

MB/M/02/2009 final

Minutes of the Meeting of the Management Board 23/24 April 2009

# I. Documents submitted to the Management Board

(MB/A/02/2009 rev. 01)
(MB/M/01/2009)
(MB/16/2009)
(MB/17/2009) (MB/17/2009 rev.01)
(MB/18/2009)
(MB/19/2009 rev.01)
(MB/20/2009 rev.01)
(MB/21/2009 rev.01) (MB/RD/01/2009)
(MB/22/2009)
(MB/23/2009) (MB/24-29/2009)
(MB/30/2009)
(MB/31/2009)
(MB/32/2009)
(MB/33/2009)
(MB/34/2009)
(MB/35/2009)
(MB/36/2009)

### **II.** Summary Record of the Proceedings

Introductory remarks

The Chair opened the meeting by welcoming the other Board Members and summarising the agenda items foreseen for the meeting.

He introduced the observers attending the meeting and informed the Board Members of the proxy votes of which he had been notified (details are listed in Annex IV of these minutes).

The Chair regretted that Mr Arnold van der Wielen could, for personal reasons, not participate at the meeting, which would most likely have been his last meeting as member of the Board. He asked the Dutch expert replacing him for this meeting to extend, from the entire Board, their best wishes and thanks to Mr van der Wielen. Later during the course of the meeting, Ms Odile GAUTHIER informed the Management Board that she has changed her position in the French administration and will consequently be replaced as Board Member. The Chair thanked Ms GAUTHIER for her valuable contribution and active involvement in the setting up of ECHA since June 2007. This was followed by applause.

# 1. Agenda (MB/A/02/2009 rev.01)

The Board took note of the draft agenda.

The Chair informed the Board about the room documents that had been made available for the meeting.

A Board Member appointed by the Commission to represent interested parties, announced that he would like to make a statement on the state of play of the implementation of REACH. Another Board member appointed by the European Commission to represent interested parties informed the Management Board about the list established by the European Trade Union Confederation which contains substances that could fulfil the criteria of substances of very high concern. it was agreed that these issues could be dealt with under either the "Report of the Executive Director" or "Any other Business".

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/01/2009*)

The minutes of the meeting on 23/24 February 2009 were approved with two technical modifications (see corrigendum in the annex).

It was agreed that the minutes should in future include a list of follow-up actions that have been identified in the course of the meetings.

# 4. Information by the Commission on the budgetary procedure 2010 (*MB/16/2009*)

The floor was given to a Board Member representing ECHA's parent Directorate General in the European Commission, who updated the Management Board on the state of preparations of the budget for the year 2010. The Board member explained the procedure for preparing the Commission's preliminary draft budget (PDB) and the further steps which will ultimately lead to the adoption of the final budget by the budgetary authority in December 2009 (the term "budgetary authority" refers to the European Parliament and the European Council).

The Board Member reported that the adoption of the Commission's preliminary draft budget was foreseen for 29 April 2009. For this reason, the Commission was, at the time of the meeting, not in the position to predict the outcome of the procedure. In line with the decision taken at the February meeting of the Management Board, ECHA's parent Directorate General had requested a Community subsidy of 45m EUR for 2010 and provided the arguments on which this request for a temporary "bridging" subsidy is based.

In the negotiations with the Commission's Directorate General for Budget, two aspects proved to be of particular relevance: the accuracy of the estimates and the question of whether ECHA will be able to spend the full subsidy. These aspects remain important given that the EU Financial regulations do not easily allow for the unused financial funds assigned to Agencies to be used for other purposes. An accurate estimate of the needs and a high budget execution rate are therefore of crucial importance. Against this background, ECHA's parent Directorate General had, in early April, asked the Agency to evaluate the minimum amount of funding needed in 2010.

Independently of this, the Board Member pointed out that it will be difficult for the Commission to foresee the full amount of 45m EUR in the PDB, not least due to the financial crisis which puts pressure on the Commission to use the budget, as far as is possible, to provide incentives to stabilise the European economy. He emphasised at the same time that the Commission's PDB is only the first step in the budgetary procedure and that the decision would ultimately lie with the Member States and the European Parliament. The Commission would be committed to ensuring that the functioning of ECHA was not put at risk. As the peculiar budgetary situation for 2010 results mainly from the postponement of the first registration deadline, and thus from a decision taken by Parliament and Council, the Commission would also be confident that the budgetary authority will support ECHA's case.

The Commission representative concluded that the Commission may come forward with a significantly lower amount than requested by ECHA and its Management Board, which would

require ECHA to prepare a contingency plan, which could put some of its activities at risk. However, he also emphasised the important role that the Management Board has to play in the course of 2009 in defending ECHA's needs within their Member States, with a view to ensuring a favourable Council resolution. Equally important would be that the Board Members actively approach key Members of the European Parliament. Experience in the past would show that such initiatives are very helpful for efficiently communicating the needs of agencies.

The floor was then given to the Executive Director who outlined how the Agency was estimating the budget needs for 2010 by simulating the revenue and expenditure for 2010 based on different parameters and scenarios. The amount of 45m EUR was still the most realistic estimate. Following the Commission's demand to evaluate the minimum needs for 2010, ECHA had analysed which expenditures could be postponed, e.g. by delaying planned recruitment or IT-projects. However, as large parts of the Agency's expenditure are fixed positions related to staff and building costs, none of the calculations led to an amount below 35m EUR. The Executive Director stressed that the measures that would result in this lower than requested subsidy amount, would severely affect the timing of the Agency's activities. Moreover, any lower amount than requested should, in his view, be accompanied by a review clause, which would create the possibility of increasing the subsidy in case of cash flow problems due to lower than anticipated fee revenue. In summary, a Community subsidy of less than 45m EUR would require a different planning of ECHA's activities over the year 2010 while an amount less than 35m EUR would force ECHA to identify negative priorities and hamper REACH activities.

On the request of a Board Member, the Executive Director clarified that the estimates made by ECHA with regard to the number of registrations and resulting fees, had not changed since February 2009. Following the request of another Board member, the Executive Director also agreed to circulate a copy of the letter that he had sent to the Commission on the subsidy request, as an additional room document.

