

## Minutes of the 40<sup>th</sup> meeting of the Management Board Held in Helsinki from 16 to 17 December 2015

### I. Summary Record of the Proceedings

The Chair opened the meeting by announcing that the Commission appointed three new Board members to represent interested parties: Stefan SCHEUER proposed by the European Environmental Bureau (EEB) and the European Consumer Organisation (BEUC), Peter SMITH from the European Chemical Industry Council (CEFIC), and Esther LYNCH<sup>1</sup> from the European Trade Union Confederation (ETUC)<sup>2</sup>.

#### 1. Agenda

The Chair introduced the draft agenda<sup>3</sup> and the following room documents:

- Planned activities related to testing methods and alternatives to animal testing
- Summary Report of the 5th MSCA Directors' annual planning meeting

The agenda of the meeting was then adopted.

#### 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 40<sup>th</sup> Management Board meeting were identified.

The Chair also informed the Board that she has reviewed the renewed annual declaration of interest of the Executive Director.

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.

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<sup>1</sup> Excused for the meeting

<sup>2</sup> The names of other persons attending the meeting and the proxy votes of which the Chair was notified are listed in Section IV of these minutes.

<sup>3</sup> MB/A/04/2015

### 3. Minutes of the 39<sup>th</sup> Management Board Meeting

The draft minutes<sup>4</sup> of the 39<sup>th</sup> Management Board meeting, held from 24 to 25 September in Luxembourg, were approved.

### 4. Quarterly Report on ECHA's Activities

The Executive Director and the Deputy Executive Director provided the quarterly report<sup>5</sup> on ECHA's progress in reaching the 2015 Work Programme targets, including the work programme indicators and monitoring of risks.

The Executive Director highlighted that results for the most important performance indicators were well above the target, except the percentage of biocides establishment posts filled, which is a result of the substantial reduction in establishment plan posts for 2016.

The Management Board congratulated the Secretariat for the achievements and exchanged views on a number of topics of interest.

This included the progress made with compliance checks of 'substances that matter most'. The Board noted that the target of 100 completed checks in 2015 was reached. However, several members emphasised the need for continuously maintaining a high level of ambition. In this context, the interplay between compliance checks and substance evaluation and the need for closer coupling of these processes in order to avoid delays were noted.

The Board also took note of relevant institutional developments, such as a resolution of the European Parliament (EP) of 25 November 2015 related to an authorisation application<sup>6</sup> and the publication of the Commission's circular economy package.

As regards the EP Resolution it was agreed that the Board should hold a more in depth discussion at its next meeting on the role of the Committees within the application for authorisation process. In particular, with respect to the assessment of the socio-economic factors, based on preparations by the Secretariat, to ensure ECHA's opinions are formulated in a scientifically rigorous manner and the reputation of the Agency is safeguarded. In this context it was emphasised that ECHA needs to continue to strive for clear communication on what authorisation aims to achieve.

Concerning the Commission's circular economy package, the Secretariat confirmed that the potential impact on ECHA's work will be analysed and further monitored. ECHA had already started to consider the impact of the Commission initiative related to the circular economy before the recent publication.

In the biocides area, Board members noted the high number of dossiers arrived in 2015 and the number of 50 Biocidal Products Committee (BPC) opinions adopted in 2015. It was acknowledged that substantial additional workload is expected in 2016, due to the significant number of applications that arrived after the date of 1 September 2015 when the list of substances and the substance and product suppliers<sup>7</sup> 'Article 95 list' became

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<sup>4</sup> MB/M/03/2015

<sup>5</sup> MB/44/2015

<sup>6</sup> European Parliament resolution of 25 November 2015 on draft Commission Implementing Decision XXX granting authorisation for uses of bis(2-ethylhexyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P8-TA-2015-0409+0+DOC+PDF+V0//EN>

<sup>7</sup> List in accordance with Article 95 of the Biocidal Products Regulation (BPR), as amended by Regulation (EU) No 334/2014 of 11 March 2014

enforceable. It was also noted the workload will increase due to the higher number of Union Authorisations that arrived in 2015, IT development and the work related to the renewal of the anticoagulant rodenticides.

As regards PIC, the work for processing export notifications is expected to increase after the technical amendment of the PIC Regulation of 1 December 2015.

The Board welcomed that the Committee for Risk Assessment (RAC) reached the number of 200 opinions for harmonised classification and labelling in December. Views were also exchanged on the future of ECHA's CLP platform, which has had only a limited use by industry so far. The Secretariat explained that ECHA will initiate a second (limited) pilot in 2016 to confirm the results of low activity by industry. An interested party representative confirmed that discussion between companies on classification and labelling is more difficult than initially thought.

The Management Board took note of the quarterly report. On behalf of the Board, the Chair congratulated the Agency for the work done and its performance since the last meeting in September.

