EUROPEAN COMMISSION

ENVIRONMENT DIRECTORATE-GENERAL
Water, Chemicals & Biotechnology
Chemicals & Nanomaterials

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Chemicals, metals, mechanical, electrical and construction industries; Raw materials
Chemicals - REACH

Brussels, 01 September 2010
Doc. CA/77/2010

DRAFT SUMMARY RECORD
5th Meeting of Competent Authorities for REACH and CLP

15-16-17 June 2010

Centre A. Borschette,
Rue Froissart, 36, BE-1040 Brussels, Belgium
Room 1A

Day 1 – 15 June 2010

The Commission (COM) welcomed participants and apologised for the late submission of a few documents.

1. Adoption of the draft agenda

The Chair apologised for an editorial oversight – there was no Point 4 on the Draft Agenda.

The Chair announced that COM was approached on Friday before CARACAL by industry association PPG with the request to remove the point concerning the restriction of acrylamide from the agenda of the meeting. COM proposed not to remove the point from the agenda but had invited the representatives of the association to the meeting. There were no objections to this procedure.

One MS asked about the date for a discussion on substances in articles. Chair replied that this issue is scheduled for the October 2010 CARACAL meeting.

One MS requested update on borates and suggested not to discuss Annex II but provide information on state of play of the guidance on the compilation of Safety Data Sheets.

The agenda was adopted with the following changes: AOB 9 – Agenda Points 9.3 and 9.4 will be handled at the beginning of that session.

2. Follow-up of the 4th meeting of CARACAL

2.1. Draft summary record

The draft summary record (DSR) of the 4th meeting of CARACAL was adopted with no changes.

2.2. Actions from the meeting

The majority of the actions from the last meeting were either completed or will be dealt in this CARACAL.

One MS made comments a specific nature regarding the action points:

- On the tracking document: COM has intention to continue updating this document and plans to do it in the coming months.
- On the update of the Biocides review: update will be provided at the next CARACAL meeting.

Two MS mentioned their preference to discuss substances in the closed session.

SESSION A : GENERAL ISSUES

3. Overall workplan for CARACAL

Workplan
An updated version of the plan was distributed as a room document. The estimates are made on the "best effort" basis.

Regarding the timing for the adoption of Annexes XII, XI, XVII (PFOS) COM made a conservative estimate.

One MS asked whether the planning is realistic, taking into account the many amendments to Annexes scheduled for September – October 2010. Chair responded this looked possible and hoped to benefit from the discussions in this meeting.

One MS asked about the rationale for discussing the Test Method Regulation. COM responded that the inclusion of a test method in the ATP will not be adopted via a written procedure, but there will a possibility for a discussion in the REACH committee.

A MS asked why COM has separated the adaptations of Annex I & V to the CLP. COM responded that first will go ahead with Annex I as the work is more advanced than for Annex V.

COM mentioned that the Council will take several corrigenda to REACH in one go.

Next CARACAL meetings

Chair announced the following dates for the next meetings:
CARACAL 6: 25–27 October 2010
CARACAL 7: 7–9 February 2011
CARACAL 8: 8-10 June 2011
CARACAL 9: 26-28 October 2011

Dates are tentative until six weeks before the meeting therefore no bookings of flight tickets should be made before confirmation of dates.

SESSION B

5. REACH REGISTRATION AND SCOPE

Chair introduced the topic by saying that the initial discussion, started in the open session, would be continued in the closed session.

5.1. Reporting on Directors' Contact Group (DCG)

COM presented the recent activities of the DCG and presented a number of issues in order to receive comments from CARACAL.

COM informed that industry associations identified 27 issues, the resolution of which would facilitate Registration; 7 issues were prioritised for June 1st although DCG made an attempt to address all issues before this date.

Several issues of a very technical nature can be dealt by ECHA. For some issues COM needs to consult CARACAL as they involve enforcement (intentions, expectations from MS). Few other issues are very specific such missing the Registration deadline when industry is active in good faith but prevented from registration e.g. – a lead registrant goes bankrupt two weeks before the registration deadline.

One MS mentioned that if the lead registrant had not submitted the dossier or if a registration dossier is not complete then ECHA will need to find a solutions and not MS. This position was supported by several MS.

COM replied that if the lead registrant fails the completeness check twice, there is a mechanism by which the other registrants have sufficient time to find another lead registrant. The co-registrants are given a number of months to complete the dossier and their part is considered partially complete. The MS CAs are informed about this situation in order to allow them to judge whether the company is misusing the system or that there is a real problem.

One MS mentioned that in case of a legal entity change, ECHA can take a decision but MS are not in the position to find solutions which are legally binding. COM replied that the change of a legal entity is a nationally regulated matter and not by REACH; this can only be verified by the MS in their enforcement capacity.

One MS said that any problem with registration is an issue between that respective company and ECHA and it would urge ECHA to take a decision but MS cannot facilitate contacts between ECHA and registrants.

As a summary of COM and ECHA replies to comments made during the discussion, COM said that DCG will refine its conclusions and agreed with one MS saying "do not unnecessarily disturb the market and do not allow abuse" therefore MS enforcement is a part of this solution.

Concerning the issue of the helpdesks, there is a need to have new means and new avenues to spread the message to the SMEs and DU in order to explain the obligations under REACH rather than creating the dossier for them. Helpdesks are the crucial element in ensuring that the obligations under REACH are met.

Concerning the topic of the functioning of SIEFs – from an enforcement perspective – there can be a role for the MS which have to be aware of the advice given by COM to SIEFs.
Some MS were concerned about abuse of information available in REACH-IT by some registrants; COM reminded that these issues are regulated by national legislations.

A stakeholder (CEFIC) thanked the DCG for the pragmatic work and also thanked ECHA for the publication of the list of substances. CEFIC asked for the recommendation regarding the possibility to add substances which are not on ECHA's list. Also, CEFIC reminded that for 40% of SIEFs there are no lead registrants at this point in time and asked whether DU can continue to use a substance in case the substance will not be registered.
Another question concerned the situation after December 1st, 2010: how will DU know that substance has been registered?

On the issue of abuse of the REACH-IT, ECHA commented that it will look into pragmatic ways to improve the system after the registration deadline.

5.2. Communicating about REACH

Chair introduced the paper which sets up the messages to different audiences to be used while communicating about the registration process. This is a follow-up on the discussion of the work of the DCG.

5.3 Annex I and V of REACH – adoption to CLP

COM presented the working version of the draft amendment of Annex I by adaptation to CLP Regulation and mentioned that an adaptation of Annex V still needs to be drafted.
COM asked for written comments by July 6th, 2010. The comments thus received will be incorporated in the revised draft version in form of track changes.

5.4 Article 2.1b) of REACH – input from COM

COM presented a paper on interpretation of Article 2(1) b REACH. The paper seeks to clarify the exemption provision of REACH concerning its application to substances imported on their own, in mixtures or in articles.

MS welcomed the paper and stressed the need for close cooperation with DG TAXUD in this matter. Some of the MS asked for clarification of certain issues like the status of importer or examples of allowed handling in a free zone.

Time until 6 of July has been given for additional MS' comments and observations.

6. REACH AUTHORISATION

6.1. Update on the implementation of the agreement reached by VP Tajani and Commissioner Potočnik on 25th March.

COM presented the agreement between Commissioner Potočnik and Vice President Tajani concerning Annexes XIII and XIV to REACH, and the Guidance on Authorisation.

The draft Annex XIII has already been uploaded on CIRCA while draft Annex XIV was distributed as a room document.

