

Minutes of the 36th meeting of the Management Board Held in Rome, Italy from 16 to 17 December 2014



I. Summary record of the proceedings

The Chair opened the meeting by welcoming new Board members: Mr Bojan VIDOVIĆ Croatian representative, appointed for the period 25 September 2014 to 26 September 2018 and Mr Keşütis SADAUSKAS appointed as of 1 December 2014 as Commission representative. She also informed of Judīte Dipāne's attendance as an observer, pending her appointment as the new Latvian representative.

The names of other participants attending the meeting and the proxy votes of which the Chair was notified are listed in Section IV of these minutes.

1. Agenda (MB/A/04/2014)

The Chair announced that the following room documents have been made available:

- Revised annexes to documents MB/47/2014 and MB/48/2014 (Budget and Work Programme annexes 2015) which align the documents with the outcome of the EU budget procedure for 2015.

A Board member appointed by the European Commission to represent interested parties proposed to discuss under agenda item 8 a letter sent by the European Environment Bureau, a public interest non-governmental organisation, on the day before the Board meeting, suggesting ECHA should provide technical support to the 'Strategy to review the chemical BREFs'¹.

Another representative of the European Commission suggested relieving future Management Board agenda's by means of a written procedure before the meeting, leaving more time for discussions.

The agenda of the meeting was then adopted.

¹ Best Available Techniques (BATs) reference documents

2. Declaration of specific interests

The Chair informed the members of the Management Board that she reviewed the members' declared interests, together with the Secretariat, in accordance with ECHA's policy on conflicts of interest. No conflicts relating to the agenda of the meeting were identified.

Afterwards, she invited the members to further declare any specific interests that could not be drawn from their declarations of interest and which could be considered to be prejudicial to their independence with respect to any items on the agenda. No further specific interests were declared.

3. Minutes of the 35th Management Board meeting (MB/M/03/2014)

The draft minutes of the 35th Management Board meeting, held from 25 to 26 September 2014 in Helsinki, were approved with the modifications indicated under heading V of these minutes.

4. Quarterly report on ECHA's activities (MB/42/2014)

The Management Board heard the quarterly update on the progress made in executing the 2014 Work Programme, including the work programme indicators.

The Executive Director highlighted that most indicators reached the target in the last quarter, some being well above the target:

- Testing proposal examinations concluded for dossiers received by the 2013 deadline (target 33%, result 45%).
- Follow-up evaluations, due in the given year, performed within six months after the deadline (target 75%, result 81%).
- ECHA Helpdesk questions answered within the established timeframe for the BPR (target 70%, 81%).

However, there are two quality indicators which were below the target:

- Percentage of dossier evaluations treated within the legal timeframe (one testing proposal exceeded the deadline by two days).
- Percentage of unanimous Member State Committee (MSC) agreements (target 80%, result 60%).

The Deputy Executive Director continued with a more detailed report on all activities.

Board members welcomed the achievements and congratulated the Secretariat for the comprehensive report and impressive work done.

Further clarifications were requested on registration submissions, confidentiality claims, new updates of IT tools (IUCLID 6), as well as a recent European Ombudsman report concerning ECHA.

In response it was clarified that ECHA will report in the General Report 2014 in more detail on the number of non-phase in (new) substances registered and the ratio of confidentiality claims accepted or rejected. In addition, a more detailed update on the progress made in the biocides area was provided by the Director of Risk Management.

The discussions also touched on substance evaluation appeals and the fact that the Secretariat informs by default of the opportunity for Member States to intervene and

defend their case work. The appropriateness of such interventions was debated and different positions were taken by Board members. The Secretariat committed to review the draft invitation letter sent to Member States on the matter.

One Board member suggested taking further actions for effectively reversing the burden of proof on registrants in three areas:

- Legitimate access to information (in joint submissions),
- Substance identity information,
- SME verification.

In each case, the accuracy of the information submitted to the Agency should fully fall in the responsibility of the company submitting the information.

On nanomaterials and the related planned revision of the REACH annexes, several Board members expressed concern at the lack of progress with an announced Commission implementing act. This could lead to a situation where the Agency would be unable to fulfil its plans by mid-2016 in preparing for guidance updates and IT tools.

For this reason, it was suggested to consider an alternative plan by the summer of 2015 for developing the necessary support tools. A representative of the Commission clarified that the work related to the update of the REACH annexes is ongoing and the agreement of all stakeholders will be needed to finalise the implementing act.

The Management Board took note of the information.

Courtesy visit of the Italian Industrial Stakeholder Forum

A delegation of the Italian industrial stakeholder forum paid a courtesy visit to the Board. The Chair welcomed the delegation and highlighted that external meetings of the Board are always a good opportunity for better understanding the country specific situation.

The delegation asked specific questions related to ECHA's work, activities and tasks of the SME Ambassador, functioning of REACH and CLP, the 2018 registration deadline, communication in the supply chain and exposure scenarios and SDS for mixtures.

They welcomed the Agency's efforts to simplify the authorisation process and IT tools and highlighted specific difficulties encountered by Italian SMEs, downstream users and only representatives.

The Executive Director provided responses to the questions raised and invited the stakeholder representatives to join ECHA's networks and eventually contact the Agency for further support. He assured the audience that the whole Agency is SME-oriented and more support will be given in the coming years for the 2018 registrants.

The Agency's cooperation with industry and the Commission will provide simplified tools and formats (e.g. for the extended SDS²), best practice for registrants of low volumes, and an implementing act to be issued by the Commission.

The delegation was encouraged to participate in meetings with industry – ENES³ network, SH workshop – and follow webinars remotely – e.g. on downstream users' obligations, best practice for registrations, etc.

