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

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SUMMARY RECORD

7th Meeting of Competent Authorities for REACH and CLP

7-8-9 February 2011

Centre A. Borschette,
Rue Froissart, 36, BE-1040 Brussels, Belgium
Room 0A

8 February 2011

SESSION A: GENERAL ISSUES

1. Adoption of Agenda

The Chair welcomed the delegates and apologised for late documents. Furthermore, she added that Commission services and ECHA had set a meeting to discuss ways to improve the organisation of CARACAL.

Chair indicated that documents for the following agenda points were distributed as room documents: AP 2.2, 4.6, 6.2, 11, 15. . Although indicated in the draft agenda, documents N° 24 and 25 do not exist.

Changes to the agenda points were announced and accepted, as follows:
AP 9 (report of Closed Session) was moved to after agenda adoption.
In the AP 9 timeslot the item "Links between MS CA and Forum" was inserted.
AP 2.3 and AP 4.2 were removed.

MS questioned why the item on interpretation of 68(2) was not on the agenda and underlined the importance to continue a detailed discussion in the next CARACAL. One MS requested that a discussion paper be forwarded to next CARACAL, even in the case of no final COM internal agreement.

The Agenda was adopted with the above changes.

2. Follow up from 6th meeting of CARACAL

2.1 Draft Summary Record (CA/02/2010)

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/03/2010)

Updated Action List from the previous CARACAL meeting was introduced as a room document. This version included an additional field: "State of progress".

MS made comments to the action list, which were taken into account by COM.

One MS asked COM to put back on the Action List the AP35 from CARACAL-5, concerning interpretation of CLP.

2.3 Criteria for Open or Closed sessions

This point was removed from the agenda.

2.4 Work plan for CARACAL (CA/05/2011)

COM presented the planning document listing REACH Committee meetings and their subject items. COM underlined that the dates in the document were only indicative.

Several MS inquired about the topics for the upcoming REACH Committee meeting, in particular the meeting scheduled for 8th March. COM explained that the dates are tentative in order to book the meeting rooms. Dates will be cancelled if there are no topics for the meetings.

The document also gives dates for the next CARACAL and its subgroups meetings for the remainder 2011.

3. REACH Reviews

3.1 Reflection paper on 2012 reviews and Art 117 reporting

COM presented information on the Commission's approach to REACH 2012 review and reporting. The presentation included a list of review obligations provided by the REACH

Regulation and a list of thematic studies which were or will be launched and which address issues which may provide inputs to the Commission services during the review.

It is still early to update on any result of the study as the draft second interim report will be submitted in early March. Until now the COM has had an advanced submission with the first part of the second interim report containing the analysis of legislation pertaining:

- Products and chemical substances
- Water
- Food
- GMOs
- Air quality
- Health and safety of workers
- Laboratory animals

It also contained a draft analysis of how existing EU legislation applies to a selected number of substances, namely:

- Formaldehyde
- Estradiol
- Nonylphenol
- Cadmium
- Benzo(a)pyrene
- Triclosan

The stakeholder consultation was closed on 1 December 2010. 57 different stakeholders took part in the consultation. The most commented pieces of legislation were those on biocides, plant protection products, medical devices, RoHS, carcinogens and mutagens at work, waste framework directive, ecolabel, CLP, toys, construction products and chemicals agents at work.

A MS intervened to obtain confirmation that the legislation on chemicals agents at work was going to be analysed under the Scope Contract. The Commission confirmed that both directives 98/24/EC and 2000/39/EC were part of the project.

One MS, supported by others asked about the opportunities for the MS to provide input into the review.

Some CARACAL members asked about the possibility to have access to the reports of other MS It was decided to add a point to the list of actions asking MS for agreement to disseminate Article 117 reports on the Commission website.

A MS asked if updates from ongoing studies will be provided and commented that the section 5 of the document lacks info about economic benefits and wondered if the studies launched would provide this knowledge.

Industry representatives commented that analysing of functioning of the European Chemical market after the introduction of REACH regulation would be a very challenging task,

especially with regard to estimating of impact on economy and benefits to health and the environment.
Industry representative pointed out at the possibilities to tackle individual problems with the implementation of REACH through the development of guidance. He also asked also about if there were plans to review the guidance on intermediates and its impact.

In its reply, COM informed that it was the intention to keep the CARACAL updated on the REACH review process. The outcome of the process will be will presented as a package by June 2012.
More details on the studies will be provided at the next meeting.

3.2 Update on overview of Art 117 MS reports

COM updated CARACAL on the situation further to the questions posed to MS in the previous CARACAL meeting on whether they would agree to give access to their reports, further to a request of access to information by an NGO. The Commission had to ask MS up to three times for their responses with the result that not all MS agreed to give access to their reports (to date, one MS had denied access, one had only agreed to partial access and 2 MS had not replied). The request by the NGO was only partially satisfied for the reports of the MS which agreed to give access and a confirmatory application was sent by the NGO to the Commission.