COM explained that following the agreement on the substitution plan, the guidance will be updated accordingly and published in the Official Journal of the European Union (OJEU).

Also, COM informed that the two Commissioners agreed to accelerate the process of including substances in the Candidate list. As a consequence, COM counts on the MS to prepare the majority of dossiers. COM will ask ECHA to prepare five dossiers.

COM confirmed that there will be no postponement of the registration deadline of November 30, 2010.

Some MS commented about the time pressure put by COM to comment quickly on the draft Annexes XIII and XIV. COM replied that it is justified by the fact that these drafts were already submitted to the process of the Inter-Service Consultation.

6.2 State of Play on draft Authorisation and SEA/Authorisation Guidance documents

COM presented the status and made additional comments on the procedures for both guidance documents.

Concerning the Authorisation guidance, COM mentioned that 9 comments were received from CAs and during the written procedure launched on 21 May and that ECHA made technical comments, available as a room document.

The draft guidance on application for Authorisation will be updated on the basis of those comments, translated in all official languages and published as draft in the OJEU. The publishing in the OJEU will be a 'one-off' procedure.

Some MS voiced their surprise that the guidance will be published in the OJEU. COM responded that the purpose of the publication in the OJEU is to increase legal certainty on the long-standing question of the role of the substitution plan and to ensure that the Guidance will be available in al official languages as soon as possible. The publication on the OJ is the part of the agreement between the Commissioners.

CAs endorsed the guidance on application for authorisation.

Concerning the SEA guidance, COM called the CAs to comment by 7 July and, answering a question of one MS, COM confirmed that for SEA Guidance a written procedure will launched soon after CARACAL seeking endorsement from CAs. The SEA guidance will be then handed over to ECHA which will publish it on its website. ECHA confirmed that the SEA guidance will be published very quickly after the handover from the Commission.

6.3. Draft Regulation for the Amendment of Annex XIII

COM briefly presented the draft revised version of Annex XIII to REACH and pointed out that the draft new version:

- included of the weight of evidence approach and the screening criteria and
- indicated information which could be taken into account while assessing the PBT / vPvB properties.

The numerical values were not modified in the new version. The draft Annex XIII is scheduled for adoption in 2011; a two year deadline for implementation by industry was proposed.

Three MS mentioned that they appreciated the new draft. There was a consensus that some time is needed to provide comments. One MS expressed its dissatisfaction with the proposed version because it would not provide legal certainty for registrants. COM asked for comments by 7 July. The proposal will be submitted to the REACH Committee on 20-21 September for the comitology procedure.

6.4. Draft Regulation for the Amendment of Annex XIV

The draft proposal follows, to a large extent, the recommendation of ECHA of June 2009: ECHA recommended the inclusion of 7 substances; COM retained 6 because 1 substance (SCCP) was in the meantime included in the POPs Convention.
An exemption was given for 3 phthalates for use in immediate packaging; use in medical devices was not explicitly exempted because this exemption derives from the fact of being regulated under a different legislation.
The draft will be sent to the WTO Technical Barriers to Trade (TBT) for consultation and will be submitted to the REACH Committee on 20-21 September for the comitology procedure.

One MS inquired whether the EU acquis are maintained; COM confirmed that acquis are maintained.

ECHA added that although Guidance on Authorisation indicates 12 months as application deadline, ECHA gave 24 months. ECHA kept the sunset date of 18 months after the application date.

7. REACH RESTRICTIONS

7.1. PAH in consumer products

A MS introduced a paper submitted to CARACAL members by its CA concerning a proposal for restrictions of Polycyclic Aromatic Hydrocarbons (PAH) in consumer products due to their hazardous properties based on their carcinogenic and mutagenic properties as well as their potential for being toxic to reproduction. The proposal is accompanied by a restriction dossier and is based on the requirements of Annex XV including an analysis of RMOs, of alternatives and of socio-economic impacts as well as consultations with various NGOs, companies and industry associations.

The proposal concerns 8 PAH compounds, for which COM is asked to propose restrictions in accordance with Article 68(2) of the REACH Regulation; the route via Article 68(2) was considered as preferred RMO, allowing a direct and fast track approach for CMR substances in consumer products..

Eight MS supported the initiative of significantly reducing the content of PAHs in consumer products. One MS underlined specific problem with PAH in children articles.
The suggested procedure (Art. 68(2) route) was supported explicitly by one MS, also because this would allow to see if the fast track procedure can be applied in practice and how to tackle this approach. However, seven members questioned the proposed procedure and indicated that the legal procedure, based on submission to ECHA an Annex XV dossier for which ECHA (RAC and SEAC) would issue an opinion also has its merits. The submitting CA was asked for the reasons for choosing the fast track procedure and whether the submitting CA considered using procedure based on article 68 (1) or intentionally omitted it.

One MS suggested that article 69(5) of REACH should rather be used because there are already some PAH compounds in the Annex XVII.

One MS mentioned that including PAH compounds in Annex XVII does not solve the problem and would require a lot of communication with industry. Another MS shared concerns about enforcement.

The submitting MSCA answered regarding the choice of article 68(2) versus 68(1) that the fast track/ Art. 68(2) route seems to be appropriate as there is broad available information on exposure in the EU and that PAH containing articles are still imported into EU. There is also a growing public concern and the Art. 68(2) route would allow COM to react quickly. It would be also a possibility to see how the fast track works in practice.

COM summarized that there is support to do something on PAH in consumer products, but that there are questions regarding the adequacy of the proposed fast track procedure.
COM committed to do some further analysis and to inform CARACAL about the results in October CARACAL meeting. In addition during the summer period, COM will develop an approach to sue 68(2) and submit to discussion.

However, COM encouraged the German CA following the legal procedure and submitting an Annex XV dossier to ECHA.

7.2. Restriction of:

- Cadmium in brazing materials, jewelleries and PVC
- Report from workshop held on 26 March 2010
- Proposal amending the current restriction for Cadmium

COM introduced the proposal for restriction of Cadmium in brazing materials, jewellery and PVC and informed about outcome of a workshop on migration of Cadmium from PVC held in this context.

The COM proposal extends the current restrictions to the use of cadmium in jewellery and in brazing sticks. As regards the use of Cadmium in PVC, the proposal foresees a total ban of Cadmium in PVC (and goes in this sense further than the current restriction) except for certain applications for PVC containing recycled PVC. The time-limited exemption is suggested behind the background that it allows improved resource efficiency (recycling of PVC) and less CO2 emissions (resulting from incineration of PVC waste). In order to discuss the impacts and possible risks for the environment from the use of recycled PVC a Workshop has been held.

During the workshop all experts from the six MS presented concluded that on the fact that the migration of Cadmium to the environment was extremely low and provided that the recycled PVC is only used in internal layers of the pipes, the risk for the environment of the use of recycled PVC in pipes was negligible.

Two MS have a national ban for cadmium and the COM proposal concerning recovered PVC was qualified as relaxing the status on the substance which is dangerous or even a step backwards if compared to what was done in some EU countries. COM clarified that the proposal will cover applications that are until now not restricted such as window profiles. The time-limited exemptions are given to a limited number of applications only and this in order to allow recycling. The proposal could therefore not be qualified as a relaxation of the existing restriction.
One MS asked for more detailed information about removing Cadmium from recycled PVC.
One MS mentioned that the logo foreseen for marking PVC containing recovered PVC gives no information about the cadmium content (%).
Two MS underlined the need to align with the existing waste legislation.

One MS reminded that although COM had been provided with proposals for methods for measuring (for enforcement) still there were no EU analytical methods available. COM responded that no specific harmonised method exists in the EU and the time needed to develop a new standard method is 3 years.

