



Minutes of the 29th meeting of the Management Board Held in Dublin on 21-22 March 2013

I. Summary Record of the Proceedings

The Chair opened the meeting by welcoming the participants and thanking the Irish authorities for the invitation to Ireland as well as the Dublin-based EU agency, Eurofound, for hosting the meeting.

The Chair then welcomed the following new members and observers from accession countries to the Board:

- Biserka BASTIJANČIĆ-KOKIĆ Head of the Department for Chemicals and Biocides in the Croatian Ministry of Health - participated as observer
- Krzysztof MARUSZEWSKI, Director of JRC participated for the first time as Board member

The names of other observers attending the meeting and on the proxy votes of which the Chair had been notified are listed in section IV of these minutes.

1. Agenda (MB/A/01/2013 rev.1)

The Chair reminded that a revised draft agenda was circulated on 11 March 2013, removing an initially foreseen agenda point on the remuneration of co-opted Committee members¹. The item will be dealt with at a future Board meeting.

The Chair introduced the room documents that had been made available for agenda items 7, 10 and 12 and announced that the following additional item would be dealt with under "Any Other Business":

- Helsinki Chemicals Forum in June 2013 – participation of Management Board members

On this basis, the agenda of the meeting was adopted.

¹ Doc MB/13/2013 does, therefore, not exist.

2. Welcome speeches by the hosts of the meeting

a) Speech by Mr Richard Bruton T.D., Minister for Jobs, Enterprise and Innovation

Richard Bruton T.D. welcomed the Management Board members to Ireland. He referred to the successful REACH Conference on 20 March, the day before the Board meeting, which was one of the events organised under the Irish presidency and in which many of the Management Board members participated.

The Minister mentioned that the Irish Presidency priorities reflect clearly both the immediate challenge of coping with the economic crisis and the mid-term ambition to achieve progress towards a competitive and fair Europe. Particularly, the Ministry for Jobs, Enterprise and Innovation would strongly promote research and innovation, focus on the internal market (e.g. pharmaceutical, IT sectors), and support local companies, especially SMEs which cover about 80% of the jobs in Ireland.

The Minister invited to continuously explore for smarter and effective regulations, easy to implement, in which all interested parties are equally informed, including SMEs. He emphasised the important role of both ECHA and the national authorities in working closely with industry, developing a culture of compliance, fostering innovation and job creation.

Minister Richard Bruton T.D. congratulated ECHA for the great work done since 2007 and wished success as regards to the new obligations that have been given to the Agency.

b) Address by Juan Menéndez-Valdés Director of the European Foundation for the Improvement of Living and Working Conditions

Director Juan Menéndez-Valdés welcomed the Management Board members to Eurofound. He explained the mandate of the Eurofound which was established in May 1975 as 2nd EU agency. The Agency contributes to the planning and design of better living and working conditions in the European Union.

Juan Menéndez-Valdés highlighted the similarities and differences between Eurofound and the sister agency ECHA, and welcomed the opportunity to strengthen interagencies collaboration to the benefit of all parties. In this regard he referred to ECHA's excellent coordination work of the network of agencies in 2011/12.

3. Declaration of interests

The Chair asked if any Board member has any interest which could be considered to be prejudicial to her or his independence with respect to any points on the agenda. No conflicts of interest were declared.

The Chair also mentioned that most of the annual declarations of interest of members are due for renewal. She reminded that the Secretariat had circulated a message in advance of the meeting with information on the renewal of the annual declarations, including the forms to be used. It was, furthermore, reminded that Board members are invited to send a CV to the Secretariat for publication on the Agency's website.

4. Minutes of the 28th Management Board meeting (MB/M/04/2012)

The draft minutes of the 28th Management Board meeting on held 13-14 December 2012 were adopted without amendments.

The Chair informed about the status of the follow-up actions from previous meetings, noting that the review of rapporteur remunerations would be a longer term issue and that the Executive Director's report would provide an update on the stakeholder involvement in the authorisation process. A list of mandates of the Board's subgroups has been made available by the Secretariat after the last meeting.

5. Report from the Executive Director (MB/01/2013)

The Management Board received the quarterly report from the Executive Director covering the progress made in achieving the annual work programme, including the results on work programme indicators.

Exchange of views took place on issues related to regulatory requirements for nanomaterial, intermediates, applications for authorisation and enforcement aspects. Further discussion topics included the need to establish efficient interfaces with other EU legislation and authorities, ECHA's input into the implementation of the Commission's SVHC² Roadmap or the need for the Agency to "brand" its policies and approaches in the areas of nanomaterials, authorisation or dossier quality.

On request, the Executive Director and the senior management provided clarification on results in the areas of (targeted) compliance checks and the assessment of confidentiality claims.

Several interventions addressed the preparation of the Biocides Fee Regulation under the responsibility of the European Commission and issues raised by Member States in the adoption process. These issues also concerned the Agency's role in the implementation of the new legislation. The ECHA Secretariat emphasised the intense cooperation with national authorities but also the tight timetable and scare resources on all levels, with ECHA being the only party with new resources because the Agency had previously no tasks in the field of Biocides. It was acknowledged that ECHA needs to increase the efforts in communicating its work and vision within the adopted legislative framework. In order to facilitate the progress towards entry into operation it was agreed that ECHA would call for a preparatory meeting with key Member States in April. The purpose of this meeting should be to facilitate common view amongst ECHA and MSCA's on ECHA's role under the Biocidal Products Regulation and on a number of operational aspects before the May 2013 Biocides Competent Authority meeting and in also clarifying the role of biocides activities in the new multi-annual work programme..

