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Water, Chemicals & Biotechnology
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ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
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Chemicals - REACH

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SUMMARY RECORD

6th Meeting of Competent Authorities for REACH and CLP 25-26-27 October 2010

**Berlaymont, Room WHALL
200, rue de la Loi, 1040 Brussels, Belgium**

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

25 October 2010

1. Adoption of Agenda

The Chair welcomed the delegates and apologised for late documents. She announced a change of sequence in the agenda points for organisational reasons. The agenda was adopted with some additional sub-items at the request of some MS (final version in attachment).

2. Follow up from 5th meeting of CARACAL

2.1 Draft Summary Record (CA/77/2010)

COM relayed the written comments received on the DSR and explained which comments were not accepted and why. The Chair asked for additional comments. The DSR were adopted including the accepted comments.

2.2 List of Actions (CA/76/2010)

A MS asked for a timely uploading of the action list including a column showing completed actions. COM promised to upload the action list well in advance of the next meetings.

3.1 Work plan for CARACAL (CA/81/2010)

COM presented the planning document listing REACH Committee meetings and their subject items. COM underlined that the dates in the document were only indicative. The document also gives dates for the next CARACAL and its subgroups meetings for the remainder of the year 2010 and 2011. MS asked about some actions that seemed to be missing from the list; such as ATP's of Annex VI of CLP, and Annex IV of REACH.

COM explained that the Annex IV and V updates were more complex than foreseen: there were different types of corrections to the annexes: substances that were included with the wrong EINECS numbers, for example not the latest EINECS numbers. Then there were language corrections and the fructose and water issue. The conclusion is that Council will issue a corrigendum (in OJ 260 page 62, end of October).

Another, new, corrigendum is underway and will go beyond Annex IV fructose and water and will include issues proposed by one of the MS. Exact timing of this corrigendum is not yet clear.

Another question was about why "CMR in Annex XVII" did not feature on the REACH Committee list anymore. This question would be answered under the restrictions agenda item.

3.2 Update on the REACH Committee – Draft Regulations amending Annexes 1, XIII, XIV and XVII

COM reported in the 20-21 September REACH Committee which amended the Annexes I, XIII, XIV and XVII. The draft Regulations were uploaded on the comitology register and would be under scrutiny in Parliament for the next three months (ending beginning of January). The acrylamide proposal received unanimous support by MS and would be under scrutiny until 7 January.

On 18 October there was another REACH Committee meeting dealing with CLP. These proposals would be uploaded on the comitology register by the end of the month (October).

On MS asked whether the COM could inform MS when measures were uploaded on the register so they could follow adoption cycle. COM agreed to do this. Another MS asked whether the COM considered putting out an information leaflet on Annex XIV which would explain the candidate list and the rules and obligations in a simple manner. COM agreed that this could be useful.

3.3 Next CARACAL Meetings

The meeting was informed about the provisional dates of the 2011 meetings:

7 th CARACAL	7-8-9 February 2011
8 th CARACAL	8-9-10 June 2011
9 th CARACAL	26 -27- 28 October 2011

COM reiterated that these dates are provisional and will be confirmed six weeks prior to the meeting.

4. Any Other Information Points

The meeting was running ahead of time so the Chair decided to take a MS question about the final conclusion of the COM Legal Service on the definition of articles and the question whether houses are articles under REACH or not. The MS requested a copy of the reply from the LS, but COM replied it does not normally provide those, however, in the previous CARACAL meeting COM gave a very clear account of the LS answer, which was also reflected in the summary record of that meeting. However, COM promised the MS to provide a complete account of the legal reasoning in a separate letter.

Another MS asked whether this conclusion would apply to other things than houses as well. COM answered that the same reasoning indeed applies to other structures such as bridges, garden swings, etc – to anything that is fixed. The question of whether it would apply to houseboats could be treated under the agenda item on guidance of substances in articles.

4.1 Toxic Substances Control Act (TSCA) Reform Bill

A representative of the US Mission to the EU gave a presentation on the TSCA Reform Bill. The speaker stressed that this was an initial presentation only, and that any specific questions should be deferred to the next CARACAL meeting, to which an EPA official would be invited. The speaker expressed appreciation for the cooperation between the US and many of the MS and also with ECHA.

The Toxic Substances Control Act (TSCA) is the general chemical control law in the US for regulating chemicals used in industrial, commercial, and consumer products. It was enacted by Congress in October 1976, and has not been significantly amended since then. Over the last two decades, a number of regulatory and enforcement barriers to effective implementation of TSCA have been identified, and there has been a growing consensus that TSCA should be amended. Under the Obama Administration, EPA has made toxic chemical reform a major priority.

The current situation challenges businesses throughout the supply chain since they are faced with different regulations depending on the state. Therefore, the overall goal of the reform is to give a general federal standard to follow for retailers and importers.

In April, 2010, Senator Frank Lautenberg introduced the Safe Chemicals Act of 2010. Congressmen Bobby Rush and Henry Waxman introduced on the same day a discussion draft entitled the Toxic Chemicals Safety Act of 2010. Both of these proposals would amend TSCA.

The most important change is the shifting the burden of proof to manufacturers and processors of chemicals, mixtures, and "articles". At present EPA has to prove that the given chemical substance is unsafe.

One of the potential impacts of the reform on national and international trade could be the burden on companies to research and discover dangerous chemicals and safer alternatives.

5.1 Questions and answers on the restrictions in Annex XVII of REACH (CA/85/2010)

The meeting discussed 4 entries in the Question and Answers document concerning the interpretation of some of the restrictions in Annex XVII to REACH, with the objective to provide guidance to both MS and economic operators for the implementation of these restrictions. These Q&A will be included in the Frequently Asked Questions document which is published on the DG Enterprise, European Commission, website.

Ammonium nitrate (Entry 58)

COM presented three questions that Competent Authorities and operators have raised concerning the implementation of the exemption in paragraph 2 (a) of Entry 58 and provided answers to those questions. One MS suggested adding some concrete examples; COM replied that the Question and Answer already contain some simple examples that it did not see the need for a change to the text.

Nickel (Entry 27)

The question on the possible interpretation of the term "prolonged" contact with the skin was raised. COM had investigated this issue and concluded that for the purpose of the implementation of the restriction on nickel, the term "prolonged" should be understood as covering a daily overall contact with skin of more than 30 minutes continuously or 1 hour discontinuously. This takes into account recent scientific information on nickel allergy. Several MS asked for more detailed information about the scientific background, especially as regards the 30 minutes exposure. One MS wanted to know if answer is based on firm scientific data or rather expert judgements. One MS mentioned that answer seems to be a pragmatic approach, but that such details would rather belong into the Regulation itself. One should also not neglect the enforceability. COM answered that basis was rather expert judgement, that the available scientific background will be made available and item could be re-discussed in one of the next CARACAL meetings.

