EUROPEAN COMMISSION

ENVIRONMENT DIRECTORATE-GENERAL
Water, Chemicals & Cohesion
Chemicals

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Chemicals, Metals, Forest-based & Textile Industries
REACH

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SUMMARY RECORD OF THE

1st Meeting of the Competent Authorities for REACH and CLP (CARACAL)[1, 2]

16-17 March 2009

Centre A. Borschette, Rue Froissart, 36

BE-1040 Brussels, Belgium

The meeting was jointly chaired by Ms Astrid Schomaker (DG ENV) and Mr Graham Willmott (DG ENTR). Mr. Jukka Malm (ECHA) led the discussions on the agenda points concerning the work of the ECHA.

The Chair made the following introductory remarks:

- Welcomed all participants and in particular the CLP CAs that were joining for the first time.
- COM hoped that the new format of the meeting will be workable. The combination of CAs for REACH and CLP at one meeting was the formula favoured by those CAs who responded to the COM request for suggestions at the last meeting.

[1] Including information about the written procedure on substances ionised in water – see page 21.

[2] Adopted at the 2nd meeting of CARACAL 15 June 2009.

- The observers were informed about the Commission's transparency initiative and they were encouraged to register at http://ec.europa.eu/transparency/regin.

- COM apologised for the late uploading on CIRCA of one document that was up for endorsement.

1. ADOPTION OF THE DRAFT AGENDA

COM drew the attention to the discussion at the last meeting about making adopted agendas and minutes publicly available on the Commission's website. As a result, the structure of the minutes and agendas will be adapted to a new, slightly less detailed format.

The Chair indicated that a number of documents received from CAs and observers had been uploaded to CIRCA and would be dealt with under the appropriate agenda items. COM also acknowledged the useful contributions to meeting documents that had been received from Member States and observers. Copies of documents uploaded late on CIRCA were available in the meeting room.

The following modifications were made to the order of agenda points:

- closed session on follow-up to action point 9 concerning non-phase-in substances legally on the market on 31 May 2008: to be taken at the end of the first day
- item 14.1 on the Market Surveillance Regulation: to be taken immediately before lunch on the first day
- item 18.3: to be taken just after 17.1 on the second day.

The following items were added to the agenda point Any Other Business:

- background on the study on mixture toxicity,
- enforcement of pre-registration in Member States
- communication strategy on CLP.

With these changes the agenda was adopted.

2. FOLLOW-UP TO THE 6TH CA MEETING (15 AND 16 DECEMBER 2008)

2.1. Adoption of the Draft Summary Record

The DSR in the new format was introduced and adopted.

One MS indicated that the use of this new format decreases the level of information and increases the need for closed session with separate minutes. The minutes should therefore be complemented by a manual of conclusions.

AISE informed the meeting that the workshop to kick off a classification network has been postponed from 1 April to 1 September 2009.

2.2. Actions from the last meeting

As agreed at the 6th meeting a new version of the list of actions including the status of the actions had been uploaded on CIRCA one week in advance of the CARACAL meeting. An updated version of this new list was presented at the meeting with addition information on the remaining actions.

Concerning action 3.5 (outstanding from meetings prior to 6th meeting) the COM reported that discussions RIP 3.7 - "Guidance on Authorisation Applications" are still ongoing. These also affect RIP 3.9-2 "Guidance on Socio Economic analysis for Authorisation". Several MS underlined the importance of these issues and that there is a need for progress. It was agreed that an ad hoc working group should discuss possible solutions for progress during the lunch break. There was agreement that COM should draft an option paper on the issues before the next meeting.

COM will send out the letter to Member States' Ministries on resource requirements for REACH as soon as it has been signed by the Commissioners (action 4.4 in section A).

The DSR from closed session of the 6th CA meeting and final summary records from the closed session of the 4th CA meeting will be sent to MSCA by email as soon as possible.

ECHA informed the meeting about their follow up concerning the non-phase-in substances legally on the market on 31 May 2008. After the December CA meeting ECHA has contacted both the EU mission to the EU and the US Personal Care Products Council and had requested specific information on the number of substances that could fall into the category of substances that were lawfully on the market before 1 June 2008, but which do not have phase-in status, as well as on the number of EU based companies (importers or only representatives) that are expected to provide an inquiry and registration dossier for these substances. The US industry had responded shortly before this CA meeting that they were still in the process of discussing the request within their scientific and regulatory committees.

ECHA also reported that very few inquiries had been received which could potentially be related to a substance used in a cosmetic product.

The chair informed the meeting that the MS had discussed the matter in a closed session and the conclusion was that there will be no more discussion of this matter at the CARACAL meeting.

Concerning the text for disclaimers (action 14) COM distributed a room document with a proposal for two revised texts to be used. The text was endorsed with a small modification in the last sentence. The endorsed version of the disclaimer on will be uploaded on CIRCA and used on the relevant COM documents to be put on COM website.

The rest of actions from 6th CA meeting had either been done or were dealt with under relevant agenda points during the meeting.

3. ORGANISATIONAL MATTERS

3.1. Inclusion of the work on restrictions in the CA meetings after 1 June 2009

COM introduced the issue and reported the conclusions from the Limitation Working Group (LWG) meeting held on 19 December 2008 and the few comments on the issue received from MS.

During the consultation with the Member States, it was agreed to continue the restriction work within the framework of the CARACAL meeting after the 1 June 2009. This will be a learning process and only on the basis of experience gained, the CARACAL members will at a later stage decide if there is a need for a specific sub group on restrictions.

If conflicting issues come up in RAC and SEAC, they might also be brought to the CARACAL meeting at an early point if this is suitable. This could also facilitate input from special industry sectors. However, duplication of RAC/SEAC work must be avoided. The 3 month deadline in REACH is short and clear opinions from the Committees will be needed on the basis of which COM can prepare any draft amendments to Annex XVII within this deadline.

There will be a last LWG meeting on the 28 of April and COM will ensure the continuity of this transitional period to REACH.

3.2. Rules of Procedure for CARACAL

COM introduced the proposal for rules of procedures (RoPs) for inclusion of the CLP regulation into for the REACH CA meeting. At the same time, COM suggested to change the name of the group to Competent Authorities for REACH and CLP (CARACAL). COM has also to take into account that REACH and CLP items should occupy distinct parts of the agendas to facilitate travel and other organisational considerations for delegates. The proposed modifications to integrate the work on CLP were generally welcomed.

