

Helsinki, 6 October 2009 SEAC/M/04/2009 final

## **Final**

Minutes of the 4<sup>th</sup> meeting of the Committee for Socio-economic Analysis

30 June – 1 July 2009

#### I. Summary Record of the Proceeding of the separate SEAC session

#### 1) Welcome notes by SEAC new Chair, apologies

Ms Ann Thuvander, Chair of the Committee for Socio-economic Analysis (SEAC), ECHA, welcomed the participants of the fourth meeting of SEAC. New members of the committee Mr Marko Sušnik nominated by Austria and Mr Mark Faherty nominated by Ireland were introduced and welcomed.

The Chair informed that apologies had been received from seven members, four of whom had sent non-voting replacements.

Members' advisors present in the meeting as well as representatives of the European Commission (COM) and six stakeholder organisations participating in the meeting as observers were introduced.

The list of attendees is given in Part III of the minutes.

The Chair informed the participants that the meeting would be recorded.

#### 2) Adoption of the Agenda

The Secretariat proposed to include in the Agenda 3c) Changes in the SEAC composition/nominations. It was requested by the members from the Secretariat to report under AOB on the status of the development of the working procedures regarding Authorisation. With these modifications the Agenda was adopted. The final Agenda is attached to these minutes as Annex II.

#### 3) Administrative issues

#### a) Declarations of conflicts of interest

No participants declared any conflict of interest to the items on the Agenda of the SEAC-4 separate session.

#### b) Feedback on using the Kaleva services

The Chair noted that for this meeting SEAC used the Kaleva travel agency's services for making the travel and hotel arrangements for the first time. Members were asked to provide feedback on using the Kaleva services by e-mail to the Secretariat. All comments and questions received from members will be collected and transferred to the responsible persons in ECHA and Kaleva for possible further actions.

#### c) Changes in the SEAC composition/nominations

The Chair informed that two new members had been appointed by the Management Board (MB) of ECHA at its last meeting on 25-26 June 2009: Mr Marko Sušnik from Austria and Mr Mark Faherty from Ireland. Mr Marko Sušnik will replace Mr Stephen Schwarzer who has resigned from the Committee.

#### 4) Status report of SEAC-3 action points

The Secretariat briefly introduced the status report of SEAC-3 action points and main conclusions.

As an action point under the Agenda Item 3e (Remuneration of invited experts serving the Committee working groups), the Secretariat had promised to clarify by the SEAC-4 meeting the interpretation of "public service" in the MB Decision on remuneration of co-opted members and invited experts serving the Committee working groups (MB/77/2008). The Secretariat informed that the intention was not to remunerate those coming from the MS competent authorities (CAs) or enforcement authorities. Thus, universities would not come under public services unless funded by REACH CAs. Since the MB Decision is not likely to be revisited in the near future, it was proposed to go forward with this interpretation, applying it on a case-by-case basis.

With regard to the Agenda Item 8b (RMOs at Community level), the Secretariat had promised to consider training for SEAC or further discussion on RMOs. The Secretariat reported that this had been postponed until the SEAC-5 meeting or later. The guidance document for preparation of a restriction dossier and in particular section 5.4.4 of it can be used as a starting point for further discussion. It was agreed that this action point would be transferred to SEAC-4 action points.

Other action points of SEAC-3 have been or are being completed.

#### 5) Conclusion of the mandate of the SEAC-RAC interaction

A presentation was given by the Secretariat to report on the SEAC-RAC Arrangement. SEAC was informed that prior to and during the second meeting of the Arrangement on 20 April 2009, its members participated in a role play of rapporteur's tasks based on a transitional dossier on MCCPs (medium-chain chlorinated paraffins). The aim of the role play was to mimic the first rapporteurs' dialogue foreseen in the working procedures of RAC and SEAC on development of their respective opinions on Annex XV proposals for restriction. One RAC member played the role of the RAC rapporteur and one SEAC member played the role of the SEAC rapporteur, other participants of the Arrangement played the role of active RAC and SEAC members. Lessons learnt and conclusions of the role play have been described in the Chair's Summary of the second meeting of the SEAC-RAC Arrangement, which was to be distributed to RAC and SEAC after the joint session. The participants of the Arrangement suggested repeating the role play in the joint RAC-SEAC meeting using a simplified Annex XV dossier. The Secretariat mentioned that RAC had already decided to close the mandate of the SEAC-RAC Arrangement in the RAC-6 meeting and proposed to SEAC to close the mandate too, as the tasks foreseen for the Arrangement in the mandate had been completed (except for the part concerning authorisation, which was proposed to be left for a later stage).

#### SEAC decided to conclude the mandate of the SEAC-RAC Arrangement.

#### 6) Working procedures for Restrictions

#### a) Working procedure on processing of an Annex XV restriction dossier

The Chair recalled that the first draft of the working procedure on developing a SEAC opinion on Annex XV proposals for restriction had been discussed in the SEAC-3 meeting in February 2009 (meeting document SEAC/03/2009/04), after which a written commenting round had been organised in Circa on the document. The meeting document SEAC/04/2009/14 includes all comments received from SEAC members as well as ECHA's response to these comments. Taking into account comments received from SEAC, RAC and the Forum, the working procedure had been revised and was presented to SEAC for agreement in the meeting document SEAC/04/2009/13. The Chair mentioned that RAC had already reached a preliminary agreement on the revised RAC working procedure in the RAC-6 meeting in April 2009 and that Forum had also discussed and adopted its working procedure for development

of the Forum advice on enforceability of Annex XV proposals for restriction in the Forum-4 meeting in April 2009. Furthermore, the dossier submitter's tasks foreseen in the working procedures of RAC and SEAC on developing their respective opinions on Annex XV proposals for restriction had been discussed and agreed by CAs in the CARACAL meeting in June 2009.

A presentation was then given by the Secretariat describing the major comments received from SEAC within the written commenting round and the major changes which had been introduced in the revised draft working procedure. SEAC was invited to agree on the presented revised working procedure and use it for the first dossiers, with a view on developing future best practice. The working procedure may later be further modified, if necessary, in light of collected experience.

One participant questioned how the Forum advice will be adopted in case there are no Forum meetings foreseen and whether the Forum working group on restrictions can adopt the Forum advice. The Secretariat replied that the Forum will have to adopt its advice via the written procedure, in case there are no meetings foreseen. It was also stressed by the Secretariat that the Forum working group on restrictions has the power to initiate the Forum advice, but the whole Forum still needs to adopt the advice.

SEAC agreed the working procedure on processing of an Annex XV restriction dossier (as presented in the document SEAC/04/2009/13) with the understanding that the working procedure lays down a starting point and will be reviewed after some experience has been gained.