COM gave a preliminary overview on some selected themes (Information and cooperation with other MS, ECHA and COM; operation of the national helpdesk and provisions of communication to the public; Annex XV dossiers prepared or (co) rapporteured; information on enforcement activities)
Furthermore COM informed that in context of the preparation of the COM general report due by June 2012 a contractor started an in depth analysis of the MS reporting and that CARACAL will be informed on progress made.

One MS, supported by some others, underlined that in the context of the in-depth analysis it would be preferable that the contractor contacts MS should there be any difficulties in interpreting the answers of the MS reports.

Presentation of the TSCA reform

Three representatives of the Environment Protection Agency participated in the meeting.
A presentation of the reforms of the TSCA was made by the Director of the Office of Pollution Prevention and Toxics of EPA in which she gave information on the implementation of the Toxic Substances Control Act (TSCA). Further, information on the State actions was given.

Then the speaker presented the outline of the TSCA reform, gave information on the legislative process in the USA and mentioned the current review of confidentiality claims.

The presentation was followed by questions on the possible impact of REACH on the TSCA reform and co-operation between EPA and ECHA. EPA replied that there were lessons to be

learned from REACH. ECHA mentioned an agreement technical co-operation without exchange of the confidential business information.

4. REACH Registration

4.1 Final recommendations DCG and update on new mandate

COM gave an oral update on the activities of Directors' Contact Group (DCG). In summary, the DCG looked into 28 issues some time ago (difficulties of the industry in the context registration) and developed solution for overcoming difficulties (done until Dec 1st 2010).

Currently the DCG is working on three issues.
The first issue is that of a DU organisations which have worries of cessation of supply of substances when the communication with supply chain is bad e.g. supplier stopped supply and did not register. DCG is examining possibilities to give DU access to the substance in such situations. For the time being, the DCG is defining the problem, exploring the issue.

The second point is a preparation of a report on the lessons learnt from the work of the DCG - what the group did, how it did and what achieved.

The third issue is a review of the mandate of the group in order to continue the co-operation with industry in view of the next registration. The informal group will continue its work with less frequent meeting but still exchanging info on practical implementation of REACH. It is envisaged to use this group to identify more issues to address (e.g. with ECHA or CARACAL) and build on the lessons learnt from the first DCG exercise.
The group will continue and bring issues up within relevant forum if necessary.

To start the discussion, one MS expressed appreciation for the work of the DCG but commented that cannot accept the situation where the DCG takes decisions and only informs MS CAs about them without prior consultation and added that it would appreciate a discussion on the 'self-mandating' of the group.

A MS asked about feedback from DUs and, regarding lessons learnt, assumed that DCG would check if the solutions proposed by the group helped to achieve what was planned.

Another MS mentioned some confusion with the objective of the DCG, taking into account that the nature of questions handled by the DCG is the same as those handled by CARACAL. Also, the wording used was considered too strong e.g. "established solutions" instead of "proposed recommendations". The same MS stated that MSs should be represented at the DCG.

An observer (Trade Unions) informed that he accepted a proposal to join the informal working group.

COM replied that words like "issues" or "solutions" were not the best choices anyhow and referred to change in wording of the REACH Regulation itself in course of its negotiations.

COM stated that the DCG proposed ways out of the identified issues. For the future, the DCG needs to improve the information flow and involve MS when needed, in function of the intended solutions.

Chair reminded that at the last CARACAL, MS indicated that they did not want to be involved in the DCG.

4.2 Lessons learnt: cost sharing

This point was removed from the agenda.

4.3 Substances under customs supervision

Commission presented the last updates to the document and asked for endorsement.

One MS commented that the paper looked simpler than the previous version but asked a couple of weeks to comment in writing.

Another commented that the document could not be endorsed on formal grounds because it was distributed only 5 days before the meeting. In addition the content was not fully satisfying. The same MS mentioned that his request for bilateral contacts, expressed at the previous CARACAL meeting was not satisfied and made additional comments: does not agree with COM recommendation to send to Forum WG, gray box on page 5 of the paper is ambiguous and difficult to understand and there is no example of what can benefit from the REACH exemption in a free zone or free warehouse.

Another MS stated that the new version of the paper was much better than previous one and is, in principle, prepared to endorse it. The same MS commented that an annex could be further extended with other examples and that the annex should be submitted to another Commission WG (Import Committee); and then submitted back to CARACAL.

Another MS commented that the paper did not propose a procedure.

Chair asked for written comments within three weeks (by March 1st). Afterwards the paper will be submitted for written procedure of endorsement.
Chair commented that national procedures are different and COM cannot be of help in this situation.

4.4 Malfunctioning SIEFS

COM introduced the document which originated from the closed session discussions.