The following issues were discussed:

- One MS requested to get a specific notification for written procedures per e-mail, as these might be missed within the high number of other automatic CIRCA notifications. COM agreed to do this. However, it was agreed that it is not necessary to mention this explicitly in the RoPs.
- Several MS wished to include a reference to a Manual of Conclusions into the ROPs. COM did not see this as a point for the RoPs and referred to the next agenda point for discussion of this issue.
- One MS asked to consider translation at the meeting and a bigger room. COM replied that this is unfortunately not possible due to practical and budgetary constraints.
- One MS suggested that items for discussion in closed sessions also could be suggested by MS. COM and ECHA agreed to consider such proposals from MS.
- The public version will be the only version of the minutes.

The RoPs were adopted as proposed by COM.

3.3. GRIP[3], New style

COM introduced the item and welcomed the proposed format for the future operation of GRIP. It supported GRIPs continued work to prepare CARACAL discussions. GRIP should act as an informal group which can organise itself in the way which fits best to the questions it wants to address.

In addition, the co-ordination between REACH Help-Net[4] and CARACAL should be improved. The new procedure to update FAQs will be one element and ECHA will upload the procedure on CIRCA once approved by REHCORN[b] the following week. Critical questions which cannot be solved through consensus at the level of REHCORN should be forwarded to COM at a more regular basis and at an earlier stage than today. This should be done as soon as it is clear that solutions might not be straightforward. COM will forward the issue to CARACAL unless the issue can be dealt with directly by COM. GRIP was invited to provide input to such issues as well as other questions it deems important to be discussed at CARACAL meetings. There was support from the meeting to maintain GRIP as an informal group. It was considered as a useful tool and a useful bridge between REHCORN and CARACAL.

Concerning the idea of a Manual of Conclusions, COM cautioned against the multiplication of documents to keep track of interpretation questions. COM proposed to first use the existing tools such as guidance, FAQ, interpretative documents such as the ones on waste and Annex V, meeting minutes etc. and then investigate after experience has been gained with the use of existing tools if creating a new document which would need to be kept up to date and consistent with the other documents would be more efficient. COM therefore suggested the creation of a tracking document instead which would allow finding the references to the discussions at CARACAL and giving the links to where in guidance, FAQ etc. the conclusions are reflected. The meeting supported the COM proposal to investigate ways of tracking the conclusions of issues discussed in CARACAL. COM will prepare a proposal for a tracking system for conclusions on REACH interpretation questions before the next meeting. The item should be discussed further at the next meeting.

A document on "REACH applying at sea and on seagoing vessels" and another on yeast extract and the guidance to Annex V were briefly introduced. Both issues are questions received by a national helpdesk. There was a short round of initial comments. In addition MS were asked to send comments in writing to the first document to the authors before 7 April 2009. COM will react on the yeast extract paper as soon as possible after 7 April 2009. Both issues will be brought forward to the next CARACAL meeting.

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[3] Group on REACH Implementation Problems

[4] EU National REACH Helpdesk Network which consist of :

a. National Helpdesks of the Member States and the ECHA helpdesk

b. REACH Helpdesk Correspondents' Network (REHCORN)

c. REACH Helpdesk Exchange Platform (RHEP)

4. UPDATE ON REACH ANNEXES AND IMPLEMENTING LEGISLATION INFORMATION

4.1. Annexes I, II, IV, V, XIII, XVII

COM informed that the Commission Communication on Annexes I, IV and V is in the pipeline and it is expected to be finalised shortly.

Some MS asked about the status of the inclusion of carbon in Annex V. COM replied that it is currently considering possible solutions and will consult CASG Nano on the outcome of the analysis.

Annex II will have to be updated to include the necessary changes coming from the newly adopted CLP Regulation and proposed to use the CA sub-group on the Annexes of REACH to discuss the draft updated Annex II. CARACAL agreed to this proposal and COM informed that it would try to organise the first meeting to consider the draft in May.

Regarding the syrups and starch issue COM stated that this requires a discussion on content and cannot be dealt with by means of a corrigendum or a clarification in the Guidance. COM will report on actions taken concerning the syrups and starch issue before the next meeting.

COM reported the following concerning Annex XIII:

- At the CA meeting in December 2008, COM presented the outcome of the Annex XIII review. The conclusion of the review is that Annex XIII needs to be amended in order to take into account the experience on the identification of PBTs.

Thus, the document discussed at the December CA meeting also contained a draft text with a view to prepare the amendment of Annex XIII. Prior to that meeting, at the meeting and following that meeting, COM has received several comments and letters from MS and stakeholders as well as from the European Parliament. The main concern voiced is that the text as was submitted to the CA meeting from a legal perspective will in practice not allow all information to be used in a weight of evidence approach.

COM has taken good note of the concerns raised. COM agrees that the legal text on Annex XIII should allow for the use of all relevant information, using a weight of evidence approach, in the identification of PBTs/vPvB substances by comparing this information with the criteria. COM is now reviewing the draft text with a view to ensuring that the text that will be finally submitted to the applicable Comitology procedure meets the objective of the review to take the above experience in the identification of PBT/vPvB substances into account while providing sufficient legal clarity.

COM reported on Annex XVII
At the REACH Committee meeting on 20 February 2009 Annex XVII was discussed. Even though the entry on asbestos fibres had triggered some critical discussions, the proposal received the favourable opinion by the Committee. The translation of changes has already been done and the draft Commission regulation has been sent to European Parliament and Council in March 2009. .

Two MS requested clarification with regard to the inventory of more restrictive national measures to be published by the Commission in accordance with Article 67(3) of REACH, COM replied that, following detailed consultations with Member States at only two more stringent restrictions were to be listed (both from NL). COM recalled that the inventory will only contain national measures that are more stringent than restrictions in Annex XVII – national restrictions in the non-harmonised area (i.e. where no Community rules exist) will not be included. COM also reminded that the inventory of such more stringent restrictions has to be published by 1 June 2009.

One MS asked about the procedures for future inclusions of CMRs and the remaining substances under discussion in the LWG. COM replied that for the next Limitations WG the following substances will continue to be discussed: 1) acrylamide and 2) the revision of the restrictions on Mercury in medical devices and other measuring devices. The fast-track procedure in Article 68 (2) to include newly classified CMRs into Annex XVII will be used after they have been included in the CLP Regulation. COM also announced that the restrictions concerning dichloromethane, organostannic compounds and lamp oils/grill lighters, which are in the process of being adopted still under Directive 76/769/EEC will be included in Annex XVII at a later stage in accordance with Article 137 of REACH.