The Board took note of the information provided and expressed its general high satisfaction with the achievements since the last Management Board meeting.

6. REACH/CLP resources in the period 2014-2020 and the impact of the revised REACH Fee Regulation (MB/02/2013)

The Executive Director gave an overview of the available information and the determining factors for ECHA's resourcing under the European Union's (EU) multi-annual financial framework 2014-20.

² Substances of Very High Concern.

The presentation covered also the impact of the revised REACH Fee. In 2012, the Secretariat had presented an analysis of the financial forecast to the Management Board and made a number of suggestions for changes to the Fee Regulation. The meeting noted that the Commission had ultimately decided to increase the standard registration and authorisation fees. At the same time, the fees for small and medium sized enterprises (SMEs) were adjusted downwards. Additionally, all fees were for the first time adjusted to the inflation rate. The latter point had been raised by the Agency. The Agency's other proposals; especially those for update fees for submitting an revised registration dossier in response to a final compliance check decision , however, were not incorporated in the revised Fee Regulation as published on 21 March 2013.

As regards to the main cost assumptions for ECHA in the coming years, the Executive Director highlighted that the revised fees would not take into account the employer's part of the pension contribution for ECHA staff working in the area of REACH and CLP. Concerning the duty to pay the pension contributions, the Management Board was informed of prevailing differences in interpretation between the Secretariat and the Commission services. The Executive Director explained that if ECHA would eventually agree to follow the Commission's interpretation, it would result in an anticipated negative financial outturn for ECHA at the end of the next multi-annual financial framework in 2014-20, even if the full amount of 385 million EUR would be reserved for ECHA.

In this context the Executive Director explained that the Agency's multi-annual financial planning is based on estimations on both the fees to be collected and the operational and administrative expenditure. There would currently be a considerable degree of uncertainty regarding both factors. At the same time, the co-existence of several legislative mandates for ECHA results partly in shared expenditure whilst certain items of this expenditure are by nature inelastic to budgetary division (e.g. rent, IT hosting services). Therefore, it would be worth exploring whether a common fee reserve could be established for ECHA to better respond to potential shortfalls in the revenue from fees and to reduce out the impact of uncertainties in funding. Such a common reserve would allow ECHA to manage its funds more efficiently and with increased flexibility and even out fluctuations in fee income under the different Regulations in a spirit of achieving synergies from the management of the four Regulations. The revision of Biocidal Products Regulation together with the upcoming revision of the Framework Financial Regulation for Agencies would constitute an opportunity to propose the relevant changes in the law.

Regarding future staff reduction for EU institutions, the Executive Director informed that whilst the Heads of States concluded in February 2013 that all EU institutions, agencies and bodies should reduce staff by 5% between 2013 and 2017, the Commission had instructed all cruising speed agencies to reduce their staff by 2% in 2014. The additional 1% cut would constitute a tax which would be used to finance new agencies or agencies with new tasks. Moreover, the Commission had started to collect estimates for the EU multi-annual financial framework, indicating that cruising speed Agencies would face a reduction in staff of approx. 12% over the period 2013-2020 (1% in 2013, 2% every year between 2014-2017, and 1% every year 2018-2020), while the other EU institutions would be asked to reduce staff numbers by 5% only over the same period. The Executive Director explained that the Heads of EU Agencies have agreed to object to the approach taken by the Commission and have communicated their position to EU institutions.

Board Members thanked the Executive Director for the detailed background analysis which showed that ECHA has to be mindful of the institutional developments. Several members recommended focusing the attention on the most important issues instead of striving to engage in several parallel discussions with the Commission and the other institutional partners.

The Board confirmed that in the light of the information provided, there is a need to convey a message to national ministries represented in the Council Budget Committee

that ECHA will need the full amount of EUR 385 million EU subsidy between 2014-20, as originally foreseen. At the same time, ECHA would strongly benefit from a reserve fund to compensate potential shortfalls in REACH and Biocides fee income.

The Management Board took note of information provided on ECHA's situation under the next multi-annual financial framework of the European Union (2014-2020); noting in particular the uncertainty over whether ECHA's financial and staff resources will be adequate to implement an ambitious multi-annual work programme.

7. Preliminary Draft Budget 2014, including outline of the work programme and draft establishment plan (MB/03/2013)

The Executive Director presented the draft estimate of ECHA's revenue and expenditure for the year 2014, together with the establishment plan and an outline of the work programme. He explained that a revised version of the budget estimate and the establishment plan had been tabled for the meeting. The estimate foresaw the payment of the employer's part of the pension contribution for REACH and CLP staff by ECHA, and a 1% reduction in statutory staff. The initial draft, sent to the Commission and the Management Board by 15 February, had foreseen a staff reduction of 2% but the payment of the pension contributions from the EU general budget.