The Chair thanked the Executive Director and the Commission for the detailed update. He proposed that the Management Board should approach the budgetary authority if the Commission's PDB did eventually fail to foresee an adequate bridging subsidy for ECHA, which could be done in the form of a letter from the Chair. This was agreed.

# 5. General Report 2008 (MB/17/200, MB/17/2009 rev.01)

The Executive Director presented the draft General Report of the Agency for the year 2008 (MB/17/2009). He explained that the structure of the document follows the ECHA multi-annual work programme and the draft work programme for 2010. In future, this would allow for an easier comparison of the planned activities *vs.* the achievements. The Executive Director continued by highlighting the main results during the first full year of independence from the European Commission, which consisted, in particular, of the successful entry into operation of REACH on 1 June 2008, the establishment of the first candidate list and the processing of a far higher number of pre-registrations than foreseen. The Executive Director also pointed to the activities that had been postponed in 2008, mainly due to the delays in IT-development. He also thanked the Commission for their ongoing support.

Following this, the floor was given to Martin LYNCH, Chairman of the Management Board's working group on planning and reporting. Mr. LYNCH informed the Board that the working group met in March 2009 in Helsinki to assess a preliminary draft of the general report. The report submitted for approval by the meeting takes into account many of the observations put forward by the group. In comparison to the first draft, the report presented to the Board more stringently focuses on the activities in 2008 and abstains from an outlook on the coming years. Other improvements suggested by the working group related to the presentation of the document, for example, a fact sheet on ECHA was added and the main results highlighted in text boxes at the beginning of each section. An important recommendation of the working group for the future would be to provide more detailed evaluation of the results of the work. However, Mr. LYNCH acknowledged that this needs a continuous and systematic monitoring over the year and could thus not be done retrospectively. Given the unforeseen workload and rapidly changing operational parameters in 2008, the working group considered it not feasible to prepare extensive analyses for 2008. In conclusion, Mr LYNCH recommended the report for adoption as a fair and good summary of the activities in 2008.

In the following exchange of views, the Board welcomed the general report and satisfaction with the work accomplished in 2008 was expressed. The Board also congratulated the working group and it's Chair for ensuring that the Board was presented such a high quality report.

Some Members made editorial remarks, for example with regard to the composition of the Agency's Committees. Other Board Members felt that some aspects of a more strategic and forward looking nature should be included into the ECHA mission statement presented at the beginning of the report, for example with regard to the future risks ECHA will face and the fact that the Agency would also have a mandate with regard to ensuring compliance with the REACH legislation. Also more feedback on lessons learned, with regard, for instance, to the network of helpdesks, was also requested.

One Board Member referred to the discussions on the draft work programme 2010 at the Management Board meeting of February 2009. He thanked the Secretariat for providing a document comparing the staff estimates of 2006 to those of 2009/2010 which he found very useful and informative. The Board member stressed however, that the information would confirm the concern that the proportion of administrative staff is becoming higher than originally foreseen.

A Board Member appointed by the Commission to represent interested parties congratulated ECHA on an outstanding performance in 2008. The Board Member continued with a statement on the implementation of the REACH Regulation, highlighting that the Agency, industry, as well as Member State authorities were all still on a learning curve with regard to the new regulatory procedures. As the central Agency for the implementation of REACH, ECHA would need to continue to monitor closely any difficulties that might arise for companies, and act accordingly.

At the moment, European industry is very concerned with the state of the implementation of REACH because the first year of operations has shown that the legislation has imperfections and that reality does not always follow the foresight of the legislators. Companies have problems adhering to the stipulations in REACH, namely with respect to the formation of Substance Information Exchange Fora (SIEF) where recent findings have revealed severe delays. Other difficulties result from the proliferation of lists of potential substances of very

high concern (SVHC) which are not consistent with REACH. These lists issued by Non-Governmental Organisations cause confusion in industry and amongst consumers.

In response to this, another Board Member appointed by the Commission to represent interested parties explained that the list issued by the organisation he represents should be seen as a contribution to the debate on SVHC, and does not aim to create confusion. It would have been made clear in the accompanying report that the only official list is the candidate list established by ECHA. For an organisation representing workers' interests it would be legitimate to point to substances that may cause occupational diseases. He asked for consideration of the fact that the success of REACH is of common interest to industry, workers, and consumers, and that society as a whole would benefit from the safer use of chemicals. This view was supported by another Board Member representing interested parties who reminded the Board that at the last meeting, under agenda item 5, those Board Members who commented on the topic of the candidate list of substances of very high concern explicitly or implicitly referred to the "SIN-list" issue by the International Chemical Secretariat (ChemSec) as a helpful instrument.

The Executive Director thanked the Board for the comments made. He explained that the mission statement cited in the text is identical to that in the multi-annual work programme adopted in September 2008. For reasons of consistency, he proposed that a discussion on revising the statement should take place later in 2009 in the context of the revision of the multi-annual work programme. He confirmed that it would indeed be ECHA's role to monitor the implementation of REACH, work towards compliance with the law and provide support to stakeholders.

The Chair summarised the discussion and proposed that ECHA would include the editorial remarks made, and in particular cater for clarification with regard to the composition of the Committees. To this end, he proposed that a revised draft should be presented to the Board. This revised draft should also contain the elements for a foreword by the Executive Director providing for lessons learned and a strategic outlook taking account of future risks. This was agreed.

The Secretariat later presented a revised meeting document MB/17/2009 rev.01.

The Chair concluded that the Board adopted the general report 2008 as modified allowing the Executive Director to develop his foreword on the basis of the agreed elements.

6. Analysis and assessment of the authorising officer's annual activity report 2008 (MB/18/2009)

The floor was given to Martin LYNCH, Chairman of the Management Board's working group on planning and reporting. Mr LYNCH presented the meeting document MB/18/2009 and the background of the decision requested by the Management Board.

The ECHA Financial Regulation (MB/57/2008) requires the authorising officer (i.e. the Executive Director) to report to the Management Board through the form of an annual activity report for the previous financial year. This report is, to a large extent, identical to the general report, but contains additional information on the accounts, staffing, budget and risk management measures. In contrast to the general report, the annual activity report contains

elements of a forward looking, strategic nature, and an assessment of risks and risk management measures.