## 5. Final Amending Budget 2015 and Notification of Transfers within the Budget

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The Director of Resources presented the final amending budget for 2015 as well as the latest budget transfers carried out under the responsibility of the Executive Director<sup>8</sup>.

Based on an analysis of the actual income received by 30 November 2015, it was proposed to increase the budgeted amount for REACH fee income by € 1.8 million to € 22 million. The increase is primarily due to the higher-than-estimated income received from registrations (+ € 2 million). The increased fee income will be used to partly finance the increase in expenditure, following the required budgeting of the employer's part of the pension contribution (circa € 7 million).

Reductions in expenditure were proposed in all three titles of the REACH/CLP budget totalling ca. € 3.2 million, which will be used to partly finance the pension contribution (the remainder taken from the 'REACH fee reserve'). The total expenditure budgeted for REACH/CLP, excluding the reserve, is increased by € 3.8 million to € 104.7 million.

The Chair of the Working Group on Planning and Reporting, Karel BLAHA, reported from the meeting of 25 November when the figures presented above were discussed. He recommended the Board adopts the amendment.

The Board members adopted the final amending budget for 2015 and took note of the budget transfers carried out under the responsibility of the Executive Director. Following the budget amendments the overall income and expenditure of ECHA totals € 120.6 million. The decision will be notified to the Budgetary Authority, the Court of Auditors and the Commission and will be published on ECHA's web page and in the Official Journal of the European Union.

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<sup>8</sup> MB/45/2015

## 6. Budget and Work Programme 2016

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### 6.1 Budget 2016

The Director of Resources presented the budget proposal for 2016 including the establishment plan<sup>9</sup>. He reminded participants that the Preliminary Draft Budget (PDB) for 2016 was adopted by the Management Board at its meeting of March 2015. On 27 May 2015, the Commission adopted the EU Draft budget, fixing the ceilings for the 2016 Budget and containing the Financial Statement for ECHA. Following the adoption of the EU budget for 2016 by the Council and the European Parliament (Budgetary Authority) on 25 November 2015 - therein determining ECHA's subsidy level and staffing - the final budget proposal for the year 2016 was drawn up and discussed with the Board's Working Group on Planning and Reporting.

The proposed total expenditure for 2016 was € 107.4 million, which is identical in size for REACH/CLP and PIC as foreseen in the Commission Draft Budget and slightly higher for BPR.

The Budgetary Authority of the European Union<sup>10</sup> authorised 420 REACH/CLP establishment plan posts for ECHA (Temporary Agents posts - that is, 10 less than in 2015). For Biocides the authorised posts total 39 (that is, 9 posts less than in 2015). For PIC, ECHA will maintain six establishment plan posts.

The Board noted that from 2016, the flexibility provided for ECHA through the financial reserve from fees collected for REACH registrations will no longer exist, while the volatility and uncertainty of fee income in both the REACH/CLP and Biocides areas will continue. Therefore, it will be necessary for the Agency to continuously monitor the budget implementation - in collaboration with the Commission - in particular for accuracy in income forecasting.

The Secretariat also highlighted different uncertainties related to the budget execution which may lead to the need for amending the budget during 2016.

The Chair of the Working Group on Planning and Reporting reported from the meeting of 25 November, when the Working Group reviewed the proposed draft budget. He noted that a special attention was given to critical areas - as for example Biocides - and recommended the Board adopts the Budget 2016, as presented<sup>11</sup>.

In the following discussion, the Board showed support for the proposal. Members also shared the concern of the Secretariat that the reduction of the BPR subsidy in final negotiation on the budget puts the next stage of the required further IT development for the BPR at risk.

A Commission representative confirmed that a number of issues categorised in the background documentation as uncertainties would need continuous monitoring and discussion with the Commission. This would in particular apply to the proposal to offer IUCLID as a service to duty holders. Taking into account that ECHA cancelled considerable amounts of its appropriations in 2014 and 2015, the potential new service may also be financed from unused funds.

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<sup>9</sup> MB/46/2015

<sup>10</sup> Council and European Parliament

<sup>11</sup> Secretary note: The Management Board received and adopted on 16 December 2015 a revised version of the budget proposal contained in document MB/46/2015 of 4 December 2015. The revised version reduced the REACH/CLP expenditure by ca. € 0.24 million, thereby aligning with the ceilings of ECHA's budgetary financial statement of the Commission Draft Budget.

Board members highlighted the importance of resources allocated to the development of IT tools for Biocides, as these are key instruments for Member State Competent Authorities and industry to process the applications. The ECHA Secretariat explained that further improvement of R4BP<sup>12</sup> and SPC<sup>13</sup> editor is planned next year, but increased fee revenue will be needed for further developments. As for the IUCLID service, a concrete plan may be presented in March 2016.