Mercury (Entry 18(a) of Annex XVII to REACH)

The question was raised as to whether the repairing and maintenance activities are covered by the restriction in entry 18(a) of Annex XVII REACH.

Two different cases were cited: (1) Devices in use before 3 April 2009 (such as fever thermometers) containing mercury are exempted and could be sold on the second hand market except in territories of MS which decided to regulate these existing instruments. Repairing and maintenance activities for these existing instruments are excluded from the scope of the restriction. In the case of repairing and maintenance activities on these devices, new measuring devices containing mercury shall not be used. (2) Antique barometers, older than 50 years by October 2007, are exempted in the same way as old articles, and their repair and maintenance are also exempted, when the objective of maintenance is to keep their historical and cultural and monitoring value.

MS commented that the discussion on this subject is very detailed and underpins the needs for an expert group like RIMEDE. One MS found the sentence in the document confusing that says "professionals may buy measuring devices containing mercury if they are destined for the repair and maintenance activities of antique measuring devices". An observer commented that their organisation found this same sentence disconcerting because in practice this concerns new mercury measuring devices. There should be a way of making sure that these repairs concern real antiques and not false antiques. COM confirmed that the exemption applies to real antiques only and that enforcement authorities are to control the correct application.

Restrictions in Entries 28 to 30

This concerns the prohibition of classified CMR mixtures in specific concentration limits. COM explained that despite the way the entries are formulated, an operator does not actually have a choice between the specific concentration limit and the concentration specified in Directive 1999/45/EC. After the phasing out of this Directive the restriction will have to be amended. The CLP Regulation already reflects the right provisions.

MS commented that the text in the Entries 28-30 should be adapted but COM argued that today's purpose was to confirm that there is a common understanding between COM, CA and operators. However COM would welcome any suggestions to improve the text, and invited MS to consider when would be the most appropriate time for amending the text.

In concluding these agenda sub-items: COM would delay publishing the nickel entry for the time being and come back to this item in the next CARACAL meeting and deliver the reasoning behind the suggested answer. The other three entries will be published on the website. CARACAL suggestions for improved formulations are welcome but COM intends to publish as soon as possible.

Asbestos – implementation of Entry 6

COM informed CA that four MS have used the possibility of an exemption for diaphragms containing chrysotile for existing electrolysis installations as described in Entry 6, 1st paragraph. COM reminded those MS that they will have to submit, in line with the provisions of Annex XVII, entry 6, a report to the Commission by 1st June 2011 describing the availability of asbestos-free substitutes and the efforts undertaken to develop such alternatives, the protection of the health of the workers in the installations on the source and quantities of chrysotile and of diaphragms containing chrysotile, and the envisaged end date of the exemption. These reports will be made publicly available.

Furthermore COM reminded the MS of the special provision on articles containing asbestos installed before 2005 in Entry 6, paragraph 2. MS may allow the sale of those articles under specific conditions ensuring a high level of protection of human health. (It has meanwhile been clarified that buildings are not articles in the scope of REACH.) COM reminded that those MS who made use of this provision have to communicate to the Commission the national measures taken to ensure a high level of protection of human health by 1 June 2011 at the latest. One objective of these reports is to identify the types of articles containing asbestos as well as to inform about the legal situation in different MS as regards old products containing asbestos. These reports will be made publicly available.

COM informed that it had received 30 parliamentary questions on asbestos recently.

Update on boric acid and borates

COM welcomed the opinion delivered by the Risk Assessment Committee (RAC) on the use of boric acid and borates in photographic applications by consumers. The RAC concluded that for some of the scenarios explored there was a relatively low but unacceptable risk to the consumer. This concerned the use of powder formulations of boron containing products. As the Scientific Committee for Consumer Safety issued an opinion on the use of boron compounds in cosmetics and on the use of perborates in hair dyes, RAC is to confirm the scientific consistency of the various opinions. Furthermore a final internal consultation as well as with stakeholders to assess the consequences of a revision of the derogation for photographic applications in line with the RAC opinion is needed. As regards the use of perborate compounds in detergents a time limited derogation in order to take into account the opinions expressed by MS is under consideration by the Commission.

A more precise restriction proposal for borates and compounds will shortly be elaborated. MS regretted the fact that the discussion of the boric acid exemption stopped the progress on the CMR restriction proposal and amendment of Annex XVII as regards the CMR substances and asked the COM when it envisaged proceeding with discussion on the CMR package. One MS asked for a concrete time schedule. COM apologised for not being able to give a concrete time schedule and confirmed to speed up the procedure and to present a revised proposal as soon as possible.

5.2 Proposal for a clarification with respect to entry 56 (MDI) of Annex XVII

A MS introduced a proposal for a clarification with respect to entry 56 (MDI), following a request for such clarification by its enforcement authorities. This paper is also available on CIRCA. EINECS gives four different entries for MDI, but current wording of entry 56 refers only to one EINECS number and may suggest that only this substance (EINECS 247-714-0) is covered whereas the other specific isomers with their specific CAS and EINECS numbers would not be covered. This was not the legislator's intention when MDI was included in Annex XVII. The MS proposed a clarification in the document provided before the meeting. One other MS supported these concerns.

COM replied it would study the matter in depth and if possible propose a clarification – if not immediately in Annex XVII then temporarily through the FAQ document.

An observer commented that indeed in the past the different isomers were covered by the restriction, but that one sees no problem as it is a mixture which is brought on the market.

In conclusion, COM stated it would collect the different elements and propose a way forward.

Additional item: 5.3 – Implementation of Article 68.2

COM informed that it is still reflecting internally on the implementation of Article 68.2 on how to deal with CMR substances in articles, having received a MS request on this subject earlier in the year and how to apply its right of initiative. The MS concerned expressed its disappointment that COM has not yet come to a conclusion after 4 months reflection time and asked for a concrete timeframe. COM answered that it is actively discussing the issue but that

it is impossible to give a concrete timeframe for the outcome of the reflection, on the MS specific question on the one hand and the general terms of the article on the other hand. The MS was encouraged to forward an Annex XV dossier under Article 69 in the meantime.