One MS asked about the list of plastics in the proposal and the COM replied that the list is the same as in the existing restriction, but COM will liook at the possibility to complete the list
One MS noted that the restriction on paints does not cover placing on the market of paints containing cadmium and the COM replied that this part of the restriction will be reviewed to take this into account.

The MS were asked to send comments in writing in order to allow a better understanding of concerns and further in depth discussion of the proposal.

- Acrylamide in grouting applications

COM reminded the participants about a fax received on the 14th of June 2010 from the Polyelectrolyte Producers Group (PPG) with the request to withdraw the draft Commission Regulation on acrylamide from the agenda and that COM proposed not to remove the point from the agenda but had invited the representatives of the association to the meeting.

COM introduced the draft Commission Regulation regarding the restrictions of acrylamide in grouting applications. Since the COM took the decision to follow the previous discussion of the Limitations Working Group, further evaluations were made which also included the information provided by industry and presented during the last CARACAL meeting in February.

COM informed, as presented in the document circulated via CIRCA that the information were not sufficient to justify any derogation from the general ban for the use of acrylamide in small grouting applications.
Based on information received from Member States since 2006 and on a recent market survey conducted by the COM, alternatives to acrylamide were identified which can be used for micro cracks and salt damps applications.
Therefore, the proposal presented is the same as proposed and discussed during the Limitations Working Group meeting in 2008 without providing any derogation.

Five MS including Norway fully supported the COM decision. One MS underlined that this proposal could have been tabled years ago and asked that the vote at the REACH Committee could be scheduled also before September and that the date for the entry into force of this ban could also be less than 18 months, They recalled that the ECHA Member States Committee is still awaiting the outcome of CARACAL on acrylamide to be able to decide whether to prioritise acrylamide for inclusion in Annex XIV.
One MS also asked if the use of acrylamide in electrophoresis gels has also been included in the ban or considered by the COM.
One of the two representatives of PPG gave his views on the Proposal presented by the Commission.
He asked to withdraw the Proposal as industry was not informed and the Proposal itself did not circulate before the meeting.
PPG recalled that the impact of such ban is mainly on downstream users.

Two main uses, large and small scale, depending on the size of the construction work, were considered in the EU risk assessment.
As it concerns the large scale application, this was represented by the tunnel scenario evaluated in EU the risk assessment. This was typically a misuse of acrylamide, confirmed also by the decision of the Helsinborg Court in September 2007. Moreover the substance used in that construction site was not acrylamide but rather NMA.
The small-scale applications were on sewer grout repairs in the USA without any relevance for the use of acrylamide in the construction industry in EU.
The US EPA considered the studies used by the European Rapporteur out of date.
On alternatives, industry claimed that the available studies (AFTES, RPA/DEFRA) also failed to identify the right substitutes.

Industry informed that a proposal for a study on exposure monitoring was submitted to UK Rapporteur last September and also to the COM but they have never received the green light to proceed.
PPG also asked if the Member State which proposed acrylamide for the candidate list for authorization has also considered the availability of alternatives.

COM replied that epoxy resins are identified as alternatives for microcracks applications, while siloxanes were considered good alternatives for salt damp application. As it regards the polyacrylamide electrophoresis gels, this application was not assessed in the EU risk assessment and was not included in the risk reduction recommendations. Therefore this use was excluded by the Proposal; COM reminded that acrylamide is a substance proposed following the Article 137 of REACH on transitional measures.

Industry replied that these alternatives are more dangerous than acrylamide and requested that their comments will be included in the minutes. COM replied that this would be done.

MS did not comment the points made by PPG.

- 1.4 Dichlorobenzene in toilet blocks and air fresheners

COM informed the CARACAL that the study on socio-economic evaluation has been finalised. It will be published on the website of DG ENTR and the CARACAL will be invited to provide comments. The deadline for comments will also be communicated to the participants via CIRCA

After having received the comments, COM will decide on the way forward.

7.3. Amendment to Annex XVII concerning PFOS and Penta BDE

COM gave an update on the developments concerning Regulation (EC) No 850/2004 on persistent organic implements (POPs Regulation). COM has drafted an amendment to the POPs Regulation to prohibit the production, placing on the market and use of a number of substances including PFOS and PentaBDE. The amendment received a positive opinion of the Regulatory Committee and the adoption should take place before 26/08/2010.
Entries 44 and 53 of Annex XVII to REACH - "Diphenylether, pentabromo derivative" and "perfluorooctane sulfonates" (PFOS) - are now redundant.
An amendment to Annex XVII to REACH deleting these entries will be drafted for adoption under the regulatory procedure with scrutiny and will be submitted to the REACH Committee in autumn 2010.
There are some differences between the amendment to POPs Regulation and Annex XVII to REACH. For PentaBDE, the limit value is lowered from 0.1% to 0.01% in mixtures and articles. For PFOS, the limit value is lowered from 0.05% to 0.01 % for mixtures. The standard developed by CEN will be applicable. Derogation for wetting agents in plating systems is limited to 5 years, with a possibility of renewal if agreed in the Convention.

Answering a question from a MSCA on the rationale to move to the POP convention, COM responded that the POP Regulation is wider as it covers waste so is the most appropriate legislative measure.

7.4. Review of existing restrictions for phthalates

ECHA presented a review of restrictions of phthalates.
COM informed CARACAL that a recommendation from ECHA was received and that COM decided to follow this recommendation. The paper circulated via CIRCA was presented.
One MS congratulated ECHA on the document and informed about its research into the combined effects of phthalates with the same mode of action (topic to be discussed in the closed session).

MS informed that registration dossiers were already submitted for some phthalates.
CEFIC informed that there will be a joint submission for DIDP and DNIP this year and added that it will submit factual corrections to the ECHA report in citations.

One MS expressed its surprise that that substances which are not classified are subject to restriction.

ECHA confirmed that for some substances registrations were received under two CAS numbers under which they are referred and added that additional information might be supplied by co-registrants.

8. REACH CASG NANO

8.1. Feedback from CASG Nano meeting on 3-4 May 20l0

COM made a brief summary of the discussions in the last CASG Nano meeting on 3-4 May 2010. Two documents were agreed for endorsement by Caracal. The first one, *Nanomaterials' information in IUCLID 5.2* (CA/68/2010), provides advice on how to insert information on nanoforms of a substance in IUCLID 5.2. The second paper on *"Overview of definitions of nanomaterials"* (CA/68/2010) presents a collection of definitions on nanomaterial. The CASG Nano also invited MS to inform about their activities related to nanomaterials. COM informed about the on-going discussions on the working definition of a nanomaterial. Most of the time in the CASG Nano meeting was devoted to the REACH Implementation Projects on Nanomaterials (RIPoNs), where JRC and the consultants presented progress reports. For RIPoN1 on substance identification, it was apparent that some fundamental questions had to be settled still, c.f. agenda item 8.3. The discussion on RIPoN 2 and 3 on information requirements and chemical safety assessment concerned the preliminary progress reports, and instructions on how to comment on the rather voluminous work. The RIPoNs will contribute to guidance update regarding nanomaterials. The next CASG Nano meeting is planned for 14-16 December.

The MS welcomed the progress made in the CASG Nano. The guidance for the insertion of nanomaterials' information into IUCLID 5.2 was considered useful and the document was

endorsed. However, reservations were expressed for the endorsement and publishing of the overview of existing definition on nanomaterials. Therefore it was recommended to be kept as a background document in the work of CASG Nano.

