

MB/M/05/2009 final

MINUTES OF THE 15<sup>TH</sup> MEETING OF THE MANAGEMENT BOARD 17/18 December 2009

### I. Documents submitted to the Management Board

Draft agenda	(MB/A/05/2009)
Draft minutes	(MB/M/04/2009)
Budget implementation 2009: amending budget and budget transfers	(MB/68/2009) (MB/RD/08/2009)
Budget and establishment plan for 2010	(MB/69/2009)
Work Programme for 2010 - update of annexes	(MB/70/2009)
ECHA contingency planning for 2010	(MB/71/2009)
REACH-IT information security policy – report on written procedure MB/WP/02/2009 and further steps	(MB/72/2009)
Mission Charter of the Internal Audit Service & establishment of an audit working group	(MB/73/2009)
Update of the Internal Audit Service's multi-annual strategic audit plan for ECHA	(MB/74/2009)
Rules of procedure for cooperation between EFSA and ECHA (Art.110 REACH)	(MB/75/2009)
Implementing rules for the Staff Regulations on performance appraisal of temporary and contract agents	(MB/76/2009)
Rules on payments to witnesses and experts in appeal proceeding before the Board of Appeal	(MB/77/2009)
Rules of the Board of Appeal on costs relating to the taking of evidence in appeal proceedings	(MB/78/2009)
Contractual arrangements related to the reimbursement of REACH tasks executed by Member States	(MB/79/2009)
Appointment of Committee Member(s)	(MB/61/2009)
Report from the Executive Director	(MB/80/2009)
Multi-annual planning on evaluation	(MB/81/2009)
Report on the status of REACH-IT	(MB/82/2009)
ECHA work plan with regard to testing methods	(MB/83/2009)
ECHA work plan for substances on nanoscale	(MB/84/2009)
Activity report from the advisory group on dissemination	(MB/85/2009)

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

Introductory remarks

The Chair opened the meeting by welcoming the other Board members.

He noted that a Council decision was pending to appoint Mr Helmut DE VOS (BE) as Board Member in place of Mr Marc LEEMANS, and Mr Arwyn DAVIES (UK) in place of Mr John ROBERTS; and reported that the European Parliament had confirmed the nomination of Mr Guido SACCONI and Mr Hartmut NASSAUER as independent persons appointed to the Board. A notification letter was expected which would formalise the appointments.

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

In the course of the meeting, Mr PERROY, who had been appointed as a Board member by the European Commission to represent interested parties, announced that he would be renouncing his office due to his retirement. On behalf of the Management Board, the Chair thanked him for his valuable and constructive contribution to the establishment of the Agency since June 2007.

## 1. Agenda (*MB/A/05/2009*)

The Chair announced that item 10.2 of the draft agenda – the Commission's Internal Audit Service's (IAS), the Internal Auditor of ECHA, multi-annual audit plan for ECHA – should, according to the guidelines of the IAS, be presented for endorsement, not as an item for information.

He indicated that two room documents had been made available for the meeting: the latest notification of budget transfers carried out under the responsibility of the Executive Director (MB/RD/08/2009 – for agenda item 5), as well as a note on a high level group with industry.

A representative of the Commission declared that he wished to inform the Board of a study on the penalties applicable in the Member States for infringement of the REACH Regulation.

On this basis, the agenda was adopted.

#### 2. Welcome statement by the Cypriot Minister for Labour and Social Insurance

The Management Board received a welcome address from Ms Sotiroula CHARALAMBOUS, Minister for Labour and Social Insurance of the Republic of Cyprus.

The Minister began her intervention by referring to the historical role of her country as a meeting point of cultures, and by thanking the Board for choosing Cyprus as a meeting venue. She especially welcomed the broad composition of the Board and referred to the importance

of the expertise of representatives from industry, trade unions and public health and environmental non-governmental organisations.

The Minister emphasised the importance of the REACH and CLP Regulations in order to address the shortcomings of the previous European chemicals legislation and to tackle the lack of safety data for the majority of chemicals. She acknowledged ECHA's key role in day-to-day chemicals management in the European Union (EU) and praised the efficient establishment of the Agency as an important achievement. However, substantial efforts by all parties would still be needed in the course of the further implementation of the REACH and CLP Regulations.

With regard to the situation in Cyprus, Ms CHARALAMBOUS pointed to the progress made in the field of the risk management of chemical substances since the country's accession to the European Union (EU). As key policy priorities for Cyprus she referred to consumer safety and in particular the tracking of articles containing harmful substances.

