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ENVIRONMENT DIRECTORATE-GENERAL
Water, Marine Environment & Chemicals
Chemicals, Biocides & Nanomaterials

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

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SUMMARY RECORD

9th Meeting of Competent Authorities for REACH and CLP

26-27-28 October 2011

Berlaymont, Room Walter Hallstein
200, rue de la Loi, 1040 Brussels, Belgium

1. Adoption of Agenda for CLP Session (CA/60/2011 Rev. 2)

The Agenda was adopted

2. Interpretation of Art 37 (6) CLP

COM informed CARACAL about a Commission discussion paper under preparation to address the problem of how to update existing entries in Annex VI CLP, when the criteria for classification change. The issue has already been raised regarding the criteria for classification of sensitisers, modified in the 2dn ATP to the CLP Regulation but could be extended to other changes. COM indicated that a discussion paper would be presented and discussed at the next meeting of the CARACAL CLP Sub-group scheduled for 21 November. The proposal should be legally sound and possible to implement without overburdening the system.

3. Follow-up Poison Centre working group meeting 15 June 2011

COM informed CARACAL about the first 2011 expert and stakeholder working group meeting, which took place on 15 June 2011. At the meeting, the three most controversial topics resulting from the November 2010 workshop were further discussed.

COM established 8 newsgroups after the working group meeting in order to provide also for those not being able to participate in the meeting the possibility to provide comments on the three topics mentioned before and five others less controversial topic.

The deadline to submit comments was 30 September. The analysis of the comments received will be presented at the next and last expert working group which will take place on 7 November in Brussels.

The meeting will be web streamed, in order to give those who cannot attend the meeting the possibility to follow the debate either on the same day or at a later point in time.

4. Nitrobenzene Entry

COM summarised the content of document CA/61/2011 regarding the current discussion in RAC to have two separate entries, one for nitrobenzene with less than 0.1% of the impurity benzene and other for nitrobenzene with • 0.1% benzene.
In the view of the Commission the current proposal is not in line with a previous CARACAL paper (CA/87/2009): it is not required to add a specific entry in Annex VI to harmonise a substance classification based solely on the presence of an impurity which in fact is already an obligation according to CLP art. 11. Therefore COM presented a proposal not in favour of the addition of a new Annex VI entry for Nitrobezene containing x% of benzene.
MSCAs supported the arguments in favour of one single entry in Annex VI CLP and encourage clarification in ECHA's guidance on substance identity to further communicate this approach. ECHA committed to check the guidance document and consider whether further communication efforts where needed.

5. C&L inventory

ECHA gave a presentation on the current state with the Inventory. MSCAs welcomed the progress made. Following aspects were mentioned in the discussion:

§ Two delegations asked for details on search functionalities of the Inventory;

§ It was stressed by one CA and STO (IND) that sufficiently detailed explanation on the actual use of the Inventory needs to be given when publishing it (delegations welcomed the planned campaign)

§ the plan to have language versions of the chemical names of harmonised entries in the Inventory in future was welcomed; in this context CAs asked if also synonyms would be included

§ details on ECHA's plans for getting notifiers together without existing SIEF on CLP were requested; IND asked if information on impurities would be also included and if yes, in which time horizon

§ One MS asked to be involved in guidance preparation.

ECHA replied that it may consider the aspect of impurities as part of the discussions on the

development of the platform; in relation to "reliability" of the Inventory – it will be part of the communication strategy to be clear that in time the reliability of the Inventory will improve. ECHA will also explore possibilities to make searches for MSs where needed.

Information will be provided at a forthcoming UN GHS mtg.

As to synonyms – they are additional to existing names; it is not seen the highest priority at the moment.

CAR 10 will get an update on the situation and first experiences after the publication.

6. ECHA Guidance update

ECHA Guidance update (AP6; CA/66/2011)

At the request of the NL CA short information was provided on the status of the update of the guidance document on the use of CLP criteria referring for more details to the paper submitted for information.

7. CLP AOB

7.1 Issues related to the UNSCE GHS

COM informed the meeting about topics discussed during the current Biennium in the SCE GHS. This concerned in particular the ongoing work in informal correspondence groups, as far as progress has been made since the last CARACAL meeting.
COM reiterated that the main purpose if this information point is to keep in particular those Member States updated which do not participate in the UNSCE GHS.

7.2 Update of CLP Notifications of national provisions for penalties

COM informed CARACAL that four MS had not yet adopted and notified the national provisions that MS were required to communicate to COM by 20 June 2010. Infringement procedures were about to be launched under Article 258 of the Treaty on the Functioning of the EU.

7.3 Update on ongoing procedures concerning the ATPs to CLP
COM updated MS on the progress and timeline regarding the 3rd ATP of CLP as well as the correcting act to the 1st ATP of CLP.

7.4 Unused diamonds on CLP label

NL asked for the discussion on the not completely clear current practice regarding unused diamonds on the CLP label, and proposed a uniform solution for the EU. The reason for bringing the issue to CARACAL is that the NL suggested solution goes beyond the current legislation. In addition it is a quite urgent issue that needs quick solution as currently IND uses different ways to deal with empty diamonds. Three delegations supported the plea for a quick solution.

ECHA gave a short background of the issue and referred to the standard procedure in place

for the revision of FAQs.

COM expressed the view that they are happy with both versions (the current wording of the FAQ as well as NL suggested amendment). No need to consult COM is identified since it is a practical issue and the normal procedure for updating the FAQs within HelpNet should be followed. However if the need arises, ECHA may bring it up to CARACAL. One CA referred to difficulties that occurred when this FAQ was discussed and expressed its agreement with the current wording of the FAQ since it reflects a pragmatic approach towards the problem and proposed to consult FORUM.

IND referred to possible negative impact (from market point of view) if blackening of non-used diamonds is used as the solution.

7.5 Legal basis for Norway to submit proposals to ECHA

A question has arisen on the legal basis for Norway to submit proposals to ECHA for the harmonised classification of chemical substances pending the incorporation of Regulation 1272/2008 on the classification, labelling and packaging of substances (CLP Regulation) into the EEA Agreement.