8.2. Main relevant international activities regarding work on nanomaterials

As requested by the last CARACAL meeting, COM presented briefly the document on the on-going international activities in SAICM, ISO/CEN and the OECD on nanomaterials and nanotechnologies. One Member State thanked COM for the report, but requested 1) a timeline for when COM would come forward with the definition of a nanomaterial and 2) more policy relevant work must be on the CASG Nano agenda.

COM took note of the concerns and agreed that the definition is a matter of high priority. The proposal for a working definition on nanomaterial common for all legislative areas i.e. not tailored for REACH only was considered possible towards the end of 2010. This will be also included in the discussions on the regulatory review of nanomaterials in 2011 and in the REACH review 2012. All these important matters will be on CASG Nano's agenda.

8.3. The cover page from DG ENTR and DG ENV on the JRC Report on RIPoN1 situation: Identification of nanomaterials and status of carbonanotubes (CNTs)

The Chairperson briefly introduced *The cover page from DG ENTR and DG ENV on the JRC Report on RIPoN1 situation: Identification of nanomaterials and status of CNTs (carbon nanotubes)* (CA/46/2010) by reminding the members and observers of Caracal that DG ENV has contracted DG JRC to manage the REACH Implementation Project on Nanomaterials on substance identification (RIPoN1) to produce an Advisory Report on the issue in cooperation with ECHA and nominated experts from Member States and observers.

The Chairperson invited Caracal to give input and assessment, from the REACH perspective , of pros and cons of the RIPoN1 approaches presented in case studies.

Nine Member States and one EEA country took the floor as well as three observers and ECHA. Except one observer, they all found that MWCNTs and SWCNTs are different substances from graphite.

A MS considered size as an identifier a complicated issue as it would lead to either all nanomaterials being distinct substances or all nanomaterials being forms of bulk (minus CNTs) and that assessment should rather take place on case-by-case basis. Therefore the discussion must be thoroughly substantiated by a relevant RIPoN1 document taking into account the legal framework of REACH..

A MS stated that not only are CNTs not graphite but even within CNTs additional identifiers are needed. The other three cased studies have demonstrated a need for additional identifiers, some of which may already be found in the revised Annex II to REACH. Therefore it would be important not to be too specific in identifiers, but rather to develop a hierarchy of identifiers. The role of size may vary from a parameter to an identifier. The importance of size also depends on the definition of ‘nanomaterial’. The definition was considered indispensable for the REACH implementation and the review.

A MS saw no scientific basis that could settle whether nanomaterials are forms of a substance or distinct substances. Therefore, the discussion should be guided by the objective of ensuring sufficient information to assess risks and their management. The Member State found that this can be done best and most pragmatically by seeing nanomaterials as distinct substances with their own dossiers

A MS found that MWCNT as well as other CNTs were separate substances bearing in mind the need to address possible legal consequences. For this MS, size might be an identifier, but before such a decision is taken, the legal ramifications have to be explored since numerous registrations need to be avoided. Therefore it will be necessary to further assess the approaches used on case studies and their advantages and disadvantages.

A MS informed the meeting about their new nanomaterials action plan. The MS suggested that each nanomaterial must have its own SDS, hence they must be seen as distinct substances. The MS encouraged industry to report nanoforms as specifically as possible in the registration and expressed understanding to industry in their difficulties to consider all nanomaterials as distinct substances. More specifications will be needed in a revised REACH.

A MS considered all nanomaterials, including nanosilver, nanoCaCO3 and nanoTiO2 as well as forms of MWCNTs, SWCNTs and DWCNTs, distinct substances and not as nanoforms of a substance.

A MS stated that the RIPoN1 experts should have worked more to resolve the technical matters before addressing Caracal. Nevertheless, the MS agrees that CNTs are distinct substances. Nanomaterials call in general for more identifiers like size, plus other parameters like surface treatment.

Three other countries considered CNTs as distinct substances, while only two of them considered size as an identifier.

ECHA appreciated the good discussion that was much needed. The technical group required a policy steer otherwise it could not progress as it was stuck in policy discussions for which it was not equipped. ECHA would state that CNTs are distinct substances if it receives an Art. (26) inquiry. Therefore further discussion on the consequences of substance identification should not be discussed in RIPoN1, but in CARACAL or elsewhere. Certain legal consequences like the loss of phase-in status for CNTs were biasing the scientific discussions. On the basis of the clear views from Caracal the case studies must be assessed as individual cases and information of relevance for the general guidance must be subtracted. Caracal can then in parallel discuss pragmatic solutions to possible legal challenges.

One observer considered substance identification in general not an easy issue and especially not for nanomaterials. Part of the RIPoN1 discussion should take place at the discussions on RIPoN2 on Information Requirements, especially those on hazard characterization. The debate is about some fundamental issues which is not yet ripe for final conclusion. The chemical identity of a substance does not depend on the size, therefore the size should not be used as substance identifier. Considering the size as substance identifier can lead to high numbers of different substances and consequently high numbers of registrations with negative impacts on the industry. It is a generally accepted fact, that the size has impacts on the properties used in the risk assessment of substances and this does not stand only for the nanoscale range but for any other size ranges (for example the powders can have different

classification and labelling while they still stay to be a same substance with their maternal substance). The observer called for a clearer assessment of potential consequences. For that, right information is necessary as well as workable approach and for CNTs, also the clarification of the phase-in status and what will happen to non-phase-in substances.

Two other observers underlined that they found that nanomaterials are distinct substances. Size should be a main identifier and it is important to implement the RIPoN project urgently.

The Chair thanked the Caracal for their comments. COM has taken note of them and will come back with a proposal. The homework of CASG Nano would be to assess where to go with them. COM and ECHA will also look at the specific request to clarify consequences of splitting substances and may consider addressing the issue in the DCG. Finally, the Chair asked the representative of JRC, whether the views of Caracal enable JRC to progress in the RIPoN1 case studies and JRC considered that possible.

9. REACH AOB

9.1. Test Methods – Presentation of test methods to be included in the 3rd ATP to the Test Methods Regulation

COM presented the priority list for the 3rt ATP of the Test Methods Regulation (TMR). The EU National Coordinators were consulted on the priority setting. The COM plans start to work on the 3rd amendment of the TMR process towards the end of the year.

A MS asked that the methods are as much as possible similar to the OECD methods.
2 MS expressed the need to include also Endocrine Disruption methods as a priority. COM emphasised that priority lies in the replacement of outdated methods and alternative testing.
One MS asked why OECD methods 421 and 422 are not included; Com replied that this is because there is currently no method in the TMR so MS can use the OECD method. As such the methods are not a priority.

MS were asked to send comments by 6 June.

9.2. Conclusion from the PFOA workshop

COM presented the outcome of the PFOA workshop which took place on May 4th, 2010. Main conclusions highlighted the work that needs to be done and included the need to further discuss issues such as the derivation of DNEL, precursors and degradation products and analytical methods. Also, PBT criteria were discussed and will need to be revised to reflect the amendments to Annex XIII.
COM mentioned that industry agreed to a voluntary reduction programme.

9.3. Review process under Article 138 (6) of REACH

COM presented the status quo of the preparations to the review of REACH.

A contractor started to work in the beginning of the year and will continue till end of August 2011 (20 months). The tasks of the contractor are as follows:

- Perform an analysis of all relevant Union legislation (about 170 pieces of legislation)
- Compare the elements analysed with REACH (in terms of aims and scope, definition, regulatory mechanisms and assessment methods)
- Assess mechanisms to avoid double regulation
- Identify the overlaps and gaps and give recommendations.