The Management Board adopted the Agency's budget for 2016 and the Establishment Plan pleading for priority on IT tools. They instructed the Executive Director to notify the Decision to the Budgetary Authority, the Court of Auditors and the Commission and have it published.

## 6.2 Update of the 2016 Work Programme

The Deputy Executive Director presented an updated version of the ECHA Work Programme for 2016<sup>14</sup>, including annexes on staff allocation per activity area and on planned procurements. The Work Programme originally adopted in September 2015 was thereby aligned with the final budget for 2016 and other budgetary relevant developments.

The proposal was prepared by the Secretariat and reviewed by the Working Group on Planning and Reporting. The Working Group also discussed an initiative called 'IUCLID as a service' which currently is not in scope of ECHA's Budget 2016 and the potential funding under discussion with the Commission as in the view of the Secretariat it presents opportunities for both ECHA and industry, especially for SMEs.

On the Work Programme, Board members commented on the need for the Commission to provide resources and support to ECHA, if new tasks related to poison centres would be given to the Agency, also mentioning the potential impact on national legislations.

On the work load drivers related to registration dossiers, some Board members requested clarification on the relation between manually examined dossiers and automated completeness checks. They suggested increasing the compliance check rate beyond 5% of registration dossiers.

On nanomaterials, it was noted that the Commission is close to concluding on the regulatory and transparency measures which may have an effect on the implementation of the Work Programme.

The Management Board adopted an updated version of the Work Programme 2016 including annexes on staff allocation per activity area and on planned procurements. One amendment to the proposal, requested by the Commission and related to work on rodenticides, was agreed<sup>15</sup>. The final document will be sent to the Member States, the European Parliament, the Council and the Commission and will be published.

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<sup>12</sup> R4BP - Register for Biocidal Products

<sup>13</sup> SPC - Summary of Product Characteristic

<sup>14</sup> MB/47/2015

<sup>15</sup> New proposed wording: '*Following the request made by the Commission in 2015, and within the limitations of available resources and in light of other priorities within the activity, support the renewal process of anticoagulant rodenticide active substances ~~may take place provided additional resources are made available~~, carrying out coordination work during the evaluation phase, the BPC opinion forming process and the European comparative assessment of biocidal products containing these active substances*'.

## 6.3 Implementation of the IT Master Plan

The Board took also note of the ECHA IT masterplan and its implementation. This concerned in particular an issue raised by the Secretariat in relation to an outsourcing framework contract concluded for the execution of that plan.

## 7. ECHA Programming

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### 7.1 Draft ECHA Programming Document 2017-19

The Executive Director presented ECHA's first Draft Programming Document, covering the period 2017-2019<sup>16</sup>. The document was prepared according to guidelines established by the Commission in cooperation with the Network of EU Agencies. It combines ECHA's activity, budget and human resources planning for the years 2017-2019 and replaces existing planning documents, such as the Preliminary Draft Budget, the Multi-annual Work Programme and the Multi-annual Staff Policy Plan.

The proposal was reviewed by the Working Group on Planning and Reporting. The Group discussed in particular potential new tasks arising for ECHA (e.g. related to poison centres or IUCLID as a service) as well as the planned review of the REACH Regulation and the evaluation of ECHA's performance.

The Board noted that the proposed subsidy and staffing requirements are in line with the Commission's Multi-annual Financial Framework Planning in 2017, except for a slightly higher amount of Biocides subsidy, which is provisional subject to confirmation of the fee regulation review study currently undertaken by the Commission.

During the subsequent discussion, Board members welcomed the document, observing that the readability for external audiences should improve. It was also noted that further changes and adjustments can be introduced into the document based on an opinion which the Commission will submit for the human resources planning and a written consultation with the Board members. Depending on the developments this could also include a reference to TTIP<sup>17</sup>-related work at Agency level and a more elaborated text on the 2020 targets established at the World Summit for Sustainable Development in Johannesburg in 2002. The further development of the document in this respect will also be influenced by a workshop organised by ECHA in January 2016 on the '2020 targets'.

The Management Board adopted the Draft Programming Document 2017-2019, in support of ECHA's preliminary draft budget request for 2017. It was agreed that a clarification concerning the terminology 'priority substances' and a reference to the 2030 World Sustainable Development targets will be added to the text. The document will be submitted to the European Commission and EU Institutions by 31 January 2016. The final version will be adopted by the Management Board in September 2016.

### 7.2 Milestones for Developing the ECHA Strategic Orientation 2019-23

The Chair presented a proposal to launch a strategic orientation exercise aiming at producing a document setting out ECHA's strategic objectives for 2019-23<sup>18</sup>.

The Board welcomed the proposal and considered it appropriate for ECHA to continue reviewing its strategic objectives in consultation with its stakeholders. It was emphasised

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<sup>16</sup> MB/48/2015

<sup>17</sup> Transatlantic Trade and Investment Partnership

<sup>18</sup> MB/49/2015

that the outcome of the upcoming REACH and ECHA review need to be taken into account and that ECHA staff need to be involved from an early stage.