ECHA commented that it agrees with COM. It noted that the document addresses only granting access to studies under Article 30, because under Article 27(6) all studies can be granted access, and not only those for vertebrate animals. ECHA commented that “a person reasonably considered by ECHA as acting on behalf of the owner of the study” needs to be understood as a person who started negotiating on data sharing. Only legitimate possession of the study does not mean that a person can be considered as the data owner.

One MS asked ECHA for additional clarifications. ECHA stated, amongst others, that Member States will be informed of ECHA decisions on data sharing.

4.5 Awareness raising towards SMEs about second registration deadline

Commission presented the background and COM current activities focusing on awareness building of SMEs with regard to REACH. It included the co-ordination of activities with SME Units of COM, such as European Enterprise Network and European Small Business portal.

At this opportunity, COM indicated that it planned to have a conference on the lessons from the 1st registration deadline. This will be a joint effort with ECHA and will rather focus on less experienced companies than on SMEs, for which the registration deadline is year 2018 (assuming that SMEs handle substances in quantities below 10 tonnes per annum).

COM asked for input from CAs regarding their activities re SMEs by 1st of March.

4.6 Update on COM opinion

- Dissemination

COM presented the document containing its interpretation of Article 119(2)(d) of REACH as regards the dissemination of the names of registrants.

A MS intervened supporting the COM view, but expressing concern that the publication of names may in fact also reveal the information on the precise composition of a mixture. Another MS intervened to support the Commission view and reminded that it was possible to claim the confidentiality of information listed in Article 119.

Some observers intervened to enquire about the intended follow up by ECHA's to implement the opinion of the COM, mentioning that the COM opinion was in contrast with the understanding ECHA has on Articles 118 and 119.

ECHA informed that the practical implications of this interpretation will be discussed in the ECHA MB Advisory Group on dissemination and that immediate implementation is not possible. It should be analysed how this affects non-classified substances, third party representative nominations etc.

- Monomers-polymers

COM presented the document containing its interpretation of certain issues related to the Guidance on monomers and polymers, as a consequence of the Court of Justice judgment in case C-558/07.

One MS disagreed and stated that the term “unreacted monomer” in the Court’s judgment can only refer to monomers before polymerisation. Another MS asked COM to make an official position out of it, in the form of FAQ or otherwise.

One stakeholder stated that this is a surprising position with far-going consequences. It would lead to a need to register all impurities of a substance and even if they are below 2%. He

further stated that risks are limited to the monomer stage; that it is rare that a polymer is being depolymerised while recognizing end-of-lifecycle concerns.

Several MS as well as industry representatives intervened to indicate that they would need to reflect on the Commission opinion, which was only made available to the group short before the meeting, and send written comments as appropriate.

4.7 Test Methods Regulation 3rd, 4th and future ATP

COM introduced the paper which provided an update on the progress of Test Methods to be included in the 3rd Adaptation to Technical Progress (ATP) to the EU Test Methods Regulation (440/2008). The meeting was also informed that work had started on reformatting OECD test guidelines to EU test methods for the 4th ATP and also that at the next CARACAL meeting an update will be provided of OECD tests methods which are currently not in the EU Test Methods Regulation

Some MS expressed their wish for higher priority for test methods for endocrine disrupting properties.

Other than comments provided at the October meeting no other MS had made comments to the paper concerning the 3rd and 4th ATP presented at the October CARACAL. COM indicated that comments were welcome on an ongoing basis and a new deadline for commenting on the present paper was announced, namely 1st March.

5. REACH Evaluation

5.1 OECD Joint Meeting report - extended one generation reprotoxicity study and further work

COM introduced the paper on the Extended One Generation Reprotoxicity Study (EOGRTS) and a report on the 46th OECD Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.

Several MS expressed their opinion on the implementation of the EOGRTS in the EU. Four MSs were in favour of starting to use EOGRTS. However, some reservations were expressed. One MS indicated that the current data requested by Annexes IX and X is from two generation studies. Another MS mentioned a willingness to use EOGRTS but did not know how to use it for Annexes IX and X.

Another MS mentioned that it needed more studies on the relevance of the second generation study; and also that the cost to benefit balance of using EOGRTS should be established. A need to assess the consequences of using EOGRTS and, in general, a need to take precautionary approach to the OECDS guidelines was mentioned by one MS.

One MS pointed out that the test proposal has to be judged from the point of view of information requirements in REACH and suggested that ECHA should check how the one generation study fulfils the requirement.

Another MS commented that the procedure is unclear, namely who takes what initiative in order to change the test method regulation. This MS foresaw a strong role for policy making co-ordination and requested COM to describe the clear steps of the implementation, on which CAs could comment without waiting for the next CARACAL meeting.

COM replied that the agreement was reached at OECD but many questions remained open (e.g. whether the two generation study should still be used. COM also indicated that the two generation study was more relevant for pesticides and biocides and less for REACH.
Chair invited comments from the MS by 1st of March.