The report is drawn up under the responsibility of the Executive Director who also signs a declaration of assurance with regard to the correctness of the information. Therefore, the Board was not asked to amend or adopt this report but noted that the working group was able to comment on an earlier draft and the advice of the group was now reflected in the final version. The Board was charged with providing the budgetary authority and the Court of Auditors with an analysis and assessment of the document: according to the Financial Regulation, this analysis and assessment should also be included in the General Report 2008 (as adopted under agenda item 6).

Mr LYNCH presented the outcome of the deliberations of the working group which agreed on the analysis and assessment contained in the meeting document.

The Chair thanked Mr LYNCH and the working group for their thorough preparation and informed the Board that a room document had been made available containing the proposal by a Board Member appointed by the Commission to represent interested parties to add a reference in the document, to the delayed work on the public dissemination of non-confidential information of chemical substances. This work had to be postponed in 2008 due to the workload linked to pre-registration and the delays in IT-development.

In the following discussion, Board members expressed their satisfaction with the Executive Directors report and the proposed analysis and assessment. Several members supported the proposal to add information on the postponement of activities related to the dissemination of information to the public. Additional remarks were made with regard to the presentation of the Management Board in the analysis and assessment, which should be seen as part of the Agency and not as an external body.

Individual members raised the question of whether the tone of language used in the document was, in part, too positive and thus not fully reflective of the difficulties ECHA had had to face in 2008 due to external factors. After discussion, it was agreed that the work of the Agency and the staff in 2008 merits sincere congratulation and the Board should show its appreciation.

With regard to the budget execution in 2008, one Board Member raised the question of whether ECHA could have performed better in this regard. The Executive Director responded by explaining that the figures in the report related to the percentage of payments executed in 2008, not the amount of funds factually committed, which would be higher. In addition, the amount of funding needed in ECHA's first year of financial independence was estimated by the Commission and, by default, subject to a certain margin of error. The Agency would automatically improve in this regard when more experience on the operations of ECHA is gained.

The Chair summarised the discussion and presented a proposal for including reference to the delayed work on the public dissemination of information in the text. This proposal by the Chair was agreed<sup>1</sup>.

8

<sup>&</sup>lt;sup>1</sup> The following words were added to cipher 3 of the document: ", whilst stressing at the same time the importance of some of the postponed activities, in particular the work on the public dissemination of non-

In addition, the Chair proposed that the Secretariat should present a Roadmap on the public dissemination of non-confidential information in accordance with Article 119 of the REACH Regulation at the next Board meeting. The Executive Director welcomed this proposal and agreed to foresee an agenda point at the June Management Board meeting.

Subject to some agreed minor corrections to the text<sup>2</sup>, with regards to the role of the Management Board - which should be seen as part of ECHA and not as separate body - the Management Board adopted the analysis and assessment of the authorising officer's annual activity report.

7. Report of the working group on reimbursement of REACH tasks to Member States (MB/19/2009, MB/19/2009rev.01; MB/20/2009, MB/20/2009 rev. 01)

The agenda item was introduced by the Executive Director, who presented the context and legal framework of the report, its several annexes, and the draft decision contained in documents MB/19/2009 rev.01 and MB/20/2009 rev.01.

The Management Board had decided in February 2008 to establish a working group on the reimbursement of REACH tasks to Member States and provided it with a precise mandate. The working group has since reported back on several occasions to the Management Board, the last time being in February 2009. In advance of the entry into operation of the restriction title of the REACH Regulation, the first formal decision would now be required. A review is foreseen at the end of 2011.

The proposal of the working group for the reimbursement of Member States for substance evaluation and work as rapporteurs on restrictions, consists of a fixed-time estimate per task (75 days for substance evaluations; 20 days for RAC 'rapporteurships' and 25 days for SEAC 'rapporteurships' in the case of a restrictions proposal), a fixed rate of € 799 per day, and the applications of the most recently available correction coefficients per Member State to ensure that the real costs of the Member State are reflected. It was noted that the working group favours fixed-time estimates rather than reimbursement linked to the time effectively spent on a given task, in order to prompt MSCAs to undertake the work efficiently.

In order to take account of currency fluctuations, the report proposes that payments to Competent Authorities located outside the Euro zone shall be made in the local currency, whereby the Euro amounts will be converted at the average exchange rate of the year for which the coefficients have been published.

Finally, the report also proposed a ceiling of 2.3% for the reimbursements to Member States as a proportion of the fee revenue for the period 2009-2013.

This was followed by an exchange of views in which the report and the draft decision were welcomed by Board members.

confidential information via the Agency's website in accordance with Article 119 of Regulation (EC) No 1907/2006."

<sup>&</sup>lt;sup>2</sup> Cipher 2 and 4: "Congratulates *the management and staff of* the Agency." Cipher 4: "from the Agency's *Secretariat* towards stakeholders and towards the Management Board"

Some Members proposed clarifications to be added such as that the Management Board can not place obligations upon national authorities. Questions were also raised with regard to situations in which rapporteurs and co-rapporteurs were from different Member States; the format of the invoices eventually used; and whether the system would also allow for the payment of lower transfers to Member States if the work on a specific dossier was less than the average time foreseen in the draft decision.

The practical problems which could occurre when a national competent authority would not perform the REACH tasks delegated to it, and outsource the work were raised. In such situations, the competent authority may not be entitled under national law to receive payments from ECHA.

In response, the Executive Director welcomed the comments and provided clarifications. He proposed to include some of the points raised but emphasised that it would not be possible for ECHA to provide payments to individuals or private institutes – the REACH Regulation and other relevant EU legislation would only allow for payments to the competent authorities. It would however be possible to arrange the contracts in compliance with European law and taking at the same time into account this specific situation. This was confirmed by a representative of the Commission.

The Executive Director further proposed that the possibility of paying lower fees in justified cases should be explored in the context of the revision of the decision. In addition, he proposed that ECHA could provide guidance on the invoicing procedure.

The Chair summarised the discussions and invited the Secretariat to present a revised draft decision which includes the possibility for competent authorities to subcontract REACH tasks.

