

Minutes of the 43rd meeting of the Management Board

Held in Bratislava from 28 to 29 September 2016

I. Summary record of the proceedings

The Chair opened the meeting by welcoming the participants¹ and thanking the host country, Slovakia, for the warm welcome extended to Board members.

Address of the State Secretary of the Ministry of Economy of the Slovak Republic: Mr Rastislav Chovanec

Mr Rastislav Chovanec, the State Secretary of the Ministry of Economy of the Slovak Republic, welcomed on behalf of the Slovakian EU Presidency the Board members participating in the 43rd ECHA Management Board meeting.

He expressed the host country's support to ECHA's work, in particular in the areas of the protection of human health and the environment, and he welcomed ECHA's mission to be the world's leading regulatory authority on the safety of chemicals. The State Secretary praised the joint achievements of ECHA and national authorities in the field of chemicals safety and pointed out common challenges for the future, as well.

1. Agenda

The Chair introduced the draft agenda² and the room documents that were made available. It was decided to take points *9 Contractual arrangements for Board of Appeal members - update* and *10 Pre-selection process for the post of the Executive Director – nomination of a Management Board observer* on the second meeting day, 29 September. The agenda of the meeting was adopted on this basis.

2. Declaration of specific interests

The Chair informed the members of the Management Board that she reviewed the members' declared conflicts of interests, together with the Secretariat, in accordance with ECHA's policy on conflicts of interests. No conflicts relating to the agenda of the 43rd Management Board meeting were identified.

The Chair invited the members to further declare any specific interests that could not be drawn from their declarations of interests and which could be considered to be prejudicial to their independence with respect to any item on the agenda. No further specific interests were declared.

¹ The names of all participants attending the meeting and the proxy votes of which the Chair was notified are listed in Section IV of these minutes.

² MB/A/03/2016

3. Minutes of the 42nd Management Board meeting

The draft minutes³ of the 42nd Management Board meeting, held from 22 to 23 June 2016 in Helsinki, were approved subject to one modification indicated in these minutes⁴.

4. Election of a Chairman and a Deputy-Chairman of the Management Board

The Management Board elected Ms Sharon MCGUINNESS (IE) as Chairperson for a first term of office starting from 1 October 2016 and Mr Karel BLAHA (CZ) as the Deputy Chair for a second term of office starting from 25 September 2016.

The second term of office of the previous Chair, Ms Nina CROMNIER, expired on 30 September 2016. The first term of office of the Deputy Chair, Mr Karel BLAHA, expired on 24 September 2016

Ms Sharon MCGUINNESS stood for election as Chair and Mr Karel BLAHA as candidate for the Deputy Chair position.

Mr Peter SMITH (Cefic) and Mr Stefan SCHEUER (European Environment Bureau) were appointed as tellers. After hearing both candidates, Board members cast their votes by secret ballot for both positions.

Ms Sharon MCGUINNESS was unanimously selected as the Chair on the first voting round, for a first term in office. Ms MCGUINNESS accepted the position and thanked the Board for the confidence they had expressed by voting.

Mr Karel BLAHA was selected as the Deputy Chair on the first voting round with the required qualified majority of votes (two-thirds majority of members with voting rights). Mr BLAHA accepted the re-appointment and thanked the Board for their renewed trust.

5. Quarterly report on ECHA's activities

The Management Board took note of the quarterly report⁵ on ECHA's progress in reaching the 2016 Work Programme targets and congratulated the Agency for the work done and its performance since the last meeting in June 2016.

In particular, Board Members noted that ECHA has started the manual verification of technical completeness checks, as well as the high number of processed PIC notifications. The Board welcomed the achievements in the delivery of IT-tools; the preparation of a practical guidance on substance evaluation (to be published in 2017), the planned extension of the quality certification to environment, the study on substitution, the workshop on socio-economic analysis and the fact that the Agency's committees have made good progress with authorisation applications during their September meetings.