The Management Board endorsed the proposed approach for defining ECHA's future strategic orientation, noting that the precise timeframe for the next strategy can be subject to further discussion. A first milestone will be a Management Board workshop in June 2016 and the work stream would conclude with the adoption of a strategic orientation document at the latest in June 2018, after a public consultation.

## 8. Report of the Quality Manager

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The Executive Director presented the Quality Manager's Annual Report outlining the progress made in 2015 with the ISO 9001:2008 certification of the Agency's Integrated Quality Management System<sup>19</sup>. He informed the meeting that ECHA successfully passed the regular surveillance audit in November 2015, confirming that ECHA continues to fulfil the requirements for certification against ISO 9001:2008.

Moreover, ECHA also accomplished a certification audit, approving the extension of the scope of the certification to the PIC Regulation, as well as a transition audit, confirming that the Agency's management system is advanced and meets the requirements of the new standard ISO 9001:2015.

The Board took note of the report and the commitment that ECHA will strive in future also for an environmental certification, first under the ISO Standard and afterwards in line with EMAS<sup>20</sup>.

## 9. Report from the WG Audit and Information on Ex-ante/ Ex-post Evaluations<sup>21</sup>

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The Chair of the Working Group on Audit, Kassandra DIMITRIOU, informed the other members of the meeting of the Group on 15 December, covering the audit planning for next year, the findings of the 2015 IAS<sup>22</sup> audit on forecasting, calculation and collection of fee income and charges under the REACH, CLP and BPR Regulations.

The Working Group on Audit dealt in its meeting with the following topics:

- IAS, IAC<sup>23</sup> and IQMS<sup>24</sup> audit plans 2016
- First report from the annual audit of the European Court of Auditors
- ECHA report on the follow-up of discharge recommendations
- 2015 audit reports from IAS and IAC
- Follow-up of the Data Centre assessment audit
- ECHA's approach in ex-ante and ex-post evaluations
- Revision of the IAS Mutual expectations paper
- Progress of ECHA's building project
- IAS's annual declaration of Organisational Independence

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<sup>19</sup> MB/50/2015

<sup>20</sup> EMAS is the EU Eco-Management and Audit Scheme for environmental management.

<sup>21</sup> MB/51/2015

<sup>22</sup> Commission Internal Audit Service

<sup>23</sup> ECHA's Internal Audit Capability

<sup>24</sup> ECHA's Integrated Quality Management System

- Implementation of the Unified IT Security Declaration
- Implementation of the Infrastructure as a Service (IaaS) decision

The IAS plans to conduct in 2016 an internal audit on 'ECHA Operations under the Biocidal Products Regulation'. The IAC audit plan for 2016 includes the follow-up to dossier evaluations; expert groups in ECHA; appeal proceedings before the Board of Appeal; substance evaluation; and quality audits with ECHA's Quality manager.

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Concerning ECHA's SME verification activity it was noted that the language in which supporting documents are submitted continues making the evaluation of the documents resource-intensive. However, the Executive Director confirmed that ECHA is taking firm actions to deal with the existing backlog, and will in 2016 present a proposal to the Management Board to adjust the scope of the SME verification activity.

The Board took note of the report and encouraged a continued timely follow-up of audit recommendations.

## 10. Report from the AG Dissemination (and live preview of ECHA's new Dissemination web section)<sup>25</sup>

The agenda item was presented by the Director of Registration. In the absence of the Chair of the Advisory Group on Dissemination and other participating members, the Director also informed participants of the outcome of the Group's last meeting on 18 November 2015<sup>26</sup>.

The Advisory Group reviewed and supported in this meeting ECHA's strategy to achieve the publication of exposure scenario information from the REACH Safety Data Sheet which will be implemented in the context of the release of IUCLID 6.1 (Quarter 2/2016).

This was followed by a live presentation of ECHA's future dissemination pages which are to be launched on 20 January 2016, constituting a major step forward in terms of availability of public data on chemical substances. The pages will be redesigned and offer a tiered approach for regulators, academics or citizens when consulting information on chemicals via ECHA. The starting point will be an easy to understand and general InfoCard, after which more detailed brief profiles of substances can be consulted and, as needed, in depth scientific data and regulatory lists (e.g. candidate list of SVHCs) in ECHA's databases. The pages will offer a single point of access for all information held by ECHA on a specific substance. Also the search functionalities will be substantially improved and it will be possible to consult aggregated data for specific substances, for example regarding the differences in classification applied by industry.

The Board welcomed the newly developed dissemination portal with applause. In the exchange of views, members considered the foreseen improvements as impressive and thanked the Secretariat for the work. Questions were raised concerning the awareness of users about the validation status of the information and translations. The Secretariat confirmed that both aspects have been considered and may be addressed in the future, noting that translations are technically feasible but would require substantial additional funding.