#### b) Terms of reference for (co-)rapporteurs

The Chair recalled that the draft terms of reference (ToR) for (co-)rapporteurs had been discussed by SEAC in the SEAC-2 meeting in October 2008 and in the SEAC-3 meeting in February 2009. There had been two written commenting rounds on the draft ToR and comments submitted by SEAC members within the last commenting round had been compiled and responded to by the Secretariat and were presented in the meeting document SEAC/04/2009/16. A second document submitted to SEAC under this Agenda Point (SEAC/04/2009/15) contained the revised draft ToR. The Chair noted that RAC had already reached a preliminary agreement on the revised ToR in the RAC-6 meeting in April 2009.

A presentation was then given by the Secretariat summarising the major comments received from SEAC members within the last written commenting round and the major changes introduced in the document.

SEAC members asked the Secretariat to provide the adopted Forum working procedure on the development of the Forum advice to SEAC for information.

SEAC agreed the terms of reference for (co-)rapporteurs (as presented in the document SEAC/04/2009/15).

# c) Lessons learnt from the accordance checks useful to be transferred in the conformity check procedure

An accordance check for dossiers proposing harmonised classification and labelling has similarities to conformity checks for restriction dossiers. Practical experience gained within the 16 accordance checks completed so far was shared by the Secretariat and several recommendations for conformity check were given.

#### **7) AOB**

#### a) Next meetings

The Chair informed that the SEAC meeting in September had been cancelled. The next SEAC meeting will therefore take place on 18-20 November 2009. The meeting dates proposed for SEAC plenary meetings for 2010 had been listed in the Room document provided to the participants. The Chair emphasised that the number of the meetings, the dates as well as the duration of each meeting are tentative.

#### b) Status report of the preparation of the guidance document on SEA in Authorisation

A representative of the COM recalled that in the last SEAC meeting the Committee was informed that the COM had intended to present the guidance document on SEA in Authorisation in the CARACAL meeting in June 2009. Unfortunately, this had not happen as some issues related to the guidance document were still being discussed within the COM. The guidance document on SEA in Authorisation is now planned to be presented to CAs in the next CARACAL meeting.

#### c) Status of the development of the working procedures regarding authorisation

The Chair explained that it will probably take around two years until the first authorisation applications will start to arrive and for that reason the Secretariat had not yet planned to start the preparatory work in the Committees. The Chair proposed that the work plan on how to prepare for authorisation could be discussed in the SEAC plenary meeting in November 2009.

#### 8) Action points and main conclusions of SEAC-4

SEAC endorsed the SEAC-4 action points and main conclusions (as presented in Part II of the minutes).

#### II. Summary Record of the Proceeding of the joint RAC-SEAC session

#### 1) Welcome notes by RAC and SEAC Chairs

Ms Sharon Munn (Chair of the Committee for Risk Assessment, ECHA), who chaired the first half of the meeting, welcomed the participants of the joint session of the Committee for Risk Assessment and the Committee for Socio-economic Analysis held within the seventh meeting of RAC and the fourth meeting of SEAC. The Chair informed the meeting that among the participants of the joint session there were 30 RAC members and 26 SEAC members, two replacements of RAC members and four replacements of SEAC members, four advisors of RAC members and five advisors of SEAC members as well as three representatives of the Commission services and nine representatives of stakeholder organisations participating in the meeting as observers. The list of attendees is given in Part III of the minutes.

The Chair informed the participants that the meeting would be recorded.

#### 2) Adoption of the Agenda for the joint session

The Agenda of the joint session (RAC/A/07/2009, Part I and SEAC/A/04/2009\_rev.1, Part II) was adopted without any changes.

No participants declared any conflict of interest to the items on the Agenda of the joint session.

#### 3) Preparatory session for the role play

The Chair explained that prior to and during the second meeting of the SEAC-RAC Arrangement on 20 April 2009, its members participated in a role play of rapporteurs' tasks based on a transitional dossier on MCCPs (medium-chain chlorinated paraffins). The participants of the Arrangement suggested repeating the role play in the joint RAC-SEAC meeting using a simplified Annex XV dossier. A presentation was then given by the Secretariat describing the purpose of the role play, suggesting how to structure the discussions in the break out groups, explaining the roles of different players as well as providing other useful advice on how to work during the role play. The main aim of the role play was to simulate the discussions between the RAC and SEAC rapporteurs during their first dialogue foreseen in the working procedures on developing RAC and SEAC opinions on Annex XV restriction dossiers. Each group was assigned to exchange views and form a preliminary opinion on the appropriateness of the proposed restriction on MCCPs in leather fat liquoring and not proposing a restriction on the use of MCCPs in metal working fluids.

#### 4) Role play in break out groups

Parallel discussions were held in eight break out groups on a simplified MCCP dossier.

#### 5) Welcome notes by Executive Director

Mr Geert Dancet, the Executive Director of ECHA, welcomed the participants of the joint plenary session of RAC and SEAC. He explained that such a joint meeting was the first of its nature and that ECHA considered it was important to bring these two key ECHA Committees together at an early stage as their future work on authorisations and restrictions will be very closely linked.

The Restrictions title of REACH provides that the Committees for Risk Assessment and Socio-economic Analysis shall each formulate an opinion on a restriction proposal, which will then be submitted by ECHA to the European Commission for a decision. Therefore, the need to find a "common language" for the two Committees is core. Mr Dancet recalled that it was with this objective in mind that a crash course on socio-economic analysis was provided for the members of RAC in early 2009 and a chemical safety assessment course was provided for the SEAC members prior to the joint RAC-SEAC session. The Executive Director expressed his hope that these training sessions had served to broaden the common understanding of the respective roles of the Committees.

Mr Dancet also stressed that the joint plenary session provided a unique opportunity for the members of both Committees to get to know each other and try to understand each others concerns and needs in their work. He added that the meeting would hopefully enable a fruitful and successful collaboration between the Committees and the individual members so that the Agency, of which the two Committees are part, can deliver high quality opinions to the decision makers.

#### 6) Lessons learnt from the role play

A presentation on the lessons learnt from the role play, prepared together with the facilitators of the break out groups, was given by the Secretariat. The discussion on the lessons learnt as

well as the presentation given by the Secretariat have been summarised and presented in Annex III of the minutes.

The Secretariat proposed to finalise the presentation and upload it to Circa by 7 July 2009 and would also upload to Circa the Chair's summary from the second meeting of the SEAC-RAC Arrangement.