6. REACH Registration and Scope

6.1 Substances in stock (CA/99/2010)

COM presented a document that had been modified including comments received after CARACAL 5. The issue concerns a HelpNet draft FAQ question on which no consensus was reached. The question was: may batches of pre-registered substances that are manufactured or imported before the relevant registration deadline be placed on the market after this deadline without a registration? The answer to this question is: yes but under the condition that the manufacturer or importer have ceased manufacturing or importing before the registration deadline, and are just supplying from stock. The registration duty depends on the role of the entity according to the specific REACH definitions at the relevant time (i.e. manufacturer, importer, supplier of a substance or a mixture) and not on the time of the manufacturing or import of the specific batches. Downstream users, distributors and suppliers are not required to submit registrations under REACH.

Some MS suggested broader terms such as distributor rather than supplier, however COM underlined that it preferred to use the REACH definitions.

MS and observers welcomed the paper and requested that this paper be posted on the ECHA Helpnet FAQ list urgently, to which ECHA agreed.

Additional agenda item: substances under customs supervision (CA/41/2010 rev. 1)

The paper was posted under the information items but some MS wished to discuss the contents. They were not satisfied with the complexity of the paper, which in its current form would be unsuitable to communicate to industry, which was the intended use of the paper, as well as for cooperation with customs and enforcement authorities. The paper focused too much on the exceptions and not enough on the general rule. COM agreed to streamline the paper's conclusion along the lines of the MS suggestions.

6.2 Test methods – presentation of test methods to be included in the 3rd ATP to the Test Methods Regulation (CA/84/2010)

In relation to TMR ATP in the paper presented at the June meeting (CA/53/2010) approximately 25 methods were identified for inclusion in the next ATP.

Information from National Coordinators & expert input from JRC was used in the preparation of this list.

The paper (CA/84/2010) presented the potential way forward for including test methods in the EU TMR subject to the agreement of the meeting. It took the information presented in June together with the commitment as indicated at that time to prioritise alternative methods. The work will be conducted in two phases as conducting the work in one big batch may slow the process down. It will also give a chance to fine-tune the process, take on board lessons

learned from previous ATP and move-forward with a continuous work flow set-up and in place.

Phase I will include alternative methods already adopted at the level of OECD whereas Phase II will include a selection of remaining methods on the list – these prioritised methods include methods which are currently not present in the TMR and also updates of tests present in the TMR.

COM had started on phase I and would, in parallel, start on phase II (and not wait for completion of phase I). This way of working would result in a faster passage and would avoid one large batch to get stuck in the process.

MS welcomed this approach. Some questioned the priority that had been given to the 5 tests that belonged to phase I, and underlined other test methods that were important to them, such as OECD TG 309. Another MS questioned why there was only one test for endocrine disrupters whereas there are 8 tests available. Considering the fact that endocrine disrupters are difficult to determine more tests would be welcome. Also with regard to ecotoxicology tests it was said that a biodegradability test was needed. One MS wondered what the estimated reduction in the use of animals would be thanks to these tests.

COM replied that it examined the test methods and attempted to balance priorities, resulting in the current 5 tests which were considered a best attempt. Regarding the tests highlighted, COM commented that it understood for some MS these tests were a priority. In return, COM would have some flexibility until mid-December to add or to delete other test methods for phase 2. MS were invited to inform the COM in writing by mid-December of the specific methods that they would wish to include/exclude. In reference to available OECD tests and Endocrine Disruption, COM commented that it was closely following the OECD work in relation to Endocrine Disruption and would bring forward the appropriate recommendations when this process had progressed sufficiently.

6.3 Reporting on the closed session

The closed session discussed a variety of REACH implementation issues.

Discussions started off with a review of the proposed mandate for the new CA subgroup 'RIMEDE', this is a MS-only subgroup that will provide an informal platform for MS to discuss RMOs for individual substances and provide technical input into comitology discussions. The mandate will be further refined over the coming weeks.

The session then revisited the DCG, discussing in particular the involvement of Member States in this forum.

Next, the Commission provided an overview of its work in relation to the Art 117 report it has to deliver in 2012 as well as some ongoing reflections on 2012 review, the exact content of which remains work in progress. Progress on the review will be monitored by CARACAL.

There was a brief discussion on the relationship between the work of the forum and that of CARACAL, information on a forthcoming DE workshop on SVHCs. The session took note of opinions expressed in relation to the intermediates issue.

ECHA reported on progress made in relation to evaluation, in particular how best to organise the crucial cooperation between ECHA and MSCAs in the context of dossier and substance evaluation and follow-up to any findings that ECHA or MSs may make in this context. The state of play on follow-up to NONS decisions was also discussed as was how to best organise the work to ensure that proper follow-up to these decisions would take place.

There were also a number of questions and answers to MS access to REACH-IT.

The Commission then delivered a short report on the October expert group meeting on RM activities which served in particular to prepare the forthcoming REACH Committee vote revising the existing cadmium restriction. In addition, an exchange of information on RM activities took place, which served, i.a., to review the state of play on SVHC identification.

Finally, the CAs reviewed a number of specific SIEF-related data sharing issues and discussed a helpdesk question on whether steel blooms and slabs are to be considered as mixtures or articles. On the latter question it was concluded that further analysis will be necessary.

6.4 Reporting on Director's Contact Group

DCG had held a meeting just before CARACAL – having identified problems and developed solutions, the Group was now awaiting its effects on registration. The DCG solutions were published on the ECHA website. The Group has been monitoring industry preparedness for registration, and so far has not detected any major disruptions because of REACH.

The Group held a meeting with DU's to address their specific concerns – the Group identified one potential problem in the area of very long and complex supply chains. It would investigate and analyse that type of situations and come up with solutions.

In the ensuing discussion one MS commented that ECHA's website currently features the DCG conclusions, but would be interested in seeing more detailed background information on the issues covered, in particular issues 10, 21 and 22. Other MS commented about the lateness of the publication of the conclusions. They also questioned whether DU should not have been part of the DCG in the first place.

COM replied that DCG was set up to ease the way to registration – since only manufacturers and importers have to register the primary purpose was to help them. DU do not have to register themselves but they were invited to inform DCG of potential problems, which they did. As one of the MS had pointed out as well, many DU problems would only emerge after the 1 December deadline.

A discussion on the continuation of the DCG (original mandate ends at registration deadline) investigates the inclusion of DU in the group. Finally the COM speaker apologised for the lack of communication during the summer period.

With regard to DU ECHA commented that it had published a list of substances that companies intended to register, which had been compiled with industry assistance, and that DU associations had been encouraged to indicate any missing substances since April 2010. The list includes approx 4500 substances. ECHA also said it was working to make the DCG list of solutions more visible on its website, and that background papers with detailed

reasoning and conclusions would be made available on request by companies and after checking their status.