One observer requested COM to act in order to correct misleading information on the EU restrictions concerning asbestos in Canadian newspapers. COM informed that it had prepared a letter for the EC Ambassador in Ottawa.

4.2. Implementing legislation
- 1st ATP of Test Methods Regulation

COM informed that a favourable opinion on the 1st ATP of Test Methods Regulation was given by the REACH Committee on 19 February 2009. Translation of changes has been done and the draft Regulation was sent to European Parliament and Council in March 2009. European Parliament scrutiny might last until 9 June, but hopefully there will be a faster reply. MS will also be asked to do a language check on their language versions. The report to European Parliament on issues raised concerning test methods has been uploaded on CIRCA.

There is a need to discuss working procedures at the next CARACAL meeting.

5. NANOMATERIALS: SUBSTANCE IDENTIFICATION

COM introduced the revised document and underlined the importance of endorsement of the document due to the ongoing work in the pre-SIEFs and the fact that companies are already taking decisions on substance identity in that framework. . COM had also received comments from some MS and CEFIC just before the meeting.

The discussion showed that there are still a lot of questions related to the phase–in status of nanomaterials, parameters to be used for the identification of nanomaterials either as physical forms of a substance or as a different substance as well as on the criteria for distinguishing nanoforms from the bulk substance. Several Member States as well as observers questioned the added value of this document. Some other MS were of the opinion that a document will be useful if it provides clear answers to the most important questions.

Based on the discussion at the meeting COM concluded that it would consider preparing a short version of the document limited to the key non-controversial aspects that would already contribute to a more coherent approach to nanomaterials in the pre-SIEF discussions. The COM will prepare the document in close co-operation with a few MS and in case of a feasible compromise is achieved, it will be sent for written approval to the members of the CARACAL. The specific issues will be brought back to CASG Nano for further discussions.

6. EXEMPTIONS IN THE INTEREST OF DEFENCE (ART. 2(3))

The issue had been put on the agenda after input from different MS as well as discussions in other fora. As this is a MS responsibility, one MS introduced the issue and informed the meeting about their current practice. The short discussion afterwards showed that several MS have similar provisions for exemptions given by defence ministries after consultation of health and economy ministries. Some MS wanted some type of co-ordination mechanism and, as far as possible, mutual recognition of exemptions. Other MS underlined they would need further discussions before taking a position on mutual recognition. In addition it was considered important that representatives from different administrations within each MS should be in contact to secure good coordination of the issue. The Forum needs to be kept informed as well. There was an agreement that more time should be given for discussion of exemptions in the interest of defence at the next meeting.

7. IONIC MIXTURES

COM introduced the subject with one illustrative slide. As the document was sent out very late, there was no intention to ask for endorsement of the document at this meeting. However, it was considered important to reach agreement and to move this issue forward so that the guidance document can be changed as soon as possible. In addition, a Q&A pair on this issue might be drafted for inclusion into the FAQ. All MS that took the floor supported the approach proposed by COM and emphasized the need for a fast publication. One MS suggested to also address imported solutions in the document.

COM agreed to revise the document based on comments from participants. The final document should then be sent out for endorsement by written procedure. The time limit for the response will be 2 weeks as this is a matter of urgency. After approval ECHA will integrate the conclusions on this item into Guidance on Annex V as well as issue a Q&A pair for the FAQ.

8. REACH BASELINE STUDY

EUROSTAT presented a summary of the “baseline” study. This study aims to establish scores for the quality of information on risks from chemicals as well as on the degree of risks that are perceived at this stage. It is planned to repeat the assessment at a later stage to identify whether REACH has improved our knowledge of risks and contributed to

reduce risks from chemicals. The full report of the baseline study will be available shortly. There were no comments to the presentation.

9. COMMISSION REPORT ON REACH (2012)

COM presented the eight different objectives of the Commission Report in 2012. The first five objectives relate to the collection of data while the remaining three will be to provide a general overview of how REACH is working to that date, capture information with a view to carrying out future reviews and lastly to provide information on funding made available by COM for the development and evaluation of alternative test methods.

COM underlined the importance to acknowledge that this report is not only a duty but also an opportunity to make a useful analysis of REACH implementation. MS should provide written comments before 7 April 2009.

10. MS REPORTING UNDER REACH: PROGRESS REPORT

COM has launched a contract with a consultant concerning MS reporting under REACH. The contractor gave a progress report on the work done since the start of the project. This included the outline of a possible electronic reporting approach and the reporting on Task 1 and 2. Under Task 1 format is defined for information to be submitted under Article 117(1). Under Task 2, up to five existing IT tools are assessed which could be used to facilitate data extraction/encoding and reporting. As similar reporting request also exist within the Water Framework Directive, the contractor is also looking into if there are experiences from this reporting which can be used in the reporting on REACH. There have already been meetings with MS to define which information should be submitted by MS. The contractor would within the next weeks also contact some MS for more detailed discussion of the themes and information requirements.

One MS underlined the importance of knowing which data that will be included as soon as possible as these data are supposed to be reported within 15 months from now. COM will come back with more information as soon as possible.

11. THE STATE OF PLAY WITH REGARD TO PESTICIDES

A representative from DG SANCO gave a report on the update on EU draft Regulation concerning the placing of plant protection products (PPP) on the market. The important objectives of the proposal are the protection of human and animal health and the environment, to safeguard the competitiveness of agriculture, to provide for a common market and to speed up the decision making process. The formal approval of the proposal by Council is expected during spring 2009 and it is expected to entry into force in the middle of 2010. The major issues that have been discussed are zonal mutual recognition, substitution and comparative assessment, data protection and improved protection of animals, information of neighbours and criteria for approval. More information of the legislation is available at http://ec.europa.eu/food/plant/protection/evaluation/index_en.htm.