The contractor will also receive and process stakeholder feedback. Such feedback must be properly substantiated and provided through a form in a dedicated website www.reachscope.eu, until 1 December 2010.

Some MS asked about the role of MS in the consultations and whether they can provide input to the scope of the review. One MS suggested discussing the scope of the review at the next CARACAL meeting.

COM commented that the process is at an early stage now and the scope of analysis is not yet finalised for some studies therefore, at this stage it cannot specify what input will be needed from MS. However, MS are welcome to provide feedback to the contractor through the website. The Commission also appreciates MS role in communicating the existence of this exercise to stakeholders in MS.

One MS asked whether the results of the study on REACH might also lead to changes on other legislations. COM replied that it cannot prejudice at this stage if it will recommend to other services in the COM to adapt other legislation.

COM will reflect on how to involve CARACAL when the bulk of the project is done.

9.4. Substances on stock and Article 5 of REACH

This agenda point was introduced at the request of a MS prior to the meeting.

Two MS asked COM whether batches of pre-registered substances that are manufactured or imported before the relevant registration deadline can be placed on the market after this deadline without a registration.
One MS presented a written opinion on this matter.

Based on the provision of Article 5 REACH COM said that such batches of pre-registered substances require registration before they can be placed on the market by a manufacturer or importer. However once legally placed on the market they can still be used after the relevant registration deadline. . This position was shared by one of the MS who sent the question to the COM. The position of the other MS was opposite and was supported by some MS and a stakeholder.

It was agreed that the opinion of COM needs further reflection. A document will be produced and submitted for comments.

9.5. Application of the definition of article in REACH to buildings

The Commission has been working on the interpretation of the definition of article in REACH and its application to buildings. In doing so DG ENV and DG ENTR requested the advice of the Commission Legal Service. The elements of the interpretation are the following:

- REACH belongs to the realm of Union legislation on free movement of goods. This refers amongst other things to imports and exports which do not cover commercial transactions in land or buildings which belong to the realm of the free movement of capital.
- The Commission also looked at the intent of the legislator and it was clear that the definition of article in REACH only intended to cover movables. This is exemplified by the provision on articles in REACH which require notification or registration under certain conditions of substances present in articles above a concentration of 0.1% w/w. The impossibility of weighing buildings would make these provisions unworkable.
- The Commission also looked into other legislation, as the definition of article is not exclusive to REACH. In particular, we looked into the consequences for the POPs Regulation and the new proposal for a Regulation on biocides.

The conclusion was that buildings do not constitute articles under REACH so long as they remain fixed to the land on which they stand. The same applies to other structures such as bridges, as well as smaller structures such as garden swings, etc, so long as they remain fixed to the land.

9.6 Corrigendum of the amendment to Annexes IV and V to REACH

The Commission has been working on identifying the appropriate procedure to adopt a corrigendum of Annexes IV and V. There are two distinct types of corrections to be made: linguistic corrections following the 2008 amendment of the annexes and corrections in the EINECS name or EC number of the substances listed in Annex IV further to the 2008 amendment, but also including corrections to the original 2006 REACH Regulation.

As the Commission cannot do the corrigendum for the later corrections, we discussed the issue with the Council, which in turn cannot do corrections to the recitals and enacting terms or the 2008 Regulation with the exception of the annexes. An agreement was reached that the Council would take on all the corrections in Annex IV pertaining to EINECs name or EC numbers, while the Commission will take on board all linguistic corrections further to the 2008 amendment.

We hope that we could see this corrigendum finalised in the coming months.

Day 2 – 16 June 2010

CLOSED SESSION

A summary of the closed session was presented when the CARACAL resumed in the open session.

- Further discussions on work of Directors' Contact Group (DCG) took place, focusing on the role of enforcement authorities.
- Issues related to SIEF functioning not yet addressed by DCG were raised, focusing on data sharing; it was agreed to examine those issues further.
- The discussion on the evaluation process continued, covering in particular, issues related to substance ID, compliance check including CSR and exploring the respective roles and mandates of ECHA and MS in this context with a view to ensuring maximum REACH compliance.
- The authorisation discussion related to the speeding up of the authorisation process was already mentioned in the open session on the first day of the meeting. Ideas for the next steps in the process, how to implement Article 57(f) and how to organise the work were exchanged.
- Finally, the CAs exchanged views about RMOs for a number of substances for which they may, or may not, at some stage, wish to prepare Annex XV dossiers. The need to deepen the discussion on PBT identification was pointed out in this context. ECHA offered some first conclusions on the type of information that RMO paper could consider.
- The UK and FR reported on the progress on assessing the new data on DecaBDE and informed the meeting that if a concern remains, the UK would consider preparing an RMO paper with support of FR.
- ECHA announced that they would organise a CA workshop in October to continue the discussion on substance evaluation.

SUB-SESSION B.2: ECHA POINTS

10. AUTHORISATION

10.1. Revised format for Annex XV SVHC reports

After minor changes the revised version will be made available.

10.2. SVHC submission dates for 2011
The planned submission dates for 2011 of 24 January & 1 August were endorsed.

10.3. Preparations for authorisation applications
ECHA has to be prepared for early authorisation applications, and then later there are likely to be a high number. Internal processes are in development & planning how RAC & SEAC operate & produce outputs of more use to COM in making decisions. Communication to industry is important. MSCAs appreciated the document provided and the fact that ECHA was preparing itself (well) in advance of the actual submissions.

11. INTERMEDIATES IN REACH: THE OUTCOME OF ECHA'S FIRST SCREENING ACTIVITY UNDER EVALUATION

Document
There was a presentation and discussion of the ECHA report on evaluation of chemical intermediates dossiers. MSCAs appreciated that ECHA had started these evaluations and

agreed on the cautious approach taken until now but nevertheless expressed some concern as to how long ECHA would continue applying this 'soft' approach in dealing with non-compliant dossiers (i.e. by QOBLs). ECHA clarified that it normally proceeds directly to draft decisions in potential incompliant cases under compliance checks and plans to apply this approach also for intermediates in the future.

12. STATE OF PLAY ON GUIDANCE UPDATES

ECHA gave an update on guidance, including the draft Annex II SDS guidance as requested by the one MS. One MS asked about the moratorium in guidance necessary for registration, i.e. on scope of exposure assessment. CEFIC confirmed that their SCC guidance will be updated to for better explaining rigorous entailment as understood by the chemical industry, and this is worked out with examples. One MSCA expressed concern that diverging views already seem to be arising. Another MSCA asked whether the SDS guidance would be translated quickly once available as the document is important for industry. It was agreed to have longer commenting periods.

ECHA replied that the guidance on SDS will be translated. Furthermore, reference was made to the discussions in the DCG and that an analysis of lessons-learned from the first registration and notification deadlines and how to apply them to the further development of guidance documents will be made.

Several MSs again questioned the status of PEG experts, claiming that they understood the experts to be totally dissociated from the CA's. ECHA clarified that the role of experts in Guidance update in general and in PEGs in particular was already discussed at the 5th REACH CA meeting held in September 2008 following a request by Member States and subsequently clarified in November 2008 in the paper Doc CA/52/2008. As a core element of the PEG consultation exercise, ECHA seeks to achieve that PEGs are composed not only of individual experts who provide the best possible scientific advice to ECHA in the Guidance development process, but also of representatives acting on behalf of their nominating organisation or Member State. Hence in this sense they are their representatives. The ECHA Secretariat selects the PEG members from a list of experts nominated by stakeholder organisations with a EU-wide membership and mandate and by institutional interested partners including MSCAs. These experts are selected by ECHA based on several criteria as specified in the Consultation procedure on Guidance. Among these criteria are the required scientific and technical expertise to be addressed and the field covered by the nominating organisation. From this it is clear that scientific and technical expertise really matters. Their input in the Guidance development process is critical. The detail of the relationship between a PEG expert and the nominating organisation is an internal matter outside ECHA's field of concern or influence. One MSCA expressed that it understood the role of the experts in the PEG as explained by ECHA.