#### 7) Common restriction issues

#### a) Overview of current restrictions in Annex XVII

A presentation was given by the Secretariat describing the Annex XVII restrictions. According to the REACH Regulation (Article 3(31)), a restriction means any condition for or prohibition of the manufacture, use or placing on the market. This definition is broad and open and gives a lot of possibilities to build up a restriction. Article 68(1) of REACH sets the basic conditions for the introduction of a restriction and these are unacceptable risk to human health or the environment, and Community-wide action required to address this risk. Important restriction characteristics are effectiveness (targeted to the effects, capable of reducing these effects to an acceptable level and within a reasonable period, proportional to the risk), practicality (implementable by the actors concerned, enforceable and manageable by the authorities) and monitorability (possible to monitor the result of the implementation). The content of the updated Annex XVII, which entered into force on 27 June 2009, was explained as well as the main elements of the Annex XVII entries. The Secretariat explained the difference in regulatory approach between a total ban and a targeted restriction, and illustrated both types with examples. Possible restriction conditions were also described and examples were given. Finally, some reasons for the diversity of restrictions were highlighted. It was concluded that the approaches and conditions are likely to be diverse in the future restrictions, too.

A participant asked whether it is possible to set conditions under REACH which would be very close or even the same as they would be under other legal instruments, such as the Water Framework or IPPC Directives. The Secretariat replied that as a restriction is defined as "any condition" under REACH, it would be in principle possible to introduce such a condition. However, for legal coherence and consistency, it would not be appropriate to propose conditions under REACH if they would be more appropriately addressed under other legislation.

#### b) Examples of process in the past for development of these Annex XVII entries

The Secretariat presented an example of how the restriction had been developed in the past, based on the organotins case. Organotins are mono-substituted organotins (e.g. used as plasticisers, catalysts), di-substituted organotins (e.g. stabilizers, catalysts) and tri-substituted organotins (historically used e.g. as biocides in anti-fouling products, consumer products, wood treatment and as pesticides). Exposure to certain organotin compounds has been scientifically proven to disrupt the endocrine system and cause harm to human health and the environment. Organotins are used in a large number of different applications, including many consumer products; consumers are therefore exposed to a range of different products containing organotin compounds. The starting point was the restriction on placing on the market and use of organotins through amendments to the Marketing and Use Directive (76/769/EEC – "Limitations Directive"), which covered the main biocidal uses of organotins. The Commission Directive 2002/62/EC of 9 July 2002 restricted the use of all organostannic compounds in quite general terms, but specified the use – in biocides – in some detail and was thus practically directed towards tri-substituted organotins. Further work in years 2002-2009 was prompted by national concerns and the amended broader restriction was adopted on 28 May 2009 (Commission Decision 2009/425/EC). The actors and the main documents in the

restriction process were described as well as observations given regarding the discussions, the process, the stakeholders` participation and the progress. Finally, equivalent points in the REACH process were identified.

A participant observed that for a lot of other substances under the Directive 76/769/EEC, almost the same discussions took place in the working group of the Council as in the Limitations Working Group. The process was therefore very time-consuming in the past. Another participant emphasised the preparatory work of the dossier and expressed the concern that REACH does not give much possibility for involvement of other MS competent authorities (CAs) or stakeholders in the preparatory phase. The Secretariat responded that the Registry of Intentions (RoI), which is publicly available, provides information on the restrictions under preparation and gives thus a possibility to the parties concerned (including stakeholders) to contribute early in the process. Stakeholder consultation during the preparation of a restriction dossier is highly recommended. A participant asked how many restriction dossiers the Committees and the Secretariat will have to handle. The Secretariat replied that the number of dossiers will depend on MS CAs (how active they are) and on the Commission who can ask ECHA to prepare the restriction dossiers. The Secretariat added that a discussion forum had been created for MS CAs to discuss their intentions before submitting them officially into the RoI. Such an informal RoI provides a good possibility for ECHA to know well in advance which dossiers are coming and when.

#### c) Draft opinion and background document template

The Secretariat recalled that SEAC had discussed the document "The opinion of SEAC on a restriction proposal" (SEAC/03/2009/05) in its third meeting in February 2009. In April 2009, RAC discussed a parallel document "The opinion of RAC on a restriction proposal" (RAC/06/2009/19), prepared as a revision of the SEAC document. In drafting the document for RAC, ECHA had carefully taken into account the results of the discussion in the SEAC-3 meeting as well as the written comments submitted by SEAC afterwards. In addition, the Secretariat had consulted the Commission services as the opinion ultimately needed to be useful in the "comitology" process (with parliamentary scrutiny reservation). The meeting document (RAC/07/2009/31 and SEAC/04/2009/17) had been updated on the basis of the discussion in the RAC-6 meeting and was now presented to both Committees for agreement. The Secretariat explained that the template aimed to provide a general outline and structure for the opinions and it was proposed to be used as a starting point for the work. Once experience had been gained on preparing the opinions and the background documents, the template could be modified as appropriate. Furthermore, the Secretariat stressed that as dossiers would probably vary considerably, the template needed to be used in a flexible manner (e.g. how the exact wordings were formulated).

RAC and SEAC agreed on the proposed Opinion and Background Document template.

#### d) Clarification of the support available to RAC and SEAC rapporteurs

The Chair explained that the meeting document RAC/07/2009/32 for RAC and SEAC/04/2009/18 for SEAC summarised the sources of support that would be available to RAC and SEAC (co-)rapporteurs within the process of development of RAC and SEAC opinions on Annex XV restriction dossiers. The Chair recalled that the need for such a summary was flagged by the Committees within their discussions on the terms of reference for (co-)rapporteurs (ToR) and originally the intention was to include it in the ToR as an annex. However, it was later not considered appropriate to include it in the ToR and it was decided to produce a separate document on this topic instead. A brief presentation was then given by the Secretariat describing all sources of support available to RAC and SEAC rapporteurs listed in

the document - MS, dossier submitter, ECHA Secretariat, other Committee members, *ad hoc* working groups, invited experts, members' advisors and observers. It was stressed that the main support to a (co-)rapporteur should be provided by his/her MS and thus, before accepting the nomination to become a (co-)rapporteur, the Committee member should make sure that the MS would be ready to provide adequate support to execute his/her tasks.

A participant proposed to make this document available also to MS CAs. It was agreed that the Secretariat would forward the document to CARACAL for their next meeting.

# 8) Information on the registered intentions for submitting Annex XV dossiers proposing restrictions

The Secretariat informed the meeting that Title VIII of REACH had entered into force from 1 June 2009 and that there was already a few intentions registered in the RoI (by Norway and France). The RoI is publicly available on the ECHA website<sup>1</sup>. The Secretariat asked RAC and SEAC members to consider volunteering for rapporteurships and co-rapporteurships on the basis of the information provided in the RoI. It was also noted that according to the Committees' working procedures, the appointment of rapporteurs and co-rapporteurs should be done at the earliest possible stage and further formalised at the latest after the Annex XV dossiers proposing restrictions have been submitted.