The Management Board noted that the review of the Management Board decision on the remuneration of co-opted members⁶ will take place based on 18 months of operational experience, i.e. by June 2017, when the peak in applications for authorisation is expected to decline. The Board also noted that the co-opted members are fully operational and active in the Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) and their services are required until at least June 2017.

³ MB/M/02/2016

⁴ See Corrigendum in Annex V

⁵ MB/30/2016

⁶ MB/07/2015

The Board discussed the impact of a recent Board of Appeal decision on the number of substances in the next substance evaluation action plan (CoRAP) and that the C&L Platform is discontinued as of June 2016, and emphasised the need for continued joint efforts for improved self-classification by industry. The Board also expressed concerns related to the progress in achieving some of the 2016 Work Programme priority outputs, in particular in the areas of dossier evaluation and the Read-Across Assessment Framework on environmental endpoints.

6. Delegation agreement for setting up an EU-wide observatory for nanomaterials

The Management Board was consulted on the draft delegation agreement that the Executive Director intends to sign with the European Commission to set up an EU-wide observatory on nanomaterials, and to undertake a feasibility study for an EU chemicals legislation finder⁷.

According to ECHA's Financial Regulation, the Management Board is to be consulted before the signature of any delegation agreement. The delegated task will, if accepted by the Executive Director, be included in the ECHA Programming Document for information.

The Deputy Executive Director presented the content of the delegation and the reasons why ECHA should undertake these new tasks based on an assessment of the benefits and potential drawbacks. He added that the current draft of the delegation agreement, which was circulated shortly before the meeting, is the Commission proposal to which the Agency will still provide its proposals for textual changes.

A Commission representative subsequently explained that, due to cost-efficiency and potential synergies, the Commission foresees tasking ECHA with setting up the observatory as a complement to the changes in REACH annexes and the revision of the nanomaterial definition. The Commission has concluded based on an Impact Assessment that the observatory is the best option for increasing the transparency around nanomaterials on the EU market. The observatory is intended to collect and disseminate available information for various audiences – including that from other agencies and Commission services - on nanomaterials, and their safety aspects. Should the resources turn out to be insufficient the delegation could be revised.

The foreseen financial resources are reserved in the Commission's budget and will be included in ECHA's budget under separate accounting. This budget would be 800 000 EUR for the first year, and 600 000 EUR annually thereafter. ECHA will be able to use the funds partly for staff costs (including engagement of an estimated additional three FTEs), and partly for operational costs (such as outsourced studies, IT analysis and development, website development and translations).

The Deputy Chair provided the opinion of the Working Group on Planning and Reporting that he chairs, stressing that the text of the delegation agreement was not available to them at that stage. The conclusion was positive but concerns were expressed on the limits of the scope, the legal boundaries inherent to an observatory, and the possible impact on the reputation of ECHA. An early evaluation of the new task would be beneficial.

Board members discussed the advantages and drawbacks of accepting the tasks, emphasising that this should not hinder the execution of ECHA's core mandate and that a process needs to be put in place to appropriately monitor the operation of the observatory, in particular the adequacy of resources.

Concerns were also raised related to the quality of information that can be obtained and to not meeting the expectations in relation to transparency, labour safety and consumer

⁷ MB/31/2016

products. An additional concern was that there might be legal impediments to using information from other databases which the Commission anticipates to be a major source of information.

A number of members were supportive of ECHA taking on the tasks, discussing the potential synergies this task could create and on its impact on ECHA's long-term plans and visibility. Nevertheless, Members debated and strongly highlighted the challenge for ECHA to build the observatory with rather limited resources, while potentially facing a wide range of expectations from stakeholders. It was welcomed that the ECHA Secretariat is analysing the challenges in order to manage expectations with clear communication and to avoid resources being taken from primary ECHA tasks. As for the text of the delegation agreement, comments were provided with regard to the reference to the translation practice of ECHA, the validation of the information to be published, the confidentiality of information that ECHA would need to obtain from national authorities having a registry, the dependency on other agencies and Commission services holding relevant information.