6. REACH Authorisation

6.1 2nd ECHA recommendation: follow-up

Commission introduced a paper on the 2nd ECHA Recommendation for inclusion of substances in Annex XIV and explained the timeline for adoption. The amendment to Annex XIV will be submitted to the REACH Committee by June 2011and the procedure with scrutiny is expected to end by final adoption by mid-November 2011.

One MS asked circumstances where COM would be departing from the ECHA recommendation and suggested to communicate with the informal group of CARACAL. This was supported by another MS.

6.2 Update on the publication of the first amendment to Annex XIV

For information purposes COM mentioned that the first amendment to Annex XIV of REACH would be adopted in the second week of February 2011.

6.3 Reporting on the closed session

The Chair presented a summary of the closed session.

The meeting of the closed session started with a discussion and a presentation on the new rules applying to the Commission Expert Groups as a consequence of the inter-institutional agreement between Commission and European Parliament.

In this context it was agreed that the Commission will look into the Rules of Procedure to assess the needs of possibly amend that in the light of the modified circumstances.
As a consequence, the discussion on the CASG RIMEDE was suspended.

The meeting continued with presentations on Evaluation activities, on criteria to apply to Art. 69(5), and on MS intentions in relation to authorisation.

7. REACH Restrictions

7.1 Entry 56 on Methylenediphenyl diisocyanate (MDI)

COM presented the opinion paper in reply to the proposal of one MS to modify the restriction on MDI by adding CAS numbers of other isomers of MDI. COM explained that the intention of this restriction entry was to cover all the isomers identified by different CAS numbers. This will be confirmed in the Q&A document which is published on the web. In COM's understanding, there should be no enforcement related problems as the commercial substances are those which are referred to in the restriction.

One MS commented that a reference to the Belgian RAR should be mentioned in the paper (page 2). Although this MS would prefer to have other CAS numbers included in the Annex XVII but can accept in the meantime the suggested way forward by COM.

One MS supported the initial proposal for modification of Entry 56.
One MS commented that the COM proposal has certain weaknesses as regards the enforcement.

One MS mentioned that COM might envisage doing the technical changes to Annex XVII at the next opportunity.

COM commented that the text in Q&A will not be the full document as presented to CARACAL and added that legally the scope of the restriction is clear.

One industry representative commented that he would accept the COM proposal but would see no problems with updating Annex XVII.

The chair summarised that as a first step there will be a clarification in the Q&A. The possibility of technical update of Annex XVII will be explored at a later date.

7.2 Handover of queries on restrictions in Annex XVII to ECHA

Commission informed CARACAL that queries on restrictions in Annex XVII have been handed over to ECHA. ECHA agreed to reply to interpretation questions on current restrictions the same way as to other questions related to REACH. All necessary preparations were done; in the future operators will need to contact the national helpdesks or, in case of valid reasons ECHA, with their inquiries.

7.3 Update on activities related to restrictions on phthalates

Commission presented an update on the ongoing review of the scientific information concerning the 6 Phthalates, REACH Annex XVII entries 51 and 52. As a follow up to the ECHA recommendation to wait for the first registration deadline before deciding on possible further action on this group of substances, COM requested after the first registration deadline has passed in December 2010 ECHA to review and analyse the information coming from the registration dossiers in order to complete the review reports.

The review concerns the classified phthalates, entry 51 (BBP, DBP, DEHP) and the non-classified phthalates, entry 52 (DIDP, DINP, DNOP) For the non-classified phthalates, entry 52 (DIDP, DINP, DNOP), request has been made to ECHA to review and analyse new scientific information, if any, coming from the registration dossier with the view of

completing the assessment of information already included in the existing review reports and if appropriate, revise the ECHA conclusions, including the need or not for further actions.

For the classified phthalates, entry 51 (BBP, DBP, DEHP): these compounds will be part of the Annex XIV/authorisation list and their use will be prohibited in 2015 unless companies have applied for authorisations under Title VII of REACH. Moreover these compounds are also included in the Danish notification of intention to prepare a restriction dossier. As a consequence the Commission has requested ECHA to assess whether at this stage any further actions on basis of the registration dossiers is needed.

A MS asked whether ECHA would provide information on substitutes as it was important to evaluate substitute plasticisers used in toys. ECHA commented that at first stage ECHA will evaluate the registration data in line with the COM request. Based on the outcome of the review report, the next steps could cover potentially the evaluation of alternatives.

Replying to a question from an observer, ECHA clarified that the answer from ECHA can be expected within one year from the start of the work.

7.4 SCCP most appropriate risk management options

Based on a document submitted by a MS on the most appropriate risk management option for short chain chlorinated paraffins (SCCPs) in the light of the UN-ECE decision on SCCP COM introduced a paper evaluating the MS proposal, an alternative approach and the way COM suggests to proceed.