² SDS - safety data sheets

³ ENES - Exchange Network on Exposure Scenarios

5. Revision of the Decision on classification on services for which charges are levied (MB/29/2010) (MB/43/2014)

The Management Board reviewed a proposal for a revised Decision on the administrative charge levied in the context of the SME size verification. The basis for such a charge is provided for in the REACH Fee Regulation⁴, which foresees that the European Commission has to give a favourable opinion before the Management Board Decision can be adopted.

This followed discussions in the September Board meeting where the Board was updated on the results of the REACH fee verification activity concerning fee reductions applicable to small and medium-sized enterprises (SME).

The proposed revision also took into account the recent ruling of the General Court of the European Union in case T-177/12 Spraylat GmbH versus ECHA. In this case, an ECHA decision concerning an individual company had been annulled because the administrative charge imposed in the specific case breached the principle of proportionality. To this end, it was proposed to introduce a cap limiting the charge levied in the context of SME verification to a maximum of 2.5 times the financial savings a company made by incorrectly indicating its company size.

With regard to this judgement of the General Court, the Board was also asked to consider possible implications for cases handled in the past by ECHA .

The Management Board discussed the proposals and expressed broad support for the proposed cap. However, some Board members requested further clarifications on the proportion between the work undertaken by the Agency and the revised charges, suggesting the analysis of other options for approaching the SME verification activity with less workload for ECHA and consequently lower charges. Given the high number of companies incorrectly claiming to be entitled for fee reductions, it was also questioned if ECHA could do more to reverse the burden of proof in this area.

Board members also questioned the intention behind the incorrect declarations made by a large number of companies declaring that they would qualify as SMEs. The Secretariat noted that the Agency might consider reporting cases to OLAF, if appropriate, and will call upon Member States to use their power to impose fines to complement the actions of the Agency.

The Executive Director addressed the questions and comments, highlighting that the new proposal is based on the principle of full cost recovery for ECHA, in the same way as the existing decision. Certain cost factors have changed, for example a Board of Appeal decision has led to the necessity for increased translations which involve costs.

Overall, the costs would have remained in balance. He also stressed that ECHA's SME verification activity helps to ensure equal treatment and fair competition on the chemicals market. In addition, the reversal of the burden of proof will be improved for the 2018 registration deadline, when registrants will have the opportunity to self-examine their SME status by using a tool available in all languages of the EU.

The Board also discussed the implication of the General Court judgment for SME verifications carried out in the past. No clear position could be established in this regard and it was agreed to revert to this issue in the March 2015 Board meeting.

The Management Board agreed with broad support to introduce a cap limiting the charge levied in the context of SME verification to a maximum of 2.5 times the financial

⁴ Commission Regulation (EC) No 340/2008

savings a company made by incorrectly indicating its company size. A corresponding proposal will be submitted to the Commission for its opinion. The Management Board will come back to this issue, and related aspects, in its next meeting.

6. Strategic development of ECHA by 2018 - including Multi-Annual Staff Policy Plan key figures (MB/44/2014)

The Executive Director informed the Board of the current status of the work related to identifying ECHA's future strategic priorities. The aim of this exercise is to support the preparation of proposals for Management Board decisions related to the planning of work and budget, taking into account the over 10 % staff reductions foreseen for ECHA until 2018 and even more importantly the long-term vision for ECHA 2020 and beyond.

The Management Board Working Group on Planning and Reporting was dealing with the issue in September and November and a survey had been conducted amongst all Board members in October/November 2014.

The Executive Director invited Board members to provide further guidance to the Secretariat for continuing the work. He reminded that to balance the increasing workload with a reducing workforce, ECHA launched two initiatives in 2014:

- a) defining ECHA's vision and areas with resource saving potential by 2018, and
- b) a structured efficiency development programme.

Overall, ECHA does not expect a fundamental change in the coming years to its mandate or the expertise required to carry out its tasks. Wider internal discussions on ECHA's future showed however that ECHA needs more flexibility – for example, increased internal mobility based on staff competences – a stronger focus on stakeholders, efficiency through increased prioritisation and cooperation.

The Executive Director also informed of the benefit linked to delaying further resource cuts after the third REACH registration deadline, arriving ultimately at the same reduction target. In this regard, ECHA made a proposal to the Commission that instead of a continued >2 % reduction of its staff annually until 2018, an alternative plan (i.e. reducing staff only after 2018) would have less undesired consequences for REACH registrants and stakeholders.

The Chair of the Working Group Planning and Reporting and the representative of a European Commission expressed their opinion that despite staff reductions, ECHA will as a well-managed organisation face the challenges ahead and will demonstrate its capability to carry on its responsibilities. They also supported the proposal of delaying the full impact of the staff cuts after the third REACH registration deadline in 2018, highlighting at the same time that no Commission position has been established on this and that support for the horizontal Commission services will be needed.

In a discussion, several members supported the view that ECHA should be able to deliver on its current and future mandate regardless of the reductions in staff numbers. Some proposals were made for lowering the workload of the Agency, for example, by reducing the number of network meetings. It was also considered important to avoid overly affecting the support to industry when implementing the staff reductions.

For continuing the discussions it was proposed to establish a list of negative priorities amounting to resource cuts at the double of the currently foreseen scale. Together with a list of all resources needed for informal network meetings and similar activities, this would support an informed continuation of the discussions in the next meetings.

In the light of the debate on the staff reduction, the Secretariat ensured in the meeting that the Agency is committed to delivering on the legislation and demonstrate that

REACH works while keeping staff motivated and respecting the rules on promotion, which were also challenged by one member during the discussion. The emphasis of the management will be to set direction, remove obstacles, and support staff in these efforts.

Several members also referred to the letter sent on 12 November 2014 by seven Member States and Norway to the Commissioners on priorities for EU chemicals policy (the letter was annexed to the document MB/44/2014). This letter emphasised the importance of chemicals regulation, both for the European business and the protection of consumers, workers and environment and defined a number of issues which should be addressed with high priority: improving the quality of REACH registrations, substituting the use of substances of concern, endocrine disrupters, nanomaterials and substances in imported articles.