The Management Board concluded that, even recognising the risks, ECHA is the most appropriate body to host the observatory.

7. ECHA Programming Document 2017-2019

The Management Board adopted the Programming Document of ECHA for the period 2017-2019⁸. Board members furthermore requested that the ECHA Secretariat proposes at least one key performance indicator for the EU-wide observatory for nanomaterials, as soon as the delegation agreement is signed with the Commission. The Board also noted that a room document was circulated with the updated Risk Register (Annex VIII) of the Programming Document taking into account all the (potential) risks related to the implementation and to the delivery of the IUCLID Cloud system.

The Programming Document combines the multiannual objectives and resource outlook with the activity planning and was prepared with the help of the Working Group on Planning and Reporting.

The Programming Document is based on the preliminary draft budget which was included in the first draft of the Programming Document 2017-2019, adopted by the Management Board in December 2015 and subsequently sent to the European Commission in January 2016. The Commission adopted its formal opinion on this draft Programming Document on 7 September.

The Management Board decided to respond to the comments on resources, as needed, during its 44th meeting in December 2016, based on preparations of its Working Group on Planning and Reporting, following the final adoption of the EU general budget and the adoption of the final ECHA budget and establishment plan. The procurement plan in Annex IX will be submitted to the Board for approval with the final budget in December.

The planned activities for 2017 focus, among others, on providing support to industry in their preparations for the 2018 registration deadline; the successful execution of the Integrated Regulatory Strategy; the approval of the first EU applications for biocidal products; the continuation of the Biocidal Products Review Programme and the support to the European Commission's review of the REACH and CLP Regulations.

A representative of the Commission expressed their appreciation for the Programming Document, which is in line with the Commission's expectations. The same representative of the Commission also outlined key priority areas for ECHA, including developing IT

⁸ MB/32/2016

solutions that support industry, in particular SMEs; improvements in the work of ECHA's committees and striving for scientific-technical excellence.

8. Second amending budget 2016, amendment to the procurement plan and notification of budget transfers

The Management Board adopted the second amendment to ECHA's 2016 budget⁹, including the corresponding amendment of the procurement plan and took note of the budget transfers carried out under the responsibility of the Executive Director.

Following this amendment, the required EU subsidy for 2016 is reduced by € 2.4 million and € 2.8 million for REACH/CLP and the BPR respectively. The EFTA contribution is reduced accordingly. The amended revenues from fees and charges reflect ECHA's latest best estimates and are increased to € 31.1 million for REACH and to € 7.4 million for the BPR. The total expenditure for REACH/CLP is reduced to € 100.5 million and increased to € 8.4 million for the BPR, focused on further IT development. The overall expenditure and fee income levels for PIC are not amended at this time.

It was noted that once the delegation agreement for setting up an EU-wide observatory for nanomaterials is concluded, the corresponding amount for the new tasks will be included in an amending budget, which will be presented to the Board for approval through a written procedure, which could also include further changes in the revenues and budget of the BPR activities.

The Board instructed the Executive Director to notify the decision to the Budgetary Authority, the Court of Auditors and the Commission and to publish the amended budget on ECHA's website and in the Official Journal of the European Union.

9. Contractual arrangements for Board of Appeal members - update

[The meeting took place in camera for this agenda item.]

The Management Board took note of an update from its Working Group on the Board of Appeal.

10. Pre-selection process for the post of the Executive Director – nomination of a Management Board observer

[The meeting took place in camera for this agenda item.]

The Commission provided information about the role of the observer in the forthcoming pre-selection process for ECHA's next Executive Director according to its internal guidelines and recommended that the observer should abstain from appointing the Executive Director. Two members, a representative of one of the Member States and an interested parties representative without voting rights, confirmed their interest. The Member State representative's term as Board member ends in May 2017. The Commission noted that the pre-selection process might not be terminated by then.