The new CLP regulation has clear requirements that classification dossiers for both PPP and biocides must be in IUCLID5. This format is, however, not widely used by all authorities. Several MS underlined the importance of co-ordination between the authorities responsible for REACH and CLP on the one hand and PPP and biocides on the other hand. It is important to have a better understanding of the data requirements, the possibility to exchange data between authorities and the required format of data in these different regulations. COM and ECHA informed the meeting that they had a lot of contact with EFSA (European Food Safety Agency) concerning these issues. However, due to the limited use of IUCLID5 for already created dossiers it might be necessary to find pragmatic solutions.

12. QUESTIONS FROM REHCORN

12.1. Notified substances below 1 t

COM presented the question about whether it is necessary to update a notification for a substance in volumes of less than 1 t (Annex VIIB/C substances) when it reaches the 1 t threshold or whether the first update is only necessary when the tonnage reaches 10 t. The arguments for the two possible answers to this question were put forward by COM. MS were asked to provide written comments by 7 April 2009.

13. FORMAT/CONSTITUTION OF REGISTRATION NUMBER ON SDS

One industry stakeholder underlined the concern that transfer of the full registration numbers down the supply chain would be violating business confidentiality and would raise major workability problems. One possible solution would be codification of the registration number. COM showed understanding of the potential practical problems such as the complexity of the supply chain, the frequent change of suppliers and the mixing of supplies from different suppliers. It showed also an understanding of the confidentiality concerns expressed by industry. However, due to lack of concrete proposals from industry, as promised at the last REACH CA meeting in December 2008, the progress of this issue has been hampered.

COM underlined the legal constraints in REACH that cannot be overlooked. According to its analysis, removal of the four last digits might raise compatibility problems with the regulation. COM analysed advantages and disadvantages of the different possible solutions like changing the structure of the registration number to random numbers without identifying the substance/joint registration, to integrate the registration numbers of different suppliers into an Annex of SDS or to allow coding and tracing mechanisms outside the SDS.

COM conclusions so far were that

- there seems to be a real workability issue and COM are ready to investigate practical solutions to reduce the burden for companies,

- the registration number to be indicated on the SDS needs to be registration specific and attributed by ECHA – hence it is impossible to just drop the four last digits,

- the solutions so far proposed by industry associations lack practical detail, so urgent action is needed to work out concrete solutions,

- in the absence of practical solutions (and until any practical solution is available), the full registration number needs to be indicated on SDSs.

COM invited comments on these conclusions and in particular asked Member States and observers to state clearly if they disagree with the above analysis, in particular the conclusion that the four last digits cannot be dropped, as this was the basis for any further work on practical solutions.

Some MS expressed doubts about the need for enforcement authorities to have registration numbers on SDSs and indicated that there might be different opinions about the intention of the legislator. Others agreed that there is a need to speed up the work and to find practical solutions which also work for enforcement authorities.

MS were asked to comment COM conclusions so far, including their legal arguments for this, in particular if MS consider that the four last digits are not necessary, before 6 April 2009.

14. REVIEW OF THE NEW APPROACH – WHAT APPLIES TO REACH?

14.1. Market Surveillance Regulation

COM gave a presentation of the new Market Surveillance Regulation. The Regulation was adopted in 2008 and enters into force on 1 January 2010. It provides a horizontal framework for market surveillance applying also to REACH in so far as REACH does not contain more specific provisions. One of the main elements is the requirement for Member States to present a market surveillance programme by 1 January 2010. It also makes the use of RAPEX obligatory and foresees an electronic exchange of data. Several MS argued that there is a need for further discussion at the next CARACAL meeting before concrete steps are taken. COM agreed to prepare a more detailed analysis paper on the practical implications of the Market Surveillance Regulation for REACH for next CARACAL meeting. In addition, the Forum will be kept informed.

15. OTHER INFORMATION POINTS

15.1. REACH Penalties

Article 126 of REACH provides that MS shall lay down the provisions on penalties applicable for infringement of the provisions of this regulation and shall take all measures necessary to ensure that they are implemented. By March 2009, 19 MS and three EEA-EFTA States have notified their provisions on penalties to COM. The process of launching infringement procedures against the remaining eight MS have started.

In December 2008, COM launched a contract for a study on MS penalties for non-compliance with REACH. The aim is to provide scientific and technical support to the COM to create an overview of provisions on penalties applicable for infringement the

REACH Regulation in the MS. The duration of the study is foreseen for 12 months and its results will be presented to the MS CA.

All MS' notifications containing their national provisions and additional information provided have already been forwarded to the contractor. The contractor will present the interim results of the contract at the next meeting in June 2009.

16. ECHA ACTIVITIES IN RELATION TO REACH

16.1. Progress report on Pre-registration and registration

ECHA provided a quick summary of the information provided in the paper for the meeting. Over 2.7 million pre-registrations were made by over 65,000 companies for over 146,000 substances; all of these figures were higher than predicted. The Agency had already produced a list of pre-registered substances in October, with updates in November and December and a further, final list would be published before the end of March.

In brief, all of EINECS, most of ELINCS and the list of no-longer polymers had been pre-registered; these comprised approximately 104 of the 146,000 on the list of pre-registered substances. A group of 17,000 without EC numbers but with CAS numbers had their identities confirmed by CAS, helping to refine the December list. For the final list a further small group had CAS numbers confirmed on the basis of their names. The remaining substances include a large number of multi-constituents (many of which may be individual substances pre-registered together) reaction masses, UVCBs, intermediates (which did not need to be registered under previous schemes) and mistakes. The latter may include names that do not follow standard nomenclature, names other than English or typographical errors. Future lists will have only minor changes to them.

ECHA has taken account of requests for deletion made before the pre-registration deadline in preparing the new list but the deletions are not reflected in REACH-IT. Companies that made mistakes in their pre-registrations are encouraged to use the new list to help them identify the correct substance and then to use the “similar to” tab in REACH-IT to allow them to enter the correct pre-SIEF.

Statistics were also presented showing the number of inquiries, on-site and transported intermediates, registration dossiers and PPORD notifications received so far. There had been a significant decrease in the number of dossiers accepted for further processing since REACH-IT took over verification (partly due to the number of blocked dossiers) but ECHA emphasised that they were working on measures to ensure that registrants knew what standards they had to achieve to register successfully.

Member states asked about substances for which no identity could be determined (if they are then registered, we will be able to verify their identity) those for which a registration was not made (registration is possible, for substances without the appropriate classifications, up to the 2018 deadline, after that, no market) about companies that have not pre-registered (an enforcement issue) about ECHA’s role in SIEFs (we will not take SIEFs over or manage them but we will assist generally) and support from MS (help in response to new substance claims would be very useful).