A participant asked whether it was possible to clarify from the MS CAs who have submitted their intentions whether the dossiers under preparation are mainly related to human health or environmental risks or both. Such information would be helpful for RAC and SEAC members in deciding whether to volunteer for the rapporteurship. The Secretariat agreed to clarify this with the MS CAs concerned.

#### 9) Joint information session

Starting from the Agenda Point 9, the meeting was chaired by Ms Ann Thuvander, Chair of the Committee for Socio-economic Analysis, ECHA.

#### a) Process for guidance updates

The Chair explained that the Agenda Point on the process for guidance updates was introduced in the Agenda of the joint session as a result of the request from RAC expressed in the RAC-6 meeting to clarify the possibilities for the Committee to initiate an update of ECHA guidance relevant to RAC tasks. The ECHA Secretariat agreed to raise the issue with the ECHA guidance team and to bring forward a proposal for a procedure to address this possibility which would feed into the currently agreed process for guidance updates.

The Secretariat then presented the meeting document RAC/07/2009/33 for RAC and SEAC/04/2009/19 for SEAC, which described the process for guidance updates and the role of the Committees in this process. The legal basis for ECHA to provide guidance is given in Article 77(2)(g) of the REACH Regulation, according to which ECHA's task is, where appropriate, to provide technical and scientific guidance and tools for the operation of REACH for industry, especially SMEs, and for other stakeholders. Guidance is not a legally binding document, but it provides industry and authorities with a commonly agreed view on how to implement the REACH Regulation. The Secretariat informed the meeting that a few months ago the ECHA's Framework for the Governance of Guidance Management had been adopted, which gave a general structure on how to implement the process of developing or updating

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<sup>&</sup>lt;sup>1</sup> http://echa.europa.eu/chem\_data/reg\_int\_tables/reg\_int\_curr\_int\_en.asp

guidance. According to this framework, an important step in guidance development/update is the consultation process. The Committees were informed that during the consultation procedure on a specific guidance document the consultation of stakeholders takes place through a Partner Expert Group (PEG), ECHA Committees and/or the Forum, and finally MSCAs (CARACAL). The Committees also have a possibility to raise issues themselves and were advised to channel these issues via the ECHA Secretariat. However, the Secretariat emphasised that the Committees should raise only such issues which have an impact on the Committee's work.

One participant asked whether ECHA foresees the same procedure for the updating of the guidance on CLP. The Secretariat confirmed that the same procedure will be used for the CLP Regulation.

#### b) Conclusions and recommendations from the authorisation workshop of January 2009

The Secretariat reported on the workshop on the Candidate List and Authorisation as Risk Management Instruments under REACH held in January 2009. Reasons for organising such a workshop, main conclusions as well as recommendations and follow-up actions were described. The Secretariat informed the meeting that the link to the report of this workshop had been uploaded to both RAC and SEAC Circa Interest Groups.

#### 10) Feedback from other ECHA bodies and activities

The Chair of the Committee for Risk Assessment summarised the recent developments in RAC. With regard to classification and labelling, 16 accordance checks had been completed on the submitted dossiers and six were still in process. Three public consultations were ongoing and two have already been completed. The meeting was informed that RAC would discuss its first draft opinion (on diantimony trioxide) within the RAC separate session following the joint RAC-SEAC plenary meeting. The Chair of RAC also mentioned that the working procedures on classification and labelling were being revised due to the change in the legal basis with the entry into force of the CLP Regulation.

The Chair of the MSC gave feedback from the last two meetings of the Committee – the MSC-7 held in April and the MSC-8 held in May 2009. During these meetings, the Committee discussed mainly its opinion on ECHA's draft recommendation for the inclusion of substances into Annex XIV. The opinion was drafted by the rapporteur with the help of a working group consisting of six members of the Committee, and was based on the following input: ECHA's original draft recommendation and supporting documents, comments submitted within the public consultation (altogether 365 comments were received), ECHA's response to these comments and ECHA's draft recommendation revised on the basis of the comments. The Chair of the MSC described the challenges which the Committee had faced in the preparation of the opinion and informed the meeting that ECHA's final recommendation took into account the opinion of the MSC and that the establishment of the Annex XIV by the Commission can be expected in late 2009 – early 2010. The MSC work plan for the second half of 2009 was also briefly introduced.

The Secretariat then made a brief report from the last two meetings of the ECHA Management Board (MB). In its meeting in April 2009, the MB adopted ECHA's general report of 2008 as well as the Executive Director's annual activity report of 2008. Both reports had been published on the ECHA website. The rules of reimbursement of REACH tasks to MSs were discussed and agreed. It was also noted that four new stakeholder organisations were added to the list of eligible stakeholders (the names of the organisations have been published on ECHA's website). In the June 2009 meeting, the discussion was mainly concentrated on the access of MSCAs to REACH-IT. The enforcement authorities' access to REACH-IT was also

touched upon and the MB had agreed to a document concerning the list of data in REACH-IT to which the enforcement authorities should have access. The Secretariat mentioned that the appointment of three new members of the Committees took place in the June MB meeting.

A report was also given by the Secretariat from the last Forum meeting. One of the main discussion points was the access of the enforcement authorities to REACH-IT. Co-operation with the customs was also discussed and a working group was decided to be created to facilitate this co-operation. The Forum adopted its working procedure for development of the Forum advice on enforceability of the Annex XV proposals for restriction and established a working group on Restrictions to facilitate the elaboration of the Forum advice.

Finally, a brief report was provided from the June 2009 CARACAL meeting. The access of MSCAs to REACH-IT was extensively discussed also in this meeting. Timelines for the processing of a restriction dossier as foreseen in the working procedures of the Committees were introduced to the CAs, foreseeing four possible submission dates in a year according to the cycle of Committee meetings but with a request to aim to avoid one of the dates which would lead to difficulties in one of the critical steps which would fall in the summer holiday period. The dossier submitter's tasks in the working procedures of RAC and SEAC were also presented, which MSCAs agreed to. The workshop on Evaluation planned for MSCAs for September 2009 was announced by ECHA. The Secretariat also informed the meeting that a document on the RoI was provided to the MSCAs and proposed to make this document available also to RAC and SEAC for information.

#### 11) Co-operation with other Community bodies

The Secretariat explained that the REACH Regulation contains legal provisions that address the co-operation with and co-ordination of the work between ECHA and other European Community agencies and scientific committees of relevant EC institutions and bodies (like the European Food Safety Authority and the Advisory Committee on Safety, Hygiene and Health Protection at Work). The scope of co-operation and co-ordination of the work should embrace the opinions adopted by the ECHA Committees but also possibly other types of co-operation. The Secretariat informed the meeting that the REACH Regulation calls also for formally adopted Rules of Procedure (RoPs) on the aspects of co-operation. As Committees are to be consulted when establishing these RoPs, the meeting document RAC/07/2009/34 for RAC and SEAC/04/2009/20 for SEAC presented a roadmap towards their adoption with the indication of involvement of the Committees in the process. Possible elements for the RoPs were introduced to RAC and SEAC.