The Management Board appointed Mr Thomas JAKL (AT) to act as an observer¹⁰ in the forthcoming pre-selection process for ECHA's next Executive Director.

⁹ MB/33/2016

¹⁰ MB/34/2016

11. Rules of Procedure for cooperation on food safety and worker protection

The Board took note of a report¹¹ on the review of the Rules of Procedure for cooperation with other EU bodies on matters related to food safety and worker protection, prepared by the ECHA Secretariat, according to the stipulations of these rules of procedure.

The Board agreed with the Secretariat's assessment that no modifications to these rules are needed at this stage.

The Management Board welcomed the good cooperation between ECHA and the European Food Safety Agency (EFSA).

Concerning cooperation in the area of worker protection, a number of Member State representatives expressed strong concerns on the current state of cooperation between ECHA and the Commission's Scientific Committee on Occupational Exposure Limits (SCOEL), emphasising the fundamental importance of efficient cooperation. ECHA and the Commission recognised these concerns but noted they need to be addressed outside the rules of procedure.

12. Participation of international organisations in ECHA's work

The Board approved the participation of UN sub-organisations¹², such as the International Agency for Research on Cancer, as observers in the work of ECHA, subject to agreement of the relevant committees, to compliance with their rules of procedure, and for specific cases as appropriate.

The Board charged the ECHA Secretariat with seeking the agreement of the relevant committees as to such participation and to invite the observers as appropriate. The Secretariat confirmed that ECHA's policy on the prevention of potential conflicts of interest applies to observers but that the committees' rules of procedures do not require them to make annual or spontaneous declarations of interest, due to the fact that observers are not participating in the decision-making process.

13. Appointment of Committee members

The Management Board renewed the mandates¹³ of Mr Norbert RUPRICH (DE) and Mr Slawomir CZERCZAK (PL) for the Committee for Risk Assessment and appointed Ms Luisa CAVALIERI (IT) as a member of the Committee for Socio-Economic Analysis.

14. Implementing Rules for the EU Staff Regulations

The Management Board decided to opt out¹⁴ from the Implementing Rules on the duration for recourse to non-permanent staff in the Commission services ("7-years rule") and to request the Commission's approval to opt-out from the Implementing Rules on teleworking.

As regards the Implementing Rules on teleworking, the opt-out request was necessary at this stage to avoid an automatic application of the Commission rules at a time when specific rules for EU Agencies are in preparation. The Management Board supported this

¹¹ MB/35/2016

¹² MB/36/2016

¹³ MB/37/2016

¹⁴ MB/38/2016

course of action, noting that ECHA needs modern and attractive working conditions for staff.

15. Refresher on ethics and integrity rules

The Management Board took note of a refresher¹⁵ on ethics and integrity rules applicable to Board members, as set out in ECHA's policy for managing potential conflicts of interest and related documents.

The refresher followed the recommendation of the European Court of Auditors, made in a follow-up audit to its special report on conflicts of interest in EU Agencies. The recommendation foresees that not only ECHA staff and experts would regularly receive training on this topic but that also the Management Board members should appropriately be reminded of their duties. This refresher was the first of the regular ones foreseen by the ECHA Secretariat in the future.

16. Composition of Management Board Working Groups

The Management Board renewed the mandates¹⁶ of Ms Kassandra DIMITRIOU (GR) and Mr Thomas JAKL (AT) as members of the Working Group on Audit and appointed Ms Nina CROMNIER (SE) as a member of the Working Group on Planning and Reporting and the Working Group on Audit. The Board also noted that the new Chair, Ms Sharon MCGUINNESS (IE), will discontinue her participation in the Working Group on Planning and Reporting, and will join the Working Group on Audit, *ex officio*.