With reference to the divergences in interpretation between the Commission services and the Secretariat concerning the responsibility for covering the employer's part of the pension contributions for REACH and CLP staff, the Executive Director informed that the Secretariat would maintain its interpretation as valid and defendable. However, he suggested following the Commission's interpretation in order to avoid an inter-institutional dispute. By way of background information, the Executive Director referred to intense discussions with the Commission services in the first half of March on the issue.

At the same time the Executive Director explained that the Secretariat considers the strict segregation of budgets and accounts between REACH and Biocides tasks as an obstructing factor for finding further synergies within the Agency. If this segregation would be released in the course of the upcoming revision of the Biocidal Product Regulation (BPR)³, it could also have as consequence that the Commission's interpretation on the issue of pension contributions would change and ECHA eventually not asked to pay the pension contributions in 2014 and 2015 from REACH fee income. This would have a very positive effect on the long term resource forecast. The support from MB on this point would, therefore, be essential

Overall, the budget estimate presented by the Executive Director featured the following key figures:

REACH/CLP

- A decrease of expenditure from €109,222,250 to €103,208,000, i.e. by 6% (including the 1st amending budget 2013 see below)
- A decrease of fee revenue from €38,371,640 to €18,595,000, i.e. by 52% (lower fees since there is no registration deadline in 2014)
- A decrease of the ECHA cash reserve from €97,346,847 (at the end of 2013) to €13,783,847 (at the end of 2014), i.e. by 87%
- A decrease of the number of REACH/CLP TA staff from 451 to 446; i.e. by 1%

Biocides

- An increase in expenditure from €7,220,500 to €9,264,800, i.e. by 28%
- An increase in fee revenue from €150,000) to €4,200,000, i.e. by 2,700%
- A decrease in EU subsidy €6,070,500 to €4,936,800), i.e. by 19%

³ In particular Article 78(2) of Regulation (EU) No 528/2012.

An increase of the number of Biocides TA staff from 47 to 48 staff

PIC

- A decrease in the expenditure from €1,561,500 to €1,314,300, i.e. by 16% (the reason being mainly the decreased IT development)
- A decrease in EU subsidy / EEA EFTA contribution from €1,561,500 to €1,314,300, i.e. by 16%
- An increase of the number of PIC TA staff from 5 to 6 staff

The outline of the work programme, which motivated the budget proposal, covered the continuous operational and administrative activities deriving from the Agency's legal mandate. In addition it focused on making progress in achieving the Agency's four strategic objectives e.g. in the area of dossier quality or SVHC identification or by fostering synergies between the different legislative mandates.

After this presentation, the Management Board heard the Chair of its working group on Planning and Reporting, Martin Lynch (IE). The working group had, as usual, considered the budget and work programme proposal before submission to the Board. Mr Lynch informed that the working group recommends the approval of the proposed decision. As regards the question of pension contributions, the group was, however, by majority of the view that ECHA should defend its earlier position and not align to the Commission's interpretation.

This was followed by an extensive exchange of views which focused on the question whether ECHA should align to the Commission's interpretation on the issue of pension contributions and on staff reductions.

The Management Board eventually approved the draft estimates for expenditure and revenue for the year 2014, together with the establishment plan and the work programme outline as presented to the meeting, i.e. assuming the payment of the employer's part of the pension contributions from ECHA's budget as well as a staff reduction of 1% in the area of REACH/CLP. The Commission representatives objected the budget proposal because of the lower than requested staff cuts. The establishment plan request was approved with the understanding that the final number of posts will be aligned at the year's end to the eventual decision of the budgetary authority⁴.

Noting the consequences of the strict separation which risks hampering additional synergies between the different mandates assigned to ECHA and the negative implications for the Agency's long term financing, it was, furthermore, concluded that the Chair should communicate these concerns as appropriate, also in view of a planned technical amendment to the BPR in 2013.

8. Amendment(s) to the budget 2013 (*MB/04/2013*)

The Executive Director presented a proposal for a $1^{\rm st}$ amending budget for 2013, consisting of two separate budgetary amendments: one related to the payment of pension contributions for REACH/CLP staff in 2012 and 2013, and one to allow the temporary funding of Biocides preparations from the REACH fee reserve (1 million EUR).

Regarding the first amendment, the Executive Director clarified that this would be a necessary consequence of the Board's eventual agreement to paying the employer's part of the pension contributions for REACH and CLP staff from the Agency's budget in 2012-2014 (see above).

⁴ By way of clarification footnotes were added.

As regards the funding for Biocides preparations, the Commission confirmed by letter of 21 March 2013 that an additional balancing contribution of a maximum of 1 MEUR will be provided by the year's end if the fees to be collected under the Biocides Regulation from September 2013 will, as currently anticipated, be lower than 1.15 million EUR. At the same time, ECHA must reimburse in 2013 the funds temporarily taken from the REACH fee reserve.

The Management Board adopted the amending budget and instructed the Executive Director to notify the decision to the Budgetary Authority, the Court of Auditors and the Commission, and have it published on the Agency's web page and in the Official Journal of the European Union.

9. Multi-annual Staff Policy Plan 2014-16 (MB/05/2013)

The Executive Director presented the regular update of the Agency's multi-annual staff policy plan which covers the years from 2014-16. It included the staffing figures under REACH, Biocides and PIC activities as well as the posts envisaged for the accession of Croatia to EU.