Background:

- The REACH Regulation 1907/2006 has been incorporated into the EEA Agreement in 2008;
- Article 115 of REACH gave competence to MS authorities to submit proposals for the harmonisation of classification and labelling:

Article 115
Harmonisation of classification and labelling
"1. Harmonised classification and labelling at Community level shall, from 1 June 2007, normally be added to Annex I of Directive 67/548/EEC for classification of a substance as carcinogenic, mutagenic or toxic for reproduction category 1, 2 or 3, or as a respiratory sensitiser. Harmonised classification and labelling for other effects may also be added to Annex I of Directive 67/548/EEC on a case-by-case basis if justification is provided demonstrating the need for action at Community level. To this end, Member State competent authorities may submit proposals to the Agency for harmonised classification and labelling in accordance with Annex XV."

- Article 115 REACH was deleted by Article 57(7) of the CLP Regulation and replaced by its Articles 36, 37 and 38 of the CLP Regulation;

- The incorporation of the CLP Regulation into the EEA Agreement is pending.

Analysis:

In the view of the Commission Article 115 REACH still remains the legal basis for Norway to act as competent authority pending incorporation of the CLP Regulation into the EEA Agreement.

This is because Article 115 REACH is still subject of the international agreement between EU and EEA countries. This agreement with the list of legislation constitutes the legal basis for

Norway to act as a MS CA. When the CLP Regulation will be incorporated into the EEA agreement, the CLP Regulation will constitute such legal basis.

Article 57(7) of the CLP Regulation, which repeals Article 115 REACH does not affect the EEA Agreement.

8. Adoption of Agenda for REACH session (CA/60/2011 Rev. 2)

One MS CA asked for a discussion about the contract for REACH and CLP inspection; initially it was planned as information point only. The Chair confirmed that this point will be discussed under agenda item on the REACH review.

The agenda was adopted.

9. Follow up of the 8th meeting of CARACAL

9.1 Draft summary record

The Chair asked for commenting in writing within three weeks.

9.2 List of Actions

The last version of the Action List was distributed as a room document. It was announced that the draft technical amendment to Annex XVII will be presented at the next CARACAL meeting.

One MS CA asked for distribution of Action List not later than one week before the meeting.

10. Overall Work plan for Caracal

Commission presented the Overall Work Plan for CARACAL.

The Chair addressed the specific question of three MS CAs by stating that

- A draft of the technical amendments to Annex XVII will be proposed to the next CARACAL
- formally Commission has not received information on lack of unanimity at the members State Committee re a testing proposal
- ECHA will add information on their web page regarding the status of restriction proposal sent to the Commission
- CASG nano meetings are provisionally scheduled for April and September
- A comitology meeting March 2012 is very likely to happen

The Chair confirmed that the comitology meeting scheduled for the 29 November will take place, no change in subject, invitations will go out shortly.

11. Report from the CA Session

The Chair presented a summary of the CA session, as follows:

Discussion covered a few points related to CLP, in particular the third ATP and whether or not epoxiconazole should be included. The COM heard the views of MS and will present its decision to the November REACH Committee. We also had a discussion on how to improve the CLH process covering both the ECHA and comitology parts.

We discussed some issues of largely procedural nature:

- The Commission provided some clarification on the recent COM-EP framework agreement and how confidential information is being handled under the agreement;
- how we replied to a recent very wide-ranging request for access to CARACAL documents;
- and provided an overview of ongoing REACH court cases.

We discussed the role of the candidate list and in this connection also touched on the reasons for and consequences of putting substances on this list. The discussion will be continued in a workshop hosted by ECHA in spring.

DG ENTR provided information about the new subgroup created under the Enterprise Policy Group; this group brings together representatives of economic and industry ministries and focuses on competitiveness and innovation aspects of REACH.

A discussion related to one specific substance took place to gain a better and shared understanding whether its dissolution in water would lead to a new substance. This discussion will also be continued via an informal workshop for interested CAs.

This morning ECHA provided an update on its work on intermediates aiming to clarify the division of labour between ECHA and national authorities in terms of verifying whether the conditions of Art 17+18 are met and, in a second step, where necessary, verifying compliance pursuant to Art 41.

ECHA also reported on the high number of inquiries received over the past year, many of which are of poor quality. ECHA has made progress for speeding up the inquiry process and is working on further automating the process on steps where no expert judgment is necessary.

On NONS, a brief discussion took place on the information exchange between ECHA and CAs on the update of NONS dossiers following the MS decisions requesting further data.

Finally, relations with the Forum were discussed, highlighting the need for good national coordination, but also close cooperation between CARACAL and the Forum in terms of items of joint interest.

12. Reach Review

12.1. Update on REACH review

Commission presented the update on the REACH review and informed that the survey supporting the study on the functioning of the Chemical Market received around 1600 answers. COM also reminded that a workshop is organised for December to discuss with stakeholders the preliminary results of some of the studies launched to support the Review and encouraged MS CAs to participate; until 25 October '11 only 1 MS CA has registered.

Industry association stressed the need for appropriate enforcement and, in that context, the COM reminded that a conference on enforcement will take place on 1st of March 2012.

The Chair, replying to questions from one MS CA about the timing and content of the communication relative to the final reports of the studies, said that the communication will be made on 1 June 2012; Commission will be sharing the results of consultants' studies but the reminded that those results are without prejudice of the content of the Review which is a COM responsibility. MS and stakeholders will of course have the opportunity to comment on the Communication once adopted.

12.2. Outcome of the REACH Conference of 23 September 2011

Commission briefed about the outcome of the REACH conference.

One MS CA asked for a summary of the presentation in writing. It is given here below.

- Over 400 stakeholders from 29 countries attended the REACH conference organised by the European Commission and ECHA in Brussels on 23 September. The participants were mainly from a variety of chemical or downstream user companies or representatives of industry associations or consultants. Several NGO's or national authorities were also present.
- Nearly 3400 people in 35 countries viewed the day via web stream and submitted questions online.
- The recording of the conference web streaming are available online.
- The conference aimed to do four things.

  1. Halfway between the two first REACH registration deadlines, the conference aimed to assess whether at this early stage in REACH implementation, we can already start seeing some concrete results that can be attributed to the REACH registration requirements.

  2. From a registration-technical point of view, how did things go? The work of the Directors Contact Group was presented and as well as presentations about the quality of registration dossiers and data sharing - and how things could be done better...