#### 12) Administrative issues

# a) Remuneration of RAC and SEAC rapporteurs for Annex XV dossiers proposing a restriction

The Secretariat recalled that in line with the REACH Regulation, a proportion of fees collected by ECHA under the Fee Regulation should be transferred to MSCAs to compensate them for certain REACH tasks (substance evaluation and rapporteur work done in RAC and SEAC on restrictions and authorisations). According to the Fee Regulation, it is for the MB of ECHA, following a favourable opinion from the Commission, to establish financial arrangements for such transfers, including the amounts to be transferred. The Committees were informed that the MB had discussed in its meeting in February 2008 the reimbursement of tasks executed by MSs and had appointed a working group chaired by the ED of ECHA, consisting of representatives from DE, UK, SE, the Commission and ECHA. The final report of this working group, together with the proposal for a Decision on the financial arrangements for transfer of a proportion of fees to the MSs, was presented to the MB at its meeting in April

2009, where the MB approved the proposed draft decision after which it was sent to the Commission for opinion. The Secretariat added that after receiving an opinion from the Commission, the MB will have to adopt the decision. The Secretariat presented the legal framework of the draft decision, the principles followed in the development of the draft decision as well as the scale of payments set in it.

#### b) RAC/SEAC members' access to information in REACH-IT

The Chair informed the meeting that the Room document RAC/07/2009/46 for RAC and SEAC/04/2009/23 for SEAC had been distributed to the participants of the meeting summarising RAC and SEAC members' information needs for data in REACH-IT. The presentation was then given by the Secretariat describing what kind of access to REACH-IT MS CAs, enforcement authorities and members of the Committees will have. The MS CAs will have a full access to the REACH-IT database (with the exception of the PPORD). However, as it contains confidential business data, very strict security requirements will have to be applied. The enforcement authorities will have an access limited to an extract of REACH-IT called RIPE. The Committees were informed that the MB had approved in its June 2009 meeting the list of RIPE data compiled by the Forum. The Committees' members should have access to the data needed for their work but this has to be defined. The Secretariat informed the meeting that for the moment Circa is going to continue to be used for sharing of data. However, more precise security rules will have to be applied on the handling of the data by members. The Secretariat noted that for 2010 ECHA is going to prepare a new secure system to replace Circa.

It was agreed that the Secretariat will open a written commenting round on the Room document RAC/07/2009/46 for RAC and SEAC/04/2009/23 for SEAC.

#### 13) AOB

The Secretariat informed the meeting that the MB revised in its last meeting the ECHA Guide for the Reimbursement of travel and accommodation expenses and payment of subsistence allowances and that the only change concerned the amount of deduction for lunches and dinners organised by ECHA.

#### 14) Action points and main conclusions of the joint RAC-7 and SEAC-4 session

RAC and SEAC agreed on the conclusions of the joint session and the action points to follow the joint session as laid down in Part II of these minutes.

### III. Conclusions and action points

### 1. SEAC-4 ACTION POINTS & MAIN CONCLUSIONS – 30 June 2009

(Adopted at the SEAC-4 meeting, separate session)

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
2. Adoption of the Agenda	The following points added to the Agenda: 3c) Changes in the SEAC composition /nominations AOB 7c) Status of the development of the working procedures regarding Authorisation The Agenda (SEAC/A/04/2009-rev.1, Part I) was adopted with the proposed modifications.	SECR to upload the adopted SEAC-4 Agenda to Circa as a part of the SEAC-4 separate session minutes.
3. Administrative issues		
a) Declarations of conflict of interest	No declarations of conflict of interest declared.	
b) Feedback on using the Kaleva services		Members to provide feedback on using the Kaleva travel agency's services by e-mail to SECR. SECR to transfer the comments and questions received from members to the responsible persons in ECHA and Kaleva for possible further actions.
c) Changes in the SEAC composition /nominations		
4. Status report of SEAC-3 action points	There was one outstanding action identified from SEAC-3 which was transferred to these action points	(AP 8b, SEAC-3 minutes) SECR to consider training for SEAC or further discussion on RMO.
5. Conclusion of the mandate of the SEAC-RAC interaction	SEAC decided to conclude the mandate of SEAC-RAC arrangement.	
6. Working procedures for Restrictions		
a) Working procedure on processing of an Annex XV restriction dossier	Both the Second and Final Forum's advice might be equally important for SEAC as the First Forum advice.  SEAC agreed the WP on processing of an Annex XV restriction dossier (SEAC/04/2009/13) with the understanding that the WP lays down a starting point and would be reviewed after some experience has been gained.	
b) Terms of reference for (co-) rapporteurs	SEAC agreed the ToR for (co-) rapporteurs (SEAC/04/2009/15).	SECR to provide Forum's WP on the development of Forum advice to SEAC via Circa.

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
c) Lessons learnt from the accordance checks useful to be transferred in the conformity check procedure	SEAC took note of the presentation given by the Secretariat.	<b>3</b> (1)
a) Next meetings	SEAC took note of the provisional meeting dates in 2010.	
b) Status report of the preparation of the guidance document on SEA in Authorisation	SEAC took note of the report made by the COM regarding the preparation of the guidance on SEA in Authorisation.	
c) Status of the development of the working procedures regarding authorisation		SECR to start planning the work on working procedures regarding authorisation (by end 2009).
General		SECR to upload all SEAC-4 presentations and the action points to Circa by 2 July.

# 2. JOINT SESSION OF RAC AND SEAC ACTION POINTS & MAIN CONCLUSIONS – 30 June -1 July 2009 (Adopted at the Joint Session of RAC and SEAC)

Agenda point	Conclusions / decisions / minority opinions	Action requested after the
		meeting (by whom/by when)
2. Adoption of the	The Agenda (RAC/A/07/2009, Part I,	SECR to upload the adopted
Agenda for the Joint	SEAC/A/04/2009_rev.1, Part II) was adopted without	Joint session Agenda to Circa
session	any changes.	as a part of the Joint session
56551011	No declarations of conflict of interest declared.	minutes.
	110 decidations of commet of interest decided.	innates.
3. Preparatory	Members took note of the instructions and	-
session for the role	recommendations for the role play.	
play	1 7	
4. Role play in	-	-
break out groups		
5. Welcome notes by	1	-
<b>Executive Director</b>		
6. Lessons learnt	1	-
from the role play		
a) Presentation with	Members took note of the presentation given by the	SECR to finalise the
highlights from the	Secretariat prepared together with the facilitators of	presentation (by 7 July).
discussions in the	the break out groups.	
break out groups		SECR to upload Chairman's
		summary from the second
		meeting of the SEAC-RAC