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<sup>25</sup> MB/52/2015

<sup>26</sup> The slides were before circulated to the Advisory Group and agreed by its Chair.



Board members suggested that the portal could be extended to other EU legislation on chemicals, and the Board was satisfied to learn that the Commission had asked ECHA to consider establishing an 'EU Legislation Navigator', an option which could be assessed in terms of feasibility by ECHA if funds are made available.

Lastly, it was discussed how Member States can best promote ECHA's new dissemination pages to be launched on 20 January 2016. The Secretariat committed to provide information on this together with the follow-up from the meeting.

The Management Board took note of the report and strongly welcomed ECHA's future dissemination web pages.

## 11. Report from the Working Group on Board of Appeal

The Chair of the Working Group on Board of Appeal (BoA), Catherine MIR, gave a report from the last meeting of the Working Group, which took place on 18 November 2015.

The report included updates from the Chairman of BoA on the revision of the Rules of Procedure for BoA, as well as questions related to the reclassification of BoA members and a request to the Conflict of Interest Advisory Committee on a question of principle.

The Management Board took note of the report and firmly welcomed that the BoA is functioning smoothly and achieves good results.

## 12. Appointment of Committee Members

The Deputy Executive Director recommended one new member for the Committee for Risk Assessment (RAC) and three new members for the Committee for Socio-Economic Analysis (SEAC) be appointed. With these new nominations, RAC would have 52 members (including 5 co-opted members) and SEAC 43 members (including 3 co-opted members).

In line with the proposal<sup>27</sup>, the Management Board appointed one new member nominated by Spain for RAC and three new members nominated by Czech Republic<sup>28</sup>, Italy and Sweden for SEAC<sup>29</sup>.

## 13. ECHA's Approach on Avoiding Unnecessary Animal Testing

The Deputy Executive Director presented a document describing ECHA's approach on avoiding unnecessary animal testing, together with specific actions foreseen for the years 2016-2017<sup>30</sup>.

The Management Board noted that the Agency is committed to ensure a high level of human and environmental protection and at the same time to apply the 3R principle: reduce, replace and refine vertebrate animal testing. These principles are embedded in ECHA's regulatory process by design. ECHA also provides guidance and advice to registrants on the use of alternatives, publishes information on new test methods and alternative approaches on its website, participates in the development of alternatives, and co-operates with JRC/ECVAM to advise on the regulatory relevance of alternatives.

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<sup>27</sup> MB/53/2015

<sup>28</sup> The Czech nomination will take effect only after the expiry of the term of one of the two current Czech members.

<sup>29</sup> See Annex III of these minutes for the details.

<sup>30</sup> MB/54/2015

However, it was explained that ECHA's role is changing and that there is a need to re-define and strengthen ECHA's functions. Even though the main responsibility for avoiding unnecessary vertebrate animal testing remains with companies, there are two recent European Ombudsman recommendations which require that adjustments to ECHA's operations are made. This relates to compliance checks and testing proposals, where ECHA can act to reinforce the last resort principle. Furthermore, ECHA Board of Appeal decisions are also causing a re-examination of operations. Moreover, the Deputy Executive Director explained that the understanding between the various actors involved of what is available and acceptable for regulatory use can be improved.

This was followed by a discussion. Board members welcomed that ECHA approaches these important issues proactively. Members also supported the foreseen actions to foster the last report principle, in particular the plan to prepare by the end of 2017 a comprehensive report on the validity and regulatory acceptability of alternative methods and approaches. In this regard it was recommended to engage in joint activities with other independent EU scientific bodies.

Board members also emphasised that a good balance between the need to obtain solid data for public health and environmental protection and the promotion of alternative methods is needed. The tension between these principles should be seen positively as it can lead to increased innovation and new opportunities. Other topics addressed in the debate was the relatively poor response rate to public consultations in areas where complex scientific data needs to be understood. It was also discussed how ECHA could proactively take on new alternative test methods. Furthermore, the role of national authorities under EU animal welfare legislation and its links to REACH were raised.

The Commission representatives invited ECHA to participate and contribute to a Scientific Conference on Alternatives to Animal Testing in November 2016.

The Management Board took note of the report.

#### 14. ECHA's Approach on Engaging Third Parties in Public Consultations

By way of follow-up of a conclusion from the September 2015 Management Board meeting<sup>31</sup>, the Director of Risk Management outlined how ECHA involves third parties in its REACH and CLP processes, as well as ideas on how the process can be further improved<sup>32</sup>.

It was reminded that REACH requires a high number of public consultations. In addition, ECHA organises specific calls as needed. The main aim is to ensure that all relevant information becomes available as early as possible in the processes and that interested parties are sufficiently informed, allowing them to provide their views on the proposals or to submit information. Hence, public consultations are an important contribution to ECHA's openness and the aims of REACH. Depending on the context, purpose and target audience, the consultations can however be different.