In the same manner as for the staffing for 2014 (see above), the Secretariat had submitted an initial version of the plan to the Commission and the Management Board which assumed a reduction in staff of 2% in 2014. A revised draft was submitted for the meeting with a reduction of 1% in that year (see explanations above under point 7).

At the time of the meeting, the Commission had not communicated its opinion on neither of the submitted drafts.

The establishment plan posts were foreseen to be reduced in the area of REACH and CLP from 451 to 438 until 2016. In the areas of Biocides and PIC, where ECHA has been assigned new regulatory tasks starting from 2013 and 2014 respectively, the establishment posts are anticipated to grow from 47 to 48 (Biocides) and 5 to 6 (PIC).

The Management Board adopted the Multi-Annual Staff Policy Plan 2014-2016 as presented with the modification requested by the Commission that no establishment post in the highest grade should be foreseen. Furthermore, it was agreed that the final document should feature the same clarification as mentioned above under agenda point 7 regarding the eventual decision of the EU Budgetary Authority in relation to the annual staffing levels

10. Draft Multi-annual Work Programme 2014-18 (MB/06/2013)

The Executive Director presented the draft multi-annual work programme (MAWP) of the Agency for 2014-18.

The proposal followed the approach endorsed by the Management Board in September 2012 regarding the new structure and frequency of the MAWP⁵. Accordingly, the next MAWP will be a strategic document covering five years with annual milestones. The milestones will be regularly reviewed by the Management Board whilst the core text will, as rule, remain stable.

The Management Board was consulted in writing on the draft in December 2012. The Management Board's working group on Planning and Reporting met in Helsinki on 7 February and 5 March 2013 to discuss the most substantial comments from members, and to provide its opinion on necessary amendments to the text. The comments

⁵ MB/37/2012 final.

received concerned specific issues regarding either the wording or details of the planned actions, thus no comments on the strategy as such were given. A selection of the main comments with the Secretariat's replies had been distributed to the Board.

The Executive Director explained that each of ECHA's four strategic objectives was divided for the purpose of the MAWP into strategic action areas and the main milestones are specified in an annex. The annual work programmes will provide the detail on the actions and describe the concrete deliverables. A review of the progress in the action areas and milestones will be conducted regularly during the lifetime of the programme and corrective action will be taken where necessary.

Furthermore, he highlighted that the draft presented was based on the assumption that ECHA's REACH/CLP staff will be reduced by 5% between 2013-17, in line with the conclusions of the Heads of States in February 2013 and without any further reductions.

Following a conclusion of the Board in 2008 and the planning cycle which was presented to the Board in June 2009, the MAWP will be submitted to public consultation before its final adoption. Due to the fact that the MAWP will now be fixed for five years, the public consultation will be organised in 23 EU languages. Because of the translation requirement, the consultation will take place later than previous years i.e. in June - July 2013. The final draft, taking into account the comments received, will be submitted for adoption in September 2013.

During an exchange of views many Board members welcomed the draft document. Some comments were made as regards the need to consult the Forum for enforcement or the Competent Authorities for Biocides about the programme. Concerning the content, interventions were made in relation to the possible withdrawal of registration numbers and ECHA's role in international for a vis-à-vis the Commission.

With small modifications⁶ the Management Board endorsed the draft multi-annual work programme 2014-2018 for submission to public consultation. The draft document will be available on ECHA's webpage with the possibility for the general public to provide comments.

The Chair concluded that the draft should be separately consulted with the Competent Authorities under the Biocides Regulation and the Forum for enforcement. The final adoption by the Management Board is foreseen for September 2013 and the Board expressed the wish to take the outcome of all consultations into account for this.

11. Structure of the Board of Appeal and mandates of some of its members (MB/07/2013)

The Management Board heard the Chair's explanations on the required decisions on the structure of the Board of Appeal and the prolongation of the mandates of certain of its members.

Having regard to its deliberations of December 2012^7 , the Board decided that the present structure of the Board of Appeal should be maintained and a review is scheduled for 2015.

Afterwards the meeting continued in camera.

The Board heard its working group on the Board of Appeal which is also entrusted with the duties of the reporting officers for the full-time members of the Board of Appeal.

⁶ Slightly changed wording on the issue of withdrawal of a registration number and clarification regarding ECHA representing Member States or the Commission / EU in international fora. ⁷ MB/64/2012.

On the basis of the recommendations of the working group, which had duly reviewed all individual cases, and after detailed deliberations, the Board then took decisions on the prolongation of mandates of Board of Appeal members which come to an end in 2013 or early 2014. The Board also agreed on a step-wise process for handling an individual case where an administrative procedure is pending.

The prolongation decisions were taken subject to the acceptance by the persons concerned and their compliance with the (provisional) ECHA eligibility criteria for Board of Appeal members⁸. The Agency will approach the respective members of the Board of Appeal, via its Chair, to enquire whether they are willing to serve the Agency for another term-in-office of five year and to request the confirmation as regards their compliance with the eligibility criteria. If these requirements are met, the Chair will formalise the prolongation decisions.

12. Security Model of the Agency's IT systems, incl. Unified Declaration for access to restricted ECHA IT systems (MB/08/2013)⁹

The Director for Information Systems presented a revised draft decision on the Security Model for ECHA's IT systems, following discussions in the December 2012 Management Board meeting and a written procedure in January 2013¹⁰. She referred to a room document with a separate Declaration for the Commission services and highlighted the importance of finding a solution on the Security model for a successful Entry into Operation of ECHA's mandate under the Biocidal Product Regulation in September 2013.