7. REACH AOB

7.1 EEB "Fight to know" survey on the application of Art 33.2 of REACH by some retailers

The EEB representative presented the survey on the application of Art. 33.2 of REACH, which states that consumers should at least receive the name of the SVHC, with information on how to safely use the product within 45 days of the request. EEB's purpose of the survey was to assess how well-known the legislation is and also to promote the SIN ("substitute it now") list, as well as to ask retailers whether they use the list. The method was to send letters to 5 EU Member States (B, HU, SW, DE, NL) and by different means (e-mail, regular mail...) for a selected number of products (toys, mousepads, shoes..) and substances, including 8 phthalates. The survey found that half of the 158 information requests sent to European retailers received no response. Only 22 percent of the requests received satisfactory answers that meet the legal requirements under REACH. The results also indicate that the response rate varies considerably within EU Member States. Retailers established in the Netherlands have a fair response rate (81%), followed by Germany and Sweden (62% and 59% respectively) compared to retailers in other countries such as Belgium and Hungary (30%).

The second part consisted of performing a chemical analysis on the presence of some SVHC in 93 everyday products purchased at those retailers in order to assess the adequacy of responses received. The results from the chemical analyses revealed a widespread use of plasticisers classified as SVHC in a variety of everyday consumer products.

The complete survey outcome can be viewed on the EEB website.

One observer called the survey an eye opener in the retail sector and noted that clearly more awareness-raising in companies is needed. Another remark was that the fact that retailers sell products containing phthalates does not mean that they are putting unsafe products on the market – they only place on the market what is legally allowed – noting that only 4 of the 8 tested phthalates are actually on the candidate list. This also makes it difficult for companies to understand and trace which substances or mixtures are used in articles.

MS were appreciative of the presentation – one suggested presenting it to the Forum as well. Some of them had conducted similar surveys with similar results. One MS wondered who is a consumer and what triggers the obligation for companies to reply.

ECHA POINTS

8. Registration

8.1 Current state of play and preparedness for registration (CA/86/2010)

ECHA gave an update on the current state of play in registration. CEFIC representative confirmed that companies in general should be able to register in time and some intend to take over the role of a Lead Registrant (LR) if the original LR has not taken care of the duties.

ECHA was congratulated for keeping MSs and others well informed about the registrations. CEFIC also thanked ECHA for providing technical help to the companies so that registrations can pass the registration pipeline.

9. Guidances

9.1 Draft Guidance on requirements for substances in Articles (CA/91/2010)

An overview was given by ECHA on the updated version of the Guidance. The aim is to issue the update in December, ideally without the footnote of the dissenting view.

One MS, on behalf of MSs with the dissenting view, gave a presentation of the 0.1% limit value interpretation of candidate list substances in articles: the concept was, in simple terms, 'once an article, always an article'. They believe the original question to COM Legal Services is not any more relevant as it is assumed to be asking about homogenous parts of articles. The MSs having dissenting views have developed their concept and argumentation and they are referring to "articles within articles" and not, as some thought, to homogeneous parts of articles. COM are preparing a request for a COM Legal Services opinion on the latest 'dissenting' MS's view of the 0.1% limit for candidate-list substances in articles, but it is very unlikely this will be available for mid November when ECHA would need to finalise the revised guidance so the Executive Director can consult ECHA Management Board (MB). MSs asked for this request be provided to CARACAL, so although COM cannot release complete internal legal service opinions, but will expose all the elements that can be released, they will find out what portion of the question can be released to CARACAL.

There was an extensive discussion. One MS felt great sympathy for the new presented approach without the homogeneous sub-parts of articles from the dissenting MSs and wished this had been addressed in the PEG. They are disappointed that COM did not ask for legal advice earlier. Hence they suggest a road map with the aim of solving the problem without resorting to referral to the MB. Another MS is now more sympathetic with the new dissenting view, but can live with either interpretation so long as it is practical and can be operated by industry and enforced. Their priority is to get agreement for the guidance. They consider the obligations related to imported articles are challenging irrespective of which approach is taken. A further MS is sympathetic to the dissenting view, but had accepted the original COM legal interpretation on the assumption that it was valid, and they are prepared to accept the possible new COM legal interpretation – this was backed by another MS. Yet another MS is sympathetic to the new dissenting view interpretation as they think it would ensure more equal treatment of imported and manufactured articles.

ECHA proposed a way forward. The merits of the revised dissenting view should be further considered from practical point of view and in the case the LS interpretation does not solve the matter it could be clarified in the REACH revision. The guidance will nevertheless be

published in December, even without unanimous agreement from MSs as ECHA is committed to publish it well in advance of the June 2010 notification deadline. NL insisted that the letter requesting the legal advice request is provided to CARACAL. COM does not accept that the previous advice is not relevant. COM does not release complete internal legal service opinions, but will expose all the elements that can be released and also what portion of the question can be released to CARACAL.

9.2 Guidance on derivation of DMELs/DNELs from human data (CA/94/2010)

In the framework of the further development of the Guidance on Information Requirements and Chemical Safety Assessment, ECHA has prepared a draft Guidance on Derivation of DNEL/DMEL from human data.

During the CARACAL consultation on the draft Guidance, initiated on 1 June 2010, a number of comments were received from two Member State Competent Authorities and one observer.

One MS thanked the initiating MS for their discussion paper and pointed out the concern connected with the derivation of DMELs based on non-harmonised acceptable cancer risks. He informed the participants that the issue has been raised in the Government Interest Group of the Advisory Committee on Safety and Health at Work.

These comments have triggered a new revision of the draft Guidance. The new revision has overcome objections raised. Consequently, the ECHA Secretariat will publish the aforementioned consolidated draft in December 2010.

9.3 Human health criteria for endocrine disrupting substances in context of Art 57.f

MS had received a (late) BAUA paper with the above title – mainly intended for their comments by 1st December, whereas a discussion on the substance would take place later.

Joint issues on REACH & CLP

10. Cooperation with OECD/UN

10.1 OECD and REACH interface – state of play (CA/92/2010)

ECHA presented their proposal to use Annex XV and harmonised classification dossiers on a case-by-case basis for OECD assessment programme. There would be a link with the ECHA committee processes by inputting OECD member countries' views in the public consultation. The process will be piloted. The proposal was generally welcomed and supported by CARACAL. NL suggested OECD discussions within SIAMs on categories/read-across are highly relevant to the work of ECHA. Two MSCAs expressed concerns that the same dossier could be discussed in two different processes with different outcomes. ECHA explained that the proposal tries to minimise that option.