The Chair and the Executive Director thanked the Minister for her encouraging words. The Chair also shared the view that the establishment of ECHA should be considered as a success and mentioned that the Agency has, despite her recent creation, already around 350 staff working in Helsinki. The Executive Director noted here that the ECHA Secretariat hoped to welcome a first staff member from Cyprus in the near future.

#### 3. Declaration of specific interests

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

4. Minutes (*MB/M/04/2009*)

The minutes of the meeting on 29/30 September 2009 were approved.

5. Budget implementation 2009: amending budget and budget transfers (*MB/68/2009*; *MB/RD/08/2009*)

The Management Board adopted a first amendment to the Agency's budget for the financial year 2009. The amendment was necessary in order to reflect the  $\leqslant$  1.35m reduction in fee income as compared to the estimates of December 2008, and a specific and earmarked Community contribution of  $\leqslant$  136 410 to cover the costs for preparatory measures for the participation of (potential) candidate countries in ECHA and their cooperation with the Agency.

The Board also took note of the latest budget transfers carried out under the responsibility of the Executive Director.

6. Budget and establishment plan 2010 (*MB/69/2009*)

The Director for Resources presented the Agency's draft budget for the financial year 2010:

- 1) Title 1 includes staff related costs, and mainly covers salaries, recruitment, training, work related travel and external services amounting to a total of  $\leq$  47.2 million (an increase of 24% on 2009) in line with the projected growth of staff from 324 temporary agents to 426 temporary agents.
- 2) Title 2 includes the rental cost for ECHA's building as well as other basic infrastructure and information technology expenditure totalling €12.9 million (an increase of 20% on 2009) and reflecting the growing space needs alongside the growing number of staff.
- 3) The operational Title 3 directly supports the implementation of the Agency's Work Programme. An amount totalling € 25.9 million is foreseen (an increase of 15% on 2009).

Board members welcomed the structure of the budget which had been revised and aligned to ECHA's work programmes. Apart from being consistent with the key activities and largely also with the organisational structures of the Agency, the new budget structure leads to the improved transparency and increased accountability of the authorising officers. It also serves as a first step towards activity-based budgeting.

The Executive Director noted that the expected refundable Community contribution of € 35.15m will be factually lower than the amount voted on by the European Parliament in its first reading in October 2009. However, the funding for ECHA will eventually be higher than foreseen in the preliminary draft budget of the Commission and, in particular, higher than voted on by the Council throughout the budgetary procedure. Together with certain transitional arrangements for the payment of rent and salary costs, the Executive Director estimated the financial resources as being sufficient to cover ECHA's cash flow needs in 2010. In this context, an observer from the European Commission reiterated that assurance had been given to the budgetary authority that the Agency's financial situation in 2010 would be closely monitored in order to react swiftly should any shortcomings arise. Accurate budgetary updates would therefore be needed on a regular basis.

On request, it was clarified that the staff costs included in the budget are calculated on the basis of the Commission's annual proposal for salary adaptations for officials and other servants of the European Union for 2010. The calculation method for the annual Commission proposal is defined by the EU Staff Regulation and is based on an indexation of salaries of national civil servants.

It was also explained that the resources allocated for the payment of Seconded National Experts (SNE) could in principle be used for employing officials from non-EU Member States. In light of previous discussions in the Management Board on the participation of third countries in the work of ECHA, such an engagement would not be likely in 2010.

The Management Board adopted the Agency's budget for 2010 with the understanding that the (temporary) Community subsidy of € 35.15m and he 102 posts to be newly established will be confirmed with the adoption of the general budget of the European Union.

### 7. Work programme 2010: Update of Annexes (*MB/70/2009*)

The Executive Director explained that following the adoption of ECHA's work programme for 2010 in September 2009 (MB/56/2009), two annexes to this document were submitted for adoption, as updates. Annex 3 would update the resources for 2010 and align these to the budget as adopted under agenda item 6. Annex 4 would complete the work programme 2010 with a procurement plan. This relates to a recommendation issued in the context of an audit performed by the Commission's Internal Audit Service to the Agency and follows the practice from the previous year.

During the following exchange of views, members addressed the ratio of staff allocated to operational activities, in particular evaluation, as compared to administrative tasks; the expected workload in the field of the authorisation procedure; and some specific positions listed in the procurement plan.

Responding to this, the Executive Director explained that operational activities are equally carried out by staff not directly allocated to the main REACH operations, e.g. the Committee Secretariats or the Helpdesk and Guidance teams. He further clarified that the "management line" includes the operational directors. In addition, he referred to the Board of Appeal as a specific body not existing in all other organisations. With regard to resources for evaluation, he informed the Board that additional staff had been allocated to this activity since preliminary resources planning in February 2009. In future, the Agency would strive to further increase the staff numbers allocated to evaluation. The Executive Director signalled at the same time that it is difficult for ECHA to bring sufficient new staff with the required high scientific expertise to Helsinki. Experienced experts who had been successful in ECHA competitions would often be reluctant to accept a job offer with negative implications on the recruitment target.