The proposed Declarations for Member State authorities and the Commission and the connected Standard Security Requirements were not modified compared to the versions presented in December and January; the reason being that the Secretariat had confirmed its analysis concluding that the security level required for IT applications used under the Biocidal Product Regulation should the same as for REACH data.

As announced with the outcome of the written procedure in January, the Secretariat had been in contact with the dissenting Member States to resolve technical issues that prevented them from agreeing to the proposal.

The proposal tabled for the meeting to accommodate remaining technical difficulties was requesting the Management Board to authorise the Executive Director to allow access to the ECHA IT systems for a limited time without signing the Security Declaration. To this end the authorities concerned would have to submit a justified request that indicates their security efforts. If considered secure enough for the transitional period the Executive Director would grant access to the ECHA systems on this basis. This would involve that the Biocides data may for a certain time not see the same level of protection as REACH data.

This was followed by an exchange of views during which several members asked for more time to analyse the new proposal, in particular with view to concerns raised by Competent Authorities for Biocides concerning tele-working possibilities. The proposal was made to launch another written procedure after the Security Officers Network (SON) meeting in May 2013. Several Board members, including a member appointed by the Commission to represent interested parties, supported the proposal made by the Secretariat, stressing that the security level for industry data submitted under the

⁸ MB/38/2012/D final of 28 September 2012.

 $^{^9}$ The order of agenda items in these minutes follows the draft agenda as adopted at the beginning of the meeting, not the actual order of events during the meeting. 10 MB/WP/01/2013.

Biocides Regulation has to be the same as for REACH data. It was also recommended to review the language of the Standard Security Requirements in order to render it more positive and less commanding and to open the Security Officers Network for Biocides Authorities.

The Executive Director responded to the remarks made and explained why another written procedure before the June meeting would be difficult to arrange time-wise. He also emphasised that most of the Member States still have access only to REACH-IT and not the new and more advanced REACH IUCLID Member State database. The new declarations would give also these Member States access to an improved and more flexible use of the REACH data. Since the majority of Member State seems to be ready to accept the proposal made by the Secretariat already in December and January, he made a plea to the Board to allow at least these Member States to proceed on the basis of the current proposal.

After thorough deliberations, the meeting eventually approved with one abstention that the unified Declarations of Commitment and connected Standard Security Requirements as presented to the Board can be the basis for Competent Authorities (CA) to obtain access to ECHA's IT systems. This will allow those CA that can comply with the Security Requirements as presently defined to get connected with ECHA and prepare the Entry into Operation of the Biocides Regulation. The conclusion was reached with 21 members with voting rights present or represented by proxy vote, i.e. less than required to act formally on behalf of the Management Board. For this reason, it will have to be confirmed by written procedure after the meeting.

With regard to persisting difficulties of some Biocides CAs to subscribe to the Security Requirements, the meeting also required the Security Officer's Network to present for the next Board meeting a proposal how to integrate tele-working into the IT security framework. The Management Board will on this basis be able to eventually decide on modifications of the Security Requirements in order to prepare the ground for all remaining CA's to commit to the Security Declaration.

13. ECHA General Report 2012 (MB/09/2013)

The General Report 2012 covering the activities of the Agency during the previous year was presented to the Management Board by the Executive Director. He reported on main achievements e.g. testing proposals from 2010 phase-in registrations examined by the deadline; good progress on compliance checks on 5% of highest tonnage band dossiers; the first CoRAP including 90 substances adopted; 67 SVHCs added to the Candidate List; C&L inventory published; new versions of REACH-IT, IUCLID and Chesar; publication of translations; and preparatory work for Biocides and PIC. The Executive Director informed also of the limited areas where the targets were not achieved.

The floor was afterwards given to the Chair of the working group on planning and reporting who explained that the group had considered the document and recommends the Board to adopt it.

In the following discussions, Board members raised questions concerning statistics on compliance checks, asking for clearer definitions in future reports. Other interventions were made on ECHA's estimates for Downstream User notifications. All members who took the floor valued the achievements and the commitment of ECHA.

With small modifications¹¹ the Management Board adopted the General Report 2012 and instructed the Executive Director to submit the document to the Member States,

¹¹ Modification to the annexes (Annex 4 was replaced by a link to the candidate list and Annex 5 removed).

the European Parliament, the Council, the Commission, the European Economic and Social Committee and the Court of Auditors, and to have it published.

14. Analysis and Assessment of the Authorising Officer's Annual Activity Report (MB/10/2013)

The Executive Director presented his annual activity report as authorising officer under ECHA's Financial Regulation. He explained that the annex on authorised staff resources needs to be aligned with the first amending budget adopted by the Board in 2012.

Following this, the Chair of the working group on Planning and Reporting presented the Board a proposal for the required analysis and assessment of the Management Board thereof. The proposal had been prepared by the working group during a meeting on 5 March 2013.

The Management Board took note of the Annual Activity Report for 2012 of the Executive Director. With some minor changes, the Board adopted its analysis and assessment of the report as prepared by the working group¹². The Executive Director was instructed to send the analysis and assessment of the annual activity report to the Budgetary Authority and the Court of Auditors by 15 June 2013.