ECHA systematically collects feedback on its practices. The results lead the Secretariat to conclude that overall the consultations fulfil their purpose. Challenges remain, however, in particular in reaching all relevant interested third parties and in motivating proactive comments, e.g. on alternatives in the authorisation context.

For further developing the current approach, the Secretariat plans to make improved use of multipliers from industry, trade unions and civil society, MSCAs, Commission, Enterprise Europe Network (EEN) etc., to establish more targeted communication (e.g.

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<sup>31</sup> See the minutes of the Management Board of September 2015, document MB/M/03/2015.

<sup>32</sup> MB/55/2015

with specific sectors, the media or academic disciplines) and to increased social media use. It will also be necessary to provide more consistent advice on what information is useful to get targeted and fit-for-purpose input through the consultations.

This was followed by an exchange of views in which many members welcomed the commitment to continuous improvement, emphasising the importance of public consultations as a key component of the participatory approach of REACH.

A call for creative measures was made, for example by establishing an award for particularly helpful contributions or a similar way of increasing the awareness of the opportunities linked to consultations. In this context, the proposal for an 'ECHA Third Party Ambassador' was reiterated. Other members preferred a more factual analysis and improved indicators for enhancing the effectiveness of the consultations. It was also suggested ECHA looks into an increased role of its Helpdesk in the process.

Another aspect brought to the discussion by several members was the clarity of the questions asked and the quality of the feedback provided to contributors.

Based on their own experiences, Board members also highlighted the limits of public consultations for obtaining usable input despite substantial efforts made by regulators.

Following a proposal of an interested party representative appointed by the Commission, the Board concluded to continue the mandate of the Advisory Group on Dissemination for discussing possible improvements to the public consultations. This should particularly focus on getting access to information on alternatives in the context of applications for authorisation. The Group could also help evaluating the effects of recent changes to the consultations on testing proposals and applications for authorisations. Furthermore, several members suggested that the Group could provide its expertise and advice also to other aspects of the authorisation application process which are relevant for the effectiveness of public consultations, such as the scope of applications in terms of uses covered.

## 15. Composition of Working Groups

The Board confirmed the composition of Management Board subgroups<sup>33</sup>. Judite DIPANE representing Latvia and the three new members appointed by the Commission to represent interested parties: Esther LYNCH (ETUC), Stefan SCHEUER (EEB-BEUC), and Peter SMITH (CEFIC) will join the Advisory Group on Dissemination.

## 16. Items for information

### 16.1 ECHA's Translation Practice

The Director of Cooperation informed the Board of planned changes to ECHA's translation practice, explaining that efficiencies will be sought by reducing the amount of translated administrative documents, focusing on added value for ECHA's stakeholders<sup>34</sup>.

ECHA will continue translating the key materials relevant for the SMEs and the general public as well as those related to the individual correspondence/interaction with companies according to the needs. For other documents, such as Work Programmes, General Reports or other Annual Reports, which feature a low interest in the language versions, ECHA will translate summaries. Thereby ECHA strives to ensure a good

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<sup>33</sup> MB/56/2015

<sup>34</sup> MB/57/2015

customer service and that language is not a barrier to compliance or to know what ECHA does.

This was followed by an exchange of views. In response to a suggestion to provide translated summaries in the context of public consultations, the Executive Director suggested that this could be an aspect to be looked into by the Advisory Group on Dissemination in the context of the upcoming work on public consultations<sup>35</sup>.

The Management Board took note of the report.

## 16.2 Report from the SME Visit Programme

The Board heard a report from the Director of Cooperation<sup>36</sup> on the ECHA SME visit programme, designed to provide an insight into the daily life of an SME, understanding the working environment and business models of the selected SMEs<sup>37</sup>. ECHA selected companies from a list of volunteering SMEs and matched them with ECHA staff who expressed interest in participating and speaking the national language of the country hosting the company.

In some countries, representatives of national authorities, EEN contacts or industry associations accompanied ECHA staff or inquired about the visits, while some others covered the events in their newsletters. Direct discussion with managers and employees allowed staff members to collect valuable feedback on issues preoccupying SMEs.

Some SMEs stressed the overloaded information on ECHA website, in the guidance documents or IT manuals. Some others stressed the burden of cumulative chemical legislations rather than REACH as such. Unfortunately, none of the visited companies were aware of the criteria of fee reduction applying to them. Also, a number of well-performing companies were found neither to be subscribing to the ECHA e-news nor consulting the ECHA web pages but appreciated ECHA's Dissemination Portal and they are keenly awaiting ECHA's new InfoCard.