The Management Board took note of the status of the work on the strategic development of ECHA by 2020 – including Multi-Annual Staff Policy Plan key figures.

The work of the Management Board in shaping the Agency's future work focus will continue in 2015. The Chair will work closely with the Secretariat to design the process for doing so with the aim to have a common view of the Management Board on where the Agency should position itself in 2020 and beyond.

7. Budget 2014 (MB/45-46/2014)

The Management Board received an update on the budget transfers carried out by 12 November 2014 and the second amendment to the 2014 budget.

7.1 Transfers within the budget

The Management Board took note of the latest budgetary transfers carried out under the responsibility of the Executive Director.

7.2 2nd amending budget

The Management Board adopted a final amending budget for 2014, increasing revenues and reducing expenditure to the real situation. The amendment resulted in an overall surplus of ca. 8.9 million EUR which will be transferred to ECHA's reserve for the coming year. The Board members instructed the Executive Director to notify it to the Budgetary Authority, Court of Auditors and the Commission and to have it published.

8. Budget and Work Programme 2015 (MB/47-48/2014)

8.1 Final budget and establishment plan (MB/47/2014)

The Deputy Executive Director presented the budget of the Agency for 2015 including the staff establishment plan as well as corresponding updates of two annexes of the Work Programme 2015. He explained that the proposals submitted to the Management Board on 5 December 2015 were updated by way of two room documents to take into account the outcome of the EU budget process for 2015 after the European Parliament and the Council reached an agreement during the week before the meeting. Compared to the original proposal the final budget foresaw a further reduction of seven Temporary Agent posts for REACH/CLP, totalling a workforce reduction in this area of 11 posts compared to 2014 (four posts already reduced in the original budget proposal).

The foreseen total expenditure budget 2015 of the Agency amounts to EUR 115.2 million and the overall budget proposal is EUR 1.9 million higher than the 2014 second

amending budget, representing an increase of 1.7%. For the first time since 2010, REACH/CLP operations will no longer be funded exclusively through own income from reserve, fees and charges but a balancing EU subsidy of EUR 7.8 million is programmed to fund EUR 105.7 million.

Biocides activities will continue to be funded with a combination of EU subsidy and own fee income, while PIC will be financed solely from EU subsidy.

With regard to a letter received from the European Environment Bureau on possible synergies between EU legislation through technical work of ECHA in the area of BREFs⁵, the Director of Risk Management confirmed that the proposal appears sensible and it would probably not constitute a significant resource investment for ECHA to carry out the suggested work, should the Commission decide to request this support from ECHA.

Referring to the letter received a day before the meeting, a Board member representing interested parties reminded in this respect that tasks can be allocated to the Agency only through the work programme agreed by the Management Board on the basis of a proposal from the Executive Director or requests made by the Commission, other EU institutions or Member States in accordance with the legislation.

The Management Board adopted the Agency's budget for 2015 including the establishment plan in line with the outcome of the EU budget procedure. The total expenditure budget 2015 of the Agency amounts to ca EUR 115.2 million.

The establishment plan as adopted by the EU budgetary authority foresees 431 posts for REACH/CLP, 47 posts for Biocides and 6 posts for PIC activities. As the REACH post reductions will only be imposed at the end of 2015, it was clarified that there would be no material impact on the ability of ECHA to deliver against the 2015 Work Programme agreed by the Management Board in September 2014. The Executive Director was instructed to notify the decision to the Budgetary Authority, Court of Auditors, and the European Commission and to have it published. The budget will become final following the final adoption of the general budget of the European Union.

8.2. Update of the annexes to the Work Programme (MB/48/2014)

Following the adoption of the budget for 2015, the Board also updated two annexes of the Work Programme 2015 (concerning resource allocation and procurement planning), and instructed the Executive Director to forward the documents to the Member States, European Parliament, the Council and the European Commission and to have them published.

9. Key figures for the provisional draft Budget and structure of the Work Programme for 2016 (MB/49/2014)

The Executive Director presented the key figures for the provisional draft budget and structure of the Work Programme for 2016.

According to the applicable procedures, the Secretariat shall send the Commission by 31 January 2015 a first provisional draft budget estimate for 2016. Further, on the basis of a draft drawn up by the Executive Director, the Management Board shall approve and forward a preliminary draft budget proposal with an establishment plan by 31 March 2015. This shall include an outline of the work programme. The Commission will take this into account and present its overall EU draft budget in mid-2015. On this basis, the Council and the Parliament will agree on an EU draft budget 2016. The Management Board will adopt the final ECHA budget for 2016 in December 2015.

⁵ Best Available Techniques (BATs) reference documents

As for the budget 2015, the original proposal for 2016 as submitted on 5 December 2014 assumed further posts reducing by 1 % in 2016 in the area of REACH and CLP. Since the EU budget 2015 did eventually foresee a 2 % reduction, the Executive Director confirmed to plan a 2 % reduction also for 2016 when responding to the Commission's budget input request in January. Equally, the Management Board will receive a proposal for a preliminary draft budget decision in March 2015 based on a continued 2% annual reduction. For the Commission's consideration, a complementary note will however explain the benefits of postponing further cuts after 2018.

For Biocides, ECHA will ask for an additional subsidy of EUR 3 million to finance the non-fee-based activities, while discussions continue with the Commission on the appropriate level of staffing.

The formal preliminary draft budget request for 2016 will be submitted to the Management Board together with the final outline of the work programme for approval in March 2015. This will be the budget request for ECHA and the starting point for the 2016 budget procedure.

The Secretariat also introduced a new structure of the Work Programme 2016, with simplified content, linking the horizontal activities to the operational ones thus reducing the total number of activities. The new structure provides a better understanding of the objectives of the Agency and how resources are used.

The Chair of the Working Group on Planning and Reporting informed that the group welcomed the new structure and provided comments which will be taken into account by the Secretariat during the further preparations.