As regards the workload for authorisation in 2010, the Director for Assessment referred to the still valid assumptions in the work programme 2010, i.e. the processing of 30 dossiers for identification as substances of very high concern.

It was also clarified that a position referred to in the procurement plan as "miscellaneous" in the context of guidance and helpdesk activities would, in particular, include services linked to Partner Expert Groups for guidance development or to the network of national helpdesks (HelpNet), including training on REACH .With regard to services foreseen to support the preparation of dossiers for harmonised classification and labelling, it was agreed that the procurement plan should specify that these services are foreseen to support the ECHA Secretariat in its own tasks.

The Board adopted the revised Annexes 3 and 4 of the work programme for 2010 as contained in document MB/70/2009, subject to the above mentioned clarification regarding support in the preparation of harmonised classification and labelling dossiers.

### 8. ECHA contingency planning for 2010 (*MB/71/2009*)

The Executive Director introduced ECHA's contingency planning for 2010. The planning is part of the Agency's risk management activities and shall ensure that the two upcoming operational deadlines, the first registration deadline of 30 November 2010, as well as the deadline for classification and labelling notifications, will be successfully handled.

The Executive Director reminded the Management Board that careful planning for 2010 is critical as ECHA faces high uncertainty regarding the number of registration dossiers and notifications that will be received and will need processing. Therefore, the plan had been designed to cope with a number of registration dossiers up to three times higher than originally estimated. Scenarios have also been developed simulating an underperforming or failing IT-system and higher numbers of appeals. Implementation relies on the internal mobility of staff, various modes of recruitment, on a monitoring mechanism to be supervised by a contingency manager, as well as resorting to the identification of negative priorities.

This was followed by an extensive exchange of views during which it was highlighted that communication activities targeted at stakeholders will play a crucial role. Members requested several clarifications as to the assumptions for the workload of the Agency and the likelihood of the different scenarios materialising or being exceeded by reality.

The scenarios developed for underperforming or failing IT-systems and the plan to outsource certain technical tasks were particularly appreciated. Several members pointed however to sensitive aspects linked to the subcontracting of regulatory activities, in particular in view of confidentiality duties; the specific case of outsourcing legal advice; and the general challenge to find sufficient adequate personnel on the market in Finland. Against this backdrop, Board members appointed by the Commission to represent interested parties recommended that the Agency's own staff should be drawn on as much as possible. The option of support being provided by Member State experts was also mentioned.

The Executive Director provided clarifications on the remarks made by Board members. He explained that the workload estimates were based on the expected number of substances for the first registration deadline. Extensive work with industry associations would however be needed in early 2010 to verify the current conclusions. If the scenarios proved to be too low, the Secretariat would present an amendment to ECHA's budget which would be covered by an accordingly higher share of fee income. He further referred to the need to cooperate closely with Member States and the national helpdesks and mentioned, as an example, the training on REACH-IT for national officials which was planned to be reinforced in early 2010 and be complemented by new REACH-IT manuals which were currently being translated into the official EU languages.

As regards support from external interim staff, the Executive Director explained that the profiles for interim staff will mainly be administrative, i.e. no specific expertise needed in addition to the training foreseen by ECHA. He assured members that confidentiality aspects were being duly considered, however interim staff would normally only be involved in very specific technical steps and as such, have only limited access to sensitive information. The experiences gained so far with support from interim staff, and also the preparedness of ECHA staff to support registration activities temporarily, had been very positive. At the same time,

the Executive Director stressed that the workload and stress level of Agency staff was already at a high level.

The Management Board broadly welcomed ECHA's forward planning and supported the approach taken. In order to exercise its supervisory function, Board members expressed the wish to be regularly informed about the developments via short monthly reports from the Secretariat, starting with the data and experiences gained from February 2010 onwards.

9. REACH-IT information security policy – report on written procedure MB/WP/02/2009 and further steps (MB/72/2009)

The Management Board received a report on the outcome of the written procedure MB/WP/02/2009 on a revised REACH-IT Security Declaration and the Standard Security Requirements to be implemented in the Member States.

Members took note that within the deadline for submitting replies, a two thirds majority of members with voting rights approved the proposals made. Twenty-three members submitted positive replies, while two negative replies and three abstentions were received. Three members generally approved the proposals but voiced certain reservations.

