

SEAC/M/07/2010 FINAL

Final

Minutes of the 7th meeting of the Committee for Socio-economic Analysis

2-3 June 2010

Part 1: Summary record of the Proceeding

1) Welcome and apologies and changes in SEAC Composition

Ms Ann Thuvander, Chair of the Committee for Socio-economic Analysis (SEAC), ECHA, welcomed the participants of the seventh meeting of SEAC.

The Chair informed that apologies had been received from six members, two of whom had sent an invited expert as a replacement. Members' advisers present at the meeting as well as observers of the European Commission (COM) and observers of six stakeholder organisations participating in the meeting were introduced.

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

The Chair informed the participants that the meeting would be recorded and the records would be destroyed after the adoption of the minutes.

2) Adoption of the Agenda

The Chair introduced the agenda of SEAC-7. The following suggestions for items to discuss under AOB were made by the members:

- Information Notice of a Project on Abatement Costs

The Agenda was adopted without any changes. The final Agenda is attached to these minutes as Annex II.

3) Declaration of conflicts of interest to the Agenda

One member (as well as his advisers) declared a conflict of interest to the item 10 of the SEAC-7 Agenda with regard to the discussion on the restriction dossiers on Dimethylfumarate (DMFu) and Lead in jewellery. SEAC was asked to take account of this in future when a quorum is needed in decision making situations regarding the DMFu and Lead dossiers.

4) Administrative issues

Report back on the outcome of the written procedures on the conformity check of restriction proposals

SEAC was informed about the outcome of the written procedure on agreement on the conformity of the DMFu and Lead in jewellery dossiers. Both dossiers had been found to be in conformity. The Committee for Risk Assessment (RAC) already had agreed on the conformity of both dossiers at its plenary meeting on 26 May 2010.

Report back on the outcome of the written procedure on the SEAC-6 Minutes

The Secretariat informed SEAC about the outcome of the written procedure on the adoption of the minutes of the SEAC-6 meeting. SEAC-6 minutes had been adopted by consensus.

Update on the contract for remuneration of rapporteurs

The Secretariat gave an update on the recent developments regarding the establishment of cooperation agreements for the remuneration of (co-)rapporteurs. SEAC was informed that ECHA will shortly send out the cooperation agreements to the Member State Competent Authorities (MSCA) for their signature. At the moment priority is given to those MSCA of countries from which members have been appointed/started to work as (co-)rapporteurs for restriction dossiers. For some of the countries in question (UK and France), the contact information was still missing.

After the cooperation agreements have been established, specific service requests would be sent to cover the services to be provided by the (co-)rapporteurs. The Secretariat explained that the main document describing the tasks and responsibilities of the rapporteur will be the Terms of Reference earlier agreed by the Committee. The service request does not contain any additional information regarding the tasks to be carried out. The Secretariat agreed to circulate the service request template and its annexes to SEAC by 4 June.

a) Changes in the SEAC composition/nominations

The Chair informed that two SEAC members had resigned: Ms. Sharon McGuinness (IE) and Mr. Luca Maria Recchia (IT).

b) Report from DG SANCO WG

Members of SEAC (Mats Forkman and Stavros Georgiou) reported on recent activities of the DG SANCO working group dealing with possible improvements in risk assessment approaches in view of risk management needs and effective risk communication.

The working group had discussed the concept of integrated risk assessment, which is assumed to integrate environmental and human health risk assessment as well as risk management and risk assessment. Furthermore, the working group had considered whether integrated risk assessment should cover in addition to adverse effects on individual organisms also effects on whole eco-systems and the value eco-systems can deliver.

During the last meeting of the working group, the focus was on the need to adapt the risk assessment carried out for the purposes of justification of regulatory action to European decision making bodies. It was observed that there is a great variability in the scope of this type of risk assessment and therefore also the scope of the effect in terms of number of people and environment affected (European wide air pollution problems vs. limited effect due to the use of specific devices or products).

The working group had not yet arrived on any firm conclusions. The task of the working group is complicated by the wide range of areas and legislation to be looked at without any systematic review. The next meeting of the working group will be held in June.

Stavros Georgiou agreed to circulate his paper regarding socio-economic analysis to be prepared on request of the working group within SEAC once available. SEAC would benefit also from having access to the case studies dealt with by the DG SANCO working group. The Secretariat will provide these case studies to SEAC and keep SEAC updated of the developments in the DG SANCO working group.

5) Status report of the action points of SEAC-6

The Secretariat provided an update of the status of SEAC-6 action points and main conclusions. The Secretariat reported that most actions had been completed on time.

6) Feedback from other bodies

The Chair noted that for SEAC-7 a meeting document had been prepared that covered the feedback of some of the other bodies (on RAC and Member State Committee (MSC)). One member requested more information on the Manual of Conclusions and Recommendations that RAC had discussed in RAC-10. The Chair explained that the Manual is intended for documentation of decisions taken by RAC which might be important for the Committee's work in terms of consistency. The Secretariat agreed to start developing such a Manual of Decisions also for SEAC.

The Chair briefly updated SEAC on the discussions that took place in RAC-11 (25-27 May). The Chair reported on the issues raised by RAC when discussing the two restriction dossiers submitted in April. A SEAC (co-)rapporteur for one of the April restriction dossiers, who had attended the RAC meeting, also gave his feedback.