The Management Board endorsed the preliminary key figures concerning the budget year 2016 together with the new structure of the work programme.

10. ECHA Committees (MB/50-52/2014)

10.1 Appointment of members (MB/50/2014)

The Deputy Executive Director recommended that three new members for the Committee for Risk Assessment (RAC) and five new members for the Committee for Socio-economic Analysis (SEAC) should be appointed, two members of RAC and one member of SEAC renewed as all (re)nominating Member States had declared commitment of time availability of the nominees and of the support to the members by the national competent authority (MSCA), and there were no general potential conflicts of interest identified in line with the eligibility criteria adopted by the Management Board at its 31st meeting.

He also provided information about the assessment of the nominations in relation to the needs of the Agency and the ECHA independency policies and stated that specific training will be offered for one of the candidates.

The Management Board appointed the new nominees for RAC and SEAC and renewed the three-year term of a number of RAC and SEAC members (see Annex III). With these (re)nominations RAC will have 45 members and SEAC will have 37 members.

10.2 Managing the workload of RAC and SEAC (MB/51/2014)

The Deputy Executive Director presented means to increase the membership and further mobilise members and rapporteurs to address the rapidly increasing workload of RAC and SEAC, following-up discussions of the Board in the September 2013 meeting and the 4th MSCA Directors' meeting in November 2014. The presentation covered

developments under REACH (restrictions and authorisations) as well as Harmonised Classification and Labelling (CLH).

The Committees have seen the number of members grow over the last year, showing that the combined efforts of the Management Board and the MSCA Directors' have had a positive effect. RAC has increased from 40 members in 2013 to 45 in 2014 (December Management Board projection), while in the same period, SEAC has increased from 30 to 37. The re-nominations and the skills that the new replacement and/or members brought since 2013 were highly appreciated.

It was underlined that authorisation applications are foreseen to increase intensely with 100+ applications for chromates in the second half of 2015 through to 2016. ECHA started a dialogue with MSCAs to find out how many more teams of rapporteurs and how many applications per team their nominees can handle with their support.

Ways to improve the capacity of the committee were proposed, e.g. co-opting members as foreseen in the REACH Regulation, increasing the pool of active members, commitment of a minimum of 50% work time, possibility for Member States to nominate a second active member, and offering candidates for membership to other Member States without expertise or capacity. Other identified ways of increasing the capacity were:

- For authorisations: amending committee procedures, reducing the number of meetings and the time per application, introducing key issues already at the conformity check
- For restrictions: recommendations of the Restrictions Task Force being implemented
- For CLH: new committee procedure: fast-track listing and agreement of less critical endpoints without committee debate

In a discussion, several members preferred the option of increasing the capacity through additional regular members and/or invited experts to co-opted members, the latter were rather considered as a last resort solution.

The Secretariat was requested to reiterate the invitation addressed to Member States for new nominations for RAC and SEAC before the March meeting.

The Management Board took note of the increased resource needs for RAC and SEAC and endorsed efficiencies to manage an expected peak workload caused by the expected authorisation applications through 2015 and 2016. If this would be not possible in the next three months, the option of co-opted members may be proposed to the Management Board as a temporary measure in the March 2015 meeting.

10.3 Observers' attendance in the authorisation application process (MB/52/2014)

The Director of Risk Management presented the Secretariat's conclusion to continue with the policy on stakeholder and case owner participation in the authorisation application process as presented to the Management Board in June and September 2012⁶.

It was agreed that ECHA would report back on the implementation of the policy and make adjustments, if necessary. The Secretariat described how the policy was implemented, the options for its further development and steps to be taken from 2015 onwards.

⁶ See document MB/46/2012

As a minor adaption, it will in future be possible for accredited stakeholder observers to be given specific speaking rights, ensuring at the same time that comments on the cases themselves would be avoided. Such comments are possible during the established 'trialogues'.

The Secretariat invited Board members for their views on the matter. The initiative of having an open process and reduce any perceived claims of unfair hearing was welcomed and fully supported. Clarifications were requested on stakeholders' speaking rights and confidentiality of information.

The Secretariat informed that this arrangement worked well so far and ECHA did not receive major comments indicating that a change to its current approach is needed. The progress or potential shortcomings will be reported to the Board in due time.

The Management Board was informed on conclusions of the Secretariat to continue with the policy on stakeholder and case owner participation in the authorisation application process. Observers will, however, get limited speaking rights and the approach will help to improve transparency, as increased transparency is an overall aim of ECHA.

11. Substance Identification in registration dossiers – a strategy for improvement (including completeness check) (MB/53/2014)

The Director of Registration informed the Management Board of the strategy for increasing the availability and transparency of essential substance identification (SID) information in registration dossiers before issuing the registration number.

In its Multi-annual Work Programme (MAWP) 2014-2018, ECHA has committed to reviewing the completeness check formats, tools and processes and to reinforce the checks in relation to substance identity, as appropriate. Accordingly, ECHA assessed in 2014 possible actions to further address SID deficiencies in individual dossiers and at the level of joint submission.

The Secretariat submitted a draft proposal to the Working Group on Planning and Reporting on 26 November. The results from a joint pilot project with German authorities were also considered. The Chair of the Working Group explained that following discussions in the Group, a strategic approach was proposed with measures proportionate to the nature of the shortcomings.

The aim of the proposal is to raise the availability and increase the transparency of essential substance identity information in registration dossiers and improve the understanding of the scope and sameness of the registered substances. The proposed strategy featured three main elements:

1. The reinforcement of the automatic completeness check rules.
2. Requesting an identification of the scope of joint registrations.
3. A possible manual SID verification, pending further impact analysis.

Reinforcing the automatic completeness check rules is expected to create a significant gain in efficiency and effectiveness of regulatory processes, including in particular inquiry, dossier and substance evaluation. This element was discussed at CARACAL and has support from various Member States and NGO representatives.