CARACAL took note of the COM proposal for the most appropriate solution and way forward, namely to 1. amend the POPs Regulation in line with the provisions of the Protocol, 2. amend Annex XVII REACH in order to delete entry 42 on SCCPs and 3. re-examine the new SCCPs restriction under the POPs Regulation with a view to modifying it pursuant to Article 14(2) of the Regulation.

The MS which initiated the discussion thanked COM for the precise indications and explication.

One MS held it more appropriate to amend the POP-Regulation based in particular on its Article 14 para 1.

8. REACH CASG nano

8.1 Report of CASC Nano meeting

The Commission presented the report from the December 2010 meeting of the CASG Nano group and informed about the discussions related to the 2nd regulatory review, definition of the term "nanomaterial" and the REACH Implementation Projects on Nanomaterials (RIPoNs). Concerning the regulatory review, the Commission informed also about the on-going work and the decision to compile information on nanomaterial types and uses, including safety aspects. The Commission also informed that the latter will allow, by the end of 2011, to respond to the Council about the need for the development of specific measures for nanomaterials relating to risk assessment and management, information and monitoring, including the further development of a harmonised database for nanomaterials. Finally, the

Commission also proposed to discuss with those MS currently contemplating to establish national databases.

8.2 Nanomaterials on the market – preliminary assessment

The Commission introduced a paper on the nanomaterials on the market, highlighted its importance for the communication about the situation and asked for endorsement since no comments to the paper had been received before the meeting.

One MS, supported by four other MS proposed to add a sentence in the last paragraph "*Furthermore Italy, France and Belgium and experts from the Competent Authorities of Germany and the Netherlands are presently studying the content for national databases of nanomaterials as substances on their own, contained in mixtures and or in articles and in consumer products, and working towards a harmonized common basis for those databases so that exchange on information is easy*". The Commission agreed with this.

One MS pointed out a mistake in the last sentence in the first paragraph of the section 4 that can lead to misunderstanding about the coverage of REACH and CLP. It was proposed to be deleted and that was agreed. An observer proposed to change *'considered'* to *'classified'* hazardous and another observer proposed to add text calling for a check whether nanomaterials currently on the market are really registered under REACH. A MS commented that there was an urgent need for ECHA to produce an assessment of the registration data. Another observer informed that the majority of nanomaterials mentioned on page 4 are not placed on the EU market therefore it might be difficult to have a link to the registration data.

The Commission agreed with these comments and read out the text modifications. The Commission also explained that ECHA would work in accordance with its annual work programme where an assessment of nanomaterial dossiers for the Commission Communication on regulatory aspects of nanomaterials is envisaged. ECHA warned against using the term "evaluation" in the context of reviewing the dossiers regarding registration of nanomaterials as it had other legal connotations.

The Chair concluded that the document was not mature for endorsement and asked for written comments by 1st of March.

9. AOB

9.1 Link CA – Enforcement Authorities

One MS requested to establish a link between the national Enforcement Authorities and the MS CA and suggest the meeting of both types of organisations as back-to-back to CARACAL and added that policy makers and enforcement authorities might have different priorities.

Chair commented that relationship between CAs and Enforcement Authorities is an internal MS issue but COM would be interested in seeing what issues might be discussed.

9.2 Endocrine disruptors

The issue of identification of substances with endocrine disrupting properties was commented in papers submitted by two CAs. The CA – author of the first document considered that there was a deep difference between both papers and added that another paper will be prepared for a discussion during the at the meeting back-to-back to the meeting of the Member state Committee April this year.

Another MS welcomed both papers and commented that the second paper presented an approach giving a possibility to capture a wider range of EDs.

Industry representative commented that written comments will sent and stated that at the first reading the proposed approach was a serious extension of OECD definition and added that there was no scientific proof of link between ED and obesity.

COM proposed to have a short discussion at the next CARACAL regarding activities by COM and MS in the area of endocrine disruptors.

CARACAL members were requested to comment on the second paper by March 1st.

9 February 2011

Session B REACH Issues - ECHA points

10. REACH

10.1 Update and follow up first registration deadline (statistics, quality of dossiers)

ECHA briefly introduced the paper summarising the outcome of the registrations submitted to ECHA by first registration deadline.

One MS asked for details on so-called missing substances and proposed further analysis on the type of substances (e.g. CMRs, R50/53) that were finally not registered as expected.

One delegation asked for similar summary on CLP notification deadline – ECHA informed that the first summary is available already on its website and at the moment ECHA is analysing further steps – additional information will be given at the next CARACAL meeting.

It was pointed out that potentially enforcement actions would be needed to trace those companies that did not register their substances by the first deadline as required.

One MS recalled that the way forward would be cooperation between MSCAs and National Enforcement Authorities (NEAs) – and reminded about the proposal to organise a joint session between the two bodies CARACAL and the Forum. ECHA in reaction to this asked also the CAs to liaise with their NEAs to get support for such a session.