A revised draft decision MB/20/2009 rev.02 was presented to the Board (on screen) containing a revised wording for Article 3, 4 and 5 in order to accommodate the comments made by the Board<sup>3</sup>.

The Chair thanked the Secretariat for the revision and pointed out that the other documents presented with the report of the working group, namely the framework contract and the draft letter to the Permanent Representations to the European Union would also need adaptations in accordance with the amended draft decision. He invited the Secretariat to provide the Member States concerned with practical guidance on the contractual arrangements and information on the invoicing procedure.

Article 4(1) was revised as follows: "Each Member State shall nominate entities, including a Member State Competent Authority, which shall be parties to a Framework Contract with the Agency for the payment of the amounts to be transferred under this Decision."

<sup>&</sup>lt;sup>3</sup> In Article 3(2) the words "the Agency shall invite" was added after "Article 7" and the word "shall" in the second line of the paragraph replaced by "to".

In Article 5(1), the words "the entity nominated by the Member State concerned" were replaced by the words "and the parties to the Framework Contract referred to in Article 4(1)" and Article 5(3) was revised as follows" Payments shall be made against an invoice according to the Framework Contract."

The Management Board adopted the decision on the scale of fees regarding payments to Member States contained in document MB/20/2009 rev.02. The decision will be forwarded to the European Commission for agreement.

# 8. REACH-IT Information Security (MB/21/2009; MB/21/2009rev.01; MB/RD/01/2009)

In his introduction, the Chair clarified the purpose of the agenda item which was to approve ECHA's general overall approach for granting access to REACH-IT to the Member State Competent Authorities (MSCAs) and the relevant Commission services. The Management Board was not asked to decide on the content of each of the individual documents presented by the Secretariat.

The Chair informed the other Board members that two room documents had been made available: a revised meeting document MB/21/2009 rev.01, taking into account the outcome of the discussions in the Security Officers Network (SON) which took place two days before the meeting, and a draft declaration, for signature, of the legal representatives of the MSCA prior to granting them access to REACH-IT.

The floor was then given to the Executive Director who outlined the broader context of the foreseen access to REACH-IT for Member States. The REACH Regulation (EC) No 1907/2006 does not stipulate that MSCAs or Member States shall have full access to the data held by the Agency. The implementation of REACH however requires access to necessary information for certain MSCA tasks. In order to ensure effective co-operation, at an early stage prior to the establishment of the Agency it was agreed, by the Commission and the MSCAs that the latter would get full access to the REACH-IT database.

Based on the outcome of the work of the Security Officers Network, the Executive Director presented ECHA's approach for granting access to REACH-IT. MSCAs will be granted full access to REACH-IT on the condition that the legal representative of the authority signs a declaration assuring compliance with the standard security requirements prepared by ECHA, on the basis of the security policy discussed by the SON. By signing the declaration, the MSCA would also accept the full legal and financial responsibility of the consequences of the harmful disclosure of confidential REACH-IT data by staff and experts given access through its systems.

The Executive Director emphasised that REACH-IT data would be made accessible under these conditions which correspond to the level of REACH-IT security at the Agency. ECHA would however retain the full ownership of the data with the effect that further distribution of information held in REACH-IT or its use for non REACH related purposes, would depend on ECHA's explicit consent.

With regard to enforcement, the Executive Director reminded the Board that a dedicated IT system is in preparation which will enable enforcement authorities to access relevant data from REACH-IT, per country. Pending the completion of this system, MSCAs would be allowed to give enforcement authorities on-site access to data strictly necessary for (well justified) enforcement purposes

This was followed by an extensive exchange of views in which most of the Board members took the floor.

The Board clearly acknowledged the fact that security aspects are crucial for the confidence of industry in the REACH system and appreciated ECHA's cautious approach to granting access only when a high standard of security is respected. With regard to the detailed requirements, many Board Members expected a corresponding degree of flexibility on how these standard requirements were to be implemented, without lowering the overall level of security. Some Member State representatives raised concerns with regard to the approach taken to identify the specific security requirements which MSCA's would have to respect. It was equally noted that a more detailed preparation of the technical details would have been desirable.

A representative of the Commission stressed that such flexibility must not result in lower security standards. The Board member also called for a high degree of conformity to the security standards. A Board member appointed by the Commission to represent interested parties concurred with this and expressed its understanding for both ECHA's approach to allocate clearly the responsibilities for securing the data, as well as for the need by Member States to allow for some flexibility as long as compliance with security rules is audited. He nevertheless stressed the critical importance of data security for industry.

A discussion also took place on the relationship between national and European laws on access to information and the confidentiality requirements provided for by REACH.

The Chair concluded that the Management Board would not be in the position to formally approve ECHA's approach at this point of time. However, the Board would fully acknowledge the high priority of the security of data contained in REACH-IT. The Chair also pointed to the need for a solid legal interpretation on the relationship between REACH and horizontal national or European legislation on public access to data.

The Management Board decided that it was not ready to formally approve ECHA's approach, but expressed its willingness to take a decision on the issue at its next meeting, in June 2009. The Secretariat would then provide an amended version, including a solid legal interpretation on the relationship between REACH and horizontal national or European legislation on public access to data, after further consultation with the network of Security Officers (SON). It would also provide a presentation on the subject at the next CARACAL meeting.

The Management Board expressed its commitment to guaranteeing a high level of protection of confidential REACH-IT data, so that the level of security for REACH-IT access in the Member States would be as high as that required at the ECHA premises.

9. Appointment of the alternate / additional technical members of the Board of Appeal (*MB*/22/2009)

The deliberations took place in camera.

The floor was given to the Vice-Chair who had taken the role of Chair of the Preparatory Group in charge of assessing the candidates. He presented the Group's findings and the recommendations contained in the Group's report to the Management Board (MB/22/2009).

The Chair thanked the Preparatory Group for its work and clear recommendations, and explained the voting procedure. He suggested proceeding in the same way as for previous appointments, i.e. with an *en bloc* vote on the basis of the recommendation of the working group. This was agreed.

Two Board Members without voting rights were designated as tellers.

The vote took place by secret ballot and the recommendations of the Preparatory Group were approved in line with the requirements of Article 82 of the REACH Regulation.