  3. How can the lessons learnt from 2010 be applied to 2013 to ease the way for that registration deadline. The conference was a launching pad for ECHA for the 2013 awareness raising campaign.

  4. Set out the why, how and what of the REACH 2012 review to dismiss any (widespread) misunderstandings about this exercise.

Some highlights:

Janez Potocnik placed REACH in the global context, looking back to the 1992 Earth summit which called for the safe handling of toxic chemicals and for building up knowledge on chemicals in general. And he looked ahead to the 2020 commitments. He also praised industry and ECHA for their good work in 2010.

Geert Dancet gave 8 examples of the follow up work that ECHA is doing after the 2010 deadline, including the search for "missing substances", checking companies' confidentiality claims, improving the presentation and searchability of data, evaluation of dossiers and of course preparing for the 2013 deadline.

The Panel, which was asked to reflect on REACH' early results, had some interesting insights:

- REACH is a European success story of which Europe does not have many. Why succes story? When first learnt that 1,000 's of chemicals that are part of our daily lives are not investigated, and we use them? REACH is a success because it put an end to this situation.

- REACH is a success because it works, despise sceptical or negative prognoses.

- The EU industry wants to make REACH work. REACH is a marathon and we have completed the first kilometres.

- For industry's sake, we need to build up confidence in REACH. Send out positive messages to the public that chemical data is now being built up in a structured manner for EU authorities and EU industry.

- Industry does not want more guidance but long term guidance.

- REACH is not the factor but could be a factor for a company to decide to relocate its production outside the EU.

- Sobering words by the European Trade Union Institute: In the EU, each year 74,000 workers die of using hazardous chemicals during work time in the chemical sector and DU. And one in 3 occupational diseases is caused by chemicals! So far, no visible REACH results here yet.

- A weakness in the REACH system: no possibility to withdraw a registration number to a company in case of incomplete dossiers. This would be a way to apply the "no data no market" clause.

- The main REACH benefit is to get rid of exposure of dangerous chemicals (over time). However, REACH is a slow vehicle. Too slow for the NGO's speaking on behalf of citizens.

- Nanomaterials. Only 3 dossiers out of 25,000 registrations register the nano form of a substance yet in Germany alone 900 companies are producing nanomaterials. REACH needs to be adapted urgently to make it nano-specific!

The other sessions were less political but more technical: The conference speakers highlighted the following issues:

- The Directors Contact Group will continue to work and keep the finger on the pulse
- The current registration dossiers show quite a few shortcomings in general but ECHA presented 10 top tips on how to improve registration dossiers – highly recommended viewing
- Industry wishes for open communication with ECHA and steady rules
- SIEFs are an industry responsibility – don't sit around, take the initiative – Sandra Carey's presentation, equally recommended for viewing
- Don't reinvent the wheel for SIEFs, there are many models
- SMEs need short and specific guidance
- Downstream users need to be much more involved in communication flows
- National helpdesks are there to help in particular SMEs

In the discussions, the many DU in the audience (in particular aerospace) spoke up and made us aware of their uncertainties about supplies in the future. The DU feel sidelined or victim of REACH procedures and need to feel much more part of the information and communication flows.

Many in the public commented about the registration expenses, the human resources involved, the level of competence needed to fill in the registration dossiers, or were wondering about financial support for innovation.

The Commission presented the REACH review as a legal obligation in the framework of better administration and reassured the audience that this would not lead to legislative changes for the 2013 deadline.

All presentations and discussions were very informative. We will be publishing the conference proceedings before the end of the year.

13. REACH REGISTRATION

13.1 Update on OECD TG 443 (EOGRTS) CA/78/2011

§ The discussion of the Expert Group (EG) was based on scientific matters mainly. During this discussion legal, regulatory, financial and practicality related questions were raised for which not all the information is available yet. Overall, the decisions made in practice will be the result of balancing the EG recommendations with the protection of human health, legal, regulatory, financial and practical possibilities and implications of applying OECD TG 443. The impact on the 3R's will also be considered.

§ The expert group, based mainly on scientific considerations, was of the opinion that OECD TG 433 (EOGRTS) is the preferred option for fulfilling the information requirement in Annex IX and X 8.7.3 in preference to the OECD TG 416 (2nd generation study). TG 443 provides additional assessment of parameters for reproductive toxicity

(anti-androgen effects, AGD and nipple retention), additional analysis of functional development endpoints, hormonal measurements, increased statistical power and sensitivity and overall an increased sophistication in the manner the animals are analysed.

- The expert group were not in agreement on the default content of OECD TG 443 to be used to fulfill the information requirements of Annex IX and X 8.7.3 in particular in relation to the requirement for the production of the 2nd generation and the conduct of the DNT and DIT cohorts but also in relation to some test parameters (e.g. duration of the pre-mating dosing period (for bioaccumulative substances), required number of cohort 1B animals, termination time of 2nd generation litters and criteria for dose level selection). In this context and with one of the main reasons being to address the uncertainty surrounding the added value of the P1/F2 generation compared to the results of the first (F1) generation or other available data, the EG recommended setting up a review phase where OECD TG 443 studies will be conducted and then analysed and reviewed in a prospective study.

- Recommendations based on the Expert Group (EG) mandate:
  - A review phase
  - Exposure as a criteria to trigger the assessment of the 2nd Generation
  - Scientific criteria to trigger the omission of the DNT and DIT cohorts
  - Update relevant REACH guidance to account for recommendations in relation to assessment of 2nd Gen & omission of DNT/DIT cohorts

The mandate of the EG was extended to the next CARACAL to provide information and address the 3Rs benefits and cost & practicalities questions. COM and CEFIC will provide a draft paper to the EG to begin this discussion and for a final paper to be available for the March meeting.

Other recommendations made by the EG but not in the EG mandate (indicate this is provided for information and that the main discussion is on the recommendations based on mandated items for the EG)**:**

- The inclusion of OECD TG 443 in the EU TMR
- The revision of REACH information annexes.
- Commission/ECHA to further investigate legal issues on the use of TG 443 and DNT & DIT cohorts in REACH.
- With regard to outstanding regulatory questions, COM will provide some questions to RAC on how regulatory decision making would deal with TG 443 +/- F2 compared to TG 416 and additionally the value of the information provided by DNT and DIT cohorts for C&L and risk assessment purposes.
- EU participation in the preparation of OECD GD 151was necessary.
- The OECD confirmed that there it had no information indicating that there was any US & CAN progress on use of TG 443.