15. Exchange of views with the Irish Authorities

Sharon McGuinness from the Health and Safety Authority (HSA) introduced the authorities responsible for implementing, inspecting and enforcing REACH, CLP and PIC Regulations in Ireland.

She informed the participants that collaboration with ECHA on REACH and CLP issues started already in 2009. Even under staff constrains, the core activities of HSA are dedicated to the Committees of ECHA (MSC, RAC, SEAC), CARACAL, working groups, Forum and enforcement projects.

At national level, HSA is the leading Irish competent authority continuously focussing on practical aspects and links of REACH with different chemical regulations; providing policy input to the government, supporting stakeholders via helpdesk, offering consultation and raising awareness, as well inspecting and enforcing. HSA reports annually on planned inspections and has agreements with customs authorities, in which roles of the parties are clearly defined.

The key approach of HSA is to discourage risk-taking behaviour by informing its stakeholders of potential consequences of non-compliance. Strong focus is given on advice to duty holders and companies are encouraged to approach the authority.

John Harrison gave an overview on the priorities as well as challenges faced by national Irish Biocides authorities in implementing the new Biocides Regulation. The Department of Agriculture, Food and the Marine, Pesticide Registration and Control Division is the Competent Authority for the implementation of the EU biocides legislation.

He summarised the activities in relation to the approval of active substances, biocidal product notifications, as well as enforcement under the Biocides Regulation (BPR). Enforcement activities in Ireland are subject to an annual inspection plan and would include routine inspections and sampling.

 $^{^{12}}$ These changes in formulation concerned points 2(d), 7 and 8.

John Harrison referred at the new partnership between Competent Authorities and ECHA, in which all parties should take an active role. He gave an Irish perspective of important aspects for ECHA to consider, which included the following priorities: the review programme for active substances; the technical equivalence workload and operational provisions of the BPR as well as the coordination group meeting as a continuation of the current product authorisation and mutual recognition facilitation group. In conclusion, he highlighted that good cooperation between the Member States and ECHA would be essential for making the new regime start successfully in September.

A broad exchange of views with the presenters took place. Some members referred to the impressive number of inspections and wanted to know more about their outcome. ECHA representatives asked for more information on the review programme and the time invested by the Irish authorities.

The Chair thanked Sharon McGuiness and John Harrison for the comprehensive presentations, as well as for inviting the meeting to Dublin.

16. Update of the IAS multi-annual strategic audit plan (MB/11/2013)

The Chair introduced the agenda point, explaining that the annual update of the Commission's Internal Audit Service's (IAS) multi-annual strategic audit plan was limited by the service to a review and assessment of major changes at ECHA, as well as the latest implementation status of the action plans regarding the processes presenting high residual risks. As a result of the assessment, IAS concluded that the Strategic Audit Plan 2011/2013 from the previous update in 2010 was still valid. For 2013, it was proposed to carry out an audit of expert management by the Committees and Forum Secretariats, including the respect of avoidance of conflicts of interest.

The Working Group on audit matters has considered the plan in its December 2012 meeting.

The Board took note of the information provided.

17. REACH Review (1st General Report under Art. 117(4) REACH and Art. 46(2) of CLP and review of certain elements of REACH) (MB/12/2013)

The Director of Regulatory Affairs presented the Secretariat's preliminary view on the implementation of the recommendations addressed to ECHA in the Commission's REACH Review report¹³, which he noted to be mostly in line with ECHA's own findings.

It was mentioned that out of 20 recommendations or actions recommended by the European Commission, 14 were addressed to ECHA (alone or together with other actors).

Overall, ECHA welcomed the report and noted that Commission's conclusions are broadly in line with ECHA's four strategic objectives. Most of the recommendations are already covered by ECHA's planning (e.g. quality of the registration dossiers, SME support). For certain recommendations the Secretariat believed it would be more appropriate that another body would take the lead (such as development of an "inventory of all existing restrictions in EU legislation on individual substance basis" or more specific guidance on operation of SIEFs).

 $^{^{\}rm 13}$ The European Commission adopted and published its REACH Review Report on 5 February 2013 – see COM(2013)49 final.

In partnership with other actors, ECHA generally would be prepared to take an active role in many activities recommended by the Commission.

A broad exchange of views took place. The following issues were discussed: more specific guidance on transparency, non-discrimination, fair cost-sharing, and more guidance on the operation of SIEFs; enforcement of REACH and CLP in the remit of Member States; effectiveness of the Committees; nanomaterials, and ECHA's aspiration to increase its resources, both to provide more advice and support to industry but also to address the obvious non-compliances in registration dossiers covering nanomaterials. Other interventions concerned the need to support innovation and the role of the Directors' Contact Group (DCG).

The Management Board took note of the information on the impact of the Commission's review. There was general support for the assessment and the Commission's communication was welcomed. Further discussion would be needed to decide on the appropriate follow-up. The Commission announced the preparation of a work programme for this in cooperation with national authorities and ECHA. The Secretariat confirmed that it would reflect the activities resulting from the REACH review in the final multi-annual work programme, taking into account ECHA's resource constraints.

18. Amendments to the Rules of Procedures of the MSC (MB/14/2013)

Without discussion, the Management Board approved the revised Member State Committee (MSC) Rules of procedure as previously endorsed by the Committee at its 28th meeting.