One MS asked for further explanation of the difference between pre-registered and then registered substances. Analysis of these discrepancies has been carried out since the pre-registration deadline and one of possible explanations is actually that companies wanted to be on ‘safe side’.

Cefic thanked ECHA for assistance provided in the period before the registration deadline and confirmed that so-called DCG solutions which although used only in exceptional cases were extremely useful.

10.2 Update on MS access to REACH–IT

A presentation was given as a follow-up of the discussion held earlier at the CARACAL and at MSC updating the situation with MS connection to REACH-IT.

MSs confirmed the need for MS to have access to registration data to be able to prepare for CoRAP. One MS had prepared a paper summarising the needs and asked for summary of all search functionalities available.– The MS paper was supported by number of other delegations and will be sent to COM and ECHA. MS's have already received ECHA's excel sheet providing information on registered substances that could be used when screening candidates for substance evaluation. This information was considered as useful but not sufficient.

In addition, some delegations and stakeholders (Concawe) raised questions with regard to timing of the whole issue (allowing access to MSs) referring to possible facilitation announced at the last MSC and also in relation to dissemination changes.

One MS specifically mentioned the need MSs being treated equally – which according to it is now not case with only 18 MS currently having the access to REACH-IT.

Concawe representative asked for details/timing of announced upgrade of IUCLID.

ECHA promised to prepare a more detailed roadmap for next steps. In any case, MS's were encouraged to speed up their connection to REACH-IT which is the main channel for access to dossiers. Meanwhile, security aspects have to be borne in mind when providing any interim solutions.

10.3 DMEL and the German traffic light model

Germany introduced in a presentation "DMEL and the German traffic light model". DE proposed to host a workshop to provide the opportunity to interested participants to discuss in more detail the implications of the German approach.

One MS thanked for the presentation by Germany and asked for an adaptation of the discussion paper Doc. CA/94/2010 Revision 1, emphasising that the establishing of an "acceptable risk" is a political task which cannot be left to the current practice by industry. They also asked to make a clear reference in the document to the principle of minimising exposure at the workplace as required by EU provisions on occupational health and safety.

10.4 Substances in articles

Update on COM opinion

COM presented their updated interpretation on the application of Art.7(2) and 33 of REACH.[1] ECHA complemented that in the light of the opinion a discussion is envisaged in the March MB meeting – updated guidance will then be published as soon as possible after the MB.

FR took the floor to express their disappointment with the COM opinion, whose reasoning they had difficulties following. They did not understand how it could be argued that *on the one hand* an article continues being an article after being assembled *whereas on the other*

[1] See document CA/26/2011

hand Articles 7(2) and 33 of REACH do not apply to it. FR expressed doubts on the concept of component in view of REACH. They stressed that it was correct to say that in the COM interpretation EU and non-EU manufacturers of complex articles were on equal footing, but that the level of information should not be different when the article is assembled in the EU or imported.

DK complained about the time it had taken the COM (more than half a year) to come back with their views on the dissenting Member States views and now it is too late to have discussions on the issue as the foreseen deadline for publication of the guidance and for entry into force of the obligations in Article 7(2). The document reflecting the COM views was made available to CARACAL just soon before the meeting, so they had not time to reflect on it. Therefore, they will have to have a close look at it. So far, DK could not follow the argumentation of the paper. There seems to be a new term being used, i.e. 'component'. DK wondered how the COM position could apply in practice: for example a wheel would be an article, when assembled in the car it would stop being an article, to become an article again once it is taken out of the car.

DE agreed with previous speakers and expressed their disagreement with the second indent of the COM opinion on the components. DE will further scrutinise the document.

BE expressed general support for the views of the dissenting Member States.

AT showed their disappointment and said that they still needed to analyse the COM opinion in detail. They could not understand how it could be argued that an article ceases to be an article when assembled.

SE, like previous speakers, had problems following the reasoning in the COM opinion. In particular, SE questioned COM's reasoning that if an article is included into a complex article it becomes a component that no longer has an autonomous function. SE meant that an article (e.g. a screw) that is included into a complex article may still have its function (e.g. as a screw). Besides, the included articles works together to give also the complex article a function. Moreover, the terms component, autonomous, and complex article are not dealt with by REACH. SE believed the COM opinion would not convince SE to change their views, but committed to look into the matter again.

NO could not understand the reasoning either and were not very optimistic that the COM opinion was to provide the solution to the issue at stake.

NL said that they had no remarks to the COM opinion and expressed that in their view all elements were now on the table. They indicated it was detrimental to the implementation of REACH to defer taking a decision.

IT expressed that they had had sympathy for the dissenting MS in the past and agreed with the perplexity of some MS. They wished to wait until further assessment was done on the COM opinion.

One observer stated that the new opinion does not take into account the aim of Art.33.

The Chairman (ECHA) intervened to tell participants that if they wished to send comments to the COM it would be their choice. The COM had not asked for comments to the document.