A majority of Member States indicated their preference for EOGRTS over the 2-generation reproductive toxicity study to address the information requirement in annex IX and X 8.7.3. They agreed, as a fair compromise, with the criteria set out for the assessment of the 2nd generation in a limited manner and the omission of the DNT and DIT cohorts in the overall context of a review phase. This will develop more knowledge and experience to determine the default design of EOGRTS for REACH.

In general, Member States agreed on a need for the following measures:

1. The test method to be placed in the EU test method regulation (Reg. EC 440/2008)
2. The adaptation of the relevant REACH annexes to include the EOGRTS.
3. Review and update relevant REACH guidance
4. Liaise with RAC in relation to regulatory questions concerning EOGRTS

Addressing these measures will remove legal uncertainty surrounding the use of EOGRTS to address the data requirement 8.7.3 in Annex IX and X.

13.2. Update on Test Methods Regulation

Commission introduced two papers concerning the Test Methods Regulation (TMR) – the first one was on the ATPs to the TMR. The progress of the 3rd ATP (adoption for summer 2012) and a timetable for the 4th ATP, 5th and 6th ATP was presented.

The second paper was on the specific procedures for the meetings of the national coordinators (NC) for test methods. Two MS CAs made comments to the second paper which, with some changes, was endorsed. The first comment was provided by DE who asked that in section 2, in the first paragraph, line 2 of the text be amended to as follows: ". The National Coordinators are invited to attend the NCM and the Competent Authorities are informed accordingly". If this line is agreeable, the paper will be endorsed. In section 5 (4), FR sought that formal approval be provided after the commenting round in the written procedure. This was not accepted as the process is considered long enough and to add a formal approval step is considered too cumbersome. A tacit approval is an acceptable form to complete the written procedure.

13.3 Coordination HELPEX – CARACAL

This agenda point was suggested by a MS CA who asked ECHA about the increasing number of unsolved HelpEx issues.

The proposing MS CA introduced paper covering this agenda point. Its purpose was to try to find ways to accelerate the work of the HelpNet; the MS CA reminded that it was unclear what was happening to the unsolved issues for which there was no agreement and needed to know the reasons for disagreement. Also, it was suggested, as next step, to bring the unsolved issues to CARACAL.

The paper was supported by six MS CAs. One MS CA announced that a paper on this topic will be provided after CARACAL, and suggested setting up a small working group to solve the pending issues. If no solutions can be found, then the issue should be submitted to CARACAL.

ECHA commented that the question of unsolved issues was discussed at the last meeting of the Steering Group of HelpNet and reminded that so far HelpNet has handled about 6000 Q&A whereas the number of pending issues is 20.
Referring to a suggestion made during the discussion, ECHA commented that bringing unsolved questions to CARACAL is not the best cure as some cases are sent to the Commission for legal interpretation. ECHA also had reservations about communicating the

preliminary ECHA opinions on the issues under discussion but underlined the need for transparency.

One MS CAs mentioned a specific HelpEx issues which ahs not been concluded although considered relatively easy (HelpEx issue N° 5036).

Commission commented that the specific issue N° 5036 has been solved already abut COM is in the process of refining the reasoning and reminded that questions coming to the Commission are those which cannot be answered elsewhere - every answer requires reasoning science and legal aspect. In addition, one cannot modify a specific issue without ramification elsewhere – Commission needs to analyse the impact on other processes as REACH is a complex legislation with mutual interlinks.
In summary, the current status with HelpEx questions is 10 issues late and 10 cannot be solved, many others were solved.

Industry association stated that speeding a process of solving HelpEx issues is agreeable for everybody – it is important to get quick answers but it is most important to get the correct answer, i.e. first of all the quality of the answer.

13.4 EC Numbers and provisional list numbers CA/76/2011

DE introduced the paper which states that ECHA should be mandated to provide official numbers.

ECHA replied in reaction to providing official numbers:

§ If the List number is provided further to an inquiry, the SID has been checked and the number could become official easily. When the List number is automatically provided by REACH-IT, it would require first a proper assessment – it may be a complex process, e.g. when a company has given a more specific name for a substance which is also listed under a generic EINECS entry as it has happened with some hydrocarbon solvents. This might have impact to other areas regulated.

COM will provide clarification with regard to the relation to the old chemicals legislation.

In reaction to question of one CA ECHA explained that the paper put to the last CARACAL was mostly to inform that some registrants use list numbers in official safety data sheets. In reply to the question on the type of difficulties ECHA was facing on SID, ECHA informed on the challenges of the UVCBs, for which the registrants do not provide sufficient information on their composition and omit to provide adequate spectral data; ECHA also reminded that substance ID has been overlooked in case of existing substances.

14. REACH RESTRICTIONS

14.1. Implementation of restrictions – application of Art 68(2), Art 69(1) and Art 69(4)

Commission introduced the paper, which summarizes comments received on document CA/52/2011, describing the current understanding of the Commission of the distribution of

responsibilities to initiate a Restriction, between COM and MS. The paper also mentions next steps to be taken by the Commission – launch of a scoping study and work on the development of criteria to be used for assigning priorities for implementation of Art 68(2).

There was an overall approval for the Commission initiatives re the scoping study and the development of criteria.
Two specific questions were asked – whether a MS has an obligation to prepare an Annex XV dossier in case when a national authority considers that there might be a risk (i.e. use of Art 69(4). Another question was how Commission will handle the issue of non-threshold CMRs.

Commission responded that if a MS considers that there might be a risk, this should be a reason to prepare an Annex XV dossier. On the second question – the case mentioned in the paper was chosen as an illustrative scenario and should not be considered a definitive COM position.

Replying to questions from an NGO, the Chair said that that the scoping study would be available by the end of the next year (2012) and that the next steps will depend on the results of the study.

14.2. PAHs in consumer articles

Commission introduced the paper summarizing comments to the COM proposal for a restriction of Polycyclic Aromatic Hydrocarbons (PAHs) in articles that could be used by children under the age of 14 and presented a summary of the workshop on PAHs which took place on October 24th, 2011 in Brussels.