Whether or not the new rules can be applied to updates of existing registrations needs to be further clarified and the Commission's advice was requested in this regard.

Regarding the scope of joint registrants, it was noted that relying only on a common main identifier is often not sufficient to guarantee that the substances registered within a joint submission represent the same SID.

The Board members were informed that the Secretariat will carry out a cost/benefit analysis for implementing a manual SID verification during the registration process, which could introduce additional verification of SID information as a part of the completeness check. The level of human resources required is still to be estimated and the costs and benefits in the post-registration processes would need to be better analysed. The Working Group Planning and Reporting was in principle positive about the approach and the Commission services committed to ascertain the legality of the proposal.

In a discussion, Management Board members welcomed the approach, supported the proposal while complimenting for diligence. The MAWP was appreciated as essential for the implementation of REACH and the improvement of the IT tools was perceived as a wise step to take to avoid poor quality registration dossiers. It was recommended to further investigate the envisaged benefits and the costs associated, provide more technical information and carry out a legal assessment together with the services of the European Commission. The workload for ECHA in times of shrinking resources should also be carefully considered.

The Management Board endorsed the proposed measures as first steps of a future approach for improving the information in incoming registrations, noting that the work is still not concluded and discussions will continue in the March 2015 Management Board meeting.

The Board took also note that the Secretariat will carry out a cost/benefit analysis for implementing a manual SID verification during the registration process and that the Commission will provide clarifications on different legal questions. The Management Board stressed the importance of having a broad scope when carrying out the cost/benefit analysis. A decision on the potential manual check could be taken in the March 2015 Board meeting on the basis of a proposal prepared by the Working Group on Planning and Reporting.

12. Revision to Guidelines on managing cash reserves deriving from fees and charges (MB/54/2014)

The Acting Director of Resources presented a revision of the guidelines on managing cash reserves deriving from fees and charges. Currently, all of ECHA's reserves invested are held with three different financial institutions on fixed term deposits ranging from one month to 12 month maturity dates. Previously, the reserve was mostly invested with the Bank of Finland (BoF) and the European Investment Bank (EIB). In December 2012, the agreement with the EIB was extended for a further two years and is due to expire at the end of 2014. The arrangement with BoF was extended from December 2013 for a further 12 months and is also due to expire at the end of 2014. BoF indicated that no further extension to this arrangement will be granted and was recently not providing any reward for keeping part of ECHA's cash reserve on their accounts.

As the reserves for investment of the Agency are likely to be exhausted by the end of 2015, it was proposed not to extend the agreement with the EIB either. The current cash management guidelines will thereby become *de facto* obsolete.

Management of the Agency's cash reserves will also in future be based on prudential rules applied to financial activities in accordance with sound financial management and best banking practice. To limit the interest rate risk, the Agency's cash reserves shall be placed in bank deposits with a maximum maturity from the value date of 12 months.

In order to help ensure risk minimisation, the total amount invested with any single counterparty must not exceed 50 % of the Agency's excess cash reserves (which is in line with MB/42/2009). However, when the excess cash reserves fall below EUR 50 million a maximum of EUR 25 million may be invested with any one financial institution.

With one editorial clarification on the limits of the cash reserves, the Board approved a revision of the guidelines on managing cash reserves deriving from fees and charges.

13. Adoption of implementing rules (MB/55-56/2014)

13.1 ECHA Financial Regulation (MB/55/2014)

The Acting Director of Resources presented a proposal for Agency specific implementing rules to ECHA's Financial Regulation which entered into force on 1 March 2014. Following the adoption by the Management Board, the Implementing Rules would enter into force on 1 January 2015.

The following limits for the evaluation of significant spending were proposed:

| % to be applied | Range in EUR | ECHA limits |
|------------------------|---------------------|--------------------|
| Ex-ante range 2-5 % | 0.5 m to 1.275 m | 1.0 m |
| Ex-post range 5-10 % | 1.275 m to 2.5 m | 2.0 m |

The Secretariat noted the divergence in views between the Secretariat and the Commission (DG BUDG) on the entry into force date of the new implementing rules, the latter considering that a retrospective application of the new rules appropriate. However, for reasons of legal certainty, the Secretariat favoured applying the rules as of 1 January 2015.

The Management Board adopted implementing rules to ECHA's Financial Regulation, entering into force on 1 January 2015.

13.2 EU Staff Regulations (MB/56/2014)

The Management endorsed a request to opt-out from the Commission Implementing Rule on working time (working time regime, flexitime, credit/debit balance – specific for working conditions in Finland) and instructed the Secretariat to send the request to the Commission.

14. Audit (MB/57-59/2014)

14.1 Report from the Working Group audit – including report on IAS audit on applications for authorisation for advance information (MB/57/2014)

The new Chair of the Working Group Audit informed of important audit reports, action plans and related developments, discussed in a tele-meeting on 10 December:

She informed that ECHA's Internal Audit Capabilities (IAC) audit plan for 2015 included:

- KPI's in the Agency-level reporting.
- ECHA Helpdesk.
- Contract management and payments.
- Substance evaluation.

- Quality audits with ECHA's quality manager.

As regards the Integrated Quality Management System (IQMS), the following audits were planned:

- Management.
- Scientific IT tools.
- Information and communication technology.
- Committees.
- Risk Management.
- Biocides.

Other topics highlighted in the report included:

- IAC's external quality validation.
- IAS⁷ audit on application for authorisation.
- IAC audit on staff training and development.
- Update on the IAS audit plan for ECHA.

The Board members took note of the report and the supporting documents and welcomed the action plan, particularly the recommendations for the practical implementation of the application for authorisation (AfA). Defining the roles of the authorisation team members and introducing a common approach for time recording in the AfA process recommendations were mentioned as a first important step taken by the Agency to enhance the process.