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
		Arrangement to CIRCA (2 July).
b) Lessons learnt from the role play		SECR to include the conclusions of the role play in the Joint session minutes (after the meeting)
7. Common		
restriction issues	M 1	
a) Overview of current restrictions in Annex XVII	Members took note of the presentation given by the Secretariat.	-
b) Example of process in the past for development of these Annex XVII entries	Members took note of the presentation given by the Secretariat.	-
c) Draft opinion and background document (BD) template	RAC and SEAC agreed the document on the opinion and background document (BD) template (RAC/07/2009/31 or SEAC/04/2009/17).	-
d) Clarification of the support available to RAC and SEAC rapporteurs	Members took note of the sources of support available to the rapporteurs.	SECR to forward the meeting document (RAC/07/2009/32 or SEAC/04/2009/18) to CARACAL (by next CARACAL meeting).
8. Information on the registered intentions for submitting Annex XV dossiers	Members took note of the report given by the Secretariat.	SECR to clarify whether the dossiers under preparation are related to human health and/or environmental risks.
proposing restrictions - Registered intentions for submitting an Annex XV restriction dossier (by 30 June 2009)		SECR to launch the procedure for the appointment of (co-) rapporteurs in RAC and SEAC based on the current list of registered intentions (after receiving the information mentioned above).
9. Joint information		
a) Process for guidance updates	Members supported the proposal of the Secretariat for the Committees' involvement in the initiation of guidance update and in the guidance consultation process.	-
b) Conclusions and recommendations from the authorisation workshop of January 2009	Members took note of the outcomes of the authorisation workshop.	-
10. Feedback from other ECHA bodies and activities	Members took note of the feedback reports from the recent developments in RAC, MSC, the Forum, the MB and CARACAL.	SECR to forward the document on the registry of intentions presented at CARACAL to RAC and SEAC.

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
11. Co-operation	Members took note of the elements of the RoPs for	8 4 /
with other	co-operation with EFSA and ACSHW and their role	
Community bodies -	in the process towards their adoption.	
Presentation of the		
possible elements of		
rules of procedure		
(Article 110(2) and		
(4) of REACH) for		
co-operation with		
EFSA and ACSHW		
12. Administrative		
issues		
a) Remuneration of	Members took note of the principles of remuneration	
RAC & SEAC	of RAC & SEAC rapporteurs.	
rapporteurs for	The state of the s	
Annex XV dossiers		
proposing a		
restriction		
b) RAC/SEAC	Circa will be used for the distribution of confidential	SECR to launch a Circa
members` access to	data to RAC and SEAC until a new more secure IT	newsgroup on the document
information in	tool is available. Additional security measures will be	(RAC/07/2009/46 or
REACH-IT	applied.	SEAC/04/2009/23). RAC and
112.101111	ирричи.	SEAC to provide comments
		in writing within 2 months
		from launching of the Circa
		newsgroup.
13. AOB		
General		SECR to upload all Joint
		session presentations and the
		action points to Circa by 2
		July.

## IV. Lists of Attendees

# 1. List of Attendees of the separate SEAC session:

SEAC members:	Advisors to the SEAC members:
	DOMINIAK, Dorota (advisor to RYDLEWSKA, Izabela)
BASTOS, Henri	
	BEEKMAN, Martijn (advisor to LUTTIKHUIZEN, C.)
BENDL, Jiri*	
BRIGNON, Jean Marc	GOORMACHTIGH, Nando (advisor to LUTTIKHUISEN, C.)
BRIGITOIT, Jean Marc	KIISKI, Johanna (advisor to SALONEN, H.)
BROKAITE, Kristina	THISTIP, FORMING (advisor to 5712-51(2))
,	FIORE, Karin (advisor to BASTOS, H.)
COSTEA, Ion	
DALTON, Marie **	GRANDI, Silvia (advisor to RECCHIA, L)
DE GIGLIO, Franco	
ECONOMIDES, Aristodemos	Representatives of the Commission:
FAHERTY, Mark	GIL, Sebastian (DG ENV)
FANKHAUSER, Simone	ROZWADOWSKI, Jacek (DG ENT)
FEYAERTS, Jean-Pierre	
FOCK, Lars	ECHA staff:
FORKMAN, Mats	FUHRMANN, Anna
FURLAN, Janez	HOLLINS, Stephen
GEORGIOU, Stavros	KARHU, Elina
HAJAS, Martin	LIPKOVA, Adriana
KOZAK, Kristof	LOGTMEIJER, Christiaan
LANGTVET, Espen	MUNN, Sharon
LOURENÇO, João	PELTOLA, Jukka
LUTTIKHUIZEN, Cees	SADAM, Diana
RECCHIA, Luca Maria	STOYANOVA, Evgenia
RYDLEWSKA-LISZKOWSKA, Izabela	SUNDQUIST, Anna-Liisa
SALONEN, Heikki	THUVANDER, Ann
SCHUCHTAR, Endre	VAINIO, Matti
SIMON, Franz-Georg	VASILEVA, Katya
SUSNIK, Marko	YLÄ-MONONEN, Leena
TELLING, Aive	
THEOHARI, Maria	
THIELE, Karen	
VANDERSTEEN, Kelly***	
*replacing BIZKOVA, Rut	
**replacing McGUINNESS, Sharon	
***replacing DANTINNE, Catheline	

# 2. List of Attendees of the joint RAC-SEAC session:

SEAC members:	RAC members:
BASTOS, Henri	ALESSANDRELLI, Maria*
BENDL, Jiri*	ANDERSSON, Alicja
BRIGNON, Jean Marc	BARANSKI, Boguslaw
BROKAITE, Kristina	BORGES, Maria Teresa