17. Any other business

Update on ECHA's building project

The Management Board took note of an update on ECHA's building project from the Advisory Group established to follow the project. The Advisory Group informed Board members that the deliverables planned for the third quarter of 2016 have been completed and a sufficient number of attractive offers were received. The next steps include the evaluation of proposals, the establishment of the merit list and inviting the best-ranked candidates to a negotiated procedure.

6th MSCA Directors' planning meeting on 16-17 November 2016

The Management Board took note of the preliminary draft agenda of the 6th MSCA Directors' annual planning meeting, as presented by ECHA's Executive Director.

Board members welcomed the new concept of the meeting, where the one day will be dedicated to the cooperation between Member States and ECHA in the field of the Biocidal Products Regulation and on the other day, MSCA Directors will be invited to discuss strategic challenges in achieving the EU's international commitments related to chemicals safety and ECHA's future strategy.

¹⁵ MB/39/2016

¹⁶ MB/40/2016

Next meeting and closure

On behalf of the Secretariat, the ECHA Executive Director warmly thanked Ms Nina CROMNIER (SE) for her service of four years as Chair of the Management Board. This was followed by applause.

On behalf of the Board members, the Chair warmly thanked the host for the invitation to Slovakia. She noted that the next meeting of the Board is scheduled to take place from 13 to 14 December 2016, in Helsinki.

II. Documents submitted to the Management Board

Draft agenda	MB/A/03/2016
Draft minutes of the 42 nd Management Board meeting	MB/M/02/2016
Election of a Chairman and a Deputy-Chairman of the Management Board	MB/29/2016
Quarterly report on ECHA's activities	MB/30/2016
Delegation agreement for setting up an EU-wide observatory for nanomaterials	MB/31/2016
ECHA Programming Document 2017-2019	MB/32/2016
Second amending budget 2016, amendment to the procurement plan and notification of budget transfers	MB/33/2016
Pre-selection process for the post of the Executive Director – nomination of a Management Board observer	MB/34/2016 rev.01
Rules of Procedure for co-operation on food safety and worker protection	MB/35/2016
Participation of international organisations in ECHA's work	MB/36/2016
Appointment of Committee members	MB/37/2016 rev.01
Implementing Rules for the EU Staff Regulations	MB/38/2016
Refresher on ethics and integrity rules	MB/39/2016
Composition of Management Board Working Groups	MB/40/2016

III. Decision taken/Conclusions reached by the Management Board

The Management Board:

- Adopted the agenda for its 43rd meeting.
- Approved the minutes of its 42nd meeting with one modification.
- Appointed Ms Sharon MCGUINNESS as the Chair (33/0/0) and Mr Karel BLAHA as the Deputy Chair (31/0/2).
- Was consulted on the intent of the Executive Director to sign a delegation agreement to set up an EU-wide observatory on nanomaterials and to undertake a feasibility study for an EU chemicals legislation finder.
- Adopted the ECHA Programming Document 2017-2019.
- Adopted a second amending budget for 2016 and amended the ECHA procurement plan accordingly.
- Took note of budget transfers carried out under the responsibility of the Executive Director.
- Appointed Mr Thomas JAKL (Austria) to act as an observer in the pre-selection process for ECHA's next Executive Director.
- Approved the participation of United Nations sub-organisations as observers in the work of ECHA, subject to agreement of the relevant committee and for specific cases as appropriate and charged the ECHA Secretariat with seeking the agreement of the committees as to such participation and invite the observers as appropriate.
- Re-appointed two candidates for the Committee for Risk Assessment membership and appointed one new candidate for the Committee for Socio-Economic Analysis:

Member State	RAC member	SEAC member
Germany	Mr Norbert RUPRICH	
Poland	Mr Slawomir CZERCZAK	
Italy		Ms Luisa CAVALIERI
- Decided to opt out from the Implementing Rules on the duration for recourse to non-permanent staff in the Commission services ("7-years rule") and to request the Commission's approval to opt-out from the Implementing Rules on teleworking.
- Renewed the mandates of Ms Kassandra DIMITRIOU and Mr Thomas JAKL as members of the Working Group on audit matters and appointed Ms Nina CROMNIER as member of the Working Groups on Audit and on Planning and Reporting.