SESSION C: JOINT ISSUES REACH/CLP

13. COOPERATION WITH OECD/UN

13.1. Coordination with OECD work on test methods
COM introduced the issue of co-ordination the work on tests methods and mentioned that it will start discussions with OECD secretariat on how to include OECD methods into Test method regulation.

COM introduced the issue of co-ordination of the work on tests methods with OECD. The goal is to adapt the OECD methods as much as possible to EU standards in order to minimise the changes needed for adopting the methods in the Testing Methods Regulation. In that context, MS are asked to inform their OECD representatives on the importance of this matter.

One MS mentioned that the changes required are not that big, especially in comparison with the changes that needed to be made for the implementation of GHS into CLP and also is pessimistic on the possibility to make changes at OECD level.

One MS had a detailed comment on the comparative table of CA/51/2010. MS were asked to send other comments as soon as possible as the vote on the 2nd ATP is very close to being launched for written procedure.

13.2. Extended one generation reprotox

COM briefly introduced the topic that was put on the agenda to inform MS of the ongoing discussions on the extended one generation reproductive toxicity study (EORGTS).

Several MS and stakeholders took part in the discussion. MS and stakeholders raised concern whether the extended one generation study will provide sufficient information and indicated a retrospective analysis would be needed to appreciate the new endpoints introduced.

COM emphasised that there was no intention to conclude the discussion at this CARACAL meeting but that it wanted to inform CARACAL on the ongoing work and that the possible impact on REACH will have to be discussed in the future.

MS were asked to send comments in writing by mid July.

The study will be discussed en of June by EU experts and at a joint meeting with OECD in November.
RAC was informed about the extended but there are no plans to have parallel activity (to national coordinators).

14. COMMISSION ACTIVITIES

14.1. Outcome of workshop on penalties under REACH and CLP

COM briefly introduced the results of the workshop on penalties.
In conclusion, the report does not give a full picture – it provides info on legislative tool but not on implementation in practice. COM will continue to monitor.

The report has been published on the COM website.

Day 3 – 17 June 2010

SESSION D: CLP

COM drew attention to three documents which have been recently uploaded in CIRCA (CA/73/2010 regarding test methods to be used for classification of substances and preparations as harmful with R65; CA/74/2010 regarding the recast of the Dangerous Preparations Directive and CA/75/2010 with an update on the 2nd ATP to CLP) and a room document n° 1 regarding the confidentiality of IUPAC names in the C&L Inventory. COM will seek initial reactions to some of these documents under AOB.

The agenda was adopted without further changes.

SUB-SESSION D.1: COMMISSION POINTS

15. CO-ORDINATION OF SCEGHS

COM announced that, as a consequence of the changes introduced by the Lisbon Treaty regarding EU external representation in international organisations, it was necessary to improve coordination of common positions prior to the international meetings. COM stated in particular that as the work in the UN Sub-Committee of Experts on the Globally Harmonised System (SCE GHS) has important implications on the EU – as the outcome is implemented by an amendment to the CLP Regulation, COM and MS are bound by the duty of sincere cooperation. Internal consultations are on-going to clarify the legal situation, procedures, and the roles of COM and MS in the SCE GHS and the Committee in the future, and the outcome will be presented at the next CARACAL. In the meantime, COM, for the first time, had prepared a document to facilitate coordination of main issues to be discussed at the 19th session of the SCE GHS.

Most MS welcomed the proposal for increased coordination and agreed on the need to further reflect on whether CARACAL was the right forum to discuss the procedural formalities and/or the technical details of co-ordinated positions. For the upcoming meeting informal coordination meetings on the spot will still be needed. COM recalled its intention to clarify all legal formalities and procedural issues in the near future and suggested to concentrate discussions on the content of the paper that had been prepared. COM then presented the document.

One MS expressed concerns on the proposal on hazard communication for supply/use of aerosols due to potential inconsistencies with the transport provisions. It also expressed its surprise with regard to the comments received by another MS expert on the proposal to align the corosivity criteria in the UN transport model regulations with the GHS. It stressed the need to enhanced coordination with the transport experts to better understand the impact on the transports area.

COM agreed that coordination with transport experts should be improved and offered the possibility to organise a tele-conference prior to the meeting in Geneva to facilitate further discussions where the participation of transport experts and DG MOVE would be welcome. 3 MS confirmed their interest in joining the call. (Due to time constraints it was suggested after the meeting to use the informal MS coordination meeting at Geneva to discuss the issue.)

One MS commented that as a general issue, the level of harmonisation of classification for substances in transport and supply should improve. However, as it was not feasible to do this systematically for all substances, proposals should be made whenever a substance has gone through the harmonisation process under the CLP Regulation as then all relevant information would have been newly assessed. COM supported the general concept and the proposed way of proceeding.

Regarding the labelling of small packaging, COM drew MS attention to an INF paper prepared by the European Directorate for the Quality of Medicines & HealthCare (EDQM) in the Council of Europe. EDQM supplies about 2500 reference standards to laboratories around the world for the testing of components used in medicinal products in packaging of 3 cm long and the interpretation of the GHS labelling derogations in section 1.4.10. An observer confirmed that industry is preparing an INF paper on small packaging for the up-coming UN SCE GHS end of June.

COM informed about three documents to be considered at the SCE GHS meeting related to the issue of the merits of an internationally developed and maintained GHS classification list: (1) a proposal from the informal working group on implementation issues, (2) a consolidated paper with comments on the survey for existing international classification lists for which COM had provided input after consultation with the MS, and (3) a comparison of the transport classification and the CLP classification.
COM and MS agreed that the idea of setting up a list of classification of substances on a global level should be supported, but the resource implications need to be taken into account. COM concluded that developments should be followed but no immediate systematic action to harmonise the existing lists seemed feasible. One could expect that over time, the C & L Inventory and the eChem-Portal maintained by ECHA might become *de facto* global reference standards.

COM concluded on the need to further reflect with the MS on how to improve coordination, including transport experts, and offered to present suggestions at the next CARACAL meeting. In any case, it should be avoided that different MS are expressing diverging views at the SCE GHS meeting.

[The meeting documents and the minutes of the SCE GHS meeting can be found on:
http://www.unece.org/trans/main/dgdb/dgsubc4/c42010.html and
http://www.unece.org/trans/main/dgdb/dgsubc4/c4inf19.html]

16. ART. 45(4) CLP

A representative from the NL Poisson Information Centre (PIC) made a presentation to inform on the progress made so far by COM and the European Association of Poison Centres and Clinical Toxicologists (EAPCCT) regarding the project to harmonise the essential information to be provided to national PICs for medical purposes.

Following interventions by several MS regarding the possibility to set up a central data base, EAPCCT stressed that the scope of the current project was to harmonise the format with the basic information that should be sent to each national PIC but not to create a central data base.

One MS considered that the information gathered via REACH registration should be taken into account in the future to assess the need for a further data base. COM confirmed that the objective of creating a central data base, such as the one for cosmetics, was out of the scope of the on-going work. COM highlighted that the capacity of a central data base for cosmetics would be very small in comparison for one that would be needed for the chemical sector. The issue of a central database would need careful consideration and could only be explored at a later stage.