The Management Board was also informed of the next steps in the procedure for receiving access to the IT system and the planning for the future revision of the access declaration in order to ensure that all Member States have equal access to registration data.

The Secretariat reminded the Board of a note submitted to all Member State Competent Authorities on 4 December 2009 with language versions of the revised Security Declaration and detailed guidance on the necessary practical steps towards the implementation of access. Moreover, the Secretariat explained the status of bilateral contact with those Member States that can so far not support the Security Declaration with the aim of providing clarification on sensitive parts of the text. A revision of the Declaration is foreseen in early 2011, if necessary.

In the subsequent discussion, several Member State representatives reported on the status of the dossier in their countries and partly explained the remaining difficulties. A representative of interested parties appointed by the Commission was of the opinion that the debate on the policy issues involved in the matter would be wrongly placed in the Management Board. The ECHA Secretariat would be on the right track by pursuing a security orientated approach and the Board member recalled the Management Board's responsibility to protect the Agency and its staff from any potential liability risks.

Board members also called for a harmonised interpretation of the Security Declaration and stressed the need to share all interpretations with the Member States. Several members emphasised that a degree of pragmatism was needed from all parties. Some members also argued that the Security Officers Network (SON) will in future have an extended role and should thus have its rules of procedure modified.

The Executive Director thanked the Management Board for its constructive role in finding the compromise solution and noted the difficulties involved in achieving the right balance

between the interests involved. He assured that he had listened carefully to the interventions made and agreed that the SON may indeed need a wider mandate.

The Board concluded that ECHA is pursuing the right approach by bilaterally seeking to resolve remaining divergences. It was agreed that any interpretations of the Declaration which may result from this must be shared with all members. The Secretariat was invited to inform the Board of any other relevant developments.

10. Mission Charter of the Internal Audit Service & establishment of an audit working group;

Update of the Internal Audit Service's multi-annual strategic audit plan for ECHA (MB /73/2009; MB/74/2009)

The Management Board endorsed a new mission charter of the Internal Audit Service of the European Commission in relation to transitional agencies and independent bodies as well as the Internal Audit Service's strategic audit plan for 2010-2012 for ECHA.

In order to facilitate the Board's involvement in strategic audit issues, it established an audit working group which will be composed of the Chair, Marta CIRAJ, Heinz ZOUREK and Karel BLAHA. The group will be consulted on critical aspects of the action plans drawn up by ECHA in relation to audit recommendations and monitor the implementation of these action plans and report to the Management Board. It was clarified that the findings and recommendations of the final audit reports will still be submitted to the entire Board.

11. Rules of procedure for cooperation between EFSA and ECHA (Article 110 of the REACH Regulation) (MB/75/2009)

Subject to the legally required agreement by the European Commission, the Board adopted rules of procedure for cooperation between ECHA and EFSA (pursuant to Article 110 of the REACH Regulation (EC) No 1907/2006).

Board members considered these rules as highly important for the Agency's work and stressed that appropriate focus should be put on increasing synergies between the activities of the two agencies. The Executive Director assured the Board that it is indeed crucial for ECHA to avoid duplication of work and referred to other instruments available to support cooperation with EFSA, such as the existing Memorandum of Understanding or the regular meetings of the Chairs of scientific committees at the EU level.

The Management Board expressed the wish to be kept informed about the areas in which ECHA and EFSA cooperate.

12. Implementing rules for the Staff Regulations on the performance appraisal of temporary and contract agents (MB/76/2009)

The Chair introduced the agenda item by putting the decision requested into the context of the decision made by the Board in February 2009 granting him the discretion to agree to editorial amendments proposed by the Commission, in relation to Staff Regulation implementing rules which are forwarded to the Commission for agreement pursuant to Article 102 of the REACH Regulation. With regard to the present draft rules, the Commission had made minor amendments which align the text with the provisions of the Staff Regulations. However, as these were not merely editorial, the Chair could not agree without consulting the Board.

The Management Board adopted the draft decision on the performance appraisal of temporary and contract staff as submitted by the Commission on 21 October 2010<sup>1</sup>.

13. Rules on payments to witnesses and experts in appeal proceedings before the Board of Appeal;

Rules of the Board of Appeal on costs relating to the taking of evidence in appeal proceedings

(MB/77/2009; MB/78/2009)

The Registrar of the Board of Appeal presented two related draft rules on the payment of experts and witnesses appearing before the Agency's Board of Appeal.

On request by a Member State representative, the Registrar clarified that no guidelines or code of conduct would be foreseen for situations referred to in Article 2(3) of the draft rules contained in document MB/78/2009 because of the exceptional and rare character of the situations referred to therein, always requiring an appreciation on a case by case basis.