A high proportion of visited companies gave their industry associations as their main source of information as well as affiliated organisations. The positive aspects were related to the quality of safety data sheets which has noticeably improved since REACH came into force and the positive effects of the CLP Regulation improving communication about hazard information. However, they mentioned a number of shortcomings, too such as attaching labels to small products, information on labels varying between countries or investment needs for labels.

One representative of interested parties noted the good feedback received from companies and suggested continuing to communicate with them and potentially contact them again before the 2018 REACH registration deadline.

The Board members took note of the report and welcomed the initiative.

## 16.3 Report on Implementation of Discharge Recommendations

The Board took note of a report on the Implementation of the 2013 Discharge Recommendations<sup>38</sup>, submitted in accordance with ECHA's Financial Regulation. On the request of the European Parliament, the report was prepared in October and also sent to the Commission and the Court of Auditors.

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<sup>35</sup> See agenda item 14 of these minutes.

<sup>36</sup> Functioning also as ECHA's SME Ambassador

<sup>37</sup> MB/58/2015

<sup>38</sup> ECHA reference D(2015)3649

## 16.4 Update on the Implementation of the Compliance Check Strategy

The Director of Evaluation informed the Board about the implementation of the Compliance Check Strategy, which prioritises 'substances that matter'. The respective report had been submitted to the Working Group on Planning and Reporting for its meeting of 25 November, and the group recommended presenting it to the December plenary meeting of the Management Board<sup>39</sup>.

The Board noted that in this context ECHA implemented an integrated selection and priority setting and strives for an effective use of compliance check by focussing on higher tier endpoints and substance identity as part of an overall integrated strategy for effectively dealing with priority substances.

The quality of registration dossiers is also expected to improve as a consequence of a reinforced completeness check process, which is in development<sup>40</sup>, and complementary measures, such as increased transparency on ECHA website, REACH 'Art. 36 letters' and targeted letter campaigns and sectoral approaches.

The challenges to be addressed include the currently low quality of use and exposure information which prevents effective prioritisation and requires additional measures by ECHA. The same applies to the established high number of poorly documented read-acrosses which the Secretariat addresses through the read-across assessment framework and advice to registrants as well as targeted campaigns. Furthermore, ECHA's IT tools require further development for allowing an advanced tracing and tracking system of checks and their outcomes.

The ambition expressed was to have by 2018 at least 1400 of the substances checked for compliance to various degrees of intensity, including at least 500 substances that matter checked according to the new strategy. In addition, over 300 priority substances should by then be evaluated by the Competent Authorities and more than 1100 testing proposals examined. Confirmed concerns for specific chemicals are addressed through compliance check, analysis of Risk Management Options (RMO) and substance evaluation. This is expected to lead to increased proposals for the identification of Substances of Very High Concern (SVHC) and proposals for restrictions and for harmonisations of classifications and labelling. By 2018, the Secretariat also strives to have a strategy in place that enables ECHA to address the remaining substances in order to conclude whether they deserve further action or are of no or lower priority.

The Management Board took note of the report and firmly welcomed the approach taken by the Secretariat for integrating the regulatory strategies under the different REACH processes.

## 17. Any other business

The Slovakian representative in the Management Board informed that the upcoming Slovakian EU Presidency in Q3-4/2016 will kindly host the September 2016 Management Board meeting.

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<sup>39</sup> MB/59/2015

<sup>40</sup> See minutes of the Management Board of June 2015, document MB/M/02/2015.

## Next meeting and closure

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The Chair noted that the next meeting of the Board is scheduled to take place from 17 to 18 March 2016, in Helsinki.

- 17-18 March (Thursday-Friday)
- 22-23 June (Wednesday-Thursday)
- 28-29 September (Wednesday-Thursday - in Bratislava, hosted by the Slovakian EU Presidency)
- 13-14 December (Tuesday-Wednesday)

## II. Documents submitted to the Management Board

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|  |              |
|--|--------------|
| Draft Agenda   | MB/A/04/2015 |
| Draft Minutes of the 39 <sup>th</sup> Management Board Meeting   | MB/M/03/2015 |
| Quarterly Report on ECHA's Activities  | MB/44/2015   |
| Final Amending Budget 2015 and Notification of Transfers within the Budget   | MB/45/2015   |
| Budget and Work Programme 2016   |              |
| Budget 2016  | MB/46/2015   |
| Update of the 2016 Work Programme<br>(incl. Background Information on IT Planning)                                 | MB/47/2015   |
| ECHA Programming   |              |
| Draft ECHA Programming Document 2017-19  | MB/48/2015   |
| Milestones for Developing the ECHA Strategic Orientation 2019-23   | MB/49/2015   |
| Report of the Quality Manager  | MB/50/2015   |
| Report from the WG Audit and Information on Ex-ante/ Ex-post Evaluations (incl. Report on IAS Audit on Fee Income) | MB/51/2015   |
| Report from the AG Dissemination (and live preview of ECHA's new Dissemination web section)                        | MB/52/2015   |
| Report from the Working Group on Board of Appeal   | -            |
| Appointment of Committee Members   | MB/53/2015   |
| ECHA's Approach on Avoiding Unnecessary Animal Testing   | MB/54/2015   |
| ECHA's Approach on Engaging Third Parties in Public Consultations  | MB/55/2015   |
| Composition of Working Groups  | MB/56/2015   |
| ECHA's Translation Practice  | MB/57/2015   |
| Report from the SME Visit Programme  | MB/58/2015   |
| Report on Implementation of Discharge Recommendations  | D(2015)3649  |
| Update on the Implementation of the Compliance Check Strategy  | MB/59/2015   |