COSTEA, Ion	DUNAUSKIENE, Lina
DALTON, Marie **	DUNGEY, Stephen
DE GIGLIO, Franco	GRUIZ, Katalin
ECONOMIDES, Aristodemos	GREIM, Helmut
	HUTORAN, Svetlana**
FANKHAUSER Simons	JENSEN, Frank
FANKHAUSER, Simone	KADIKIS, Normunds
FEYAERTS, Jean-Pierre	LARSEN, Poul Bo
FOCK, Lars	LE CURIEUX-BELFOND, Olivier
FORKMAN, Mats	LEINONEN, Riitta
FURLAN, Janez	LOSERT, Annemarie
GEORGIOU, Stavros	LUND, Bert-Ove
HAJAS, Martin	MELANITOU, Maria
KOZAK, Kristof	MULLOOLY, Yvonne
LANGTVET, Espen	NUNES, Céu
LOURENÇO, João	ORPHANOU, Maria
LUTTIKHUIZEN, Cees	<u> </u>
RECCHIA, Luca Maria	PICHARD, Annick POLAKOVICOVA, Helena
RYDLEWSKA-LISZKOWSKA, Izabela	<u>'</u>
SALONEN, Heikki	PRONK, Marja
SCHUCHTAR, Endre	SCHULTE, Agnes
SIMON, Franz-Georg	SMITH, Andrew
SUSNIK, Marko	STOLZENBERG, Hans-Christian
TELLING, Aive	SULG, Helen
THEOHARI, Maria	TARAZONA, Jose V.
THIELE, Karen	VAN DER HAGEN, Marianne
VANDERSTEEN, Kelly***	VAN MALDEREN, Karen
*replacing BIZKOVA, Rut	VILANOVA, Eugenio
**replacing McGUINNESS, Sharon	ZGLOBIU, Mariana-Elena *replacing DI PROSPERO, Paola
***replacing DANTINNE, Catheline	**replacing RUPPRICH, Norbert
	replacing North Recht, Nortest
Advisors to the SEAC members:	Advisors to the RAC members:
DOMINIAK, Dorota (advisor to RYDLEWSKA, Izabela)	ANNOLA, Kirsi (advisor to LEINONEN, Riita)
BEEKMAN, Martijn (advisor to LUTTIKHUIZEN, C.)	GRACZYK, Anna (advisor to BARANSKI, Boguslaw)
KIISKI, Johanna (advisor to SALONEN, H.)	HAKKERT, Betty (advisor to PRONK, Marja)
FIORE, Karin (advisor to BASTOS, H.)	MORKA, Heidi (advisor to VAN DER HAGEN, Marianne)
GRANDI, Silvia (advisor to RECCHIA, L )	

Representatives of the Commission:	Stakeholder observers:
GIL, Sebastian (DG ENV)	ANNYS, Erwin (CEFIC)
ROZWADOWSKI, Jacek (DG ENT)	DINTCHEVA, Ralitza (UEAPME)
WISTUBA, Christine (DG ENV)	HOLLAND, Mike (EEB)
	LEENAERS, Joeri (Eurometaux)
ECHA staff:	MÄKELÄ, Kari (EMCEF)
BLENCOWE, Tom	MEISTERS, Marie-Louise (ECETOC)
DANCET, Geert	MUSU, Tony (ETUC)
DE BRUIJN, Jack	VAN SLOTEN, Rene (CEFIC)
FUHRMANN, Anna	WEFFERS, Heribert (EEB)
HERDINA, Andreas	
HOLLINS, Stephen	
KARHU, Elina	
LEFEBVRE, Alain	
LEFEVRE, Remi	
LIPKOVA, Adriana	
LOGTMEIJER, Christiaan	
MUNN, Sharon	
PELTOLA, Jukka	
RODRIGUEZ IGLESIAS, Pilar	
SADAM, Diana	
STOYANOVA, Evgenia	
SUNDQUIST, Anna-Liisa	
THUVANDER, Ann	
VAINIO, Matti	
VASILEVA, Katya	
YLÄ-MONONEN, Leena	

#### V. List of Annexes

- ANNEX I. Lists of documents submitted to the Members of SEAC for the separate SEAC session and to the Members of RAC and SEAC for the joint RAC-SEAC session
- ANNEX II. Final Agenda of SEAC-4 meeting
- ANNEX III. Conclusions of the role play

### 1. Documents submitted to the Members of SEAC for the separate SEAC session

Revised Draft Agenda of the SEAC separate session	SEAC/A/04/2009_rev.1,
(Agenda Point 2)	Part I
Conclusion of the mandate of the SEAC-RAC arrangement	SEAC/04/2009/22
(Agenda Point 5)	
Revised draft working procedure for processing an Annex	SEAC/04/2009/13
XV proposal for restriction (Agenda Point 6a)	
Responses to comments received by SEAC members on the	SEAC/04/2009/14
document SEAC/03/2009/09 (Agenda Point 6a)	
Revised draft terms of reference for SEAC (co-)rapporteurs	SEAC/04/2009/15
(Restrictions) (Agenda Point 6b)	
RCOM on Revised draft terms of reference for SEAC (co-	SEAC/04/2009/16
)rapporteurs (Restrictions) (SEAC/03/2009/06) (Agenda	
Point 6b)	
Proposed meeting dates for 2010 (Agenda Point 7a)	Room document

# 2. Documents submitted to the Members of RAC and SEAC for the joint RAC-SEAC session

Revised Draft Agenda of the joint RAC-SEAC session	RAC/A/07/2009,	SEAC/A/04/2009_re
(Agenda Point 2)	Part I	v.1, Part II
The opinion of RAC and SEAC on restriction	RAC/07/2009/31	SEAC/04/2009/17
proposals (Agenda Point 7c)		
Clarification of the support available to RAC and	RAC/07/2009/32	SEAC/04/2009/18
SEAC rapporteurs (Agenda Point 7d)		
Process for guidance updates (Agenda Point 9a)	RAC/07/2009/33	SEAC/04/2009/19
Possible elements of rules of procedure (Article 110(2)	RAC/07/2009/34	SEAC/04/2009/20
and (4) of REACH) for co-operation with EFSA and		
ACSHW (Agenda Point 11)		
Remuneration of RAC and SEAC rapporteurs for	RAC/07/2009/35	SEAC/04/2009/21
Annex XV dossiers proposing a restriction (Agenda		
Point 12a)		
RAC/SEAC members` information needs for data in	Room document	Room document
REACH-IT (Agenda Point 12b)	RAC/07/2009/46	SEAC/04/2009/23



30 June 2009 SEAC/A/04/2009\_rev.2

# Final Agenda Fourth meeting of the Committee for Socio-economic Analysis

## 30 June – 1 July 2009 ECHA Conference Centre (Annankatu 18, Helsinki)

30 June: starts at 11.30 1 July: ends at 18.00

#### Part I

#### **SEAC SESSION**

30 June: starts at 11.30 30 June: ends at 13.00

#### Item 1 – Welcome notes by SEAC new Chair, apologies

#### Item 2 - Adoption of the Agenda

SEAC/A/04/2009, Part I

For adoption

#### Item 3 – Administrative issues

a) Declarations of conflicts of interest

For information

b) Feedback on using the Kaleva services

For information

c) Changes in the SEAC composition/nominations

For information

#### Item 4 – Status report of SEAC-3 action points

For information

#### Item 5 – Conclusion of the mandate of the SEAC-RAC interaction

SEAC/04/2009/22

For discussion and decision

#### **Item 6 – Working procedures for Restrictions**

a) Working procedure on processing of an Annex XV restriction dossier

SEAC/04/2009/13

SEAC/04/2009/14 (RCOM)