This was followed by a DE presentation of a proposal for restrictions of PAHs in consumer articles; DE proposes a wider scope of the restriction than the one made by COM as it covers articles intended for both children and adults.

There was a general support to the DE proposal, which extends the scope of the restriction proposed by Commission to adults. The reasons for supporting an extended scope were:

- Risks are to the whole population and not on children only;
- Enforcement of the actual restriction proposal is expected to be challenging as it is sometimes impossible to distinguish between articles intended for children (up to 14 year old) and adults. This may lead to a difference in enforcement according to the MS as well as confusion amongst industry which articles are covered by the restriction and which are not.
- Consistency in the final restrictions for articles intended for children on the one hand and for adults on the other, if going through different routes.

The DE proposal included also a content limit of 0.2 mg of PAHs, which was explicitly supported by three participants.

Another part of the discussion concerned the application of Art 68(1) and 68(2). Most of the MS supported the application of Art 68(2) for the restriction with an extended scope while 4

MS (NL, UK, IT, MT) expressed their preference for going through the normal route (Art. 68(1)).

The Chair thanks participants for the input and concluded saying Commission will consider the outcomes of the Expert Meeting, as well as the further information provided by MS, and will prepare a new draft proposal within the shortest possible time.

14.3. Report about legislation for asbestos in articles already in use

Commission introduced a paper which reports on exemption in articles, granted by Member States. The report was well received by the MS CAs. During a brief discussion it became clear that asbestos fibres were still imported by two MS.

COM confirmed being aware of the imports and informed that discussions with the importing MS are ongoing. Commission also announced the intention to ask ECHA to examine the current restriction on asbestos.

14.4 Update concerning draft amendments to Annex XVII REACH

Commission briefly introduced a paper on the status of the work on four restriction dossiers. The draft restriction for the use of DMFu will be at the attention of the REACH committee on 29 November while the COM plans to submit the other draft measures to the REACH committee for its session on 27-28 March 2012.

An industry association commented that there was a difference in the opinion between two ECHA committees (RAC and SEAC), on the proposed restriction for lead in jewellery. Concerning this specific issue, the association would prefer use of the concentration to determine the content of Pb rather than migration as the measurement of concentration is more cost efficient.

14.5. COM Activities under 69(1): request to prepare Annex XV dossiers, 1,4 DCB

COM informed about the formal request sent to ECHA to prepare an Annex XV dossier for restriction of 1,4-dichlorobenzene (1,4-DCB).

One MS CAs raised the question of preparation of RMO analysis prior to preparation of the Annex XV dossier and pleaded for the respect of this discipline and asked to put this point on the Action List.

ECHA confirmed receipt of the formal request and indicated that the document will be provided in April 2012. ECHA is planning to discuss this request further with COM.

15. REACH NANOMATERIALS

15.1. RIPoN1, 2 and 3 - report from COM on the written procedures and response to comments

The Commission reported on the further process of the RIPoN reports. The next steps covered two distinctly different processes; one for RIPoN1 which was discussed in CARACAL/58/2011/rev1 and one for the RIPoN2-3 which was, after written consultation of CASG Nano, ready to be forwarded officially to ECHA with a view to enable ECHA to make use of them for the urgent update of guidance and REACH implementing activities.

The Commission reminded CARACAL of the discussion on RIPoN1 in June followed by a written procedure in which the Commission received a high number of inputs from Members and observers. In light of these comments and discussions with those who had contributed CARACAL/58/2011 had been revised and was now considered final by the Commission. However, in light of the complexity of substance identification, not least for nanomaterials, the Commission would propose to consider the paper a living document that could be considered a reference point at present to be revised in light of new insights from practical work in ECHA.

The meeting agreed on keeping the document on the table as a living document. Some members continued to be of the opinion that further weight should be given to consider size as an identifier with a view to keep registration dossiers specific to nanomaterials or bulk materials. The meeting took note of these views but agreed to keep the document as drafted and return to the discussion at a later point when there is a more complete evidence base.

15.2. Definition of nanomaterials and how to make it operational in context of REACH and CLP

The Commission presented the adopted Recommendation on the definition of a nanomaterial to CARACAL. The definition was based on scientific input from SCENIHR, JRC but also a broad range of stakeholders who had provided comments either as part of the public consultation or through dedicated meetings. The final definition was based on size only. Another very important feature that had caught a lot of interest was the metric chosen to discriminate nanomaterials from other materials. SCENIHR had strongly argued to in favour of the number size distribution as the more accurate way to describe a nanomaterial compared to mass. This was a difficult choice as the number distribution was most correct but could prove a challenge to handle in practise. The Commission would therefore need to work further on a number of practical aspects.

As regards the use of the definition it should be noticed that it was addressed e.g. to Union Agencies, it was therefore the expectation that ECHA would start urgently reflecting on how it could help with the implementation of REACH.

Finally, the Commission invited all Members to carefully review the different language versions of the definition as the translation had proven to be difficult. As the plan was to use the Recommendation in various regulatory settings, it was important that the text was accurate.

In response to comments from the floor the Commission underlined that the definition did specifically include aggregates and agglomerates and that these could be larger than 100 nm for as long as the constituent particles for more than 50 % of the number of particles were 100 nm or smaller.

16. REACH AOB

16.1 Chemical mixtures

An NGO asked for the update on the preparation of the Commission report on mixtures which is under preparation following the Council conclusions in 2009.

Commission presented an update on chemical mixtures.

Following the Council conclusions in December 2009, the Commission continued gathering and processing information on combination effects of chemicals. In February 2010 DG ENV has published results of a comprehensive scientific study reviewing current approaches to the assessment of chemical mixtures called "State of the Art Report on Mixture Toxicity".

This study report was a starting point for further engaging in a discussion with other Commission services, Member States, industry, NGOs and all other interested stakeholders through consultations and workshops dedicated to the content of the State of the Art Report and to the cocktail effect issue in general.

In parallel, the Commission's three scientific Committees (The Scientific Committee on Health and Environmental Risks (SCHER), Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and Scientific Committee on Consumer Safety (SCCS)) are working on an opinion concerning "Toxicity and Assessment of Chemicals Mixtures". Their draft opinion has undergone public consultation that ended on 9 September 2011.