The Secretariat informed that the last Management Board meeting had been cancelled due to volcanic ash cloud. Therefore, written procedures had been launched instead to address the different issues on the agenda. Stakeholders observers' access to MSC meetings when evaluation cases are being discussed had been one of the issues addressed in written procedure. The topic is rather sensitive due to highly confidential business information being at stake. The subject, however, had not been concluded and would be addressed at next MSC and Management Board meetings. It was noted that both RAC and SEAC will soon need to deal with the same issue as it is equally relevant for authorisations. The Secretariat agreed to start a discussion on the presence of case owners in SEAC meetings.

The Secretariat gave an update on the last Forum meeting, which had taken place on 19-21 May 2010. Among others, the following issues were noted:

- The Forum had agreed on a new project on the restriction entry regarding the use of extender oils containing polycyclic-aromatic hydrocarbons (PAHs) in tyres.
- The Forum had adopted its advice to COM on inclusion of analytical testing methods within Annex XVII of the REACH Regulation. In this advice, the Forum proposes not to include harmonised methods in all entries of Annex XVII but only to produce guidance on suitable analytical methods. For restricted substances prioritised for coordinated enforcement activities, the Forum suggests a mandate to be given to third bodies to develop specific analytical methods for the purposes of enforcement. If COM decides for an implementation of harmonised analytical methods in Annex XVII, the Forum recommends that priority is given to those Annex XVII entries that are most relevant for enforcement.
- A draft checklist to examine proposals for restrictions had been presented to the Forum for comments.

A question was raised on the study on penalties with regard to the REACH Regulation in the Member States. The Secretariat clarified that the study had focused on a review of penalties legislation in different Member States and not on their coordinated enforcement. The Secretariat agreed to provide the link to the COM web site on REACH enforcement where the study on the penalties can be found.

The Secretariat agreed to provide SEAC the letter with which the advice on inclusion of analytical testing methods within Annex XVII would be sent to COM, via CIRCA.

Feedback from Workshop on Assessing Health and Environmental Impacts in the Context of Socio-Economic Analysis under REACH: 19th May 2010, Brussels

COM reported back on the Workshop organised within the project on Assessing Health and Environmental Impacts in the Context of Socio-Economic Analysis under REACH. Experts from relevant fields met at this workshop to review the scientific and methodological basis of a draft logic framework for identification and assessment of health and environmental impacts that had been developed in the project. A number of issues related to bridging of the gap between risk assessment and socio-economic analysis (SEA) were pinpointed in the workshop, e. g. use of datasets in different ways under risk assessment and SEA ('reasonably worst case' scenarios vs. 'realistic' or 'best' estimates) and the potential of impact estimation techniques, such as statistically-derived estimates of disease burden using epidemiology data, life cycle impact assessment (LCIA) techniques, the use of proxy's for effect (e.g. exposure/emissions), and ways forward for the assessment of PBT and vPvB substances.

Karen Thiele, a member of SEAC, who had participated in the workshop, gave her reflections from the SEAC perspective. She highlighted that the LCIA model seems to be interesting for the exposure estimation of chemicals as it can provide valuable inputs for SEA. As qualitative information is likely to play an essential role in the work of SEAC, optimal communication and consistent terminology between the risk assessment and SEA are needed to ensure that qualitative information is used consistently in SEAC's opinions. Ms Thiele saw the logic framework as a good basis for discussion in SEAC on how to assess qualitative information.

During the discussion it was noted that the study would continue focusing on the identification of impacts and description of the significance of impacts. The Chair recognised that the outcomes of the study will be important for the work of SEAC and for the update of SEA guidance documents. COM confirmed that LCIA would be investigated further within this project to see its potential for SEA. One SEAC member suggested COM to coordinate various ongoing activities and knowledge transfer related to the work of the ECHA Committees.

The Chair concluded the discussion by stating that the Secretariat would keep SEAC updated on the developments in COM's project and collect information relevant for the update of SEA guidance documents.

7) Reporting back from meetings with rapporteurs on 15 March 2010

Mr Stavros Georgiou, one of the SEAC (co-)rapporteurs for the restriction dossiers submitted in April, reported on the meeting that took place on 15 March 2010 at ECHA. In this meeting the rapporteurs of both RAC and SEAC met to kick-off the work on the April restriction dossiers (DMFu and Lead in jewellery). The meeting served mainly to clarify the means of support from the Secretariat, to agree on the dates for the first rapporteurs' dialogues and to become familiar with the dossier timelines. A similar meeting to prepare the rapporteurs for their tasks would be held 3 June, back-to-back to SEAC-7, with the rapporteurs for the June dossiers.

Mr Georgiou expressed his appreciation of the meeting as a good opportunity to meet with the RAC counterparts and ECHA staff involved in the restriction process. However, he did not see it necessary to repeat a meeting in the same set-up for all restriction dossiers. Nevertheless, he encouraged (co-)rapporteurs to seek the opportunities to get to know their future colleagues. Mr Georgiou touched upon practical issues regarding remuneration, such as the Secretariat's request to keep the work time records and to inform about the split of the remuneration between the (co-)rapporteurs. To have the opportunity to meet with RAC colleagues and to limit the amount of travelling, he suggested to the Secretariat to investigate the possibilities to arrange SEAC meetings back-to-back with RAC meetings. Another (co-)rapporteur supported this suggestion.

During the discussion, the Chair noted that the scheduling of the Committee meetings is relevant also for the dossier submitters. One member asked for some guidance on the split of the remuneration between the (co-)rapporteurs. Mr Georgiou responded that in the first dossiers the split had been decided in individual negotiations between the (co-)rapporteurs. In the future, other aspects, such as specific expertise may play a larger role for the division of tasks.

