the Commission for its opinion.
- appointed Milan PAULOVIC and Ms Tomasina BARRON as members of the Risk Assessment Committee and Aristodemos ECONOMIDES as member of the Committee for Socio-economic Analysis.
- endorsed the timetable for the appointment of the Chairman, the legally qualified member and the alternate and additional technically qualified members of the Board of Appeal as outlined in document MB/74/2008.
- empowered the alternate legal member of the Board of Appeal (placed first on the list of merit, or if the latter refuses his appointment, the subsequent alternate legal member) to act on designation by the Chair of the MB as an interim Chairman of the Board of Appeal if appeals are lodged before a permanent Chair (or his/her alternate) assumes functions.
- decided that the members and alternates of the Board of Appeal shall be requested to make a declaration of commitment and confidentiality and an annual declaration of interests in accordance with the models contained in Annexes 1 to 3 of meeting document MB/75/2008¹⁵; and

¹⁵ Subject to a minor linguistic modification

gave the Registrar of the Board of Appeal the mandate to administer the practical actions related to the gathering of the declarations and their keeping.

- agreed with the conclusions of the 2nd interim report of the working group on reimbursement of REACH tasks to Member States, subject to the modification that, due to the unavailability of appropriate dossiers, no restriction test cases will be used to estimate the working hours needed in the context of the restriction procedure.
- entrusted its working group on reimbursement of REACH tasks to Member States to present a proposal for the scale of fees at the April meeting of the Management Board and agreed that the timing for the draft decision of the Board on the matter would be advanced.
- decided in accordance with Article 87(3) of the REACH Regulation and Article 15 of the Fee Regulation on the scale of fees of 300 Euro per day for the remuneration of co-opted members and invited experts as contained in Annex 2 to document MB/77/2008 with the modification that also co-opted members of the Forum shall be remunerated.
- adopted the revised version of the Guide for the Reimbursement of Travel and Accommodation Expenses and Payment of Subsistence Allowances as contained in Annex 1 of meeting document MB/78/2008 rev.01, subject to two technical modifications outlined in these minutes and with the clarification that also stakeholder organisations representing workers are entitled to reimbursement under the conditions laid out in the revised Guide.
- endorsed the work plan for international activities of ECHA 2009 as attached to document MB/82/2008.
- endorsed the IAS Strategic Audit Plan 2009-2011 for ECHA as annexed to document MB/79/2008.
- approved the charter of ECHA's Internal Audit Capability, as annexed to document MB/80/2008.
- endorsed the approach of ECHA concerning the participation of third countries in the work of the Agency as laid out in document MB/82/2008.

IV. List of Attendees

Representatives of the Member States

Maria ALAJÕE (EE)
Aurelija BAJORAITIENÉ (LT)
Karel BLAHA (CZ)
Francis E. FARRUGIA (MT)
Ethel FORSBERG (SE)
Ana FRESNO RUIZ (ES) also acting as proxy of Ekaterina GECHEVA (BG)

Claude GEIMER (LU)
Thomas JAKL (AT) also acting as proxy of Zoltán ADAMIS
Katarzyna KITAJEWSKA (PL)
Pirkko KIVELA (FI)
Antonello LAPALORCIA (IT) also acting as proxy of Odile GAUTHIER
Marc LEEMANS (BE)
Martin LYNCH (IE)
Leandros NICOLAIDES (CY)
Alexander NIES (DE) also acting as proxy of Marta CIRAJ
Edita NOVÁKOVÁ (SK)
Per NYLYKKE (DK)
Teodor OGNEAN (RO)
John ROBERTS (UK)
Fernanda SANTIAGO (PT)
Arnoldus VAN DER WIELEN (NL)
Maria-Miranda XEPAPADAKI-TOMARA (EL)

Representatives of the Commission

Heinz ZOUREK

Elke ANKLAM also acting as proxy of Grant LAWRENCE

Independent persons (appointed by the European Parliament)

Alexander DE ROO also acting as proxy of Bernd LANGE

Individuals from interested parties (appointed by the Commission)

Alain PERROY (CEFIC)
Tony MUSU (ETUC)

Observers from EEA-EFTA countries

Anne Beate TANGEN (NO)

Other Observers

Veneta VLADIMIROVA on behalf of Ekaterina GECHEVA-ZAHARIEVA (BG)
Astrid SCHOMAKER on behalf of David Grant LAWRENCE (COM)
Astrid BARTELS (European Commission)
Sharon MUNN (Chair of the RAC)
Mario BECCIO (expert accompanying Mr. LAPALORCIA)

Other persons invited by the Chair to attend the meeting

Martin FUEHR (University of Darmstadt)
Ignacio de DIOS MORALES (European Commission)

ECHA staff

Geert DANCET (Executive Director)
Andreas HERDINA (Director of Cooperation)
Jukka MALM (Director of Assessment)
Christel Musset (Director of Registration and IT-tools)
Jef MAES, future (Director of Resources)
Minna HEIKKILÄ (Senior Legal Advisor)
Régis DURAND (Audit and Quality Management)
Sari HAUKKA (Registrar of the Board of Appeal)
Leena YLÄ-MONONEN (Head of Unit 'Committees')
Alain LEFEBRVE (Head of Unit, Executive Office)
Frank BÜCHLER (Legal Officer, Executive Office)
Jody MERELLE (Legal Assistant, Executive Office)

Corrigendum to Document: MB/M/04/2008

(Agreed at the Management Board meeting on 17 December 2008)

**Minutes of the Meeting of ECHA's Management Board
held on
24/25 September 2008**

5. Appointment of alternates / additional members of the Board of Appeal
(MB/49/2008)

(Editorial change to align the minutes of this agenda point with the formal decision listed in Annex III)

[...]

With a view to the upcoming selection procedure for the Chair of the Board of Appeal, the legal member and the alternate and additional technical members, the Board decided to approach the procedure in the same manner as the present one, i.e. with a preparatory group, composed of the Vice-Chair, Grant LAWRENCE (COM) and Alexander NIES (DE)

[...]

24. Any other business

[...]

Conference in Cyprus

The Board Member from Cyprus informed the meeting about a successful REACH event in Cyprus on 28 June with third country and ECHA participation. A similar event will take place on 13 October.

[...]