The Commission has informed CARACAL Members about the public consultation and invited them to submit their comments. In total, 41 submissions of comments were received in the public consultation (from 31 organisations and 10 individual contributors). Input to the consultation was provided by public authorities from 6 MS, by 8 European industry organisations and 6 European NGOs.

The draft opinion is currently being revised based on the comments received and is expected to be finalised in late November 2011. The adoption procedures in the three scientific Committees will then follow.

Once adopted, the opinion should provide scientific basis and elements into the Commission Report to the Council, preparation of which is pending. We expect that the report should be ready by March 2012.

16.2 Endocrine Disruptors

Ahead of the meeting, an NGO asked the Commission to present an update on the development of the Commission policy regarding endocrine disrupters, quoting the Fourth progress report on EU EDC strategy.

Commission present an oral update. One MS CA asked for including the report in the minutes of the meeting.

Update by the Commission:

The Commission has established an ad-hoc group of Commission Services, EU Agencies and Member States to exchange information related to endocrine disruptors and to assists the Commission in shaping future policy on endocrine disruptors. The 3rd meeting of the ad-hoc group is being organised on 16 November 2011. The invitation has been sent to CARACAL members and members of the standing committee under Plant Protection Product Regulation.

The representatives of stakeholders (NGOs and industry associations) have been invited to participate to the meeting too.

The Commission is organizing the 1st expert meeting on endocrine disruptors to be held on 17 November 2011. This meeting is being organised as a follow up to the discussion held at the 2nd ad-hoc meeting where the participants recognised that we are working on the interface between science and policy and that questions relating to policy development and promoting co-ordination may not necessarily attract the same participants as detailed reflections on scientific issues. At the 2nd ad-hoc meeting it was therefore agreed that it was desirable to establish an expert group to focus on the scientific issues and in particular on providing advice on the scientific criteria for the identification of endocrine disruptors. The invitation has been sent to CARACAL members, members of the standing committee under Plant Protection Product Regulation and the representatives of stakeholders (NGOs and industry associations).

In order to provide a solid scientific and technical foundation for its future work, the Commission services have also launched a major study on state of the art of the assessment of endocrine disruptors. The study is expected to be completed by December 2011 with expected publication at the end of January 2012. The objective of the study is to analyze and summarize results of regulatory relevance to the scientific debate in the field of endocrine disrupting properties of substances (industrial chemicals, plant protection products, biocides, synthetic and natural hormones, pharmaceuticals, veterinary drugs) taking into account the Community Strategy for Endocrine Disrupters and the Commission Communication and Staff Working Documents on the implementation of the Strategy. The study will review the scientific knowledge published in the literature over the last 10 years and in the reports of more than 80 FP funded projects and will review the approaches for assessment of endocrine disruptors used in selected Member States, in major competing economies outside the EU and in international bodies. Based on these reviews, the study will draw conclusions and answer policy relevant questions.

16.3 Shale gas

Following a request from an NGO, Commission briefed CARACAL about the status of inquiries on the use chemicals for treatment of shale gas.

Following the email sent by the Commission on 6 June 2011 replies received from 7 Member States. There is very limited information on the substances used (or that could be used) for this purpose, i.e. glutaraldehyde**,** polyacrylamide**,** Hydrochloric acid and Fluorobenzoic Acid Chemical tracers.

According to replies received, there are no activities or permits in 3 Member States.

Other activities:
DG ENV requested ECHA to carry out a search in the Chemical Safety Reports of registration dossiers for a selected number of substances having a high probability to be used in shale gas operations.
The search was carried out with a limited number of keywords (shale, gas, conventional, unconventional, hydrocarbon, recovery). Based on this initial review, it appears that the dossiers for the selected substances do not contain references to such key words.

A more in depth assessment will be performed by JRC on the registration dossiers for the 16 substances having a high probability to be used in shale gas operations. MS CAs will be kept informed about the outcome of assessment.

DG ENV is also carrying out analysis of applicable environment acquis, here as well results will be shared in due course.

Given the uncertainties surrounding the chemical substances being used in shale gas operations, REACH MSCAs are strongly invited to liaise with respective competent authorities in charge of shale gas (most probably mining authorities) in order to ensure that information on substances used in hydraulic fracturing operations is made available in a timely manner to public authorities (including, if possible, quantities used and concentration in the overall fracking fluid), and to make sure that all operators fully comply with REACH requirements.

Commission services may also alert the Forum to the need to be vigilant re: use of chemicals for fracking.

In a discussion after the presentation, one MS CA announced an intention to conduct a study of environmental impact of substances used for the treatment of shale gas, especially that most of those substances are not identified as being used for this purpose.

An industry association confirmed that the suppliers are not always aware of this use and added that some of those substances fall under biocide regulation and not REACH

The Chair confirmed the need of additional information from the industry and said that this is a good topic for enforcement.

16.4 Better linkages between water policies and chemicals

This agenda point was requested by an NGO who asked about the link between the COM proposal on priority hazardous chemicals, expected to be published later this year (in relationship with the WFD) and the REACH Regulation.

COM presented its initial thoughts orally pointing at linkages such as the policy objectives, technical aspects and hierarchy between the two instruments. The REACH Scope review is looking at the interlinks and synergies in particular.
One MS asked about the relationship between aquatic PNEC (REACH) and water quality standards (WFD). Another MS found it important to strengthen linkages between WFD and REACH pointing at REACH helping protect drinking water and linkages between priority hazardous substances (WFD) and SVHC (REACH).
COM confirmed that the PNEC/EQS methodology is coherent and that it would provide more elaborated answer in future. COM is also in contact with services responsible for the drinking water.

16.5 Rules of organisation and procedure of ECHA's Board of Appeal

The Regulation on organisation and procedure for the Board of appeal was adopted in 2008. It contains a recital (10) foreseeing a review of the effectiveness of its provisions and their operation in practice, if necessary and on the basis of experience in its application.

Commission is to amend the provisions where appropriate based on this review.

Commission informed that COM committed to perform the review in 2011 (although no timing is foreseen in the legislation) in order to benefit from experience from the first registration deadline.

In summary, up to now 8 appeals were filed, 3 solved at a very early stage, 1 withdrawn. At the time of CARACAL, 2 appeals were pending, 2 decisions were already taken.