The Secretariat agreed to investigate further the possibilities to schedule RAC and SEAC meetings in the same week as well as to clarify technical possibilities for (co-)rapporteurs to attend RAC and SEAC meetings via tele- or videoconferencing means.

8) Authorisations

The COM observer provided a brief update on developments related to the authorisation process in COM. With regard to the identification of substances for the candidate list, the inclusion of new substances should accelerate in the coming years. Preparation of SVHC dossiers is a shared responsibility of COM and ECHA on the one hand and the MSCA on another, and will require efforts from all sides. COM is planning to discuss the division of substances between the MSCA in the upcoming CARACAL meeting. The long-term objective is that all currently relevant and known SVHCs should be included in the candidate list by 2020.

In relation to the authorisation guidance, the COM observer informed that substitution had been recognised as being an ultimate objective for both of the authorisation routes (“adequate control route” and “socio-economic route”). The related amendment to the REACH Regulation will be made at the earliest opportunity. The COM observer noted that the Guidance on the preparation of an application for authorisation was currently under consultation with the MSCA and if SEAC members wanted to provide their comments, they could do so through their CAs.

Working procedure for the appointment of (co-)rapporteurs for authorisation applications

The Chair reminded the participants that at the SEAC-6 meeting the draft working procedure for the appointment of (co-)rapporteurs by SEAC for authorisation applications had been introduced. The Secretariat had revised the draft procedure after the SEAC-6 meeting based on the comments made at the meeting by the SEAC members and the COM observers, and had initiated a written procedure in order to agree on the revised working procedure. The Chair informed that the working procedure for the appointment of (co-)rapporteurs for authorisation applications had been agreed by SEAC by consensus and uploaded to SEAC CIRCA IG.

a) Conformity check

- Content of conformity check

The Chair reminded that at the SEAC-6 meeting, the discussion paper on the scope and content of the conformity check of authorisation applications had been presented and discussed. The comments provided by SEAC members via CIRCA Newsgroup after the SEAC-6 meeting had been collected and responded to by the Secretariat in a response to comments table (RCOM) (SEAC/07/2010/10). Based on the SEAC comments as well as on the discussions between the Secretariat and COM on the conformity check process, the discussion paper had been revised (SEAC/06/2010/05_rev.1). The Secretariat gave an overview of the SEAC members’ comments and described the changes in the revised discussion paper. The discussion on the presentation and the revised document took place jointly with the discussion on the draft working procedure on the conformity check of authorisation applications.

- Working procedure

The Chair reminded that at the SEAC-6 meeting, the draft working procedure for RAC and SEAC on the conformity check of authorisation applications had been presented and discussed. After the SEAC-6 meeting, a CIRCA Newsgroup had been

opened for members on the draft procedure. The comments had been collected and responded to by the Secretariat in an RCOM (SEAC/07/2010/11). Based on the SEAC comments as well as on the discussions between the Secretariat and COM on the conformity check process, the draft working procedure had been revised (SEAC/06/2010/06_rev.1). The Secretariat gave an overview of the SEAC members' comments and presented the changes in the revised draft procedure.

One member noted that the Committee should not consider the application to be in conformity if the analysis of alternatives only referred to alternative substances, while alternative processes and technologies were not considered. The Secretariat clarified that Article 64 of the REACH Regulation refers to alternative substances and technologies – the same definition has been used in the authorisation guidance documents. The member suggested that the conformity check should not be concluded until the accordance of the Chemical Safety Report (CSR) with Annex I had been checked, which might be difficult to achieve within the short time foreseen for the conformity check. The Secretariat reminded that ECHA will have to go through the application quite thoroughly already before it is officially received (because of the invoicing). Therefore, by the time the fee has been paid, the Secretariat should already have quite a good understanding of the application. If needed, there might be a way for the nominated (not yet appointed) (co-)rapporteurs to be involved in the process. Some members said that if the Committee decides on the conformity of the application and makes this decision public, it might later be difficult to request from the applicant further information (apart from the information on alternatives). The Secretariat, however, expressed the view that it is very likely that it is in the interest of industry to provide the Committees with all possible information and therefore it would be possible to ask for and get further information also later on in the process, even if the application has been found in conformity by the Committees.

A COM observer pointed out that there is no legal requirement for the Committees to inform the applicant when the application is regarded in conformity. The Secretariat reminded that the minutes of the Committee meetings are public documents and according to good administrative practice it would be proper to inform the applicant on pertinent issues. Furthermore, the applicant may enquire about the status of his application. In this case ECHA would need to respond. Equal treatment of all applicants is also an issue.

Another member saw a problem in the (co-)rapporteurs deciding on the conformity of the application and felt that the whole Committee should be involved in such decisions. The Secretariat clarified that the (co-)rapporteurs will only be delegated the responsibility to establish the need for requesting from the applicant the information required for putting the application into conformity on behalf of the Committees. The final decisions on conformity are, however, to be taken by the Committees.

Based on the suggestion by several members, it was agreed that the Secretariat would consider further how to communicate appropriately the status of the conformity to the applicant (including e.g. a disclaimer).

SEAC agreed to leave the draft conformity check procedure for authorisation applications as it currently was. The document might need to be updated after the written commenting round in RAC. In case of no significant changes to the draft

procedure following the RAC commenting, the document is likely to be put forward for agreement at the SEAC-8 meeting. However, members may still submit comments in writing to the Secretariat if they have major concerns.