19. QSAR toolbox – update of the 2013 procurement plan (MB/15/2013)

Without discussion, Management Board approved the procurement action related to the OECD QSAR toolbox, and to thereby amend the Procurement Plan for 2013.

20. Items for information - Budget transfers and written procedure (MB/16/2013, MB/WP/01/2013)

Without discussion, the Board took note of the information provided in relation to budget transfers carried out by the Executive Director and of the outcome of a written procedure in January.

21. Any other business

<u>Commission Roadmap 'Implementation of the Common Approach on decentralised</u> agencies'

A Commission representative presented the Roadmap for implementing the "Common Approach on decentralised agencies". This followed information provided to the Board in September and December 2012.

Five priority areas have been identified where cooperation with the Network of Heads of EU Agencies would be necessary: management of potential conflicts of interest; Activity Based Budgeting /Activity Based Management and key performance indicators; evaluations; headquarter agreements; and annual work programmes. Since ECHA is one of the more recently created agencies it was noted that many of the recommendations from the Common Approach are already implemented in ECHA,

either via the REACH Regulation or in form of administrative practices established since 2007.

Commission agreements to Board decisions

The Chair informed the meeting that Commission agreements have been received by the Secretariat on the Management Board decisions taken in 2012 in relation to transfer of fees to Member States and administrative charges for false SME declarations. Both decisions have afterwards been put into force by the Chair.

Biocides Fee Regulation

The topic was not dealt with.

Day Care

An update was given on the envisaged solution for supporting day-care for ECHA staff children between 5 and 10 months. ECHA will further consider to invest in an own day care center. For the solution envisaged now, an external provider has been identified and ways to financially support ECHA staff with children in this age group are being analysed.

Helsinki Chemicals Forum 2013

The Secretariat informed that the annual Helsinki Chemicals Forum is scheduled for 18 and 19 June 2013. The June Management Board meeting will therefore start at 13.00h on 19 June and end on 20 June in the afternoon. Since the Helsinki Chemicals Forum will take place just before the Board meeting and deal with important aspects of international regulatory chemicals management, the Secretariat informed that it would be useful for interested Board members to attend. Such participation would be considered as capacity building measure for the governing board and the fees covered by the Agency. The Secretariat Board informed that Board members will be asked to confirm their interest in participating.

22. Next meeting and closure

The Chair reminded members that the next meeting of the Management Board would take place on 19-20 June 2013 in Helsinki in the Agency's conference centre, meeting room "Margot Wallström".

II. Documents submitted to the Management Board

Draft agenda	(MB/A/01/2013 rev.01)
Draft minutes of the 28th Management Board meeting	(MB/M/04/2012)
Report from the Executive Director	(MB/01/2013)
REACH/CLP resources for ECHA in the period 2014-2020 and the impact of the revised fee regulation	(MB/02/2013 rev.01)
Preliminary Draft Budget 2014, including outline of the work programme and draft establishment plan	(MB/03/2013 rev.01)
Amendment(s) to the budget	(MB/04/2013)
Multi-annual Staff Policy Plan 2014-16	(MB/05/2013)
Draft Multi-annual Work Programme 2014-18	(MB/06/2013)
Structure of the Board of Appeal and mandates of some of its members	(MB/07/2013)
ECHA IT Security Declaration	(MB/08/2013)
ECHA General Report 2012	(MB/09/2013)
Analysis and Assessment of the Authorising Officer's Annual activity Report	(MB/10/2013)
Update of the multi-annual strategic audit plan	(MB/11/2013)
REACH Review (1st General Report under Art 117(4) REACH and Art 46(2) of CLP and review of certain elements of REACH)	(MB/12/2013)
Amendments to the Rules of Procedures of the Member State Committee	(MB/14/2013)
QSAR toolbox – update of the 2013 procurement plan	(MB/15/2013)
Notification of transfers within the budget 2013	(MB/16/2013)
Outcome of written procedures	(MB/WP/01/2013)

III. Decision taken/Conclusions reached by Management Board

The Management Board:

- Adopted the agenda of its 29th meeting (MB/A/01/2013)
- Approved the minutes of its 28th meeting (MB/M/02/2012)
- Approved the draft estimate of revenue and expenditure for the year 2013, together with the establishment plan and the outline of the work programme, as annexed to MB/32/2012 and subject to the clarifications indicated in these minutes, and instructed the Executive Director to forward the documents on behalf of the Management Board to the European Commission and the European Institutions as required by the applicable rules and regulations.
- Adopted a 1st amendment to the budget for 2013 as contained in document MB/04/2013.
- Adopted the Agency's Multi-Annual Staff Policy Plan 2014-2016 as contained in the document MB/05/2013 subject to the modifications indicated in these minutes.
- Endorsed a proposal to submit the draft Multi-annual Work Programme 2014-2018 for public consultation (MB/06/2013).
- Decided that the present structure of the Board of Appeal should be maintained and reviewed latest in 2015 (MB/07/2013).
- Decided on the prolongation of mandates of Board of Appeal members which come to an end in 2013 or early 2014, and agreed on a step-wise process for handling an individual case where an administrative procedure is pending. The prolongation decisions were taken subject to the acceptance by the persons concerned and their compliance with the (provisional) ECHA eligibility criteria for Board of Appeal members ¹⁴.
- Concluded in the absence of a two thirds majority representation required for decision making (21 members with voting rights present or represented by proxy vote) that the presented Unified Declarations of Commitment and connected Standard Security Requirements can be the basis for Competent Authorities or mandated national institutions to obtain access to ECHA's IT systems (MB/08/2013 annex). Furthermore, the Security Officer's Network was required to present for the next Board meeting a proposal how to integrate tele-working into the IT security framework.