MS noted the large numbers of chemicals and the effect upon the system, the idea of targeting information to downstream users (who often do not see themselves as being in the chemicals industry), SIEF Formation Facilitators and the problems they are causing (ECHA had produced a News Alert on this issue), concerns that a low number of dossiers passed the completeness check (REACH-IT issue, see above) and questions related to a specific industry association and an individual company. MS also noted that some banned substances were pre-registered.

16.2. REACH-IT

ECHA gave an overview of the progress made in the development of the REACH-IT system in 2008 highlighting that most of the efforts had been put on pre-registration and pre-SIEF aspects. A roadmap for 2009 was presented with several areas of development: i) continuation the industry functionality by improving the current software and user interface and adding new modules; ii) access to Member States Competent Authorities; iii) first phase of dissemination; iv) start of the C&L inventory build.

The CSA tool development was also briefly presented in order to mention current challenges in the project in particular on scientific aspects, as gaps in the existing guidance on information requirements had been identified leading to difficulties to lay down IT specifications for the IT system and consequently delays in the execution of the work.

At the question raised on one MS on translations, ECHA reported that the main chapters of the IUCLID user manuals had been translated in all EU languages. These translations were available on the IUCLID web side. Regarding REACH-IT, there was a need to improve the user interface so that text could be frozen before being translated. In addition, there was a need to identify what should be translated.

At the question raised by one MS on the status of the IT system for enforcement authorities, ECHA informed that an analysis of the needs would be done when the final report of the forum working group would be finalised.

16.3. Evaluation of new and existing substances

ECHA expressed apologies for not being able to provide the guidance part for notified substances as there were still some open legal points that needed to be solved between ECHA and the Commission. The aim is to have a draft guidance for discussion in the next CARACAL-meeting.

The guidance for evaluation of transitional existing substances was well received and there were no comments on the document during the meeting. AT, NL, FR and UK replied already in the meeting that they will be able to take the responsibility of a Rapporteur for substances listed in Commission Regulation 465/2008. MSCAs are expected to confirm agreement on their nomination by 3rd April 2009. They can also by that same deadline provide comments on the document. After that the document will be finalised. OECD secretariat expressed their interest to get any updated RAR for their information also.

16.4. Report on transitional dossiers submitted under article 136(3)

ECHA presented the issue and explained the work they had done to make the content of the information that is present in the transitional dossiers better accessible for the RAC and SEAC and the MSCAs. The dossiers characterisation sheets will be made available through CIRCA, the dossiers themselves will as soon as possible be made available on ECHAs website.

In response to a question by one MS ECHA confirmed that it had also received the RA dossiers for the voluntary metals risk assessments (lead and copper) and would make these also available.

In response to a question by one MS regarding the follow up to the conclusions of the risk reduction strategies that were agreed in the past COM informed the meeting that a letter was going to be sent out to different Commission services in which the status for these dossiers would be explained and reporting would be requested regarding the progress of the implementation of the recommendations. The progress would be reported back to future CARACAL meetings.

16.5. ECHA workshop on Authorisation and the Candidate List

- Draft workshop report

  ECHA presented the outcome of the workshop on Authorisation and the Candidate List as Risk Management Instruments which was held in Helsinki on January 21-22 2009. The presentation focussed on the draft recommendations and follow-up actions.

  The Commission services welcome the conclusions of the ECHA workshop and congratulated ECHA for the successful organisation and running of the workshop. COM appreciated that the workshop had managed to conclude on a number of common views which would contribute to an overall co-ordination among the Commission, ECHA and the Member States on the implementation of the Authorisation system. COM particularly welcomed the proposal to conduct the analysis of the best risk management options as early as possible, preferably before the introduction of a new Annex XV dossier. COM also welcomed the open discussion that took place in Helsinki on the aim of the candidate list and on the reasoning for including a substance therein and agreed that, at this stage, it is best to focus the efforts on identifying the “relevant” substances for inclusion in the Candidate List and, furthermore, eventual prioritisation for inclusion in Annex XIV. In this context, the initiative taken by some MS to set up an expert group to pre-screen substances that have already been identified as fulfilling the SVHC criteria of article 57 for their possible inclusion in the candidate list and grouping those substances in “packages” was welcomed as it would provide a basis for asking ECHA to prepare annex XV dossiers accordingly to the conclusions and working procedures agreed within the group and with the other competent authorities. The COM showed its willingness to participate and contribute to the work of the MS working group.

In the further discussion several Member States took the floor and congratulated ECHA for organising the workshop and the successful outcome. One MS commented that the resources needed for carrying out enforcement actions should not play a role in the analysis for the bets risk management option. Another MS noted the importance of early discussions between Member States and stressed the fact that the workshop report still needed to be adapted to include the conclusions regarding the so-called 'grouping approaches'. Another MS concurred on the conclusion of the workshop that the candidate list is the only tool in REACH to identify PBT and vPvB substances and asked for confirmation that for substances that have been identified and have entered the candidate list the restrictions process could still be followed.

An observer expressed their concern about the proposed frequency for up-dating the candidate list because of the working implication for their members related to the article 33 obligations. ECHA responded that these considerations were duly considered by the workshop participants who nevertheless believed that a frequency of one or twice a year depending on the number of incoming dossiers would be appropriate.

ETUC welcomed the draft conclusions of the workshop and informed the meeting of the foreseen publication of the Trade Union priority list for authorisation that would be published by the end of March. H&E alliance also welcomed the draft conclusions and informed the meeting about their recent information leaflet for consumers about new rights under REACH "Harmful chemicals in the products you buy?".

The chair concluded that the meeting supported the workshop conclusions and recommendations and that ECHA would soon after the meeting publish the final workshop report on its website. ECHA would report regularly on the progress made on the implementation of the recommendations.

- MS follow-up activity on Candidate List

One MS informed the meeting about the progress made by the informal subgroup since the workshop in January referring to the work plan that had been made available to CARACAL via CIRCA in advance of the meeting. The MS informed the meeting that in particular further information was necessary on use of and exposure of the potential candidate substances as this information would be crucial for the decision to not prioritise certain substances at this stage. Further written comments from the meeting were requested before the end of March.