The Secretariat informed that a draft format to document the outcome of the conformity check (including draft conformity check questions) will be prepared for the September 2010 meetings of RAC and SEAC.

b) Formulation of SEAC opinion on authorisation applications

- Content of final Commission decisions and their effect on the format of the opinions

The Secretariat presented to SEAC the discussion note on the content of final COM decisions and their effect on the format of the opinions of RAC and SEAC on authorisation applications (SEAC/07/2010/12). The same note had also been presented to RAC in late May. The main conclusion of the presentation was that the opinions of RAC and SEAC need to underpin the overall decision making of COM. Thus, it was established that during the opinion making the Committees would include in their opinions all elements that are needed for decision making. These are: i) whether the conditions for granting authorisation have been established, ii) what the possible (additional) conditions and monitoring arrangements would be, iii) what the duration of the review period might be and iv) what the reasons for the decisions are. It would seem natural that RAC would take the lead on item ii) while SEAC on iii). It was also highlighted that irrespective of the legal base (Article 60(2), i.e. the “adequate control route”, or Article 60(4), i.e. the “socio-economic route”), both Committees would need to give an opinion.

A COM observer confirmed that the discussion note represented the shared views of ECHA and COM. He also pointed out that the review period should be linked to the availability of alternatives. Some members asked if SEAC should at all look at the information on alternatives if the application is based on “adequate control” and RAC confirming that the substance is adequately controlled. The Secretariat responded that SEAC would need to be actively involved in this case, too, because of, for instance, the need to establish the duration of the review period. One member emphasised that according to Article 55 of the REACH Regulation, the aim of the authorisation is to ensure good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. The COM observer also noted that the substitution principle should apply irrespective of the route taken by the applicant.

Overall, the approach proposed by the Secretariat and COM was found agreeable. Some members expressed their favourable view and nobody objected. It was agreed that the Secretariat would open a CIRCA Newsgroup on the discussion note after the SEAC-7 meeting (for three weeks). SEAC members’ comments will be used for developing a template for the opinion on authorisation applications for the September 2010 meetings of RAC and SEAC.

- Elements of the working procedure for developing opinions

The Secretariat gave a presentation on the elements of the RAC and SEAC working procedure for developing opinions on the applications for authorisation (SEAC/07/2010/13). Based on these elements, the detailed working procedure will be elaborated for the September 2010 meetings of RAC and SEAC.

It was agreed that the Secretariat would open a CIRCA Newsgroup on the document after the SEAC-7 meeting (for three weeks). The SEAC members' comments will be used for preparing the draft working procedure for developing opinions on the applications for authorisation.

c) Terms of reference for (co-)rapporteurs of RAC and SEAC for authorisation applications

The Secretariat introduced the draft terms of reference (ToR) for (co-)rapporteurs of RAC and SEAC for authorisation applications (SEAC/07/2010/14). The purpose of this document was to initiate discussions in RAC and SEAC on the role and the tasks of the authorisation (co-)rapporteurs and to provide input to the ECHA Management Board for its decision on the remuneration of the (co-)rapporteurs. The Secretariat clarified that the draft ToR would be revised in the future to be in line with the RAC and SEAC procedures for authorisation process (as soon as they have been agreed). Additional sections addressing subsequent applications and reviews of authorisations may have to be included in the text of the ToR.

The Chair invited SEAC members to provide comments on the draft ToR via the CIRCA Newsgroup that would be open for three weeks.

9) Action points of day 1

The Secretariat presented the action points and main conclusion from day 1 of SEAC-7. The adopted action points can be found in part 2 of the minutes.

10) Restrictions

a) General restriction issues

The Secretariat informed that there had been no changes in the Registry of Intentions since SEAC-6.

b) Presentation of Restriction proposals by dossier submitter

- DMFu

Following the presentation of the dossier submitter, SEAC was given the opportunity to ask questions to the dossier submitter for clarification.

Concerning the scope of the analysis, the dossier submitter confirmed that the proposed restriction is aimed at the production of articles that contain DMFu as well as placing on the market of imported articles containing DMFu.

The dossier submitter was requested to explain the reasoning behind the choice of the baseline (the situation without the REACH restriction). In the baseline scenario, it had been assumed that the temporary ban would either be renewed or would not be renewed. In case of non-renewal, the same risk would be heterogeneously managed throughout the EU Member States that would result in disturbance of the internal market.

The dossier submitter noted that there was no complete information on how DMFu is used. The assumption is that DMFu is used in small sachets supplied with articles or that articles or containers are sprayed before the transport. As a consequence the imported articles may contain DMFu. SEAC was reminded that imported treated articles are not covered by the Biocides Directive. However, the ongoing revision of the Biocides Directive may result in prohibiting the import of articles treated with a biocide if this use of the biocide is not authorised in the EU.

Concerning the type of socio-economic information that could be expected by SEAC in a restriction dossier, one member commented that the overall approach applied in the DMFu dossier is appropriate. However, this raised a question on what in general is expected from cost and benefit information in general and from a SEA in particular as this dossier does not e.g. describe impacts for importers, net benefits for human health and environment, etc. Another member as well as the Secretariat, responded to this by pointing out that SEA should be proportionate to the impacts and the added value of the information should be in balance with the cost of its collection.

As regards symptoms caused by exposure to DMFu, the dossier submitter clarified that the symptoms of contact dermatitis due to DMFu vary both in intensity and duration. Also the permanence and cross contamination seem to be uncertain. Consequently, it is difficult to predict an average length and/or attribute a value to this effect. Therefore the dossier submitter concluded that there was no added value of further analysis.

The dossier submitter mentioned that the current restriction proposal addresses implicitly the protection of workers as it covers the placing on the market of articles containing DMFu. ECHA's Forum had informed that methods are available to detect DMFu in articles so as to comply with the temporary ban or future restriction.