10.2 Extended One Generation Reproductive Toxicity Study (EOGRTS) (CA/93/2010)

The COM speaker presented the most significant elements of the combined OECD Working Group of National Coordinators (WNT) and EOGRTS expert group meeting which took place in Washington on the 18th -21st October 2010.

1. Retrospective analysis Part 1:

NL concluded that "in retrospect in 498 multi-generation studies there had not been a single example where the second generation mating and offspring provided critical information for the interpretation of the study in terms of the determination of the reproductive LOAEL".

2. Retrospective analysis Part 2:

49/50 substances out of 498 carry a classification for reproductive toxicity including fertility or development with one substance carrying a label for lactation. Specific effects in the P1/F2 generation were observed for a number of substances. The study concluded that in none of these cases the P1/F2 generation of the multi-generation study appears to provide information that determined C&L.

The meeting then prepared the Joint Meeting paper ENV/JM (2010)53 which considered whether information available from the production of a second generation would change the conclusion of the hazard characterisation for risk assessment and/or the GHS hazard classification of chemicals. From the discussion of the retrospective analysis and the preparation of the joint meeting paper two conclusions emerged:

- Most of the National Coordinators and experts attending the Arlington meeting agreed that the extensive retrospective analyses indicated that the production of a 2nd generation would rarely affect hazard characterization either for risk assessment or for GHS hazard classification of chemicals.
- A few participants at Arlington meeting disagreed with this conclusion. These participants considered that, based on examples provided and due to remaining scientific uncertainties with the analysis, it cannot be excluded that the 2nd generation would affect the hazard characterization, either for risk assessment or for GHS hazard classification of chemicals, in a substantial number of studies.

3. Subsequently the meeting prepared the Joint Meeting paper ENV/JM(2010)35.

A modular approach was agreed. This modular approach retained the flexibility of the test developed in the margins of the 44th Joint Meeting and extends the flexibility to the assessment of the 2nd generation. The majority of the meeting favoured option 1 whereas a small group favoured option 2.

Option 1: "Decisions on whether to assess a second generation, developmental neurotoxicity and developmental immunotoxicity should reflect existing knowledge for the chemical being evaluated, as well as the needs of various regulatory authorities. The purpose of the Test Guideline is to provide details on how the study can be conducted and to address how each cohort should be evaluated."

Option 2: “Decisions on whether to assess the second generation and to omit the developmental neurotoxicity cohort and/or developmental immunotoxicity cohort should reflect existing knowledge for the chemical being evaluated, as well as the needs of various regulatory authorities. The purpose of the Test Guideline is to provide details on how the study can be conducted and to address how each cohort should be evaluated.”

The outcome of the preparation of the draft Test Guideline is that it does not specify how it should be implemented and it is not proposed to delete TG 416 at this time. The consequences of this outcome on the implementation of the TG is that each country/region will have to decide whether and how to implement the EOGRTS to suit the needs of their respective regulatory framework.

The test guideline was then agreed for approval and was sent to the OECD Joint Meeting which was to take place in November for approval.

COM emphasised that the purpose of conveying all the meeting information was to give the MS an impression of how discussion has unfolded and to observe their reflections in a REACH context, and to see how we (MS, COM and ECHA) intend to react to the "different shades of uncertainty" as to the importance of a second generation.

The ensuing discussion focused on the uncertainty of the importance of a second generation. In addition, some MS asked for clarification of the role that ECHA played in the international OECD context.

Some MS indicated that they did not support the conclusions of the retrospective analyses and that they were of the opinion that the second generation test method was still needed; others said that the extended one-generation study could be introduced as a replacement method to reduce number of animals used in testing for reproductive toxicity; and one MS was very positive about the EOGRTS, and considered that the advantages in reducing the number of animals used in testing significantly outweigh missing a possible harmful effect. In terms of the need for including the DNT and DIT modules as an obligatory part of the guideline both supporting as well as dissenting views were expressed.

COM, ECHA and MS thanked the NL for their important work on this issue noting that the decision on whether to accept the uncertainties is a policy decision that needs to be further addressed by this meeting in the future.

ECHA explained its involvement in this discussion at the international OECD forum referring to its task in providing scientific and technical support to the Commission. In addition, ECHA explained why it had started discussions at the RAC regarding the use of the results of the future guideline for the purpose of risk assessment and/or classification and labelling.

CLP

11. Update on CLP cases before ECJ

Cases C-14/10 and C-15/10

The UK High Court of Justice has asked the ECJ whether the classifications of nickel carbonates and the classifications of borates (respectively) in the 30th and 31st ATP of

Directive 67/548 and the 1st ATP of the CLP Regulation are invalid. The Commission submitted written observations on 7 May 2010 and is currently awaiting the date for the oral hearing, expected in January.

Cases T-532/08 and T-539/08

In both cases parties sought partial annulment of the 30th ATP to Directive 67/548/EEC and of the 1st ATP to the CLP Regulation in relation to the classification of certain nickel compounds and certain borates.

COM informed the meeting that the Court had ruled on 7 September 2010 that the actions were inadmissible for the following reasons:

- The new rules on conditions of admissibility contained in Article 263 of the Lisbon Treaty do not apply to cases pending before the Court on 1 December 2009 (date of entry into force of the new Treaty). Therefore, the conditions of admissibility set forth in Article 230 of the EC Treaty apply in this case.
- The General Court ruled that the action was inadmissible under Article 260 of the EC Treaty on the grounds that the applicants did not prove that they were individually concerned by the contested act.

Case C-425/08

One MS inquired about n-propyl bromide still being the subject of action in the ECJ, apparently still holding up enforcement actions in that MS.

COM replied that there had been a judgement on this case in October 2009, following a reference for a preliminary ruling by a Belgian court. The ECJ had ruled that "examination of the questions referred has shown no factor capable of affecting the validity of Directive 2004/73/EC (29th ATP to Directive 67/548/EEC)..." Historical background: an application for direct action on this case had been introduced in 2004, when the Court did not rule on it. As a result, in 2008 Envirotech brought the action before the Belgian court alleging incorrect classification of n-propylbromide. The Belgian court referred it to the ECJ which gave its judgement in October 2009. COM had not heard of any new cases.

MS thanked COM for the update and would appreciate regular updates on cases and their references, and an overview of pending issues. The Chair remarked that these updates would be reflected in the minutes.