In response to interventions made by some of the participants the MS leading the informal subgroup stressed that the intention of the exercise is not to de-prioritise substances but to prepare some sort of working list with 'work packages' which MSCAs or COM could potentially pick up to work on. It was recognised that in any case it has to be decided which of the substances on this 'source list' will be more urgent for preparation of Annex XV dossiers taking into account that resources of the MS's and ECHA will be limited.

16.6. Update on RoI and Annex XV dossiers

ECHA presented the issue which contained various issues regarding the working processes and timelines for the Registry of Intent and the submission of Annex XV dossiers.

After discussion the meeting agreed to the timelines for submission of Annex XV dossiers for Substances of Very High Concern that were proposed by ECHA (August 3rd 2009, February 8th 2010 and August 2nd 2010). A suggestion was made that for the next recommendation for Annex XIV there might be a need to have one ad-hoc activity as a result of the outcome of the on-going consultation and opinion-making process for the first recommendation.

ECHA promised to ensure that submission to the informal RoI would be posted on CIRCA as soon as possible after their submissions allowing appropriate discussions time between the MSCAs. In addition, ECHA would try to ensure that confirmation of receipts would not only refer to a submission number but also to the substance concerned.

16.7. Guidance on Risk Communication

ECHA informed the meeting about its current activities related to Guidance on Risk Communication. Based on the feedback ECHA received from the scoping study as well as from the Risk Communication Network, the philosophy of the guidance was stated, including a proposal for its content, planning and timeframe of future activities. It is proposed that the guidance would provide MSCAs with a handbook with hands-on advice on what risks need to be communicated, when risks may need to be communicated and in particular how they should be communicated in practice. Moreover, it is intended that the guidance gives instructions on how to carry out risk communication in foreseeable real-life scenarios relevant to REACH. The Guidance consultation procedure will be followed and an indicative timeframe was stated aiming at having the guidance completed by December 2010.

One MS that took the floor raised the point of considering Article 123 & Article 77 as the legal basis for the guidance.

16.8. Report from recent ECHA meetings

ECHA gave a presentation on the recent activities of the Committee for Risk Assessment (RAC), the Committee for Socio-economic Analysis (SEAC), the Member State Committee (MSC) and of the Forum. RAC has been working on procedures for restrictions and C&L dossiers. The interaction between RAC and SEAC in preparing the opinions has been focused on jointly by both Committees. SEAC as well has addressed procedural and training issues in preparing for its tasks. MSC is preparing its opinion on ECHA's draft recommendation for Annex XIV ("authorisation list"). The opinion prepared by the appointed rapporteur will be adopted in the May meeting of MSC. The Forum has established five working groups that have been preparing Forum's activities for practical enforcement. The first joint enforcement project will be started in spring. Forum is organising an open session with stakeholders in April. The stakeholders have been invited to propose topics for discussion.

16.9. Report from workshop on Safety Date Sheet (SDS)

ECHA informed the meeting about the conclusions of the SDS scoping study and the next steps in the guidance development. The borderlines between already available guidance, priorities for providing guidance that is of particular interest for ECHA as well as areas that are of particular interest for Industry were clarified. ECHA elaborated that it would like to develop guidance on SDS together with CEFIC. A Memorandum of Understanding would clarify the different roles and requirements among them the involvement of relevant organisations that are not members of CEFIC, the involvement of MSCAs, coordination with other activities, a good project management structure with the appointment of a dedicated full-time project manager. The document that will result from this process will only after completion be processed via a standard consultation procedure (PEG, Committees and/or Forum and CARACAL). A provisional planning and timeframe of the activities were given. The start of the consultation is foreseen for January 2010. One Ms took the floor and welcomed the initiative and expressed that producers of SDS and Downstream Users (DUs) should be involved. With regard to DUs the Article 37 obligations should be reflected in the new SDS guidance. The work of UK HSE on behalf of the Commission on SDS regarding employers and DUs was mentioned.

17. REGULATION ON CLASSIFICATION, LABELLING AND PACKAGING

17.1. Implementation of CLP

COM introduced the issue about the different task for MS, CA and CA Enforcement Authorities according to the newly adopted CLP Regulation. COM has received information on some national CLP helpdesks. The remaining MS were asked to submit contact details of their national CLP helpdesk as soon as they are available. In addition COM reminded MS that the deadline for adoption of legislation on penalties for non-compliance with CLP is 20 June 2010.

Several MS commented the task for the CAs to provide ECHA with the names in the national languages of substances in Annex VI which should be included in a database. According to MS this is a task to be shared with COM. All information stored in the databases in Ispra will be taken over by ECHA and be the starting point for the new classification and labelling inventory. Several MS wanted more information and possibility to discuss different aspects of this issue. There are great differences in translation of names of the Annex VI substances into the different national languages. Some MS have worked more on this issue than others.

One MS observed that in the document from the COM the tasks for COM under the CLP regulation were missing and asked for an overview of these tasks.

One MS noted that the Generic Concentration Limits, which were included in Annex I for some substances, have now been deleted from the new Annex VI. COM explained that the reason was that industry under the CLP Regulation is allowed to set Specific Concentration Limits different from the generic ones, and that including the generic ones in Annex VI would prevent that.

The follow up of Article 53(2) regarding the promotion of the harmonisation of criteria for PBT/vPvB at the UN level was discussed. There was agreement that MS should send

their views on this. Afterwards COM should prepare an initial discussion document on the issue.

COM will upload a list of the CA for CLP on CIRCA. In this list, national Agencies dealing with CLP will be included if so is requested by MS.

17.2. Issues raised at ECHA Committee Meetings - Scope of Annex VI dossiers

COM introduced the issue that based on practical experiences at ECHA and discussions in the Risk Assessment Committee (RAC) with proposals for harmonised classifications, questions on the scope of the harmonisation of classifications have been raised. Two questions on the scope require input from the CAs before they can be answered appropriately. The first one concerning how to deal with proposals (from MS or Industry) not to classify a substance was discussed at this meeting while the second question on how to deal with proposals to classify a substance only based on the presence of a constituent for which a harmonised classification exists will be discussed at the next meeting.

There was support from MS for the conclusion from COM and ECHA. The CLP Regulation is not designed to manage proposals for no classification. As there are possibilities to establish discussions among MS CAs about whether or not a substance should be classified, it is not advisable to submit proposals for no classification as a means to obtain a scientific opinion on such a conclusion. This view is also supported by the aims of the revision of the chemicals legislation, i.e. that authorities are focussing their resources on substances of highest concern rather than confirming that a substance is not hazardous. Only in cases where there is a need to de-classify a substance (i.e. remove a classification from an entry in Annex VI due to the presence of new data), it would be appropriate to submit a proposal for “no classification” (note: This is only applicable to MS and not to industry).