The dossier submitter explained that little information was available on the number of cases of skin dermatitis from the period before the temporary ban. Either no proper registration had been done or the cases could not be unambiguously attributed to the use of DMFu. Also no information was available on when DMFu was started to be used; however, publications describing the symptoms that could be attributed to the use of DMFu had started to appear in 2007.

- Lead and its compounds in jewellery

Following the presentation of the dossier submitter, SEAC was given the opportunity to ask questions to the dossier submitter for clarification.

The dossier submitter explained that migration rate had been chosen as a basis for the restriction proposal as it is the most relevant measurement in relation to mouthing by children. No correlation had been found between the lead content and the migration rate. Using the migration rate as a basis for the restriction would allow using lead in jewellery where it is bound in the structure so that its migration rate is below the proposed limit. For enforcement purposes, migration rate tests had been found to be available.

The dossier submitter explained that no information had been possible to obtain either on the exact composition of the alloys used for jewellery or on the production techniques used. As a consequence, it had been found difficult to define fully the baseline for analysis of costs of alternatives. With information merely on the prices of alternative materials, the price difference for the jewellery with lead and with an alternative metal or alloy could not be specified, but it was expected to be small. The potential need to change production techniques due to the use of alternative materials and related investment costs had not been taken into account due to lack of information.

The choice of the target population, children younger than three years, was explained to have been made due to the risk related to children's typical mouthing behaviour. Protecting this group had been considered to imply protection of other groups (older children, teenagers and adults) as well. The dossier submitter also explained that other household objects are of lower concern, since most lead ingestion cases concerned jewellery containing lead. The Secretariat added that changing the scope of the restriction requires careful consideration. However, it was recognized that what is covered by 'jewellery' would need to be clarified.

In view of impact assessment, the dossier submitter explained that the proportion of jewellery containing lead on the market is not known. The dossier submitter explained the assumptions underlying the estimated impact of 5000 children per year in the EU ingesting a piece of jewellery. The estimation had been made based on the number of children who had ingested jewellery in France.

It was recognized that the recent study commissioned by COM on cadmium in jewellery seems to be of interest for the dossier on lead in jewellery. A lot of information in the study report is based on joint sources for both cadmium and lead. It was concluded that SEAC would benefit from familiarizing itself with this report.

c) Restriction Annex XV dossiers

- DMFu – Rapporteurs' view on conformity check process

- Lead and its compounds in jewellery – Rapporteurs’ view on conformity check process

The Chair invited the scientific dossier managers (SDM) nominated by ECHA for the restriction dossiers submitted in April to share their experience with the processing of the restriction dossiers. They briefed the Committee about the work of SDMs, dossier experts, Committee and Forum Secretariats and rapporteurs’ in the context of the restriction dossiers and they evaluated the process as running smoothly up to now. SDMs noted that the borderline between the conformity check and the assessment of the presented information for the purposes of opinion formulation requires careful consideration.

One member raised the possibility of addressing the conformity of restriction dossiers at plenary meetings instead of in written procedure and inquired why members’ comments had not been responded to during the conformity check stage. The Chair responded that the work had followed the procedures agreed by the Committee, but whether this is a good way of working or not would need to be assessed. She pointed out that the routines for responding to comments during the conformity check need to take into consideration the short timetable of the conformity check. The Chair informed that the Secretariat was preparing a proposal for revision of the conformity check procedure where among others these issues had been considered.

The Chair asked the (co-)rapporteurs of the April dossiers to give their view on the conformity check process. The (co-)rapporteurs expressed their appreciation of the cooperation between their counterparts, support from the Secretariat, the role of SDM as a general liaison, and the possibility to meet face-to-face as well as via teleconference with all those involved before and at the start of the conformity check. They concurred with the experience of SDMs in relation to the difficulties of defining the borderline between the conformity check and opinion formulation.

In order to optimise the consultation process one of the (co-)rapporteurs raised a question whether it would be possible to obtain clarifications on the dossier content from the dossier submitter during the conformity check and, based on these, to allow the dossier submitter to submit a revised dossier for public consultation. Alternatively, a clarification note could be published on the consultation web page together with the dossier. Furthermore, he proposed to establish a working document containing considerations under each heading used in the conformity check report template on conformity, desirable information, first observations, questions to the dossier submitter, questions/remarks to be considered by stakeholders during public consultation, etc. The Secretariat responded that restriction dossiers should not be modified prior to the consultation apart from editorial changes. However, it was too late for the first two dossiers. The ECHA consultation web page for restrictions includes a possibility to add restriction report specific questions that could address unclear issues in the dossier in addition to the generic invitation to provide comments on the report and the proposed restriction.

Another (co-)rapporteur highlighted the thin line between the “desired” and “required” information in the conformity check in his presentation and proposed a tool to distinguish between the two. He pointed out the need for revision of the conformity check questions in order to reduce overlaps and improve clarity and

questioned whether conformity check is an appropriate means for asking for desirable information.

In addition, the (co-)rapporteurs raised the attention of the Secretariat to the limited relevance of checking of the IUCLID file for SEAC and pointed out technical difficulties with posting messages through the CIRCA Newsgroup Service.

With regard to the DMFu dossier, the (co-)rapporteurs had identified the adequacy of the starting point (baseline) and the scope of the restriction (the question of including mixtures) as issues that needed to be addressed during the opinion forming. The level of SEA information in the DMFu dossier was deemed proportionate for the case by the (co-)rapporteurs.