The Management Board decided to appoint Mr Arnoldus VAN DER WIELEN, Mr Carlo LUPI and Ms Jonna SUNELL-HUET as well as Mr. Henricus SPAAS - from the moment his present appointment as a regular member ends due to mandatory retirement according to the applicable staff rules and for the remainder of his initial five-year term - as alternates of the technically qualified member of the Board of Appeal and additional technically qualified members of the Board of Appeal and their alternates.

10. Implementing rules for the Staff Regulations (*MB/23-29/2009*)

On the invitation of the Chair, and with the agreement of the Executive Director, an observer nominated by the ECHA Staff Committee was present for the agenda point.

The Board heard from the Director for Resources, who presented the meeting documents MB/23-29/2009

Based on the Procedure for Adopting Implementing Rules agreed upon in the 11th Management Board meeting, the Board adopted a third set of draft implementing rules, subject to the agreement of the Commission. The rules adopted include:

- a Decision on the performance appraisal of temporary and contract staff;
- a Decision on the policy and procedures for the reclassification of temporary agents;
- a Decision on part time work;
- a Decision on temporary management posts;
- a Decision on middle management staff.

Upon the agreement of the Commission, the Chair is authorised to formalise the adoption of these implementing rules.

The Chair concluded that the draft Decision on the appraisal of the Executive Director and of the members of the Board of Appeal would need some further refinement with regards to the role and function of the review assessor and the way he/she takes account of the view of the Management Board. It shall be adopted by written procedure.

11. Decision concerning terms and conditions for internal investigations in relation to the prevention of fraud, corruption and any illegal activity (MB/30/2009)

The draft decision was presented by ECHA's Senior Legal Advisor who informed the Board that the decision is a requirement set out in Article 98(2) of the REACH Regulation (EC) No 1907/2006. The decision establishes the framework for investigations by the EU Anti-Fraud Office (OLAF) at ECHA. The decision is based on a model decision adopted as part of the Inter-institutional Agreement of 25 May 1999 between the European Parliament, the Council of the European Union and the Commission of the European Communities concerning internal investigations by OLAF. The decision will apply to all ECHA staff, including staff members subject to the Staff Regulations as well as other staff such as interims and trainees.

The Management Board adopted the decision contained in document MB/30/2009.

# 12. Reporting Officers for the appraisal of the Members of the Board of Appeal (MB/31/2009)

The agenda point was introduced by the Chair who informed Members that the appointed Chair and legally and technically qualified members of the Board of Appeal were present in order to be formally introduced to the Management Board.

The Chair and the members of the Board of Appeal briefly introduced themselves to the Board. The Chair congratulated them on behalf of the Board and expressed satisfaction that the Agency would now include a fully functional Board of Appeal. The Management Board would be looking forward to a good cooperation with the Board of Appeal in the future. The Chair also thanked the Preparatory Group on the Board of Appeal that assessed and recommended the candidates.

A permanent working group on the Board of Appeal composed of three members of the Management Board, Ms Katarzyna KITAJEWSKA, Mr D. Grant LAWRENCE and Ms Ana FRESNO RUIZ, was established.

The mandate of the Group is to prepare all issues related to the Board of Appeal or its members for discussion at the Management Board meetings. The Group's members could, for example, make proposals to the Management Board on how to proceed with regard to certain administrative requests of the members of the Board of Appeal; act as preparatory group for appointment of future Board of Appeal members; and, if needed, draw up a report for the Management Board for the purposes of the procedure provided in Article 90(4) of the REACH Regulation (EC) No 1907/2006. It is also foreseen that the Members of the permanent working group would act as reporting officers for appraisals of the regular members of the Board of Appeal (Chairperson, legally qualified and technical member).

It was further agreed that the existing Preparatory Group for the Board of Appeal consisting of the Deputy Chair, Alexander NIES and D. Grant LAWRENCE would complete the appointment for the Board of Appeal resulting from the presently submitted shortlist of the European Commission.

Due to the fact that Ms Odile GAUTHIER will be replaced as a Member of the Management Board, the Board also decided to designate Mr Claude GEIMER as reporting officer for the Executive Director together with Ms Elke ANKLAM and Ms Marta CIRAJ.

# 13. Update of the list of eligible stakeholder observers (*MB/32/2009*)

The Board heard from the Director for Cooperation who introduced the agenda item. Since the last update to the Board on the issue in September 2008, nine additional organisations had expressed their interest in participating in the work of ECHA. Four of these organisations, including an organisation representing SMEs, were regarded as eligible in accordance with the criteria established by the Board.

The Board was informed that all ECHA Committees have decided to invite regular observers from 15 or 16 different organisations. Moreover, the Forum for Exchange of Information on Enforcement organised an open session at its meeting in December 2008 to which it invited those eligible organisations that had expressed their interest in the work of ECHA to participate. The next such open session will be organised at the next Forum plenary meeting of 28-30 April 2009.

The Director for Cooperation considered the experience from the participation of invited stakeholder organisations in the Committee and Forum meetings as very positive. The observers had made valuable input to the proceedings of these ECHA bodies. From the 15-16 organisations invited on average, only 5 to 8 have been able to participate in a meeting at any given time - but it was felt likely that interest would increase.

The Management Board took note of the information provided.

# 14. Report of the Executive Director, including update on Annex XIV recommendations (*MB/33/2009*)

The floor was given to the Executive Director who gave a comprehensive overview of the Agency's activities since the last Board meeting. It covered the operational activities as well as management, financial and other administrative aspects. Special attention was given to the status of the preparations of the first Agency recommendations for inclusion of substances of very high concern in the authorisation list.

The report of the Executive Director followed the structure of the work programme and assessed, via performance indicators, how the objectives set were met. The form of the presentation was warmly welcomed by the Management Board, and the report was regarded as exemplary for modern management methods. The meeting welcomed the fact that the report of the Executive Director would become a regular item on the agenda of Management Board meetings.

In the following exchange of views, several Board Members referred to recent discussions on the work of the REHCORN<sup>4</sup> network of REACH Helpdesks and stressed the importance of a timely resolution of questions relating to the implementation of REACH - in particular, if they were of legal nature. It was suggested that one possible solution to improve response times could be to reinforce cooperation between REHCORN and CARACAL<sup>5</sup>.