12. Issues related to UN SCEGHS

EU representation at the CE TDG and GHS and at the SCE GHS (CA/95/2010)

COM informed the meeting that it had consulted its Secretariat General (SG) and the Legal Service (LS) to clarify the situation with regard to the EU representation at the Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals (UN CE TDG & GHS) and at the Subcommittee of Experts of the GHS (SCE GHS) after the adoption of the Lisbon Treaty. The Lisbon Treaty introduces a new Article (Article 17 of the Treaty on European Union) which has

consequences for the external representation of the EU and may affect the work of the Commission and Member States in the CE TDG&GHS and SCE GHS in that a formal coordinated position of the EU MS in the SCE GHS and/or the CE TDG&GHS should be developed and put forward by the Commission.

After consultation SG and LS confirmed that the established practice can continue in principle, subject to the outcome of further discussions still ongoing in Council.

- The SCE GHS is considered a technical body and therefore a full-fledged EU coordination is not mandatory. For the SCE GHS meetings, informal coordination can take place in Working Groups of the Commission and on the spot before the UN meeting. The EU experts agree on common lines, but also indicate where they disagree.
- The CE TDG & GHS is considered as a political body as it is mandated to deal with strategic and policy issues. For this body full-fledged coordination is required. In this regard, the following practical arrangements are proposed:

MS and the Commission need to agree on a common position which is to be expressed by the Commission. In case of voting, as the EU is an observer, the MS must vote in accordance with the common position in the interest of the EU. The MS could also speak in support of the common position and ask for clarifications if this is previously agreed in the EU coordination.

- The informal coordination meetings 'on the spot' in Geneva should be organised, at least for the time being, by the rotating Presidency as these meetings are taking place outside of the EU. However, this might need reconsideration after all external representation issues have been settled.

Some MS reacted that they could not agree with the paper, arguing that in their view the Lisbon Treaty does not provide any changes to the current situation and that GHS is not a binding instrument. Some MS also thought that the SCE GHS is rather a political than a technical body. COM invited those MS to outline their arguments to that effect in writing.

COM asked the MS whether they agreed that there should be coordination and joint positions. MS saw the need of coordination. They considered that CARACAL was the right forum to hold this discussion. .

Most MS agreed that the current coordination practices were good, and that the discussion about future coordination practice should be extended to Transport colleagues, both nationally and also within COM.

Preparation for the 20th session of the UN SCE GHS (CA/96/2010)

The meeting discussed item by item the document, which was based on a draft version of the "list of documents and annotations" under preparation by the UN ECE Secretariat for Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals (CE TDG/GHS) and for the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of

Chemicals (SCE GHS). It aims to help to co-ordinate the view of EU Member States experts for the SCE GHS meeting.

Classification of chemically unstable gases and gas mixtures

COM asked Germany to report to CARACAL on behalf of the working group about the content of the proposal of the introduction of the classification of chemically unstable gases. Germany explained that "unstable" meant "to react with oxygen and polymerisation reactions". The Working Group proposed to add these to the subgroup of flammable gases.

COM proposed the position that "this work should be acknowledged and in principle supported by taking into account the modifications as proposed by EIGA."

One MS replied that it had not yet coordinated with Transport and therefore could not give a final position. COM said that its current purpose was mainly to find out whether MS had any problems with the COM proposals – the MS confirmed it did not have problems with this proposal.

Physical hazards and proposal to add simple asphyxiants in GHS

COM proposed the position: "This work should be acknowledged and the proposal as outlined now should be supported." One MS commented that it would have to study the proposal carefully, because it was not clear whether this was a classification issue as well as a labelling one, and whether also hazard text had to be included.

Health hazards

The annexes to the working document had been prepared by the UK. UK explained that precautionary statements were problematic in particular when there were a large number of them for one substance, and that more work needed to be done in the next biennium. COM proposed that the position for the meeting should be to support the continuation of the work. Related guidance already developed within the EU could be useful to facilitate this.

Hazards communication issues

COM proposed the position that the proposal submitted by the UK and an EU industry association should be supported. The inclusion of the proposed modifications in the 4th revision of the GHS would be beneficial to enable the Commission to transpose the new provisions in time into the related legal acts before June 2015 (CLP deadline for mixtures).

Proposal for revision of P410 gases in transportable gas cylinders under pressure

This issue had previously led to long discussions on precautionary statements, in particular "to protect from sunlight". One MS clarified that the outcome of the discussions was that if gas cylinders comply with technical standards for containment such a statement is not needed. On the proposed revision COM proposed the position "to acknowledge and support the work done".

Information relating to nanomaterials for inclusion on the guidance on the preparation of Safety Data Sheets

COM proposed the position to acknowledge Australia's work. Furthermore, a SDS under REACH also includes specific information that could be particularly relevant for nanomaterials. COM asked CARACAL whether the EU should inform the GHS Subcommittee of these provisions. MS agreed that this should be done by COM and that a document should be submitted swiftly.

Implementation of the GHS: "corrosive to metals"

Some substances and mixtures will be classified as "corrosive to metals" for supply while not being classified as corrosive to skin or eyes. The question on how to label this in the best way had also been the subject of discussion in the CARACAL subgroup during the preparation of the 2nd ATP to CLP. Industry had proposed not to use the relevant hazard pictogram in order not to confuse the general public.

One MS said that the proposed solution would be incompatible with the harmonisation principle of the GHS and would create an exemption for supply and use. A better solution would be a separate pictogram, which of course represented a lot of work. Several MS supported this idea. COM concluded that it was open to the industry position, however if there were several MS that felt differently then clearly this issue needed more time and discussion.

Practical classifications issues correspondence group

This group had worked during the last biennium to develop revisions to the GHS text which had been identified by various parties, for example the application of the bridging principle and hazards to the aquatic environment. MS experts were involved in the work.

One MS said that there were some mistakes in the environmental examples which would need to be corrected. COM suggested that the Swedish expert would write to the correspondence group with copy to COM.

The proposed position was to acknowledge and support the work, which MS agreed to.

Informal working group on GHS implementation issues: global list of GHS classified chemicals

COM and MS agreed that whilst ultimately such a list would be desirable, agreeing on a global list of GHS classified chemicals would constitute a lot of work that will require a considerable period of consensus building. The document for the GHS meeting proposed Terms of Reference for a small informal working group. COM suggested the position to acknowledge and support this work in principle, which MS agreed to.