The Secretariat also gave its reflections on the conformity check after the experience with the first two dossiers. The Secretariat elaborated further on the purpose of the conformity check by reminding that it is a check against the requirements of Annex XV (section 3) of the REACH Regulation and by stressing that it should not pre-empt the preparation of draft opinions. It had been evident also from the first restriction dossiers that the restriction cases differ; each case is unique and the information and assessment requirements need to be proportionate. The Secretariat presented also some first thoughts on possible updates of the conformity check template, in particular with regard to usefulness of the short descriptions of why the dossier conforms, clearer distinction of desirable information, overlap between current questions, and to stress the illustrative character of the conformity check questions instead of using them as an ultimate checklist, etc. It was proposed that the development of the template would be further discussed after experiences with the first four dossiers. The Secretariat also suggested some possibilities for modification of the conformity check procedure.

SEAC supported the proposal of the Secretariat to evaluate and possibly revise the current working procedure and conformity check template. The Chair asked SEAC to consider the formation of an informal working group (together with RAC) for the revision of the conformity check questions and procedure after the conformity check of the first four dossiers has been carried out.

One stakeholder observer representative clarified that they had submitted comments during the conformity check of the first two restriction dossiers in the belief that they were allowed to do so. The Chair responded that to the extent stakeholders' comments are related to the opinion formation they should be submitted at the opinion making stage. The Secretariat would provide further guidance on how stakeholder observers should submit comments on the conformity check.

The Secretariat gave an *update of the work plan* describing the main steps of the restriction process for the dossiers (to be) submitted in 2010 that would take place in the next half a year. The Secretariat informed members that due to the summer holiday season the most convenient time to launch the conformity check for the dossiers to be submitted in June would be 16 August. The Secretariat also proposed a few adaptations of the conformity check procedure for these dossiers; namely, due to the late start, to provide SEAC with the version of the conformity check report reviewed (prepared) by the (co-)rapporteurs on day one of the conformity check

process, to run only one commenting round during the conformity check and to agree the conformity in the plenary meeting in September. SEAC agreed with this proposal of the Secretariat.

d) Tracking the opinion making including public consultation

The Secretariat described how the public consultation for restriction dossiers would be organised. It was highlighted that the Secretariat intends to encourage interested parties to provide comments early in the process.

The Secretariat presented a web page, currently under construction, that will give an overview of the restrictions under consideration in the form of a tracking table. On this web page, external stakeholders will be able to find information about the status of the dossier and relevant documents. A short summary of the restriction report will be available on the website to help stakeholders to assess whether the case is relevant for them. This summary will also be annexed to the press release to be sent to media and via ECHA e-News to reach major European stakeholders. Stakeholders will be able to access the commenting form through the same web site. The commenting form will allow submission of either general or specific comments as well as answering specific questions defined by the Secretariat and (co-)rapporteurs. The Secretariat plans to invite MSCA to distribute the information about the start of the consultation to stakeholders at the national level.

One member noted that it is important how the communication is organised. He suggested ECHA to ask European stakeholders to alert their national constituencies about the start of the consultation in order for them to channel their comments via the European level stakeholder organisations. Nevertheless, the Secretariat responded that in case of more diverse target groups MSCA might be in better place to reach relevant players.

The Secretariat agreed to consider further how the information on the public consultation is going to be communicated and how to contact organisations at EU level.

11) AOB

- Information Note of a Project on Abatement Cost Curves

The Secretariat gave a presentation on an ongoing Member States project on abatement costs and ECHA's plans for a follow-up Workshop to discuss and build on the outputs from project. The project aims at establishing capacity in ECHA and Member States to assess costs of manufacturing, placing on the market or using alternative substances or techniques, relevant for both, the authorisation and

restriction processes. The project aims at getting more information on costs of abatement for industry. Once this is known, these costs can be aggregated into cost curves which might be used as a basis for an abatement cost model. Members were asked to contact the Secretariat if they are interested to participate and /or contribute to the project and/or Workshop.

12) Action points and main conclusions of SEAC-7: Day 2

The Secretariat presented the action points and main conclusion from day 2 of SEAC-7. The adopted action points can be found in part 2 of the minutes.

Part 2. Adopted action points

MAIN CONCLUSIONS & ACTION POINTS - SEAC-7, 2-3 June 2010

(Adopted at the SEAC-7 meeting for Day 1 and in written procedure for Day 2)

Agenda point	
Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
2. Adoption of the agenda	
The revised agenda (SEAC/A/07/2010_rev.1) was adopted with the following additions under AOB: <ul style="list-style-type: none"> • Presentation of project on abatement cost curves. 	SEAC-Secretariat to upload the revised agenda to SEAC CIRCA IG as a part of the meeting minutes.
3. Declarations of conflicts of interest to the Agenda	
One member declared a conflict of interest, being head of unit responsible for preparing the DMF and Lead dossier, he will refrain from commenting on these dossiers. NB: Another member expressed a conflict of interest for similar reasons (active in the preparation of the dossiers)	SEAC to take account of this in future decision making when a quorum is needed regarding the discussion in SEAC on the dossiers on DMFu and Lead.
4. Administrative issues	
4a. Changes in the SEAC composition/nominations	
SEAC was informed of the changes in the composition of SEAC.	
4b. Report from DG SANCO WG	
SEAC was updated on the last meeting of the DG SANCO working group.	Secretariat to keep SEAC updated of the developments in the DG SANCO project and to send the case studies to SEAC.
Outcome of written procedures	
SEAC was informed of the outcome of the written procedures on the conformity check for DMF and Lead.	
SEAC was informed of the status of the contracts for remunerations of the rapporteurs. SEAC was informed that the Terms of Reference (which have been agreed earlier by SEAC) are the core of the contracts.	Secretariat to circulate the service request and all the annexes to it by 4 th of June. Secretariat will also circulate to the involved rapporteurs, copies of the contracts during the meeting.
5. Status report of the action points of SEAC-6	
SEAC took note of the status report concerning the action points of SEAC-6.	