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

The Management Board:

- Adopted the revised agenda for its 40<sup>th</sup> meeting with the modification contained in these minutes.
- Approved the minutes of its 39th meeting.
- Adopted the final amending budget 2015 and took note of transfers within the budget carried out under the responsibility of the Executive Director.
- Adopted the final budget and establishment plan for 2016 with the modification explained in these minutes<sup>41</sup>.
- Adopted, subject to the amendment explained in these minutes<sup>42</sup>, an update to the ECHA Work Programme for 2016, including annexes for Resources per Activity and the ECHA Procurement Plan.
- Adopted the Draft ECHA Programming Document for 2017-19, subject to two amendments contained in these minutes<sup>43</sup>.
- Instructed the Executive Director to submit the above statutory documents to the Member States and European Union Institutions, and to have them published, as required.
- Endorsed the approach for developing the ECHA strategic orientation 2019-23.
- Appointed one new candidate for the Committee for Risk Assessment (RAC) membership and three new candidates for the Committee for Socio-Economic Analysis (SEAC):

| <b>MS</b> | <b>RAC member</b> |
|-----------|-------------------|
| Spain     | DE LA FLOR TEJERO |

  

| <b>MS</b>      | <b>SEAC member</b> |
|----------------|--------------------|
| Czech Republic | HEKRLE Marek       |
| Italy          | CASTELLI Stefano   |
| Sweden         | NORING Maria       |

- Confirmed the composition of the Management Board Working Groups. Judite DIPANE (Latvia) and the three new members appointed by the Commission to represent interested parties (Esther LYNCH (ETUC), Stefan SCHEUER (EEB-BEUC), and Peter SMITH (CEFIC)) will join the Advisory Group on Dissemination.

#### Agreed follow-up actions:

- The Management Board will revert to a more in depth discussion on the role of the ECHA Committees within the application for authorisation process at its next meeting in March 2016.
- The Advisory Group on Dissemination will further discuss possible improvements to ECHA's approach to public consultations.

<sup>41</sup> REACH/CLP budget reduced by 239k in Title 1 - lines 1500 and 1602.

<sup>42</sup> Concerning the work for the Commission on anticoagulant rodenticides, page 31, last bullet point

<sup>43</sup> Explanation concerning 10% "priority substances" on page 16: Reference to 2030 Agenda for Sustainable Development



#### IV. List of Attendees

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##### Representatives of the Member States

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

##### Representatives of the European Commission

|                   |                                      |
|-------------------|--------------------------------------|
| Antti PELTOMÄKI   |                                      |
| Keşütis SADAUSKAS | Also acting as proxy of Michael FLÜH |

##### Independent persons appointed by the European Parliament

Anne LAPERROUZE

##### Representatives from interested parties appointed by the European Commission

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

##### Persons participating on behalf of Board Members/Observers

|                 |  |
|-----------------|--|
| Laura IZZO      | on behalf of Antonello LAPALORCIA (IT) |
| Mona AARHUS     | on behalf of Henrik ERIKSEN (NO)       |
| Michael WOLTERS | on behalf of Esther LYNCH (ETUC)       |

##### Other Observers

|                 |                                |
|-----------------|--------------------------------|
| Mehdi HOCINE    | accompanying Antti PELTOMÄKI   |
| Sylvain BINTEIN | accompanying Keşütis SADAUSKAS |

## ECHA staff

|                        |                                   |
|------------------------|-----------------------------------|
| Geert DANCET           | (Executive Director)              |
| Jukka MALM             | (Deputy Executive Director)       |
| Andreas HERDINA        | (Director of Cooperation)         |
| Jack DE BRUIJN         | (Director of Risk Management)     |
| Christel MUSSET        | (Director of Registration)        |
| Leena YLÄ-MONONEN      | (Director of Evaluation)          |
| Luisa CONSOLINI        | (Director of Information Systems) |
| Shay O'MALLEY          | (Director of Resources)           |
| Wim DE COEN            | (Head of Unit, Executive Office)  |
| Frank BÜCHLER          | (Executive Office)                |
| Viorica NAGHY          | (Executive Office)                |
| Malgorzata RADZIMOWSKA | (Executive Office)                |