The Management Board adopted a decision on payments to witnesses and experts appearing before the Board of Appeal. Furthermore, the Management Board provided its agreement to related rules to be adopted by the Board of Appeal on the costs relating to the taking of evidence in its proceedings. Both documents were edited for gender neutrality.

14. Contractual arrangements related to the reimbursement of REACH tasks executed by Member States (*MB*/79/2009)

The Head of the Legal Affairs Unit provided a report on developments related to the establishment of a framework agreement on the transfer of funds to Member States for the execution of REACH tasks and presented a number of guiding principles for finalising the agreement.

The Head of Unit recalled that the draft decision MB/20/2009, adopted by the Management Board in April 2009, provides that the Executive Director shall put in place the necessary contractual and administrative arrangement in conformity with the financial rules applicable

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<sup>&</sup>lt;sup>1</sup> ECHA reference ECHA/A(2009)3662

to the Agency in order to establish the contractual arrangements necessary for the transfer of funds (Art. 4(2) of the Draft Decision - agreement by the Commission to the draft decision is pending). To this end, a model of a framework contract was presented with the final report of the Board's working group on the issue, and sent to the Permanent Representations of the EU Member States on 21 September 2009, in the official EU languages<sup>2</sup>. Following remarks received from Member States on the model contract, the Secretariat had revised the text and submitted it to the Member State Competent Authorities and Board members before the meeting.

It was noted that the agreement does, in the first phase, not include the transfer of funds for the purpose of substance evaluation because this activity would only start at the end of 2011 and the underlying procedures were still in development. The initial agreement would therefore not cover substance evaluation aspects and be time limited until 31 December 2011. It would be revised together with the (Draft) Decision which would also be due for revision by that date.

In the following discussion, many Board members noted that, pending a deeper analysis, the revised text represents a considerable step forward to finding consensus on the matter. At the same time, it was pointed out that the agreement needed to comply with national legislation and that the provisions regulating the ownership of intellectual property required careful drafting. An observer mentioned that the application of REACH in the EEA/EFTA countries should be taken into account With reference to Article 87 of the REACH Regulation, clarification was also sought on the correct contracting party signing the agreement with ECHA.

The Board thanked the Dutch representative who coordinated the input from the Member States Competent Authorities to the drafting of the agreement and welcomed his proposal to continue this coordinating role. It was agreed that feedback to a revised text should be provided by the end of January 2010.

In addition to the six guiding principles presented by the Secretariat, the Board agreed that a clear reference to the requirements of the EU Financial Regulations and any recommendations of the European Court of Auditors on such matters, which Agencies must compulsorily follow, should be added. It was further agreed that the CARACAL meeting would to be informed about the developments.

With reference to the procedure applied, two Board members voiced the opinion that the contractual arrangements should eventually be put in place by decision of the Management Board. This was agreed in principle. At the same time it was pointed out that the Board had, for the purpose of the transfer of fee revenue to Member States, delegated this authority to the Executive Director by mandating him to put in place the necessary contractual and administrative arrangements in conformity with the financial rules applicable to the Agency (Art. 4(2) of draft decision MB/20/2009).

On this basis, the Management Board gave positive feedback to the guiding principles for the finalisation of the framework agreement. At the same time it was concluded that the CARACAL meeting should be formally informed of the issue,

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<sup>&</sup>lt;sup>2</sup> ECHA Reference ECHA/D(2009)3929

### 15. Appointment of Committee members (*MB/61/2009*)

The Management Board appointed the following new Committee members:

- Dr José L. TADEO LLUCH as member of the Committee for Risk Assessment
- Mr Paulo Eurico Alves VARIZ as member of the Committee for Socioeconomic Analysis
- Ms Liliana Luminita TIRCHILA as member of the Committee for Socioeconomic Analysis

### 16. Report of the Executive Director (*MB*/80/2009)

The Management Board received a report from the Executive Director on the activities and developments of the Agency since their last meeting.

The ensuing discussion focused, in particular, on technical Guidance development for industry and the relation to guidance developed by industry associations. Special reference was made to the Guidance on authorisation applications. Other aspects covered by Board members in their interventions included international cooperation with Canada and potentially other third countries.

The Executive Director responded to the comments made. He clarified that ECHA generally has no role in Guidance developed by industry. However, he referred to an exemption, that of the Guidance on Annex II of the REACH Regulation, for which preparatory work was currently being undertaken jointly with industry associations. He informed the Board that updated Guidance on classification and labelling was scheduled to be released in summer 2010.

The Management Board took note of the report. Many members emphasised the high quality and usefulness of the Executive Director's report which would provide assurance that ECHA resources and activities were correctly focused.