Agenda point	
Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
6. Feedback from other bodies	
	<p>SEAC to start developing a manual of decisions for SEAC.</p> <p>To start a discussion on presence of case owners (applicants) in SEAC meetings</p> <p>Secretariat to circulate Forum's letter regarding harmonization of enforcement to the Commission to SEAC.</p> <p>Secretariat to provide link to the Commission homepage on REACH enforcement where the study on the penalties can be found. http://ec.europa.eu/environment/chemicals/reach/enforcement_en.htm</p> <p>Interested members and observers can contact the Secretariat if interested to participate and/or contribute to the workshop and/or to the abatement cost project</p> <p>Secretariat to keep SEAC updated of the developments in the DG ENV project.</p>
7. Reporting back from meetings with rapporteurs	
<p>SEAC was informed of the discussion that took place in the informal meeting with the rapporteurs that took place on the 15th of March in Helsinki.</p>	<p>Secretariat to investigate further the possibilities to schedule RAC and SEAC meetings in the same week (or back-to-back).</p> <p>Secretariat to clarify technical possibilities of tele- or videoconferencing for attending RAC and SEAC meetings by rapporteurs.</p>
8. Authorisations	
	<p>Members to use the possibility to comment on the guidance documents on authorisation through their respective MSCA.</p>
8a) Conformity check	
<ul style="list-style-type: none"> • Content of conformity check 	
	<p>Secretariat to draft a format to document the outcome of the conformity check for the SEAC-8 meeting in September.</p>

Agenda point	
Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
• Working procedure	
SEAC agreed to leave the conformity check procedure for authorisation applications as it currently is, the document will be updated after the discussion in RAC. In case there are no significant changes to the document following this discussion then the document will be put forward for agreement in SEAC-8	<p>Secretariat to update RAC about the discussion on this document in SEAC-7</p> <p>Members to submit any major comments in writing to the Secretariat.</p> <p>Secretariat to consider further how to communicate appropriately the status of the conformity to the applicant (including e.g. a disclaimer).</p>
8b) Formulation of SEAC opinion on authorisation applications	
• Content of final Commission decisions and their effect on the format of the opinions	
SEAC supported the overall approach presented in the discussion note.	<p>Secretariat to open a CIRCA newsgroup on the document by the 4th of June. The newsgroup will be open for three weeks.</p> <p>Secretariat to develop a template for the opinion on authorisation applications</p>
• Elements of the working procedure for developing opinions	
SEAC supported the overall approach presented in the documents on the elements of the working procedure	<p>Secretariat to open a CIRCA newsgroup on the document by the 4th of June. The newsgroup will be open for three weeks.</p> <p>Secretariat to develop a working procedure on the development of opinions on authorisation applications for the meeting in September.</p>
8c) Terms of reference for (co-)rapporteurs of RAC and SEAC for authorisation applications	
SEAC supported the overall approach presented in the draft terms of reference.	Secretariat to open a CIRCA newsgroup on the document by the 4 th of June. The newsgroup will be open for three weeks.
9. Action points and main conclusions of SEAC-7: Day 1	
SEAC agreed on the main action points and conclusions.	Secretariat to upload action points and conclusions to CIRCA by 4 June.

10. Restrictions	
10c.	
SEAC to familiarize itself with the work on further restriction on cadmium in jewellery. As the approach used for this restriction might contain valuable lessons for the Lead in jewellery restriction.	Secretariat to upload the study on cadmium to CIRCA (Socio-economic impact of a potential update of restrictions on the marketing and use of Cadmium, RPA Ltd, April 2010).
SEAC agreed on the need to evaluate and possibly revise the current working procedure and conformity check template.	Secretariat to collect ideas and proposals for update of the conformity check questions. SEAC (together with RAC) to consider the formation of an informal working group for revision of the conformity check questions and procedure, after the conformity check of the first four dossiers has been carried out.
SEAC concluded on the need to discuss as often as possible the outcome of the procedures in plenary meetings for the time being.	Secretariat to carefully plan meetings so as to match the timing of the procedures Secretariat to clarify when stakeholder observers can submit comments on the conformity check.
10e. Update of the work plan	
SEAC agreed to use only one commenting round for the dossiers that are expected to arrive in June. The document that will be submitted for this commenting round will be the draft conformity check report. The draft final conformity report will be submitted to SEAC-8 for agreement.	
10d. Public consultation as part of the restriction process	
	Secretariat to further consider how the information on the public consultation is going to be communicated and how to contact organisations at an EU level.
12. Action points and main conclusions of SEAC-7: Day 2	