COM informed MS about difficulties in identifying the right contact person for those MS where the PIC information is first send to a so-called national receiving body and invited MS to send that information to COM. Some MS provided contact details on the spot.
To conclude, COM invited MS and all other relevant stakeholders to participate in the EAPCCT workshop on 24 November 2010 and informed that the conclusions of the workshop would be shared with CARACAL to start further reflections on a future amendment to CLP.

17. TOXICOVIGILANCE

One MS introduced the paper on toxicovigilance which stressed the interest of establishing a European-wide system of toxicovigilance, covering all chemicals placed on the EU market. Harmonising of the ways in which PIC report on their activities and on incidents involving chemicals would allow to monitor whether particular chemicals created more problems than others.

One MS referred to the Risk Communication network coordinated by ECHA as a possible forum where some discussions could be envisaged. Another MS supported the objective of setting a uniform reporting system, noting also that such reporting could be used to monitor the effectiveness of restrictions or other risk management measures. The MS also referred to the financial implications of setting up a toxicovigilance system and the need to target the scope to only certain suspicious chemicals if some work was to be envisaged in the future. COM agreed that harmonisation of reporting would be desirable as well, but concluded that first it was necessary to finalise the on-going project regarding information requirements, formats and categories of chemicals before reflecting on future steps.

18. 2ND ATP TO THE CLP

COM informed that a new CARACAL sub-group for ATPs had been set up. A first meeting took place on 27 May with CLP experts to discuss the main issues of a 2nd ATP to CLP, which intends to adapt the CLP annexes to the 3rd revision of the GHS. COM presented progress made and indicated the main remaining issues for which MS had been invited to provide comments. COM gave an overview of next procedural steps and stated the intention to vote on a text at a REACH Committee meeting before the end of the year.

19. REPLY TO DK COMMENT TO COM PAPER ON IMPURITIES CA/87/2009 REV 1

COM presented the reply to DK comments on the document endorsed at the previous CARACAL concerning the classification of substances containing a CMR constituent at a concentration above its specific or above the generic concentration limit.

DK expressed satisfaction with COM reply.

One MS asked where COM would place that information so that all MS and stakeholders would be aware of the paper and to avoid that the same problem would be raised again in the future. COM indicated that it would reflect on the best way to disseminate the paper.

SUB-SESSION D.2: ECHA POINTS

20. CLP AWARENESS UPDATE

ECHA introduced a paper containing the latest developments on ECHA's CLP communication activities and encouraged participants to make use of the new CLP banner.

ECHA gave an update and invited MS to inform about the willingness to invite an ECHA expert to a national CLP workshop. The deadline for identification of national events for ECHA is 16 July 2010.

21. CLP AOB

21.1. Interpretation of Art 39(b) of CLP

One MS presented a paper questioning the latest COM interpretation of 'concentration limits' in Article 39(b) CLP, which was interpreted in a very broad sense in order to also include 'cut-off' values. The MS contended that indeed, there were no concentration limits in mixtures for substances classified as acutely toxic, which was regrettable, but if the broad interpretation presented by COM had been intended by the legislators, the text in Article 39(b) should be modified via a corrigendum to make reference to both 'concentration limits' and 'cut off values'.

COM explained the reasoning behind the broad interpretation and agreed that in the future the text could be improved by making reference to both terms. However, this could not be done via a corrigendum as it would be a substantial modification of the text. Unfortunately, this could not be done quickly and, as expressed by some MS, there were concerns to introduce changes at the legal text just before the deadline for notification.

Several MS shared concerns on the use of a broad interpretation – taking into account in particular also the workload for companies and the number of additional notifications, but agreed on the need to have a common approach. Other MS agreed with COM position to avoid a situation where substances classified as acutely toxic would not be notified when imported in mixtures. Another MS referred to ECHA's Guidance document on CLP where reference was made not just to concentration limits but also cut-off values as triggers for making notifications.

One observer informed that industry is currently discussing this issue and many companies are following the strict interpretation and would therefore only notify substances in mixtures above the concentration limits leading to classification of the mixture.

COM concluded that as the majority of MS agreed that it would be desirable to receive notifications for substances in mixtures above the cut-off values, ECHA's guidance should serve as a reference. The possibility of introducing changes to the legal text should be further analysed in the future. One MS cautioned that whilst it fully agreed with the usefulness of notifications for all substances in mixtures above the cut-off value, it considered it difficult in the light of the current text of Article 39(b) of the CLP Regulation for the enforcement authorities to pursue those companies that based their notification only on concentration limits.

21.2. Classification of substances and preparations as harmful with R65.

COM presented a document with a question from the authorities from one MS regarding the test method to be used for the classification of a varnish as harmful with R65. Since the document had been submitted just prior to the meeting, COM invited MS to provide comments by 6 July on how MS and other stakeholders apply the test methods listed in Directive 67/548/EEC for specific types of mixtures (such as paints and varnishes).

21.3. Confidentiality of IUPAC names in the C & L Inventory.

COM introduced a room document regarding confidentiality of IUPAC names in CLP – in particular with regard to the C&L Inventory to be published on ECHA's website and interaction with REACH. The document contained COM legal interpretation of the confidentiality provisions in CLP with regard to the C & L Inventory, and an ECHA proposal for a pragmatic implementation. The document had been initially discussed at the DCG, but the views of MS were important before ECHA would implement the proposed procedures. COM and ECHA invited participants to submit comments by 30 June.

FOR INFORMATION

8. Recast of the Dangerous Preparations Directive (Directive 1999/45/EC)

COM had prepared a document to inform MS of on-going work to recast the Dangerous Preparations Directive (DPD) to ensure that an updated version reflecting the changes introduced by REACH, CLP and other related pieces of legislation would be available to all authorities and stakeholders. COM stressed that the only purpose was to ensure legal clarity and not to introduce any new topic. Normally such changes should be legally introduced via a "codification", however a 'recast' was required in order to align the comitology provisions to the new rules introduced by the Lisbon Treaty. MS were invited to send comments by 16 July.

AOB - Vacancy

COM informed that the contract of a temporary agent working on CLP issues in COM expired on 31 October. A vacancy notice[1] had been published on the website of DG Enterprise and Industry, which contained all relevant details and forms. The application deadline is 1 July.

[1] Available at: http://ec.europa.eu/enterprise/newsroom/cf/itemlongdetail.cfm?item_id=4313

The Chair announced that next CARACAL meeting would take place on 25-27 October, pending confirmation of availability of rooms.