\_

<sup>&</sup>lt;sup>4</sup> REACH Helpdesk Correspondents Network

<sup>&</sup>lt;sup>5</sup> Meeting of the Competent Authorities for REACH and CLP

The Executive Director shared the concerns raised. He explained that the major cause for delays in the past was that questions of a legal nature were not identified quickly enough and duly channeled to the right interlocutor, i.e. the Commission. To remedy this situation, ECHA recently initiated a revision of the procedure for adopting FAQs, which would allow the REHCORN Secretariat to identify legal questions at an early stage and forward them to the European Commission without delay. A Board Member appointed by the Commission stated that it would be the responsibility of the Commission to strive towards a harmonised interpretation of European legislative acts, keeping in mind that the only competence for making binding interpretation would lie with the Community Courts. The Board also agreed that MSCAs should be informed by ECHA whenever a legal question is referred to the Commission.

Board Members enquired about the progress made following a request sent in 2008 to MSCAs to support ECHA in the translation of guidance documents. The Director of Cooperation explained that twelve positive replies from MSCAs had been received, and ECHA was currently looking into alternative ways of proceeding.

One Board Member reported that concerns were raised by the cosmetics industry on the relationship between REACH and the Cosmetics Directive, which would contain conflicting requirements with regard to animal testing. It was agreed that a note outlining the relationship between the two legislative frameworks would be drawn up by ECHA and presented at the next Board meeting.

One Board Member also stressed the need for ECHA to start to enhance cooperation with other Agencies whose activities may overlap with those of ECHA. For example, it was suggested that further cooperation with the European Environment Agency should be sought, not only because the announced publication of a new report on chemicals ("late lessons from early warnings"). The Executive Director supported the need for close cooperation and indicated that first steps to intensify cooperation had already been made, not only with the EEA<sup>6</sup> but also with EFSA<sup>7</sup> and EMEA<sup>8</sup>.

The Management Board took note of the information provided.

# 15. Report on Guidance activities (*MB/34/2009*)

The Director for Cooperation presented a report on ECHA's Guidance activities (MB/34/2009). The report was foreseen in the 2008 ECHA Work programme, but was rescheduled to the beginning of 2009, when sufficient information on practical experience would be available.

The Director for Cooperation provided a comprehensive update to the Management Board on the state of development of the REACH Guidance provided by ECHA, as well as an overview of the feedback so far received from Guidance users. He also informed the Management Board about the planning for future updates of the Guidance.

<sup>&</sup>lt;sup>6</sup> European Environment Agency

<sup>&</sup>lt;sup>7</sup> European Food Safety Agency

<sup>&</sup>lt;sup>8</sup> European Medicines Agency

The Chair informed the Board of a room document containing a proposal by a representative of a Member State to slightly amend the Guidance update procedure. The Board agreed to the proposal to inform MSCAs in addition to the respective Partner Expert Group for Guidance update (PEG) of the first draft of Guidance documents. The Director for Cooperation clarified that ECHA had foreseen such a step when detailing the process for Guidance updates; in addition, the regular publication of draft Guidance on the internet was foreseen in the process.

A Board Member appointed by the European Commission to represent interested parties enquired whether ECHA intends to prepare guidance for establishing a so called 'derived minimum effect level' (DMEL) for substances for which no 'derived no effect level' (DNEL) could be established. It was agreed that ECHA will provide information on the issue at the next Board meeting.

The Management Board took note of the information provided.

# 16. Readiness of the restriction procedure (*MB/352009*)

The Director for Assessment introduced the agenda item which sought to summarise ECHA's tasks under the restriction title and provide an overview of the actions that ECHA has taken to prepare for the implementation of these tasks - which will begin on 1 June 2009.

After 1 June 2009, the Member States may submit notifications of their intention to prepare a restriction proposal and the Commission may request ECHA to prepare a proposal. According to ECHA's current information, Member States are only planning to submit their first restriction proposals in spring 2010.

The Director for Assessment informed the Board that the Commission has indicated that it may request ECHA to prepare Annex XV dossier(s) as a result of the review obligations included in the current entries of Annex XVII; such requests could be received in 2009.

He informed the Board Members that ECHA will work closely with MSCAs and the Commission to ensure that the possible restriction proposals are prepared and submitted in a planned and coordinated manner, in order to allow the efficient use of the available and planned resources. In conclusion, ECHA and the Committees would be ready to deal with restrictions after 1 June 2009: there was, however, currently some uncertainty about the number, scope and timing of future proposals for restrictions.

This was followed by an exchange of views in which a representative of the Commission confirmed that the Commission may request the preparation of restriction dossiers from ECHA in 2009. This could also consist of reviewing the scope of certain existing restrictions.

Several Board Members representing Member States asked ECHA if guidance could be provided on when it would be appropriate to choose the restriction or the authorisation route for imposing risk management measures. Other issues raised by Members included the procedure for re-examining existing restrictions which require a decision by the Commission in the so called "comitology procedure".

A Board Member made reference to a joint letter by Commissioners Dimas and Verheugen calling on the Member States to provide sufficient resources for the implementation of REACH. This letter would be taken very seriously, he noted, and the Member State concerned would be interested in more information on what precisely could be done.

In response to this, the Executive Director informed the Management Board that the decision regarding whether an authorisation or restriction procedure would be appropriate in any specific case was the subject of a fruitful workshop that ECHA had organised with Commission and Member States officials, in January 2009. As a result of the workshop, ECHA was invited to produce further guidelines for Member States on the issue. Useful information could nevertheless already be gleaned from the comprehensive documentation of the workshop, which has been published on the internet.

On request, he also clarified that ECHA will make adequate resources available and may reduce or increase these resources in line with the number of restriction dossiers submitted. The same would apply for proposals for identification of substances as being of very high concern (SVHC).

With regard to the procedure for re-examination of existing restrictions, it was agreed that the CARACAL meeting<sup>9</sup> rather than the Management Board would be the appropriate forum within which to deal with the issue. At the same time, it was acknowledged that there is a need for clarification when an entry into the registry of intentions contradicts an existing restriction.