Work programme of the next biennium (2011-2012)

Proposed TOR for the Dust Explosion Hazards Correspondence Group

COM suggested to support the proposed Terms of Reference (TOR) but to carefully consider whether the GHS is the right instrument to tackle this hazard. Dust explosion hazard is not an intrinsic property as such and not solely related to chemicals. The TOR should clearly reflect the question whether this hazard needs to be included in the GHS and to look at alternative solutions.

One MS asked how this hazard was dealt with in other legislation. COM replied that in the EU and the US workplace legislation is the applicable framework. One MS noted that the draft TOR already specifically contained the question of whether the GHS was the appropriate place for dust explosion hazards, and the proposed position to support further work in line with the draft TOR was agreed.

Alignment with GHS, corrosivity criteria

The alignment of the corrosivity criteria in the transport model Regulation with the "purple book" has been under discussion in the SCE TDG since some time. In a joint meeting experts of the SCE TDG and SCE GHS could not come to an agreement for a final proposal. Therefore for the next biennium a correspondence group should be established.

One MS was wondering whether the OECD should be involved, but there is no reference to OECD in the TOR. The core issue seemed to be the definition of corrosivity.

COM proposed the position to support further work in the next biennium, which MS agreed to.

Report on the status of implementation

MS agreed to the proposal that COM would report at the 20th SCE GHS meeting about further EU implementation of the GHS, in particular the status of the 2nd ATP to the CLP Regulation which among others will incorporate the 3rd revision of the GHS.

Election of officers for biennium 2011-2012

COM proposed to support the continuation of current chairs. One MS commented that it had not yet completed its national coordination, and asked by when it could transmit written comments. COM replied that the deadline was 12 November.

Link to UN SCEGHS meetings report:

<http://www.unece.org/trans/main/dgdb/dgsubc4/c4rep.html>

13. Update on the recast of Directive 99/45/EC

COM updated on the progress made with the proposal for a recast. Comments sent by Member States after the CARACAL meeting in June had been introduced into the text and translations were on-going. COM thanked all MS for their input and in particular the detection of errors. The text is expected to be adopted by the Commission early in 2011 and will then be sent to the Council and European Parliament. Since the objective of the recast is to align the text to all the changes introduced by the other chemical legislation (REACH, CLP, SDS...) for legal certainty no major discussions were to be expected in the other institutions.

14. Update on the status of the list of the national contact persons in the context of Art. 45 CLP

COM reminded those MS who had not already done so to inform COM about the contact person for receiving information about mixtures placed on the market, in particular in those MS where this contact was not in the poison centres themselves. This information should be submitted by 12 November.

15. 2nd ATP to CLP

COM informed MS that the main aim of the Commission proposal for a Regulation to adapt to technical progress the CLP Regulation for the 2nd time is to introduce the modifications agreed in the 3rd revision of the GHS. The draft Commission Regulation received a favourable opinion of the REACH Committee by unanimity at the meeting on 18 October. In line with the comitology rules, the text will be sent to the Council and Parliament for their scrutiny during the next 3 months.

COM also informed MS about the comments raised by the USA in the context of the TBT notification procedure. Those comments had been discussed and a reply agreed by the Members of the REACH Committee prior to the vote.

16. Information on ongoing corrigenda – CLP & 1st ATP

COM explained that CLP and its first ATP contained mistakes, similar to the situation known under REACH Annex IV. The Council is responsible for the corrigendum to the CLP Regulation itself and the Commission has repeatedly reminded the Council Secretariat about the urgent need to publish the corrigenda, but cannot give an indication of the timing by when the Council will complete its work. . There are about 35 identified issues – some affect all languages and others only one language or several. There will be one corrigendum for all issues that affect all language versions and others for mistakes that affect only specific languages.

The Commission is responsible for the corrigendum for the 1st ATP. COM is working on a draft text – more than 200 mistakes have been found or signalled by MS, often repeatedly. COM is in principle ready to start the procedure for the adoption. MS were invited to send any further comments by 22 November.

Sub-session D2: ECHA points

17.1 Harmonised entries to Annex VI of the CLP Regulation – state of play

ECHA gave an update on the status of Annex VI: 160 entries need correction, 30 entries (technical mistakes, e.g. lacking 'H' in the Hazard statement) needed to be corrected to allow the establishment of the internal C&L Inventory.

Following questions from Member States related to the mistakes in Annex VI, ECHA explained that it intends to publish a web form which allows structured reporting of mistakes identified by any party. This web form will include a link to a table listing those mistakes which have already been identified and checked by ECHA and which need not be reported again.

In the meantime, the web form has been published by ECHA. It can be accessed via the following link:

<https://comments.echa.europa.eu/comments/MistakesInAnnexVI.aspx>

17.2 C&L Inventory – confidentiality of the IUPAC name

ECHA gave an update on the consultation of CARACAL on the COM/ECHA proposal presented at the last meeting. There was broad agreement that the IUPAC name can be claimed confidential in specific circumstances. As there is no basis in the legislation to request a fee, confidentiality claims cannot be checked systematically by ECHA. The public name is to be generated using the existing system from Directive 199/45/EC.

A few MS expressed some concern that IUPAC names can apparently be claimed as confidential without assessing the validity of the claim, which seems to be an advantageous treatment compared to REACH Registration. They requested ECHA to monitor and report to CARACAL about the extent of confidentiality claims following the deadline for submitting C&L notifications on 3 January. ECHA agreed to do so and announced that it intends to hold a workshop on the C&L inventory next year.

One MS raised the issue of incorrect or incomplete names being notified. ECHA informed that it cannot undertake substance identity checks because of the expected huge number of notifications. ECHA has recognised this as a potential problem. Whether ECHA will be able to verify names at a later stage will depend on the available resources and overall priorities.

Article 24 of CLP – Request for use of an alternative name for a substance in a mixture

ECHA informed of the Workshop planned in Feb 2011 in order to learn from the experience of MS on how they handled these requests in the past in the framework of Directive 1999/45/EC – so far those MS that already communicated their experience were invited, the information searched for is mainly:

- What information has been examined,
- Reasons for rejection,
- Criteria for an acceptable justification.

17.3 Initial feedback on ECHA participation in MSs Workshops on notification to the CLP inventory

Brief information on first experience with ECHA participation in MSs Workshops on notification to the CLP inventory was given, summarising the main issues raised during the workshops.