IV. List of Attendees

Representatives of the Member States

Thomas JAKL	(AT)	
Anne-France RIHOUX	(BE)	
Parvoleta LULEVA	(BG)	
Anastassios YIANNAKI	(CY)	
Karel BLÁHA	(CZ)	
Jörg LEBSANFT	(DE)	
Henrik Søren LARSEN	(DK)	
Kassandra DIMITRIOU	(EL)	
Ana FRESNO RUIZ	(ES)	
Pirkko KIVELÄ	(FI)	
Catherine MIR	(FR)	
Krisztina BIRÓ	(HU)	
Bojan VIDOVIC	(HR)	
Sharon McGUINNESS	(IE)	
Antonello LAPALORCIA	(IT)	
Judīte DIPĀNE	(LV)	
Marija TERIOŠINA	(LT)	Also acting as proxy of Aive TELLING
Paul RASQUE	(LU)	
Edward XUEREB	(MT)	
Hans MEIJER	(NL)	
Lidia WAŚOWICZ	(PL)	
Ana Lilia MARTINS	(PT)	
Luminita TIRCHILA	(RO)	
Nina CROMNIER	(SE)	Also acting as proxy of Christina RUDEN
Simona FAJFAR	(SI)	
Miroslava BAJANIKOVA	(SK)	
Keith BAILEY	(UK)	

Representatives of the European Commission

Kestutis SADAUSKAS
Antti PELTOMÄKI
Sabine JÜLICHER

Independent persons appointed by the European Parliament

Anne LAPERROUZE

Representatives from interested parties appointed by the European Commission

Peter SMITH	CEFIC –European Chemical Industry Council
Stefan SCHEUER	EEB-BEUC - European Environmental Bureau/European Consumer Organisation

Observers from EEA/EFTA countries

Sigurbjörg SÆMUNDSDÓTTIR	(IS)
Sverre-Thomas JAHRE	(NO)

Persons participating on behalf of board members/observers

Enda VESKIMÄE on behalf of Aive TELLING (EE)
Michael WOLTERS on behalf of Esther LYNCH

Other observers

Abdel-Ilah EL-AMELI	European Commission
Björn HANSEN	European Commission
Paul KRAJNIK	Austria

ECHA staff

Geert DANCET	(Executive Director)
Jukka MALM	(Deputy Executive Director)
Jack DE BRUIJN	(Director of Risk Management)
Christel MUSSET	(Director of Registration)
Leena YLÄ-MONONEN	(Director of Evaluation)
Shay O'MALLEY	(Director of Resources)
Wim DE COEN	(Head of Unit, Executive Office)
Frank BÜCHLER	(Executive Office)
Gabriella CSEH	(Executive Office)
Malgorzata RADZIMOWSKA	(Executive Office)
Jenni HOLSTI	(Executive Office)

V. Corrigendum to the minutes of the 42nd Management Board

Amendment proposed by DG GROW:

1. Agenda item 8. ECHA Cloud Service for SMEs

Addition of the following text:

[...] "A representative of the Commission drew attention to the fact that the positive and the negative impacts need to be monitored and evaluated. He welcomed the fact that ECHA will carry out an ex-post evaluation in 2018 to verify that the resources allocated were consistent with the objectives set and the results obtained correspond to what was expected. He also requested to have the SME Cloud Service as a standing point on the agendas of the WG P&R.

A representative of the Commission requested ECHA to explore how to make the Cloud Service attractive for large companies and expressed the view that in fine there should be only one delivery system of IUCLID. He also requested ECHA to update the Agency Risk Register to take into account all the (potential) risks related to the implementation and to the delivery of the IUCLID Cloud system."