The Management Board took note of the information provided.

# 17. ECHA & data-sharing within SIEFS (MB/36/2009)

The Board received a report from the Director of Registration and IT-Tools on the current situation regarding pre-SIEFs, and the progress made on SIEF formation from ECHA's perspective.

The report stressed that due to the high number of participants in some pre-SIEFs communication within them could potentially be cumbersome, leading to slow progress in SIEF formation and in the election of lead registrants. This is of particular concern for companies intending to register by the 2010 deadline, and who would soon need to start to prepare their registration dossiers.

While ECHA had observed a gradual increase in the number of pre-SIEFs being facilitated by a SIEF Formation Facilitator (SFF) since January 2009, pre-SIEF participants continued to report difficulties with communication within the pre-SIEFs - in some cases due to inactive or obstructive SFFs. An ECHA News Alert of 13 February 2009 - clarifying the role of an SFF and inviting those nominated as Lead Registrants of SIEFs to contact ECHA with their contact details - seems to have had only a limited effect on the situation.

-

<sup>&</sup>lt;sup>9</sup> Meeting of the Compentent authorities for REACH and CLP Regulation

In order to try to find practical solutions to the main problems encountered in SIEF formation, ECHA together with the Commission and industry held a workshop on 30 March 2008. The workshop proved to be fruitful, and conclusions on many practical aspects - such as the need for the lead registrant to document that all members of the pre-SIEFs had been contacted in order to ensure that data sharing obligations had been fulfilled - were reached. However, even after the workshop, ECHA still felt the need to raise further awareness on the importance of beginning to prepare joint registration dossiers and to submit them early. In this respect an imminent coordinated awareness and information campaign by ECHA, industry and the Commission, and additional support to lead registrants, will be launched, as a mere press release may not be sufficient.

Board Members thanked the Secretariat for the excellent presentation of the *status quo* and expressed their sincere appreciation for all the efforts made by ECHA to assist industry in the SIEF formation process, despite a limited remit to act from the REACH Regulation. The Board identified the need to follow these issues closely in future and expressed its full support for further actions - including the launch of the proposed coordinated awareness and information campaign.

#### 18. Any Other Business

Seconded national experts from Non-EU Member States

The Executive Director informed the Board that ECHA has been approach by a Non-EU Member State with respect to whether a position as a seconded national expert (SNE) could be taken up by an official of this country. As the decision would involve horizontal aspects, the Secretariat would appreciate written feedback from Members whether they deem such employment as appropriate.

#### **Building** issues

The Board was informed of ECHA's present plans to expand within its main building, and possibly the neighbouring building, to address the increasing office space needs. The Board will receive regular updates on the progress of the initial contacts with the building owner.

### Details of reimbursement overviews

Members received detailed overviews of the travel reimbursements from previous Board meetings. It was agreed that such information would be made available on a regular basis in the future.

#### Term of office of the Deputy Chair

The Chair informed the Board that the term of office of the Deputy Chair will expire at the end of June 2009 and thus a new election would be necessary at the June Board meeting. The current Deputy Chair informed the other Members that he would be willing to stand for another term but also to step back if there were any other Members interested in the position.

Letter of chemicals industry association to Vice President Verheugen

A Board Member appointed by the Commission to represent interested parties mentioned that the main European industry association in the chemical sector, CEFIC, had sent a letter to Commission Vice-President Verheugen asking him to look into the possibility of reduced or staggered fees under REACH, in recognition of the current economic circumstances facing the European industry.

### 19. Next meeting and closure

The Chair reminded Members that the next meeting of the Management Board would be held in Helsinki on <u>25/26 June 2009</u>, in the "Margot Wallström" room of the Agency's conference centre.

20

### III. Decisions taken/ Conclusions reached by the Management Board

#### The Management Board

- approved the minutes contained in document MB/M/01/2009, subject to the amendments indicated in the corrigendum attached to the present minutes. It was agreed that the minutes of the Management Board shall in future contain a list of agreed follow-up actions.
- adopted the agenda as contained in MB/A/02/2009 rev.01.
- agreed to take appropriate action towards the national Treasury departments and the EU Budgetary Authority if the Commission's Preliminary Draft Budget did not ultimately include a sufficiently high proportion of the requested 45m EUR "temporary" Community subsidy, for which a need was confirmed by the Management Board at its meeting of February 2009.
- adopted the general report of the Agency for 2008 as contained in document MB/19/2009 rev.01, subject to completion of the foreword as agreed at the meeting, and also instructed the Executive Director to send the document to the Committee of Regions, in addition to the Community Institutions and bodies referred to in Article 83(3) of the REACH Regulation (EC) No 1907/2006.
- adopted the analysis and assessment of the authorising officers annual activity report for 2008, as contained in document MB/17/2009, on the basis of the modifications indicated under section II.6 of the present minutes. Instructed the Executive Director to send the adopted document to the Budgetary Authority and the Court of Auditors not later than 15 June.
- adopted the decision on the scale of fees of payments to Member States contained in document MB/20/2009 rev.02, subject to the amendments indicated under section II.7 of the present minutes and pending approval by the Commission.
- decided to postpone the decision on approving ECHA's overall approach for granting access to REACH-IT for the Competent Authorities of the Member States and the Commission until the meeting of the Management Board of June 2009.
- appointed Mr Arnoldus VAN DER WIELEN, Mr Carlo LUPI and Ms Jonna SUNELL-HUET as well as Mr. Henricus SPAAS from the moment his present appointment as a regular member ends due to mandatory retirement according to the applicable staff rules and for the remainder of his initial five-year term as alternates of the technically qualified member of the Board of Appeal and additional technically qualified members of the Board of Appeal and their alternates.

Authorised the Executive Director to undertake, in agreement with the Chair, the necessary steps to inform the four candidates of the decision taken and to determine the date on which the five-year period referred to in Article 90(1) of the REACH Regulation begins for the three new appointees.