In order to broaden the approach, COM asked CARACAL members and observers as well as members of the REACH committee for input.

Commission informed that at the time of the presentation of this agenda point, no comments have been received.

One MS CA commented that with little experience up now, there was no reason to send comments but appreciated the initiative to see if the adjustment of the rules is needed.

Also, the MS CA asked if the decisions of the Board of appeal would be made public, for sake of transparency and mentioned that only a summaries of the judgment could be found.

Commission agreed to take into consideration a possibility to report back to CARACAL although this requires some further analysis.

17. EVALUATION

17.1 Update on the CoRAP development, CA/73/2011

ECHA briefly introduced paper covering main elements of the preparation of first CoRAP.

Further development and collaboration with MSs were the main discussion topics. Delegations are invited to provide information by mid-December, template letter will be provided for MSs.

ECHA expects that the 12 months period will be kept once all substances from MS arrive.

Delegations in general pointed out that speeding up the process would cause major difficulties to them. Regular meetings were proposed by one CA; some practical issues (such as reimbursement for fees, use of Art. 45) still need reconsideration.

ECHA to questions/comments:

- Initial screening was done, but more detailed one could be considered in next steps (as considerable resources were spent even on the initial one),
- Template for draft opinion not available but ECHA is open to discussing the need of such a template,
- To increase of numbers – again it is mainly on MS side and their resources that can be given to this (high workload on ECHA side was mentioned)
- As to Art. 45(5) and its implementation – no detailed plan now, but again it is one of the issues that will be further discussed, ECHA plans to do number of workshops that would be looking at different aspects in more detail,

- § Deadline for the financial arrangements – at the moment the precise information is not available but need to be in place before the evaluation starts - will be communicated as soon as it is available (in coming weeks),
- § Speeding up the process (deadline proposed in the paper is 18 November).

17.2 Dossier evaluation

ECHA gave succinct information on the latest statistics referring to reports given regularly to MSC and workshops planned (STOs are also invited) – further nominations are welcomed still in the course of the next week.

One CA asked for technical help with the access to CIRCA BC.

18. AUTHORISATION/RESTRICTION

18.1 Information note on Exchange Network on Exposure Scenarios, CA/82/2011

ECHA briefly introduced the network. The initiative was warmly welcomed by many delegations.

18.2 PBT WORKING GROUP

ECHA gave a brief introduction on the establishing of the PBT WG. Basic mandate of the group will be fixed after the meeting (updated on basis of comments but revisited after one year), self-standing ECHA expert group, nominations are sought via CARACAL. Formal letter asking for nominations will be sent to MSCAs.

Majority of delegations (9) and COM support the initiative (esp. informal nature of the group) with some MS indicating preference to start the group only with MS participants and only at the next step invite STOs. One CA and COM raised some concerns in relation to the role of the WG when dealing with providing advice to industry on details of testing to be carried out after evaluation decisions have been taken and suggested to add this option on an ad-hoc basis.

IND asked on the mandate in relation to future biocides regulation – will be considered in future.

Delegations were invited to comment on the paper by the end of the next week.

ECHA will update the mandate on basis of comments made and invite for nominations.

<u>ECHA preparations for Authorisation applications (AP18.3; ECHA ppt)</u>

ECHA gave a ppt with the overview of all related activities. Need for proper communication was highlighted in the discussion.

18.3 ECHA preparations for Authorisation Applications

ECHA gave a presentation with the overview of all related activities. Need for proper communication was highlighted in the discussion.

EUROPEAN COMMISSION

ENVIRONMENT DIRECTORATE-GENERAL
Water, Marine Environment & Chemicals
Chemicals, Biocides & Nanomaterials

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Chemicals, metals, mechanical, electrical and construction industries; Raw materials
Chemicals – REACH
Chemicals - Classification & Labelling, Specific Products, Competitiveness

Brussels, 21 October 2011
Doc. CA/60/2011 rev 2

DRAFT AGENDA
9th Meeting of Competent Authorities for REACH and CLP

26 October 2011 (09:00 – 12:35)
27 October 2011 (11:30 – 18:00)
28 October 2011 (09:30 – 16:00)

BERLAYMONT Building, Room WHALL
Rue de la Loi, 200, Brussels, Belgium

Discussion Points:

AGENDA ITEM	ACTION	TIME (APPROX.)
26 OCTOBER		
REGISTRATION		**09:00 – 09:30**
SESSION A: CLP		
SUB-SESSION A.1: CLP – COMMISSION POINTS		
1. Adoption of Agenda for CLP Session	Discussion/Adoption CA/60/2011	09:30 – 09:45
2. Interpretation of Art 37 (6) CLP	Information/Discussion	09:45 – 10:05
3. Follow-up Poison Centre working group meeting 15 June 2011	Information	10:05 – 10:20
4. Nitrobenzene Entry	Discussion/Endorsement CA/61/2011	10:20 – 10:40
Coffee break		***10:40 -11:10***
SUB-SESSION A.2: CLP – ECHA POINTS		11:10 – 11:55
5. C&L inventory	Information/Discussion	11:10 – 11:40
6. ECHA Guidance update	Discussion CA/66/2011	11:40 – 11:55
7. CLP AOB		11:55 – 12:35
7.1 Issues related to the UNSCE GHS	Information/Discussion	11:55 – 12:10
7.2 Update of CLP Notifications of national provisions for penalties	Information	12:10 – 12:15
7.3 Update on ongoing procedures concerning the ATPs to CLP	Information	12:15 – 12:25

AGENDA ITEM	ACTION	TIME (APPROX.)
7.4 Unused diamonds on CLP label	Discussion NL paper	12:25 – 12:35
MINI CLP CA SESSION FOLLOWS		12:35 – 13:00
Lunch		***13:00 – 14:00***
26 OCTOBER AFTERNOON – CA SESSION FOLLOWS		
27 OCTOBER		
REGISTRATION FOR THE OBSERVERS (COFFEE BREAK FOR THE OTHER PARTICIPANTS) 11:00 – 11:30		
SESSION B: GENERAL ISSUES		**11:30 – 12:30**
8. ADOPTION OF AGENDA	Discussion/Adoption CA/60/2011	11:30 – 11:40
9. FOLLOW UP OF THE 8TH MEETING OF CARACAL		
9.1 Draft summary record	Information CA/59/2011	11:40 – 11:50
9.2 List of Actions	Information CA/57/2011	11:50 – 12:00
10. OVERALL WORKPLAN FOR CARACAL		
10.1 Work plan for CARACAL (Comitology procedures, CARACAL written procedures, subgroup meetings)	Information CA/05/2011 Rev 2	12:00 – 12:10