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
Chemicals - Classification & Labelling, Specific Products, Competitiveness

Brussels, 15/10/2010
Doc. CA/80/2010 Rev 3

Room document

ANNOTATED DRAFT AGENDA
6th Meeting of Competent Authorities
for REACH and CLP

25 October 2010

Berlaymont, Room WHALL
200, rue de la Loi, BE -1040 Brussels

26 - 27 October 2010

Centre A. Borschette,
Rue Froissart, 36, BE-1040 Brussels, Belgium
Room 4.D

Discussion Points:

25 OCTOBER			
REGISTRATION		09:00-09:30	
Berlaymont, Room WHALL			
AGENDA ITEM	DOCUMENT	ACTION	TIME (APPROX.)
SESSION A: GENERAL ISSUES			09:30 – 12:00
1. ADOPTION OF AGENDA	CA/80/2010	Discussion/ Adoption	09:30 – 09:45
2. FOLLOW UP FROM 5TH MEETING OF CARACAL			
2.1 Draft summary record	CA/77/2010	Discussion/ Adoption	09:45 – 10:00
2.2 List of Actions	CA/76/2010	Discussion	10:00-10:15
3. OVERALL WORKPLAN FOR CARACAL			
3.1 Work plan for CARACAL (Comitology procedures, CARACAL written procedures, subgroup meetings)	CA/81/2010	Information	10:15 - 10:25
3.2 Update on the REACH committee - Draft Regulations amending Annexes I, XIII, XIV and XVII		Information	10:25 – 10:55
3.3 Next CARACAL meetings		Information	10:55-11:00
- Information on provisional dates of next meetings (each date needs to be confirmed 6 weeks prior to the meeting)			
4. ANY GENERAL INFORMATION POINTS			
4.1 Toxic Substances Control Act (TSCA) reform bill		Information	11:00 – 11:30
<i>Coffee Break</i>			11:30 – 12:00

CLOSED SESSION	<i>12:00 – 17:15</i>
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26 OCTOBER 2010			09:00
Centre A. Borschette			
SESSION B: REACH			09:00 – 12:45
SUB-SESSION B.1: COMMISSION POINTS			
5. REACH RESTRICTIONS			
<p>5.1. Questions and Answers on the restrictions in Annex XVII of REACH</p> <p>Questions and Answers relating to</p> <ul style="list-style-type: none"> - Ammonium nitrate (Entry 59) - Nickel (Entry 27) - Mercury in measuring devices (Entry 18(a), - Restrictions in Entries 28 to 30. <p>Asbestos (Parliamentary questions) Update on boric acid and borates</p>	CA/85/2010	Information / Discussion	09:00 – 10:00
5.2. Proposal for a clarification with respect to entry 56 (MDI) of Annex XVII	DE paper	Information	10:00 – 10:15
6. REACH REGISTRATION AND SCOPE			
6.1 Substances in stock	CA/99/2010	Discussion / endorsement	10:15 – 10:45
<i>Coffee Break</i>			10:45 – 11:15
6.2. Test Methods – Presentation of test methods to be included in the 3 rd ATP to the Test Methods Regulation	CA/84/2010	Information	11:15 – 11:45
6.3. Reporting on the closed session		Information	11:45- 12:15

6.4. Reporting on Director's Contact Group	CA/83/2010	Information	12:15- 12:45
7. REACH AOB			
7.1 EEB “Fight to know” survey on the application of Art 33.2 of REACH by some retailers.	EEB presentation	Information	12:45 – 13:00
Lunch			13:00 – 14:00

SUB-SESSION B.2: ECHA POINTS			14:00- 15:30
8. REGISTRATION			
8.1. Current state-of-play and preparedness for registration	CA/86/2010	Information / discussion	14:00 – 14:15
9. GUIDANCES			
9.1 Draft Guidance on requirements for substances in articles	CA/91/2010	Discussion	14:15 – 15:00
Coffee break			15:30 – 16:00
SESSION C: JOINT ISSUES REACH/CLP			16:00 – 17:15
10. COOPERATION WITH OECD/UN			
10.1 OECD and REACH interface – state of play	CA/92/2010	Information/discussion	16:00 – 16:30
10.2 Extended one generation reprotox	CA/93/2010	Information/discussion	16:30 – 17:00

27 OCTOBER 2010			09:00
Centre A. Borschette			
AGENDA ITEM	DOCUMENT	ACTION	TIME (APPROX.)
SESSION D: CLP			09:00 – 13:00
SUB-SESSION D.1: COMMISSION POINTS			
11. UPDATE ON CLP CASES BEFORE ECJ		Information	09:00– 09:20
12. ISSUES RELATED TO UN SCEGHS	CA/95/2010 CA/96/2010	Information	09:20 – 10:30
13. UPDATE ON THE RECAST OF DIRECTIVE 99/45/EC		Information	10:30 – 10:45
14. UPDATE ON THE STATUS OF THE LIST OF THE NATIONAL CONTACT PERSONS IN THE CONTEXT OF ART. 45 CLP		Information	10:45 – 11:00
15. 2ND ATP TO THE CLP			11:00– 11:05
16. INFORMATION ON ONGOING CORRIGENDA – CLP & 1ST ATP		Information	11:05 – 11:15
<i>Coffee break</i>			11:15– 11:45
SUB-SESSION D.2: ECHA POINTS			
17.1 Harmonised entries to Annex VI of the CLP Regulation - State of play		Information /discussion	11:45 – 12:00
17. 2 C&L Inventory - Confidentiality of the IUPAC name		Information /discussion	12:00 – 12:15
17.3 Initial feedback on ECHA participation in MSs workshops on notification to the CLP inventory		Information /discussion	12:15 - 12:30

17.4 CLP AOB			12:30 – 12:50
SESSION E: CLOSE OF MEETING			12:50 – 13:00

Information Points:

INFORMATION POINT & OUTLINE	DOCUMENT
1. Article 2.1. b) of REACH – input from COM	CA/41/2010 rev 1
2. ECHA update on REACH & CLP operations	CA/98/2010 ED report to 18 th meeting of the Management Board (copy of slides)
3. Paper on the C&L notification key messages (Proposed by ECHA's Communication Unit,)	Room document CA/90/2010 for information
4. Review of existing restrictions for phthalates – ECHA response to comments document (RCOM)	CA/100/2010, follow-up to June CARACAL discussion and written commenting round
5. Awareness raising on CLP	CA/101/2010 CA/102/2010 (copy of slides)
6. ECHA WP2011 as adopted by the Management Board in September/October 2010	CA/103/2010
7. Guidance on derivation of DMELs/DNELs from human data	CA/94/2010

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 Jonath.Blokker-Rowe@ec.europa.eu and Jacek.Rozwadowski@ec.europa.eu at the latest 10 days before the meeting.