- adopted five draft implementing rules for the EC Staff Regulations contained in the annexes to documents MB/24-29/2009, subject to the agreement of the Commission. Upon the agreement of the Commission, the Chair is authorised to formalise the adoption of this implementing rule. For practical reasons, the Chair is granted strictly limited discretion to accept minor technical or linguistic changes proposed by the Commission, provided that these do not alter the content of the Board's decisions.
- decided to enter into written procedure on the draft implementing rule for the EC Staff Regulations contained in annex 1 to document MB/23/2009.
- adopted the decision concerning the terms and conditions for internal investigations in relation to the prevention of fraud, corruption and any illegal activity detrimental to the Communities' interests, as annexed to document MB/30/2009.
- designated Ms Katarzyna KITAJEWSKA, Mr D. Grant LAWRENCE and Ms Ana FRESNO RUIZ to act as reporting officers for the members of the Board of Appeal.
- established a permanent working group on the Board of Appeal, composed of the members of the Management Board designated as the reporting officers for the members of the Board of Appeal; gave the working group the mandate to report back to the Management Board on all issues related to the Board of Appeal and its members.
- designated Mr Claude GEIMER as one of the three reporting officers for the Executive Director (the others being Ms Elke ANKLAM and Ms Marta CIRAJ).

### List of agreed follow-up actions

- The Secretariat will inform the Management Board of the outcome of the Commission's deliberations on its preliminary draft budget, after adoption on 29 April 2009.
- At the Management Board meeting of June 2009, the Secretariat will present a Roadmap to the dissemination of non-confidential information on substances in accordance with Article 119 of the REACH Regulation (EC) 1907/2006.
- The Secretariat will provide the Management Board with a summary outcome of the pre-registration period before the Management Board meeting of June 2009.
- The Secretariat will provide clarification to the Member State concerned on contractual arrangements for payments under draft decision MB/20/2009.in case the MSCA is not performing REACH tasks itself
- The Secretariat will provide information on DMEL (derived minimum effect level) and possible guidance development for establishing this, at the Management Board meeting of June 2009.
- The Secretariat will approach the European Environment Agency in Copenhagen on the possibility of closer cooperation in the field of chemicals.

#### IV. List of Attendees

### Representatives of the Member States

Zoltán ADAMIS (HU)

Aurelija BAJORAITIENÉ (LT)

Marta CIRAJ (SI)

Francis E. FARRUGIA (MT)

Ana FRESNO RUIZ (ES)

Odile GAUTHIER (FR)

Ekaterina GECHEVA-ZAHARIEVA (BG)

Claude GEIMER (LU)

Thomas JAKL (AT) also acting as proxy of Maria ALAJÕE (EE)

Katarzyna KITAJEWSKA (PL)

Pirkko KIVELA (FI)

Antonello LAPALORCIA (IT)

Marc LEEMANS (BE)

Martin LYNCH (IE) also acting as proxy of Ethel FORSBERG (SE)

Leandros NICOLAIDES (CY)

Alexander NIES (DE) also acting as proxy of Bernd LANGE (EP)

and Arnoldus Wilhelmus of VAN DER WIELEN (NL)

Edita NOVÁKOVÁ (SK) also acting as proxy of Karel BLAHA (CZ)

Per NYLYKKE (DK)
Teodor OGNEAN (RO)
Armands PLATE (LV)
John ROBERTS (UK)

Fernanda SANTIAGO (PT)

Maria-Miranda XEPAPADAKI-TOMARA (EL)

#### Representatives of the Commission

Elke ANKLAM

Grant LAWRENCE also acting as proxy of Heinz ZOUREK for the 2<sup>nd</sup> day

Heinz ZOUREK

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

Martin FUEHR (University of Darmstadt)

Tony MUSU (ETUC) Alain PERROY (CEFIC)

#### Observers from EEA-EFTA countries

Anne Beate TANGEN (NO)

#### Other Observers

Jan HAMMAR on behalf of Ethel FORSBERG (SE)
Josef HASA on behalf of Karel BLAHA (CZ)

Jan Karel KWISTHOUT on behalf of Arnoldus VAN DER WIELEN (NL)

Kristel LEMBIT on behalf of Maria ALAJÕE (EE)

Catherine MIR (FR)
Astrid BARTELS (COM)
Gustaaf BORCHARDT (COM)

Gwenole COZIGOU on behalf of Heinz ZOUREK (COM) for the 2<sup>nd</sup> day expert accompanying Antonello LAPALORCIA (IT)

#### ECHA staff

Geert DANCET (Executive Director)

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

Christel MUSSET (Director of Registration and IT Tools)

Minna HEIKKILÄ (Senior Legal Advisor)
Derek KNIGHT (Senior Scientific Advisor)

Alastair MACPHAIL (Head of Human Resources and Facilities Unit) for agenda item 10

Lindsay JACKSON (Head of Communications Unit)

Mervi MUSTAKALLIO (Planning and Monitoring Officer) for agenda items 5 and 6

Kari KLEMETTI (Information Security Officer) for agenda item 8
Mirco BUENNING (Chair of the Staff Committee) for agenda item 10
Mercedes ORTUNO (Chair of the Board of Appeal) for agenda item 12
Mia PAKARINEN (Legally Qualified Member of the Board of Appeal)

for agenda item 12

Henricus SPAAS (Technically qualified member of the Board of Appeal)

for agenda item 12

Johan NOUWEN (Senior Scientific Officer) for agenda item 15

Alain LEFEBRVE (Head of Unit, Executive Office)
Frank BÜCHLER (Legal Officer, Executive Office)
Andrea IBER (Legal Officer, Executive Office)

#### Annex

## Corrigendum to Document: MB/M/01/2009

(Agreed at the Management Board meeting on 23 April 2009)

Minutes of the Meeting of ECHA's Management Board held on 26/27 February 2009

### 5. Preliminary draft budget 2010

### [Page 5, last paragraph]

"On the request of the Chair, a representative of ECHA's parent Directorate General confirmed that the Commission agrees that there is a need for a bridging subsidy in 2010 and that it would be prepared to include *the* a request in the Commission's PDB

### [Page 6, 2<sup>nd</sup> paragraph, last sentence]

"It would eventually be his government's view that the funds should not be taken from the reserve available to ECHA's parent Directorate General. from the margin of heading 1a of the Community budget."