SESSION E: CLOSE OF THE MEETING

EUROPEAN COMMISSION

ENVIRONMENT DIRECTORATE-GENERAL
Water, Chemicals & Biotechnology
Chemicals & Nanomaterials

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

Brussels, 01.06.2010
Doc. CA/37/2010, rev.2

DRAFT AGENDA
5th Meeting of Competent Authorities for REACH and CLP

15-16-17 June 2010

Centre A. Borschette,

Rue Froissart, 36, BE-1040 Brussels, Belgium
Room 1A

15 JUNE	**REGISTRATION**		**09:00-09:30**
AGENDA ITEM	**DOCUMENT**	**ACTION**	**TIME (APPROX.)**
SESSION A: GENERAL ISSUES			9:30 – 10:05
1. ADOPTION OF AGENDA	CA/37/2010	Discussion/ Adoption	9:30 – 9:40
2. FOLLOW UP FROM 4TH MEETING OF CARACAL - Draft summary record - List of Actions	CA/38/2010 CA/34/2010 rev1	Discussion/ Adoption	9:40 – 9:50
3. OVERALL WORKPLAN FOR CARACAL - Work plan for CARACAL (overview of Comitology procedures, CARACAL subgroup meetings)	CA/65/2010	Information	09:50 -10:00
- Next CARACAL meetings		Information	10:00- 10:05

SESSION B: REACH			10:05 – 18:00
SUB-SESSION B.1: COMMISSION POINTS			
5. REACH REGISTRATION AND SCOPE			
5.1. Reporting on Director's Contact Group	CA/39/2010	Information	10:05 – 11:00
Coffee Break			***11:00 - 11:20***

5.2. Communicating about REACH	CA/64/2010	Information/Discussion	11:20- 11:35
5.3. Annex I and V of REACH – adaptation to CLP	CA/40/2010	Information/Discussion	11:35 – 11:50
5.4. Article 2.1. b) of REACH – input from COM	CA/41/2010	Information	11:50 – 12:00
6. REACH AUTHORISATION			
6.1. Update on the implementation of the agreement reached by VP Tajani and Commissioner Potočnik on 25th March		Information	12:00 – 12:10
6.2 State of Play on draft Authorisation and SEA/authorisation Guidances	CA/66/2010	Information	12:10 – 12:50
6.3. Draft Regulation for the Amendment of Annex XIII[2]	CA/42/2010	Information	12:50 – 13:10
6.4. Draft Regulation for the Amendment of Annex XIV	CA/67/2010	Information	13:10 – 13:30
Lunch			***13:30 – 14:30***
7. REACH RESTRICTIONS			
7.1. PAH in consumer products	Document from DE	Information from DE	14:30 – 14:50

[2] Due to the currently ongoing inter-services consultation on Draft Regulation for Amendment of Annex XIII and Annex XIV and according to Article 5 of CARACAL Rules of Procedures, the documents CA/42/2010 and CA/67/2010 will be uploaded at a later stage.

7.2. Restriction of: - Cadmium in brazing materials, jewelleries and PVC • report from workshop held on 26 March • proposal amending the current restriction for Cadmium - Acrylamide in grouting applications - 1.4 Dichlorobenzene	 CA/43/2010 CA/62/2010 CA/63/2010	 Information/ Discussion Information Information	 14:50 – 15:20
7.3. Amendment of Annex XVII (PFOS and Penta BDE)		Discussion	15:20 – 15:30
Coffee Break			***15:30 – 15:50***
7.4. Review of existing restrictions for phthalates	CA/44/2010	Information/ Discussion	15:50 – 16:20
8. REACH CASG NANO			
8.1. Feedback from CASG Nano meeting on 3-4 May 20l0	CA/68/2010 CA/69/2010	Information/Endorsement of two documents	16:20 – 16:40
8.2. Main relevant international activities regarding work on nanomaterials	CA/45/2010	Information/ Discussion	16:40 – 16:50
8.3. Identification of nanomaterials and status of carbonanotubes (CNTs)	CA/46/2010	Information/ Discussion	16:50 – 17:15
9. REACH AOB			
9.1. Test Methods – Presentation of test methods to be included in the 3rd ATP to the Test Methods Regulation	CA/53/2010	Presentation/Discussion	17:15 – 17:25

9.2. Conclusion from the PFOA workshop	CA/59/2010	Information	17:25 – 17:35
9.3. Review process under Article 138 (6) of REACH		Information	17:35 – 17:50
9.4. Substances on stock and Article 5 of REACH		Information from FR	17:50 – 18:00

16 JUNE 2010			**08:30**
AGENDA ITEM	**DOCUMENT**	**ACTION**	**TIME (APPROX.)**
CLOSED SESSION Feedback on closed session when open session resumes			08:30 – 13:30
Lunch			***13:30 – 14:30***
SUB-SESSION B.2: ECHA POINTS			14:30 – 16:50
10. AUTHORISATION			
10.1. Revised format for Annex XV SVHC reports	CA/47/2010	Presentation/Discussion	14:30 – 14:45
10.2. SVHC submission dates for 2011	CA/48/2010	Endorsement	14:45– 15:00
10.3. Preparations for authorisation applications	CA/49/2010	Presentation/Discussion	15:00 – 15:30
Coffee break			***15:30 – 15:50***

11. INTERMEDIATES IN REACH: THE OUTCOME OF ECHA'S FIRST SCREENING ACTIVITY UNDER EVALUATION	CA/50/2010	Presentation/Discussion	15:50 – 16:35
12. STATE OF PLAY ON GUIDANCE UPDATES • Annex II update (as requested by NL)	CA/58/2010	Information/Discussion	16:35 – 16:50
SESSION C: JOINT ISSUES REACH/CLP			16:50 – 18:00
13. COOPERATION WITH OECD/UN			
13.1. Coordination with OECD work on test methods	CA/51/2010	Information/ Discussion	16:50 – 17:20
13.2. Extended one generation reprotox	CA/52/2010	Information/ Discussion	17:20 – 17: 45
14. COMMISSION ACTIVITIES			
14.1. Outcome of workshop on penalties under REACH and CLP		Information	17:45 – 18:00

17 JUNE 2010			**09:30**
AGENDA ITEM	**DOCUMENT**	**ACTION**	**TIME (APPROX.)**
SESSION D: CLP			
SUB-SESSION D.1: COMMISSION POINTS			
15. COORDINATION OF UN SCEGHS ACTIVITIES	CA/54/2010	Information/ Discussion	9:30 – 10:15
16. ART. 45 (4) CLP - Assessing the possibility of harmonising		Presentation from representative EAPCCT	

information relating to emergency health response by appointed bodies in MS – Presentation of work carried out by COM and European Association of Poison Centres and Clinical Toxicologists (EAPCCT)			10:15 – 11:00
Coffee break			***11:00 – 11:30***
17. TOXICOVIGILANCE	Document from PL	Information from PL	11:30 – 11: 45
18. 2ND ATP TO THE CLP		Information	11:45 – 12: 15
19. REPLY TO DK COMMENT TO COM PAPER ON IMPURITIES (CA/87/2009 REV 1)[3]	CA/61/2010	Information/Discussion	12:15 – 12:40
20. CLP AOB			
20.1. Interpretation of art. 39 (b) of CLP	Document from PL	Information from PL	12:40 – 13:00
SESSION E: CLOSE OF MEETING			
Lunch			***13:00 – 14:00***

5TH MEETING OF CARACAL 15-16-17 JUNE 2010

Information Points:

INFORMATION POINT & OUTLINE	DOCUMENT
COM points	
1. Implications of the Market Surveillance Regulation on REACH enforcement	CA/34/2009 rev. 1, Annex I
ECHA Points	
2. Report on the recent Forum activities	CA/56/2010
3. Status report on proposals for harmonised C&L	CA/57/2010
5. Status of registrations and REACH IT	CA/53/2010

[3] Late document

6. CLP functionalities available in REACH-IT for Industry	CA/55/10
7. CLP awareness update	CA/70/2010

Rules for information points:

- Information points and accompanying documents are not allocated a specific agenda time but the documents are available on circa before the meeting;

- Information points can be prepared by COM, ECHA or MS and these documents are included in the draft agenda;

- Information points should have a title and a short outline of the main issues discussed in the document;

- Based on the outline referred to above, if any MS considers that information point may merit a specific agenda point, they should inform COM by sending an email to Raluca.Iagher@ec.europa.eu and Jacek.Rozwadowski@ec.europa.eu at the latest 10 days before the meeting.