14.2 Sharing the Internal Audit Capability with GSA Agency (MB/58/2014)

The Executive Director presented a proposal to share the staff member assuming the function as Internal Audit Capability (IAC) with the European Global Navigation Satellite System Agency⁸ (GSA). A corresponding request was received in July 2014. GSA is a decentralised European Union Agency located in Prague. The Financial Regulation requires the Management Board to agree on the practical modalities of a shared internal audit capability.

The Executive Director highlighted that the proposal by the GSA-Agency is an opportunity for ECHA to gain efficiencies and for the ECHA IAC to develop further expertise. Creating synergies between agencies is also a request from the European Institutions. The proposal is supported by ECHA's partner DG in the European Commission.

The Chair of the Working Group on Audit expressed support on behalf of the group.

The Management Board endorsed the sharing of ECHA's Internal Audit Capability with the European Global Navigation Satellite System Agency (GSA) and agreed on the practical arrangements:

- Per calendar year up to 30 days of service are foreseen by the ECHA IAC for the GSA Agency.
- For services provided to the GSA, the IAC shall report independently and exclusively to the GSA.

⁷ Commission Internal Audit Service

⁸ European Global Navigation Satellite System Agency: <http://www.gsa.europa.eu/>

- GSA shall pay an amount that corresponds to the proportion of salary, secretary support, costs of transport, accommodation and daily allowance.
- Agreement foreseen to enter into force in January 2015 and to be valid for a period of two years.

14.3 Revised mission charter of the IAS (MB/58/2014)

The Chair of the Working Group Audit informed that the Internal Audit Service of the European Commission (IAS) has provided a draft revised mission charter for the agencies and other decentralised EU bodies to the EU Agencies Network on 5 June 2014.

The Management Board adopted a revised mission charter of the IAS, aligning the charter with the new Financial Regulation.

15. ECHA Anti-Fraud Strategy (MB/60/2014)

The Head of the Executive Office presented ECHA's Anti-Fraud Strategy, explaining that in line with OLAF's⁹ methodology and guidance for anti-fraud strategies for EU decentralised agencies, ECHA has conducted a fraud risk assessment of its main activities based on the estimated likelihood and possible impact of fraud. The assessment was performed in 2014. Overall – taking into account existing controls – ECHA believes that the risk of significant undetected fraud is low.

As a result of this fraud risk assessment, the following main fraud risks were identified within ECHA:

1. Deliberate leaking of information;
2. Serious irregularities related to conflicts of interest;
3. Procurement and contract management related fraud.

To implement the anti-fraud strategy, an action plan was considered with 16 concrete actions to be implemented in 2015-2016.

During the discussion, it was suggested to consult the ECHA conflict of interest advisory Committee (COIAC). Furthermore, it was stressed that the strategy should in future also address the issue of free-riders in order to help ensure that all companies shoulder a fair share of the regulatory obligations.

With the understanding that the issue of free riders will be addressed during the next revision, the Board adopted an Anti-Fraud Strategy aiming to foster a culture of high ethical behaviour in the Agency and to prevent serious financial and reputational damage to the organisation.

16. ECHA Transparency Approach (MB/61/2014)

The Executive Director presented ECHA's draft transparency approach for adoption by the Management Board. He reminded that transparency is a core value of ECHA and a lot of progress was made over the years since its start-up, not in the least through the Management Board working group on dissemination. In 2012, during an own initiative inquiry, this work was recognised by the European Ombudsman who praised the Agency for its efforts in the field of transparency. However, since May of this year, the new European Ombudsman has taken a new interest in the activities of the larger EU

⁹ European Union Anti-Fraud Office

regulatory agencies (ECHA, EMA, EFSA and EASA) with regard to transparency. In a letter of 13 September, the European Ombudsman has requested these four agencies whether they have plans to adopt a transparency policy and to keep her informed of the developments in this area.

ECHA consulted its accredited stakeholders and also CARACAL on the Agency's approach to transparency. ECHA's commitment to transparency was appreciated and some recommendations for improvement were made, one of them was that the Agency should develop a transparency policy in collaboration with its stakeholders.

After years of experience and step-by-step improvements, ECHA came with concrete proposals, which lays down a roadmap for the Agency to further improve its transparency and respond to the expectations of the European Ombudsman.

In a discussion, Board members expressed their general positive feedback on the proposal, appreciating the Agency's sensitivity for seeking the right balance between openness and protection of business secrets.

A Board member appointed by the Commission to represent interested parties suggested adding a reference to Article 15 of the Treaty on the Functioning of the EU to the text and expressed his wish for more concrete future actions, e.g. relating to the openness of Committee meetings and details of Committee meeting minutes.

A Commission representative welcomed the proposal and recommended that ECHA should focus on improving explanation when reasons related to the protection of business secrets prevent the Agency from publishing all details of a case. He highlighted that one important additional element of a comprehensive transparency approach is to allow stakeholders to better follow the reasons behind scientific decision making at European level.

The Board adopted ECHA's Approach to Transparency with two modifications (inclusion of a reference to Article 15 TFEU and clarification regarding the effectiveness of public consultations also for aspects related to public health and the environment).

17. Annual report from the Quality Manager (MB/62/2014)

The Executive Director informed the Management Board of the successful ISO 9001 certification audit which was finalised shortly before the meeting. ECHA expects to receive the certifications still in 2014 or early 2015 which will be a major achievement in the Agency's organisational development.

The Management Board gave its appreciations on ECHA's achievement in the area of quality certification which supports efficiencies, consistency and continuous improvements.

18. Nomination Reporting officers for members of Board of Appeal (MB/63/2014)

The Board appointed two members Kęstutis SADAUSKAS and Alexander NIES as reporting officers for the full-time members of the BoA. The former was also appointed as a new member of the Working Group on the BoA.

19. Information items without discussion

Outcome report for written procedure WP/04/2014

Final revised Decision Transfer of fees for Member States

The Board was informed that the Commission gave a favourable opinion on the Management Board draft decision on the transfer of fees to Member States. The decision will enter into force as planned on 1 January 2015.