17. Exchange of views with representatives from Cypriot authorities on experiences with regard to the implementation of the REACH Regulation

The Management Board heard from Artistos ECONOMIDES, of the Cypriot Department of Labour Inspections, who presented general policy aspects of the Department, and from his colleague, Tasoula KYPRIANIDOU–LEONTIDOU, who reported on the national enforcement approach on chemicals legislation.

This was followed by an extensive exchange of views on general policy aspects, such as the preparations for the next Cypriot EU presidency, but in particular on enforcement issues. For example, experiences were shared as regards dedicated enforcement campaigns, the cooperation between customs authorities and enforcers, and the interactions with the EU RAPEX alert system.

Board members were impressed by the coherent and well elaborated policy and enforcement approaches being employed in Cyprus.

### 18. Multi-annual planning on evaluation (*MB/81/2009*)

The Director for Assessment presented ECHA's longer term planning for dossier evaluation.

The following discussion centred on the importance of realising the evaluation of the required minimum 5% of registration dossiers. As this goal is laid down in the REACH Regulation, its achievement would be crucial for REACH and the reputation of the Agency and, thus, needed careful monitoring. Furthermore, the links between enforcement and evaluation were highlighted.

Board members considered the preparation for evaluation tasks as currently one of ECHA's major challenges and called for a combination of efforts with the Member States. Other issues addressed during the discussion ranged from the criteria for priority setting, over the consequences of a potentially excessive use of waiving possibilities, to the difficulties of attaining sufficiently experienced experts to work with ECHA.

The Director for Assessment assured members that ECHA is committed to meeting the 5% target and he also referred to the evaluation progress report that will be published by 28 February 2010 as one tool for communicating the results of evaluation activities.

The Management Board took note of the information provided.

# 19. Report on the status of REACH-IT (*MB*/82/2009)

The Director for Registration and IT-tools gave a broadly welcomed high level overview on the status of REACH-IT and the planning activities related to this IT-system.

The report included detailed information on the next release of REACH-IT which will be made available over the Christmas break 2009; the background of the decision to move to IUCLID 5.2 in 2010; and the status of the development of the Chemical Safety Report tool for industry (CHESAR).

With a view to the experiences from pre-registration, Board Members explicitly welcomed the fact that ECHA is preparing for the eventuality of full system unavailability, even if this was considered as a rather unlikely scenario. It was noted that the schedule for the necessary IT developments would be extremely tight in early 2010 and potentially require a deprioritisation of less urgent projects.

Remarks were made noting that the timely training of national helpdesk officers on the system, and the availability of user manuals in the official languages, were of high relevance for SMEs, and ECHA activities in this regard were welcomed.

One Member State representative proposed that the RIPE project, a dedicated database for enforcement authorities, be postponed, in order to release more resources for evaluation tasks.

The Management Board took note of the information provided. It was agreed that ECHA would continue to report regularly on the progress of IT system development.

20. ECHA work plan for substances on nanoscale <sup>3</sup> (MB/83/2009)

The Director for Assessment presented ECHA's current work plan with regard to substances in panoscale.

Board members confirmed their high interest in the evolving area of risk management for nanomaterials and stressed ECHA's important role at the EU level in this regard. The discussions focused on the need for a harmonised definition of substances on the nanoscale, the links to the REACH Regulation (in particular with a view to the timeline for REACH implementation), and the relevant functionalities of IUCLID5. Two Member State representatives recommended consideration of the 'nanostatus' of substances during the priority setting for compliance checks. Another aspect addressed by several Board members was the OECD work on of nanosubstances and the interdependence with the timing for registration under the REACH Regulation.

The Management Board noted that the European Commission had requested scientific-technical advice from ECHA on specific aspects, for example in relation to Guidance development or the establishment of an inventory of nanosubstances. Emphasis was put on the need for the Agency to focus on aspects directly related to its mandate from the REACH and CLP Regulations. The Secretariat was asked to inform Member States if registrations for nanosubstances were submitted in 2010.

The Director for assessment responded to the comments made. He noted that nanosubstances would require a separate scientific approach as they feature specific environmental and human health fate and effects. As a consequence, ECHA would see the need to have methodologies in place to tackle these specific safety aspects. With regard to a common definition of nanosubstances, he informed the Board that ECHA would contribute to the Commission's decision making as requested. The same would apply for the review of the REACH Regulation. He noted that the aim of the future functionality in IUCLID5.2 was to enable registrants to flag the status of substances as being on the nanoscale.

The Board welcomed the work plan and ECHA's approach towards the regulatory risk management of substances on nanoscale and expressed the wish to be regularly informed about the progress achieved in the various fora dealing with the matter at the EU level.