Report from ECHA workshop

ECHA gave a summary presentation on the technical workshop held on 3 & 4 February 2011 in Helsinki.

One MS stated that it would still be useful to explore further tools for tracing SVHCs in components for some industry sectors. This may be particularly valid for simple complex articles. This may allow assessing correctly exposure to SVHCs on the basis of the concentrations of SVHCs in such articles. The general idea is that some articles may contain components with SVHCs above the 0.1% threshold and such articles will according the Commission's interpretation not always be notified. A political choice regarding the protection of human health and the environment needs to be made.

One MS explained that the technical meeting was very useful and allowed them to reassess their position and to confirm their support to the Commission's interpretation. According to this MSCA a political choice needs to be made; the alternative interpretation of the MSs with the dissenting views will put more emphasis on the hazard data instead of the real risk. Regarding enforcement in that MS the emphasis would be put on restrictions and authorization and not on enforcement of Art. 7(2) or Art.33 as they are only information triggers.

Another MS stated that with COM's interpretation there is little focus on the risk, since exposure may relate much more to a high SVHC content in an article constituting a part of a complex article, then to the much lower average content in the whole complex article. This MS added that during the workshop it presented how enforceability decreases and constitutes a problem with COM's interpretation. This MS further noted that in a group discussion on implications for industry and with substantial participation from industry there were conclusions such as that "the differences between the two interpretations are minor compared to the difficulties you have anyway in the supply chain" and that "companies need to know where, in which part of an article, an SVHC is present".

Session C: Joint issues REACH/CLP

11. OECD secretariat: new global portal

A representative of the OECD secretariat presented the information and search facilities provided by EChemPortal, the internet portal that provides free access to health and environmental data prepared for government chemical programmes (see www.oecd.org/ehs/echemportal/). The EChemPortal provides access to a number of data bases in OECD member countries and will eventually also allow access to the public parts of REACH Registration dossiers. It will eventually be fully searchable – including also queries for finding all substances with particular hazard properties.

Session D: CLP – Commission points

12. Issues related to UN SCE GHS, conclusions and follow-up

COM summarised the main outcome of the 20th session of the United Nations Sub-Committee of Experts on the GHS (UN SCE GHS) which took place in December 2010 in Geneva. COM informed the meeting about the main changes that have been agreed for the 4th revision of the GHS and which will require a future adaptation of the CLP Regulation. To integrate the periodical GHS revisions into the EU legislation the intended pattern is to develop ATPs of the CLP every 2 years. For that purpose COM will organise the necessary consultations and meetings with the CARACAL subgroup overseeing CLP ATPs. One or two meetings of the CARACAL subgroup for CLP ATPs could be convened already this year to start discussions on a 4th ATP.

One MS draw the meeting attention to the work programme for the biennium 2011-2012 (see Annex II of the UN SCE GHS meeting report ST/SG/AC.10/C.4/40) in order to ensure consistency with work planned on similar topics at EU level.

One MS noted that the 2nd ATP of the CLP Regulation to incorporate the changes from the 3rd revision of the GHS was only just about to be adopted and questioned the urgency for starting working already on a new ATP to incorporate the changes in the 4th revision of the GHS. COM recalled that the 2nd ATP concerned also some other issues in addition to the changes from the 3rd revision of the GHS which had required quite some discussions among Member States and the same might also be the case this time. Timely preparation would allow addressing such additional issues, e.g. related to small packaging exemptions. COM invited MS and other stakeholders to communicate issues that should be tackled in the 4th ATP to CLP beyond those emerging from the 4th revision of the GHS.

13. Update on CLP cases before ECJ

COM informed about latest developments in the Court Cases challenging the classification of nickel and borate compounds listed in the 30th and 31st ATP of Directive 67/548/EEC and in the 1st ATP of CLP. A hearing had taken place on 20 January and the Opinion of the Advocate General is due on 24 March.

14. Recast of Directive 99/45/EC

COM updated on the progress made with the proposal for a recast, which is planned to be adopted before the summer. One MS questioned the need to proceed with the recast given that the Directive would be repealed in June 2015. COM explained that for reasons of legal certainty the recast was appropriate as the Directive had been modified multiple times through other acts and it was difficult for authorities and industry to know exactly, which provisions were actually in place right now.

15. 2nd and 3rd ATP update

COM informed that the scrutiny period for the Council and the European Parliament following the vote on the 2nd ATP of CLP expired on 9 February. The procedure for final adoption by the Commission would be launched immediately thereafter.

COM presented the list of substances for which RAC had issued an opinion on the harmonised classification and labelling. COM is assessing whether the harmonisation is appropriate and the substances should be included in Annex VI of the CLP Regulation. Based on this assessment a proposal for the 3rd ATP of the CLP Regulation will be developed. MS and stakeholders were invited to send comments if they consider that the harmonisation of any of the proposed substance at this point in time is not appropriate.