For adoption

b) Terms of reference for (co-) rapporteurs

SEAC/04/2009/15

SEAC/04/2009/16 (RCOM)

For adoption

c) Lessons learnt from the accordance checks useful to be transferred in the conformity check procedure

For information

#### Item 7 – AOB

a) Next meetings

For information

- b) Status report of the preparation of the guidance document on SEA in Authorisation *For information*
- c) Status of the development of the working procedures regarding Authorisation

For information

#### Item 8 – Action points and main conclusions of SEAC-4

Table with Action points and decisions from SEAC-4

For adoption

#### Part II

#### **JOINT SESSION OF RAC and SEAC**

30 June: starts at 14.00 1 July: ends at 18.00

#### Item 1 – Welcome notes by RAC & SEAC Chairs

#### Item 2 – Adoption of the Agenda for the Joint session

RAC/A/07/2009, Part I SEAC/A/04/2009, Part II For adoption

#### Item 3 – Preparatory session for the role play

For information

#### Item 4 – Role play in break out groups

Parallel discussion in break out groups on the mini Annex XV dossier

For discussion

• Meeting of break out groups' facilitators for preparing of a presentation with highlights from the discussions in the groups

For preparation

#### **Item 5 – Welcome notes by Executive Director**

#### Item 6 – Lessons learnt from the role play

a) Presentation with highlights from the discussions in the break out groups

For information

b) Lessons learnt from the role play

For discussion

#### **Item 7 – Common restriction issues**

a) Overview of current restrictions in Annex XVII

For information

b) Example of process in the past for development of these Annex XVII entries

For information

c) Draft opinion and background document (BD) template

RAC/07/2009/31 SEAC/04/2009/17

For discussion and agreement

d) Clarification of the support available to RAC and SEAC rapporteurs

RAC/07/2009/32

SEAC/04/2009/18

For information

Item 8 – Information on the registered intentions for submitting Annex XV dossiers proposing restrictions

• Registered intentions for submitting an Annex XV restriction dossier (by 30 June 2009)

For information

#### Item 9 – Joint information session

a) Process for guidance updates

RAC/07/2009/33

SEAC/04/2009/19

For discussion

b) Conclusions and recommendations from the authorisation workshop of January 2009

For information

#### Item 10 - Feedback from other ECHA bodies and activities

For information

#### Item 11 – Co-operation with other Community bodies

Presentation of the possible elements of rules of procedure (Article 110(2) and (4) of REACH) for co-operation with EFSA and ACSHW

RAC/07/2009/34

SEAC/04/2009/20

For information

#### Item 12 – Administrative issues

a) Remuneration of RAC & SEAC rapporteurs for Annex XV dossiers proposing a restriction

RAC/07/2009/35

SEAC/04/2009/21

For information

b) RAC/SEAC members` access to information in REACH-IT

Room document RAC/07/2009/46

Room document SEAC/04/2009/23

For information

Item 13 – AOB

Item 14 – Action points and main conclusions of Joint RAC-7 & SEAC-4 session

Table with Action points and conclusions from the Joint session

For adoption

#### Conclusions of the role play

List of documents provided to the members for the role play:

- Mini-dossier
- o Executive summary of the mini dossier
- o Description of the role play
- o SEAC/04/2009/22

The description of the role play can be found in the aforementioned documents. These documents can be found on CIRCA in the section "role play" of the joint session. A total of eight break-out groups were organized, in each group there was one facilitator, one RAC rapporteur and one SEAC rapporteur<sup>2</sup>. In some cases a co-rapporteur or a co-facilitator was also used.

After the presentation was given to the joint session of RAC and SEAC on the results of the role play, those members who played the role of rapporteurs exchanged their experiences on the role play. The discussion that followed focused on the following items: how easy it was to be a rapporteur, were the remits of RAC and SEAC clear and what to do if not all information needs were fulfilled.

How easy was it to be a rapporteur?

Rapporteurs indicated that the task of being a rapporteur should not be underestimated. Rapporteurs need to be knowledgeable and have the appropriate experience in order to function well in their task. It was thought that a good preparation of the rapporteurs is essential for the success of the first dialogue. The experience from the groups was that having a teleconference prior to the first dialogue contributed to the success of the dialogue.

During the discussion at the plenary the point was made that a good communication and understanding between RAC and SEAC rapporteurs is needed. Rapporteurs should communicate frequently and preferably meet (at least once) face-to-face.

Rapporteurs indicated that it would be desirable that the other members of RAC and SEAC could be asked to help out rapporteurs.

Rapporteurs mentioned that it was good to have a structure available for the dialogue as it led them through the dossier. Another way to work would be to go section by section through a dossier.

Were the boundaries between RAC and SEAC clear?

The feedback from the breakout groups was mixed on this issue. In some groups the remits of both committees was clear and participants acted accordingly. In other groups there were many 'border-crossings'. However, often these crossings happened in an attempt to seek further clarification of the issues at hand, or were an attempt to seek a common understanding of the problem.

<sup>&</sup>lt;sup>2</sup> In one group (F), the RAC rapporteur was absent due to the cancelled flight.

What if most of the information needs were not fulfilled?

During the role play many participants suggested that further information was required. They felt that the information in the mini-dossier was not sufficient enough to come to an opinion. This provoked in some groups a discussion on what kind of information one needs to know, the minimum information needs required to formulate an opinion and the role of the submitting member state in providing additional information.

It was agreed that the dossier submitter plays a crucial role in the process since the quality of the dossier is deemed to be an important success factor in the process of coming to an opinion. During the discussion the rapporteurs mentioned that it is important that the dossier submitter should remain at the disposal of the rapporteurs throughout the process. It was thought that the submitter could be one of the main sources to provide further clarification and additional information where needed.

The provided information was often thought to be insufficient to come to an opinion. This was partly due to the "mini-dossier bias": the provided information being compressed and kept to a minimum level for the purposes of the role play. It was pointed out that in the future rapporteurs should be able to focus more on reviewing the information in the dossier rather than identifying information gaps.

Further to the issue of information needs, participants pointed out that industry and stakeholders can play a role in providing additional information e.g. on alternatives. This information can be provided preferably prior to submission or, otherwise, during the 6-month public consultation.

Comparison with lessons learnt in the SERAC role play.

The experience of the role play seemed to have reinforced most of the lesson learnt from the role play that was held during the second SERAC meeting, which had been distributed to the participants prior to the meeting (as part of the report of SERAC)<sup>3</sup>.

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<sup>&</sup>lt;sup>3</sup> The full Chair's summary of the 2<sup>nd</sup> meeting was distributed to the members of both RAC and SEAC after the joint session.