COM will prepare a thought starter about the second issues before the next meeting.

17.3. 1st ATP

The 1st ATP of the CLP will include substances from the 30th and 31st ATP to Annex I of Directive 67/548/EEC. The REACH Committee meeting is planned for the 25 March 2009.

17.4. Guidance (RIP3.6)

COM introduced the Module 1 "Basic guidance to regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures". This is a short user-friendly guidance intended for industry especially SMEs. It had been finalised by the working group and has been approved by the Stakeholders Expert Group (SEG). After endorsement by CARACAL, the guidance document should be handed over to ECHA for publication on ECHA guidance website.

The document was welcomed and supported by the meeting. However, some MS had some editorial comments that should be included before publication. Other MS asked for translation of the guidance as soon as possible as it is intended for SMEs where

translation is of high importance. Module 1 was endorsed with the understanding that the comments would still be integrated before publication.

COM will hand over the document to ECHA in its current version. MS were asked to send their editorial comments to ECHA before 30 March 2009. ECHA will integrate the editorial comments and publish Module 1 on its website. It will also be sent for translation.

COM presented the progress on Module 2. MS have been involved in the work in four different working groups and the document had been sent for approval by SEG at their meeting in April. The aim is endorsement at the next CARACAL meeting in June. There was an overall support for the document. However, some MS have problems with the wording of the section concerning skin irritation and testing on human skin. They asked for further editorial work on this. COM explained that this particular chapter was behind in the procedure, and was still to be updated prior discussion and approval by the SEG.

In view of the length and complexity of Module 2 one MS asked COM for a significantly extended reviewing period for the final version of the guidance paper.

One MS informed about the ongoing work to review the section for Precautionary Statements (PS) within the GHS. The work is done by a correspondence group of United Nations Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UNSCEGHS). The content of this section needs to be improved and it is important that MS take part in this work if possible.

COM was encouraged to inform the UNSCEGHS about Module 1 and 2 in writing as these guidance documents might be useful also for industry and authorities outside Europe.

18. PROGRESS REPORT ON DOSSIERS FOR HARMONISED CLASSIFICATION AND LABELLING

18.1. Progress report on dossiers for harmonised C&L

ECHA introduced the progress report on notification and submission of dossiers with proposals for harmonised C&L.

One MS expressed concern that substance ID seems to be an issue in the evaluation of the proposals. ECHA explained that the working procedures have now been changed, so the substance ID will be checked already when a MS submits to ECHA a notification of intention to propose a harmonised C&L; however depending on the amount of information provided with the notification.

Another MS expressed the hope that MSs would not re-open discussions where an agreement had been reached at the TC C&L meetings by submitting a proposal for harmonised C&L differing from the previous agreement.

18.2. Submitting proposals for harmonised C&L for REACH, biocides and pesticides

ECHA introduced the document explaining how proposals for harmonised C&L should be prepared and submitted.

Several MSs expressed the view that it should not be necessary to prepare dossiers for harmonised C&L of REACH, biocidal and pesticidal active substances in IUCLID 5 format and to prepare a report explaining the proposal, as assessment reports have already been prepared and for 56 substances agreed by the respective CAs and there would be no added value in transferring these into the format requested for C&L. Some MS also advocated for a "fast-track" procedure for such active substances, so that for the 56 substances their C&L could be agreed via comitology without involving ECHA and the Risk Assessment Committee, and for biocides and pesticides (PPP) that had already been agreed on after a rigorous procedure of risk assessment under their respective legislations that these should be processed through ECHA/RAC but negating the accordance and public consultation steps.

COM explained that the use of IUCLID 5 was already part of its REACH proposal from 2003 and that it had been repeatedly explained to the MSCAs in the years since then. Moreover, the use of the IUCLID 5 format for pesticides has also been agreed in the OECD and most of the MS took part in this decision. Finally, the COM has no mandate to circumvent the procedure described in the CLP Regulation requiring publication for commenting by parties concerned and issuing an opinion by the RAC.

Some MS queried about the fate of 56 substances for which agreements on C&L had been reached in TC C&L meetings, but which had not been included in the 30th and 31st ATPs, and suggested that their C&L could be adopted by comitology. COM explained that also for these substances, the only route was to prepare and submit a dossier for harmonised classification to ECHA.

Following these discussions, ECHA was requested to reconsider its proposal with the aim of finding simplified and practical solutions for both biocidal and pesticidal active substances and the 56 substances already considered by the TC C&L with the aim of both reducing the workload of MSs and ECHA, and ensuring that appropriate information is available for public consultation and the discussions in RAC.

18.3. Preparation by ECHA for CLP, incl. publication of the Annex VI substance names in official national languages

ECHA introduced the document informing about ECHA's planning for its tasks related to the CLP Regulation and the current stage of implementation.

Following a question, ECHA confirmed its intention to be ready to receive notifications of C&L during spring 2010 and to publish the first C&L inventory by summer 2010. The C&L inventory will also contain the list of harmonised classifications. Poland confirmed that they will provide the names of Annex VI entries in Polish, and Norway requested that it would also be possible to include the names in Norwegian.

MSs welcomed that ECHA has initiated the update of the guidance on preparing and submitting proposals for harmonised C&L incl. how to use the IUCLID 5 and asked

about how ECHA intended to involve MS and industry. ECHA replied that comments have already been received from both MS and RAC, and the agreed procedure for update of guidance will be followed including consultation of stakeholders via establishing a Partner Expert Group (PEG).

One MS questioned whether ECHA's obligation to handle requests for use of an alternative name for substances in mixtures only applies from 1 June 2015. COM and ECHA was requested to clarify this issue by next CARACAL meeting.

19. ANY OTHER BUSINESS

- One MS asked about the intention of the study "State-of-the-Art report on Mixture Toxicity" and what the study will be used for. COM informed that the aim of the study is to provide the scientific and regulatory state of the art in assessing mixture toxicity. There are several possible uses e.g. for ECHA in CSA for mixtures. The study will be presented to CARACAL when it is ready.