The Management Board took note of the information provided.

<sup>3</sup> The order of the agenda headings presented in these minutes follows the order in which the items were ultimately dealt with at the meeting. Due to time constraints, agenda item 20 was postponed to the next meeting.

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### 21. Activity report from the advisory group on dissemination (*MB*/85/2009)

The Management Board heard Ms FORSBERG, Chair of the advisory group on the public dissemination of information on chemical substances. The report included an outline of the group's planned activities in 2010. Ms FORSBERG reminded the other Board members that the dissemination of safety information of chemicals was one of the cornerstones of the REACH Regulation.

The Management Board welcomed the progress made in implementing the Road Map on dissemination which was presented at the Board meeting in June. Particular welcome was given to the fact that the prototype of the dissemination tool went online on the day of the meeting on 18 December 2009. At the same time, it was acknowledged that the prototype had to be seen as a first step and that the published data needed to be accompanied by appropriate communications activities. This would apply in particular to the fact that REACH shifts the responsibility for the safety of chemicals to industry. The information submitted to ECHA is, therefore, normally not verified by the Agency.

Members received a short presentation of the dissemination tool which would be further developed and made more user-friendly whilst the amount of data would be constantly complemented with information from incoming registrations. The newly designated Belgian representative volunteered to join the working group upon his formal appointment to the Board. The group would meet again in February 2010.

The Management Board took note of the information provided.

#### 22. Any other business

High Level Task Force with industry on SIEF/lead registrant support

The Management Board received a note from the Executive Director concerning the creation of a High Level Steering Group with industry to support the work in the Substance Information Exchange Fora and in particular lead registrants. The group would be chaired by the present Director for chemicals policy in the Commission's Directorate General for Environment. Board members welcomed the initiative and agreed that the term "task force" would be preferable to "steering group".

Status of the renovation project in the ground floor of the Agency's main building

The Executive Director informed the Management Board of the status of the renovation project in the ground floor of ECHA's main building: Following a favourable vote in the European Parliament and the approval of the budget transfer needed by the Management Board, the relevant contractual agreements were due to be signed before the end of 2009.

Study on penalties for non compliance with the REACH Regulation

The Management Board received information from a Commission representative on the draft results of a study on penalties for non-compliance with the REACH Regulation in the Member States.

#### New title for the Management Board Flash Report

The Chair announced that the "Flash Report" prepared by the Secretariat directly after each Board meeting would in future be titled "Preliminary Conclusions". The new terminology would better reflect the internal status of the document and in particular the fact that it does not contain an approved record of the Board's proceedings. The name change would be without prejudice to the discretion of members to distribute the report within their organisations.

#### 23. Next meeting and closure

The Chair reminded members that the next meeting of the Management Board would be held in Helsinki on 04/05 March 2010.

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

#### The Management Board

- approved the minutes of its 14<sup>th</sup> meeting contained in document MB/M/04/2009.
- adopted the agenda for the 15<sup>th</sup> meeting as contained in MB/A/05/2009, subject to the modifications indicated in these minutes.
- adopted the amendment to the Agency's budget for the financial year 2009 as presented in document MB/68/2009 and took note of the budget transfers notified in document MB/RD/08/2009.
- adopted the Agency's budget for the financial year 2010 as contained in document MB/69/2009.
- adopted Annex 3 and 4 of the ECHA Work Programme for 2010 as attached to document MB/70/2009 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.
- endorsed the mission charter of the Internal Audit Service of the European Commission in relation to ECHA as contained in the annex to document MB/73/2009. The Chair was empowered to sign the document and the Executive Director instructed to submit it following his signature to the Director General of the Internal Audit Service.
- established a working group on audit issues and nominated the Chair, Marta CIRAJ, Heinz ZOUREK and Karel BLAHA to participate in this group.
- endorsed the strategic audit plan 2010–2012 for ECHA as prepared by the Internal Audit Service and contained in document MB/74/2009.
- adopted the Rules of Procedure for Cooperation between EFSA and ECHA pursuant to Article 110 of the REACH Regulation as annexed to document MB/75/2009, subject to the agreement of the Commission, and instructed the Executive Director to forward the draft rules to the European Commission for agreement.
- adopted the decision on the performance appraisal of temporary and contract staff as annexed to document MB/76/2009.
- adopted the decision on rules for the calculation of the amounts and advances to be paid in relation to the taking of evidence in appeal proceedings before the Board of Appeal of ECHA as proposed in annex 1 to document MB/77/2009.<sup>4</sup>

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<sup>&</sup>lt;sup>4</sup> The Board agreed that the text should be kept gender neutral (in Article 3 (1) b the term "he" to be changed to "the witness").