ECHA Roadmap towards 2018 REACH registration deadline

The Executive Director referred to the ECHA Roadmap towards the 2018 REACH registration deadline which was prepared in close collaboration with ECHA's stakeholders, revised and submitted to CARACAL-16 in November 2014.

Report on follow-up of discharge 2012

The Executive Director referred to the regular ECHA follow-up report for the discharge 2012. For 2013, the discharge procedure has started with a positive draft recommendation from the Chair of the EP ENVI Committee.

Summary report from 4th MSCA Directors' annual meeting

The Chair mentioned that 4th MSCA Directors' annual planning meeting took place on 20 November in Helsinki and participants from 23 countries and representatives of the European Commission attended the meeting. The summary report and the feedback provided by participants will be made available to members by email in due course.

20. A.O.B.

It was noted that the Board should continue improving its working methods in order to be able to take decisions as informed as possible. The new structure for Management Board documents received a positive appreciation, specifically for informing systematically of other options considered in addition to proposals made to the Management Board.

Next meeting and closure

The Chair reminded members that the next meeting of the Management Board will take place from 19 to 20 March in Helsinki.

II. Documents submitted to the Management Board

| | |
|---|-------------------------|
| Draft agenda | MB/A/04/2014 |
| Draft minutes of the 35 th Management Board meeting | MB/M/03/2014 |
| Quarterly report on ECHA's activities | MB/42/2014 |
| Revision of the Decision on classification on services for which charges are levied (MB/29/2014) | MB/43/2014 |
| Strategic development of ECHA by 2020 - including Multi-Annual Staff Policy Plan key figures | MB/44/2014 |
| Transfer within the budget 2014 | MB/45/2014 |
| Second amending budget 2014 | MB/46/2014 |
| Final budget and establishment plan 2015 | MB/47/2014 rev.1 |
| Update of the annexes to the Work Programme 2015 | MB/48/2014 rev.1 |
| Key figures for draft Budget and structure of the 2016 Work Programme | MB/49/2014 |
| Appointment of Committees members | MB/50/2014 |
| Managing the workload of RAC and SEAC | MB/51/2014 |
| Observers' attendance in the authorisation application process | MB/52/2014 |
| Substance Identification in registration dossiers – a strategy for improvement (including completeness check) | MB/53/2014 |
| Revision to Guidelines on managing cash reserves deriving from fees and charges | MB/54/2014 |
| Adoption of implementing rules | MB/55-56/2014 |
| ECHA Financial regulation | MB/55/2014 |
| EU Staff Regulations | MB/56/2014 |
| Report from the Working Group audit – including report on IAS audit on applications for authorisation | MB/57/2014 |
| Sharing the Internal Audit Capability with GSA Agency | MB/58/2014 |
| Revised mission charter of the IAS | MB/59/2014 |
| ECHA Anti-Fraud Strategy | MB/60/2014 |
| ECHA Transparency Approach | MB/61/2014 |
| Annual report from the Quality Manager | MB/62/2014 |
| Nomination Reporting officers for members of Board of Appeal | MB/63/2014 |
| Report from written procedures | MB/WP/04/ 2014 |
| Final revised Decision Transfer of fees for Member States | COM(2014)929 2 final |
| ECHA roadmap towards 2018 REACH registration deadline | |
| Report on follow-up of discharge 2012 | |

III. Decision taken/Conclusions reached by the Management Board

The Management Board:

Adopted the agenda for its 36th meeting.

Approved the minutes of its 35th meeting.

Adopted a draft revised decision on classification on services for which charges are levied, subject to the positive opinion of the European Commission.

Took note of the latest budgetary transfers carried out under the responsibility of the Executive Director.

Adopted a final amending budget for 2014, instructed the Executive Director to notify it to the Budgetary Authority, Court of Auditors and the Commission and to have it published.

Adopted the Agency's budget for 2015 including the establishment plan, instructed the Executive Director to notify it to the Budgetary Authority, Court of Auditors and Commission and to have it published.

The budget will become final following the final adoption of the general budget of the European Union.

Adopted two updated annexes of the Work Programme 2015 (resources and procurement planning) and instructed the Executive Director to forward the Work Programme, as amended, to the Member States, European Parliament, the Council and the Commission and to have it published.

Endorsed the preliminary key figures concerning the budget for 2016 together with the new structure of the work programme.

Appointed Christine HÖLZL (Austria), Andreas KALOGIROU (Cyprus) and Ralf STAHLMANN (Germany) as new members of the Committee for Risk Assessment.

Renewed the membership in the Committee for Risk Assessment (RAC) for:

| Member State | RAC member | Expiry date of the current three-year term |
|----------------|----------------|--|
| Austria | Sonja KAPELARI | 20 May 2015 |
| Czech Republic | Marian RUCKI | 25 June 2015 |

Appointed Silva KAJIĆ (Croatia), Martina PÍŠKOVÁ (Czech Republic), Ivars BERGS (Latvia), Jānis LOČS (Latvia) and Gary DOUGHERTY (United Kingdom) as new members of the Committee for Socio-economic Analysis (SEAC).

Renewed the membership in the Committee for Socio-economic Analysis (SEAC) for:

| Member State | SEAC member | Expiry date of the current three-year term |
|--------------|-------------------------|--|
| Portugal | João Henrique ALEXANDRE | 14 December 2014 |

Endorsed an approach and corresponding first steps to reinforce the automatic completeness check rules on Substance Identification (SID) information and to request an identification of the scope of joint registrations with regard to SID information in REACH-IT, and took note that the Secretariat will carry out a cost/benefit analysis for implementing a manual SID verification during the registration process.

Approved, with an editorial clarification, a proposal for revised guidelines on managing cash reserves deriving from fees and charges.

Adopted, after having received the Commission's agreement, implementing rules to ECHA's Financial Regulation with ECHA specific thresholds for "evaluations" and a deviation regarding the entry into force on 1 January 2015.