Part 3. List of Attendees

SEAC Members:	Advisers to the SEAC Members:
BASTOS, Henri	BEEKMAN, Martijn (adviser to LUTTIKHUIZEN, C.)
BENDL, Jiri	DOMINIAK, Dorota (adviser to RYDLEWSKA, I.)
BROKAITE, Kristina	FIORE, Karine (adviser to BASTOS, H, representative of a dossier submitter)
DALTON, Marie*	GULBRANDSEN, Magnus Utnus (adviser to LANGTVET, E.)
DANTINNE, Catheline	KIISKI, Johanna (adviser to SALONEN, H.)
FANKHAUSER, Simone	VERMANDE, Emilie (adviser to BASTOS, H, representative of a dossier submitter)
FEYAERTS, Jean-Pierre	
FOCK, Lars	Representatives of the Commission:
FORKMAN, Mats	GIL, Sebastian (DG ENV)
FURLAN, Janez	KUBICKI, Michal (DG ENTR)
GEORGIOU, Stavros	
GUSTAFSSON, Lars	ECHA staff:
GRANDI, Silvia**	ANFÄLT, Lisa
KOZAK, Kristof	JAQUEMIN, Katline
LANGTVET, Espen	KARHU, Elina
LUTTIKHUIZEN, Cees	KOWALSKI, Ulrike
RYDLEWSKA-LISZKOWSKA, Izabela	LANKOSKI, Jussi
SALONEN, Heikki	LIPKOVA, Adriana
SCHUCHTAR, Endre	LOGTMEIJER, Christiaan
SIMON, Franz-Georg	MERKOURAKIS, Spyridon
SUSNIK, Marko	MÜLLER, Birgit
TELLING, Aive	PELTOLA, Jukka
THEOHARI, Maria	SADAM, Diana
THIELE, Karen	SIHVONEN, Kirsi
TIRCHILA, Luminita	STOYANOVA, Evgenia
VARIZ, Paolo	THUVANDER, Ann
VOIVONTAS, Dimosthenis	VAINIO, Matti
	YLÄ-MONONEN, Leena
	Stakeholder observers:
	DIMTCHEVA, Ralitza (UEAPME))
* invited expert replacing McGUINNESS, Sharon	HOLLAND, Michael (EEB)
** invited expert replacing RECCHIA, Luca Maria	LEENAERS, Joeri (Eurometaux)
	MUSU, Tony (ETUC)
	VYBOLDINA, Elena (CEFIC)

List of annexes

Annex I List of documents submitted to the members of the Committee for
Socio-economic analysis

Annex II Final Agenda

Annex I

Documents submitted to the Members of the Committee for Socio-economic analysis.

Revised Draft Agenda, Seventh meeting of the Committee for Socio-economic Analysis	SEAC/A/07/2010_rev.1
Feedback from other bodies	SEAC/07/2010/09
Revised Discussion Paper on the scope and content of conformity check of authorisation applications	SEAC/06/2010/05_rev.1
RCOM on the Discussion Paper on the scope and content of conformity check of authorisation applications (SEAC/06/2010/05)	SEAC/07/2010/10
Revised draft working procedure for RAC and SEAC on conformity check of authorisation applications	SEAC/06/2010/06_rev.1
RCOM on the draft working procedure for RAC and SEAC on conformity check of authorisation applications (SEAC/06/2010/06)	SEAC/07/2010/11
The content of final Commission decisions and their effect on the format of the opinions of RAC and SEAC on authorisation applications	SEAC/07/2010/12
Elements of RAC and SEAC working procedure for developing opinions on the applications for authorisation	SEAC/07/2010/13
Draft Terms of Reference for (co-)rapporteurs of RAC and SEAC for authorisation applications	SEAC/07/2010/14
Provisional Meeting dates 2011	SEAC/07/2010/15 (room document)

Final Agenda
Seventh meeting of the Committee for Socio-economic Analysis

2-3 June 2010
ECHA Conference Centre (Annankatu 18, Helsinki)
2 June: 09:00 – 18:00
3 June: 09:00 - 16:00

1st Day, 2 June

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

SEAC/A/07/2010
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Administrative issues

a) Changes in the SEAC composition/nominations

For information

b) Report from DG SANCO WG (Stavros Georgiou or Mats Forkman)

For information

Item 5 – Status report of the action points of SEAC-6

For information

Item 6 – Feedback from other bodies

Feedback from Workshop on Assessing Health and Environmental Impacts in the Context of Socio-Economic Analysis under REACH: 19th May 2010, Brussels (Sebastian Gil, DG ENV)

SEAC/07/2010/09

For information

Item 7 – Reporting back from meetings with rapporteurs

Item 8 – Authorisations

a) Conformity check

- Content of conformity check

SEAC/06/2010/05_rev.1

For discussion

SEAC/07/2010/10 (RCOM)

For information

- Working procedure

SEAC/06/2010/06_rev.1

For discussion and possible agreement

SEAC/07/2010/11 (RCOM)

For information

b) Formulation of SEAC opinion on authorisation applications

- Content of final Commission decisions and their effect on the format of the opinions

SEAC/07/2010/12

For discussion

- Elements of the working procedure for developing opinions

SEAC/07/2010/13

For discussion

c) Terms of reference for (co-)rapporteurs of RAC and SEAC for authorisation applications

SEAC/07/2010/14

For discussion

Item 9 – Action points and main conclusions of SEAC-7: Day 1

Table with Action points and decisions from SEAC-7: Day 1

2nd Day , 3 June 2010

Item 10 –Restrictions

a) **General restriction issues**

b) **Presentation on Dossiers by dossier submitter¹**

For information

c) **Restriction Annex XV dossiers**

DMF – Rapporteurs’ view on conformity check

Lead and its compounds in jewellery – Rapporteurs’ view on conformity check

For discussion

d) **Tracking the opinion making including public consultation**

For information

Item 11 – AOB

Item 11 – Action points and main conclusions of SEAC-7: Day 2

Table with Action points and decisions from SEAC-7

¹ In case dossiers are found to be not in conformity then the dossier submitter will not be invited to the meeting.