The conclusions will be confirmed by written procedure

- Adopted the General Report of the Agency for 2012 as contained in the document MB/09/2013, subject to the modifications indicated in these minutes, and instructed the Executive Director to submit the document to the Member States, the European Parliament, the Council, the Commission, the European Economic and Social Committee and the Court of Auditors, and to have it published.
- Took note of the Annual Activity Report for 2012 of the Executive Director as ECHA's authorising officer and adopted its analysis and assessment (MB/10/2013) thereof, subject to the modifications indicated in these minutes.

¹⁴ MB/38/2012/D final of 28 September 2012

The Board instructed the Executive Director to forward the analysis and assessment to the Budgetary Authority and the Court of Auditors.

- Approved the revised Rules of Procedure of the Member State Committee as laid down in Annex to document MB/14/2013.
- Approved a procurement action related to the OECD QSAR toolbox (MB15/2013), and to thereby amend the Procurement Plan of ECHA for 2013.
- Took note of the information provided in relation to budget transfers (MB/16/2013) carried out under the responsibility of the Executive Director.
- Took note of the outcome of the written procedure MB/WP/01/2013.

List of follow-up actions

- The Board will revisit the issue of the remuneration of Committee rapporteurs and the time assumptions for their tasks and those of the Secretariat in the context of the next update on the transfer of fees to the Member States.
- The Chair will communicate the consequences of the strict segregation of budgets and accounts between ECHA's mandates as appropriate, also in view of a planned technical amendment to the BPR in 2013.
- The Secretariat will organise a preparatory ad-hoc meeting with Competent Authorities under the BPR in April 2013 in advance of the CA meeting in May.

IV. List of Attendees

Representatives of the Member States

Karel BLAHA (CZ) also acting as proxy for Ms NOVAKOVA

Nina CROMNIER (SE) Krisztina CSENGODY (HU) Arwyn DAVIES (UK)

Kassandra DIMITRIOU (EL) also acting as proxy for Mr NICOLAIDES

Jean-Roger DREZE

Simona FAJFAR (SL) also acting as proxy for Mr MALINOV

Francis FARRUGIA (MT) Ana FRESNO (ES) Claude GEIMER (LU)

Thomas JAKL (AT) also acting as proxy for Mr NIES

Pirkko KIVELÄ (FI)

Jan Karel KWISTHOUT (NL) also acting as proxy for Mr THUESSEN

Antonello LAPALORCIA (IT)

Martin LYNCH (IE) Edyta MIEGOC (PL) Catherine MIR (FR) Armands PLATE (LV)

Marija TERIOSINA (LT) also acting as proxy for Ms TELLING

Representatives of the European Commission

Gustaaf BORCHARDT

Krzysztof MARUSZEWSKI also acting as proxy for Mr BORCHARDT and Mr

PELTOMÄKI after their departure on the second

meeting day

Antti PELTOMÄKI

Independent persons appointed by the European Parliament

Anne LAPERROUZE Christina RUDEN

Representatives from interested parties appointed by the European Commission

Martin FÜHR (Environment and Health NGOs)

Gertraud LAUBER (EMCEF) Hubert MANDERY (CEFIC)

Observers from EEA/EFTA countries

Biserka BASTIJANČIĆ-KOKIĆ (CR) Henrik ERIKSEN (NO) Sigurbjorg SAEMUNDSDOTTIR (IC)

Other Observers

Gerlin KALLAS on behalf of Aive TELLING (EE)
Peter OSTERGAARD HAVE on behalf of Eskil THUESSEN(DK)

Tasoula KYPRIANIDOU LEONTIDOU on behalf of Leandros NICOLAIDES (CY) Cosmin TEODORU on behalf of Ionuţ GEORGESCU (RO)

Björn HANSEN (European Commission)
Graham WILLMOTT (European Commission)

(Observers attending part of the meeting)

Keith BAILEY expert accompanying Mr DAVIES (UK)

John HARRISON Department of Agriculture, Food and the Marine

Sharon MCGUINNESS Irish Health and Safety Authority

ECHA staff

Geert DANCET (Executive Director)

Jukka MALM (Director of Regulatory Affairs)

Leena YLÄ-MONONEN (Director of Evaluation)

Jack DE BRUIJN (Director of Risk Management) Christel MUSSET (Director of Registration)

Luisa CONSOLINI (Director of Information Systems)

Jef MAES (Director of Resources)

Frank BÜCHLER (Legal Officer, Executive Office)

Mervi MUSTAKALLIO (Planning and Monitoring Officer, Executive Office) Viorica NAGHY (Member States Relations Officer, Executive Office)

Milena STOYANOVA (Management Board Assistant)

Sari HAUKKA (Registrar, Board of Appeal) Minna HEIKKILA (Head of Unit, Legal Affairs)