Endorsed a request to opt-out from the Commission Implementing Rule on Working Time.

Endorsed the sharing of ECHA's Internal Audit Capability with the European Global Navigation Satellite System Agency (GSA) by allocating up to 30 days of service per calendar year against compensation of costs.

Adopted a revised mission charter of the internal audit service of the Commission (IAS), aligning the charter with the new Financial Regulation.

Adopted an ECHA Anti-Fraud Strategy.

Adopted an ECHA Transparency Approach with an additional reference to Article 15 Treaty on the Functioning of the European Union, and a reference to "protection of human health and environment" on page 4 of Annex 1 ("Efficiency").

Appointed Kęstutis SADAUSKAS as a member of the Working Group of the Board of Appeal (BoA).

Appointed Kęstutis SADAUSKAS and Alexander NIES as reporting officers for the full-time BoA members.

List of agreed follow-up actions:

New invitation letters for new nominations to RAC and SEAC, before the March 2015 meeting should be sent by the Secretariat to Member States.

Future quarterly reports to include statistics on confidentiality claim assessments.

IV. List of Attendees

Representatives of the Member States

| | | |
|-------------------------|------|---|
| Thomas JAKL | (AT) | Also acting as proxy of Simon FAJFAR |
| Jean-Roger DREZE | (BE) | |
| Boyko MALINOV | (BG) | |
| Karel BLÁHA | (CZ) | |
| Alexander NIES | (DE) | |
| Henrik Søren LARSEN | (DK) | |
| Aive TELLING | (EE) | |
| Kassandra DIMITRIOU | (EL) | Also acting as proxy of Anastassios YIANNAKI |
| Catherine MIR | (FR) | |
| Krisztina Klára BIRÓ | (HU) | |
| Bojan VIDOVIC | (HR) | |
| Antonello LAPALORCIA | (IT) | |
| Marija TERIOSINA | (LT) | |
| Tristan CAMILLERI | (MT) | |
| Jan Karel KWISTHOUT | (NL) | Also acting as proxy of Ana FRESNO RUIZ and Paul RASQUÉ |
| Edyta MIĘGOĆ | (PL) | |
| Luminița TÎRCHILĂ | (RO) | |
| Nina CROMNIER | (SE) | Also acting as proxy of Pirkko KIVELÄ and Christina RUDEN |
| Simona FAJFAR | (SI) | |
| Edita NOVÁKOVÁ | (SK) | |
| David John Arwyn DAVIES | (UK) | Also acting as proxy of Sharon MCGUINNESS |

Representatives of the European Commission

| | | |
|--------------------|--|---|
| Antti PELTOMÄKI | | |
| Kęstutis SADAUSKAS | | Also acting as proxy of Krzysztof MARUSZEWSKI and on the morning of the first meeting day as proxy to Antti PELTOMÄKI |

Independent persons appointed by the European Parliament

Anne LAPERROUZE

Representatives from interested parties appointed by the European Commission

| | |
|-----------------|--|
| Gertraud LAUBER | (IndustriAll - Trade Unions) |
| Hubert MANDERY | (CEFIC - Industry) |
| Martin FÜHR | (University of Darmstadt - Environment Health and Consumer NGOs) |

Observers from EEA/EFTA countries and accession countries

| | |
|-------------------------------|------|
| Tasoula KYPRIANIDOU-LEONTIDOU | (CY) |
| Hanna KORHONEN | (FI) |
| Pierre PRUM | (LU) |
| Judite DIPANE | (LV) |
| Mona AARHUS | (NO) |

Other Observers

Anton HUFNAGL
Bjorn HANSEN
Abdel-Ilah EL-AMELI

German Ministry for Environment
European Commission, DG ENV
European Commission, DG GROW

ECHA staff

| | |
|-------------------|--|
| Geert DANCET | (Executive Director) |
| Jukka MALM | (Deputy Executive Director/Director of Regulatory Affairs) |
| Jack DE BRUIJN | (Director of Risk Management) |
| Christel MUSSET | (Director of Registration) |
| Leena YLÄ-MONONEN | (Director of Evaluation) |
| Tuula HAKALA | (Acting Director of Resources) |
| Minna HEIKKILÄ | (Head of Unit, Legal Affairs) |
| Wim DE COEN | (Head of Unit, Executive Office) |
| Frank BÜCHLER | (Executive Office) |
| Mervi MUSTAKALLIO | (Executive Office) |
| Viorica NAGHY | (Executive Office) |

Italian industry stakeholder representatives (courtesy visit on the first day of the meeting)

Pietro PISTOLESE
Ilaria MALERBA
Enzo GRIMALDI
Emanuela BETTINI
Micaela UTILI

MINISTRY OF HEALTH
FEDERCHIMICA
ASSOCIAZIONE ITALIANA COMMERCIO CHIMICO
Presidenti, CONFIMI IMPRESA CHIMICA
CONFIMI IMPRESA CHIMICA

V. Corrigendum to the minutes of the 35th Management Board

1. Agenda item 6. Work Programme 2015.

Under **Scientific challenges**:

The fifth paragraph:

Development of the scientific capacity in accordance with the science strategy defined in 2014 and increasing activities to improve the quality of registration data for nanomaterials ~~in line with revised REACH annexes~~.

“Safer chemicals – focusing on what matters ~~more~~ **“most”**”

The ninth paragraph:

~~The low number~~ **The absence** of applications for Union authorisation caught the attention of some Board members who disputed the concept that all Biocides activities should be fully fee financed.

2. Agenda item 8. Revision of the Management Board Decision on the transfer of fees to the competent authorities of Member States.

Last paragraph:

“Reservations were recorded from the Belgian and French representatives who noted that the new draft decision leads to important decreases in the fee transfer per case, which may discourage ~~their~~ Member State to participate in ~~REACH activities~~ **the activity of substance evaluation**”.