AGENDA ITEM	ACTION	TIME (APPROX.)
SESSION C: REACH		
SUB-SESSION C.1: COMMISSION POINTS		
11. REPORT FROM THE CA SESSION		
11.1 Reporting on the CA Session	Information	12:10 – 12:20
12. REACH REVIEW		
12.1. Update on REACH review	Information CA/80/2011	12:20 – 13:00
Lunch		***13:00 – 14:00***
12.2. Outcome of the REACH Conference of 23 September 2011	Information	14:00 – 14:10
13. REACH REGISTRATION		
13.1 Update on OECD TG 443 (EOGRTS)	Discussion CA/78/2011	14:10 – 15:20
13.2. Update on Test Methods Regulation	Discussion CA/75/2011 (1)&(2)	15:20 – 15:35
13.3 Coordination HELPEX - CARACAL	Discussion	15:35 – 16:00
Coffee break		***16:00 – 16:30***
13.4 EC Numbers and provisional list numbers	Discussion	16:30 – 16:45
14. REACH RESTRICTIONS		
14.1. Implementation of restrictions – application of Art 68(2), Art 69(1) and Art 69(4)	Discussion CA/76/2011	16:45 – 17:30
14.2. PAHs in consumer articles	Information CA/77/2011	17:30 – 18:00

AGENDA ITEM	ACTION	TIME (APPROX.)
28 OCTOBER 09:30		
SUB-SESSION C.1: COMMISSION POINTS – CONTINUED		
14. REACH RESTRICTIONS - CONTINUED		
14.3. Report about legislation for asbestos in articles already in use	Information CA/74/2011	09:30 – 09:45
14.4 Update concerning draft amendments to Annex XVII REACH	Information CA/71/2011	09:45 – 10:00
14.5. COM Activities under 61(1): request to prepare Annex XV dossiers, 1,4 DCB	Information/Discussion CA/72/2011	10:00 – 10:15
Coffee break		***10:15 – 10:45***
15. REACH NANOMATERIALS		
15.1. RIPoN1, 2 and 3 - report from COM on the written procedures and response to comments	Information CA/58/2011 rev1	10:45 – 11:45
15.2. Definition of nanomaterials and how to make it operational in context of REACH and CLP	Information	11:45 – 12:00
16. REACH AOB		
16.1 Chemical mixtures	Information	12:00 – 12:10
16.2 Endocrine Disruptors	Discussion /Information	12:10 – 12:20
16.3 Shale gas	Discussion/Information	12:20 – 12:30
16.4 Better linkages between water policies and chemicals	Discussion/Information	12:30 – 12:40
16.5 Rules of organisation and procedure of ECHA's Board of Appeal	Information CA/86/2011	12:40 – 12:50

AGENDA ITEM	ACTION	TIME (APPROX.)
16.6 2013 Registration Deadline	Information/Discussion CA/70/2011	12:50 – 13:00
Lunch		***13:00 – 14:00***
SUB-SESSION C.2: ECHA POINTS		
17. EVALUATION		
17.1 Update on the CoRAP development	Discussion CA/73/2011	14:00 – 14:20
17.2 Dossier evaluation	Information	14:20 – 14:25
18. AUTHORISATION/RESTRICTION		
18.1 Information note on Exchange Network on Exposure Scenarios	Information/Discussion CA/82/2011	14:25 – 14:35
18.2 PBT WG	Discussion CA/83/2011	14:35 – 14:50
18.3 ECHA preparations for Authorisation Applications	Information	14:50 – 15:00
19. ART. 117(2) REPORT	Information/discussion CA/81/2011	15:00 – 15:45
SESSION D: CLOSE OF MEETING		15:45 – 16:00

INFORMATION POINTS:

9TH MEETING OF CARACAL 26-27-28 JUNE 2011		
1. Cost-sharing	Information CA/67/2011	

2. Report on 1st mandate of DCG	Information RRD/57/2010 (final)	
3. Tracking document	Information CA/36/2011 Rev 1	
4. CSA programme - overview	Information CA/68/2011	
5. Info document on ECHA activities related to DU reports and SiA notifications	Information CA/64/2011	
6. Report on activities of the FORUM WG on Interlinks	Information CA/65/2011	
7. MSCA WG on REACH-IT/IUCLID functionalities	Information CA/69/2011	
8.Contract for REACH and CLP Inspections	Information PPT	
9. Update of the Q&A document for restriction – Cadmium, entry 23 Annex XVII, para 10 and 11, Clarification of the meaning of the placing on the market and derogation	Information CA/62/2011	
10. Clarification concerning the scope of the exemption foreseen in Article 60(2) and Article 62(6) of REACH with regard to DEHP in medical devices	Information CA/85/2011	
11. Update of the guideline on the interpretation of the concept "which can be placed in the mouth" as laid down in the entry 52 of Annex XVII	Information CA/63/2011	
12. Update on ECHA Guidance activities	Information CA/66/2011	
13. REACH Registration campaign	Information CA/70/2011	
14. Submission dates for Annex XV SVHC and Restriction dossiers 2013	Information CA/87/2011	
15. Summary of the first meeting of the REACH-IT/IUCLID MSCA Working Group	Information CA/88/2011	

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 env-caracal@ec.europa.eu and entr-caracal@ec.europa.eu at the latest 10 days before the meeting.

19. ART. 117(2) REPORT , CA/81/2011

ECHA briefly introduced the background of this agenda point. One CA referred to ECHA STO survey and for structured response document on issues raised in the survey. Response to the survey will in a way be addressed in the Stakeholder event organised in November in Brussels.

One CA explicitly appreciated the report and indicated interest to some conclusions /recommendations in the report (namely possibility to withdraw the registration number, fees issue, withdrawing a substance from the Candidate List). ECHA responded these are issues COM will look at in the context of the review.