- One observer raised an issue about enforcement of REACH. Some goods have been blocked even before the end of the preregistration period. The importance of a coordinated enforcement was underlined. There were no comments from MS on the issue. Enforcement issues should also be discussed in the Forum.

- ECHA agreed to produce a paper about its communication strategy on CLP before the next meeting.

20. NEXT MEETING AND CLOSURE

COM announced that the next meeting is scheduled for 15-16 June 2009, but participants were advised not to make any booking until these dates are confirmed. A conference on CLP will be organised in Brussels on 17 June.

COM thanked the participants for their active participation and closed the meeting.

21. WRITTEN PROCEDURE CONCERNING SUBSTANCES IONISED IN WATER

The revised version of the document concerning substances ionised in water was uploaded on CIRCA 26/03/2009 and sent by email to MSCA for endorsement by written procedure. The document had been revised on the basis of the comments made at the 1st meeting of CARACAL as no further written comments had been received after the meeting.
This revised document was endorsed by the REACH Competent Authorities. ECHA will use it to update the relevant chapters of the Annex V guidance.

Annex I

EUROPEAN COMMISSION

ENVIRONMENT DIRECTORATE-GENERAL
Water, Chemicals & Cohesion
Chemicals

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Chemicals, Metals, Forest-based & Textile Industries
REACH

Brussels, 16 March 2009

1st Meeting of Competent Authorities for REACH and CLP (CARACAL)

16-17 March 2009

Centre A. Borschette, Room 2A, Rue Froissart, 36, BE-1040 Brussels, Belgium

ADOPTED AGENDA

16 MARCH	**REGISTRATION**	**09:00 – 09.30**
AGENDA ITEM	**ACTION**	**TIME (APPROX.)**
1. ADOPTION OF THE DRAFT AGENDA	Discussion	**09:30 – 09:45**
2. FOLLOW-UP OF THE 6TH REACH CA MEETING		09:45 – 10:00
2.1 Draft Summary Record	Discussion	
2.2 Actions from the meeting[5]	Discussion	
3. ORGANISATIONAL MATTERS		10:00 – 11:00
3.1 Inclusion of the work on restrictions in the CA meetings after 1 June 2009	Discussion	
3.2 Rules of Procedure for CARACAL	Endorsement	
3.3 GRIP, New style	Discussion	

[5] The follow-up of Action point 9 will be dealt with in a closed session at the end of Day 1.

Coffee break		**11:00 – 11:30**
4. UPDATE ON REACH ANNEXES AND IMPLEMENTING LEGISLATION	Information	11:30 – 12:15
4.1 Annexes I, II, IV, V, XIII, XVII		
4.2 Implementing legislation - 1st ATP of Test Methods Regulation		
5. NANOMATERIALS: SUBSTANCE IDENTIFICATION	Endorsement	12:15 – 13:15
Lunch		**13:15 – 14:15**
6. EXEMPTIONS IN THE INTEREST OF DEFENCE (ART. 2(3))	Information	14:15– 14:25
7. IONIC MIXTURES	Information	14:25– 15:05
8. REACH BASELINE STUDY	Information	15:05 – 15:30
9. COMMISSION REPORT ON REACH (2012)	Information	15:15 – 15:45
10. MS REPORTING UNDER REACH: PROGRESS REPORT	Information	15:45 – 16:15
Coffee break		**16:15 – 16:45**
11. THE STATE OF PLAY WITH REGARD TO PESTICIDES	Information	16:45 – 17:05
12. QUESTIONS FROM REHCORN 12.1 Notified substances below 1 t	Discussion	17:05 – 17:20
13. FORMAT/CONSTITUTION OF REGISTRATION NUMBER ON SDS[6]	Information/ Discussion	17:20 – 17:30
14. REVIEW OF THE NEW APPROACH – WHAT APPLIES TO REACH?[7] 14.1 Market Surveillance Regulation	Information	17:30 – 17:45
15. OTHER INFORMATION POINTS		17:45 – 18:00
15.1 REACH Penalties	Information	

[6] This document will refer to the document from CEFIC dated 20.02.2009, put on CIRCA on 02.03.2009.

[7] Item to be taken immediately before lunch on Day 1.

17 MARCH		
AGENDA ITEM	**ACTION**	**TIME (APPROX.)**
16. ECHA ACTIVITIES IN RELATION TO REACH		**09:00 – 12:30**
16.1 Progress report on Pre-registration and registration	Information	
16.2 REACH-IT	Information	
16.3 Evaluation of new and existing substances - Progress report 2008	Information/ Discussion	
16.4 Report on transitional dossiers submitted under article 136(3)	Information	
16.5 ECHA workshop on Authorisation and the Candidate List - Report by ECHA - MS follow-up activity on Candidate List[8]	Information/ Discussion	
16.6 Update on RoI and Annex XV dossiers	Information	
Coffee break		**11:30 – 12:00**
16.6 Guidance on Risk Communication	Information	
16.8 Report from recent ECHA meetings	Information	
16.9 Report from workshop on SDS[9]	Information	
17. REGULATION ON CLASSIFICATION, LABELLING AND PACKAGING		
17.1 Implementation of CLP	Information	12:30 –12:50
17.2 Issues raised at ECHA Committee Meetings - Scope of Annex VI dossiers	Discussion	12:50 – 13:10
17.3 1st ATP	Information	13:10 – 13:30

[8] Please refer to the document issued on 27.02.2009 and put on CIRCA on 02.03.2009

[9] Activity related to both CLP and REACH

AGENDA ITEM	ACTION	TIME (APPROX.)
Lunch		**13:30 – 14:30**
17.4 Guidance (RIP3.6) - Module 1 - Module 2	 Endorsement Discussion	14:30 – 16:00
Coffee break		**16:00 – 16:30**
18. ECHA ACTIVITIES IN RELATION TO CLP		**16:30 – 17:30**
18.1 Progress report on dossiers for harmonised classification and labelling 18.2 Submitting proposals for harmonised C&L for REACH, biocides and pesticides 18.3 Preparation by ECHA for CLP[10] - Publication of the Annex VI substance names in official national languages	Information Discussion Discussion	
19. AOB - background on the study on mixture toxicity, - enforcement of pre-registration in Member States - communication strategy on CLP		17:30 – 17:45
20. NEXT MEETING AND CLOSURE		17:45 - 18:00

[10] Item to be taken just after 17.1