- agreed to the rules on costs relating to the taking of evidence in appeal proceedings contained in annex 1 to document MB/78/2009<sup>5</sup>.
- endorsed the guiding principles for the revision of the model cooperation agreement for the transfer of funds to Member States under Regulation (EC) No 1907/2006 as set out in document MB/79/2009 with the understanding that a reference to the requirements of the EU Financial Regulations and recommendations of the European Court of Auditors on such matters, which are to be compulsorily followed by the Agencies, should be added.
- appointed:
  - Dr José L. TADEO LLUCH as member of the Committee for Risk Assessment
  - Mr Paulo Eurico Alves VARIZ as member of the Committee for Socioeconomic Analysis
  - Ms Liliana Luminita TIRCHILA as member of the Committee for Socioeconomic Analysis

#### List of agreed follow-up actions

- The Secretariat will in 2010 report on a monthly basis to the Management Board on the extent to which the measures set out in the contingency plan for 2010 needed to be implemented. The reporting will start from the data of February 2010.
- ECHA will inform the CARACAL meeting of the progress made towards establishing a framework agreement on the transfer of fees to Member States for executing REACH tasks.
- Any interpretations of the REACH-IT Security Declaration which may result from bilateral discussions with Member States will be shared with the entire Board.
- The Secretariat will continue to report regularly on the progress of IT system development.
- The Secretariat will regularly inform about the progress achieved in the various fora dealing with the nano-materials at the EU level.

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<sup>&</sup>lt;sup>5</sup> The Board agreed that the text should be kept gender neutral (Article 3(3) to be modified as follows: "Payments due pursuant to this Article, except advances, shall be effected only after evidence has been given by the witness or the expert has fulfilled the duties or tasks requested.")

#### IV. List of Attendees

#### Representatives of the Member States

Zoltán ADAMIS (HU)

Maria ALAJOE (EE)

Aurelija BAJORAITIENÉ (LT)

Karel BLÁHA (CZ) Marta CIRAJ (SI)

Francis E. FARRUGIA (MT) Ethel FORSBERG (SE) Claude GEIMER (LU)

Thomas JAKL (AT) also acting as proxy of Alexander NIES (DE)

Katarzyna KITAJEWSKA (PL)

Pirkko KIVELA (FI)

Jan Karel KWISTHOUT (NE) Antonello LAPALORCIA (IT)

Martin LYNCH (IE) also acting as proxy of John ROBERTS (UK)

Catherine MIR (FR)

Leandros NICOLAIDES (CY) Edita NOVÁKOVÁ (SK) Per NYLYKKE (DK) Teodor OGNEAN (RO) Armands PLATE (LV)

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

and Ekaterina GECHEVA-ZAHARIEVA (BG)

Maria-Miranda XEPAPADAKI-TOMARA (EL)

#### Representatives of the European Commission

Gustaaf BORCHARDT also acting as proxy of Elke ANKLAM (COM)

and Heinz ZOUREK (COM)

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

Martin FUEHR Tony MUSU Alain PERROY

#### Other Observers

Keith BAILEY on behalf of John ROBERTS (UK)
Helmut DE VOS on behalf of Marc LEEMANS (BE)
Corinna ENDERS on behalf of Alexander NIES (DE)
Nikolai SAVOV on behalf of Ekaterina GECHEVA (BG)

Henrik ERIKSEN on behalf of Ms Anne Beate TANGEN (NOR)

Astrid BARTELS (European Commission)
Astrid SCHOMAKER (European Commission)
Graham WILLMOTT (European Commission)

Arwyn DAVIES accompanying Mr Keith BAILEY (UK)

Anna DELOFF-BIALEK expert accompanying Katarzyna KITAJEWSKA (PL)

Sabina PICCHIONI expert accompanying Mr LAPALORCIA (IT)

<u>Participants from the Ministry of Labour and Social Insurance of the Republic of Cyprus</u> (for specific agenda points as indicated in these minutes)

Sotiroula CHARALAMBOUS (Minister) Aristos ECONOMIDES Tasoula KYPRIANIDOU–LEONTIDOU

#### ECHA staff

Geert DANCET (Executive Director)

Jef MAES (Director of Resources)
Jukka MALM (Director of Assessment)

Christel MUSSET (Director of Registration and IT Tools) Minna HEIKKILÄ (Head of Unit, Legal Affairs Unit)

Sari HAUKKA (Registrar of the Board of Appeal)

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

Mervi MUSTAKALLIO (Planning and Monitoring Officer, Executive Office)