16. On-going corrigenda CLP and 1st ATP

COM had prepared a list of entries in the 1st ATP of the CLP that have to be corrected. Discussions are currently on-going with the Legal Service to assess whether those corrections could be done via a corrigendum or whether an ATP is required. MS were invited to send comments and/or additions to the list until end February. From 1st March onwards newly detected mistakes should be sent to ECHA via the web form. Following the suggestion of one MS at the last meeting, ECHA has also published a list of all mistakes already known, which allows MS and other stakeholders to avoid multiple notifications of the same mistakes.

COM informed that the first corrigendum to the CLP was published on 20 January in the EU Official Journal (OJ L No 16). The mistakes corrected are related to the abbreviations used in Annexes VI and VII. The mistakes are different in the different language versions. At the request of one MS, COM agreed to alert MS when CLP related information is published in the EU Official Journal.

One MS queried whether it was appropriate that a corrigendum concerning a very small correction of the CLP Regulation was already published, while the much more important mistakes were still not corrected. COM recalled that the responsibility for handling the corrigenda to the CLP Regulation was with the Council Secretariat and invited MS to contact the Council Secretariat to emphasis the urgency to proceed with the corrigenda. COM had already repeatedly contacted the Council Secretariat about this.

One Member State asked for the possibility to include synonymous names in the national language versions of Annex VI in order to improve the readability by readers. The Commission stated that this would probably constitute an issue for a formal adaptation of the CLP regulation and asked the Member State to send examples of synonymous names of chemicals.

17. Reporting on the workshop on Poison Information Centres of 24 November 2010

COM reported on the outcome of the workshop and will inform MS when the final report, expected in the coming months, becomes available. COM thanked the representatives of the European Association of Poison Centres and Clinical Toxicologists (EAPCCT) for their input and emphasised that the workshop had allowed thorough discussions among all stakeholders and identification of the remaining issues for which further work was necessary. These included in particular the usefulness of company and product identification numbers and the level of detail with regard to product compositions that should be communicated to poison centres.

18. Information on comments received from Member States regarding exemptions for small size packaging

COM recalled the discussion that took place just prior to the vote on the 2nd ATP of the CLP in the REACH Committee on possible exemptions for the labelling of packaging containing less than 10 ml and 1 ml. In order to assess the need to deal with this issue in the 4th ATP to CLP, COM invited those MS that have not reacted yet, to send their position. The text of the proposal and the comments received so far from MS would be uploaded in CIRCA.

Information point 4: Member States notification of the penalties for CLP Infringements

COM reminded those Member States who had not already done so to inform COM about the penalties adopted at national level for non-compliance with the CLP Regulation (Art 47 CLP). A copy of the national legislation should be submitted by 18 February.

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, 1.2.2011
Doc. CA/01/2011Rev. 7

DRAFT AGENDA
7th Meeting of Competent Authorities for REACH and CLP CARACAL-7

7-9 February 2011

Centre A. Borschette,
Rue Froissart, 36, BE-1040 Brussels, Belgium
Room 0A

Monday 7 February 2011 ***(Expert meeting on risk management activities - RIMEDE)*** **Closed Session**			***(10:00-15:30)*** **16:00-18.00**
Tuesday 8 February 2011			
SESSION A: GENERAL ISSUES			
1. Adoption of agenda	CA/01/2011	Discussion/Adoption	09:30-09:40
2. Follow-up from CARACAL-6 and forward planning			
2.1 Draft summary record	CA/02/2011	For adoption	09:40-09:50
2.2 Action list	CA/03/2011	For information	09:50-10:00
2.3 Criteria for open or closed session	CA/04/2011	For discussion	10:00-10:30
2.4 Forward Planning	CA/05/2011	For information	10:30-10:45
Coffee			*10:45-11:15*
US TSCA reform presentation		For information/ discussion	11.15-12:15
SESSION B: REACH ISSUES – COMMISSION POINTS			
3. REACH Reviews			
3.1 Reflection paper on 2012 reviews and Art 117 reporting	CA/06/2011	For discussion	12:15-12:30
3.2 Update on overview of Art 117 MS reports		For information	12:30-12:45
LUNCH			*12:45-14:00*

4. REACH Registration			
4.1 Final recommendations DCG and update on new mandate	CA/08/2011	For information	14:00-14:10
4.2 Lessons learnt: cost sharing	CA/10/2011	For information	14:10-14:20
4.3 Substances under customs supervision	CA/99/2010	For endorsement	14:20-14:25
4.4 Malfunctioning SIEFS	CA/11/2011	For discussion	14:25-14:45
4.5 Awareness raising towards SMEs about second registration deadline		For information and discussion	14:45-14:55
4.6 Update on COM opinion - dissemination - monomers-polymers	CA/26/2011	For information	14:55-15:10
4.7 Test Methods Regulation 3rd, 4th and future ATP	CA/12/2011	For information	15:10-15:25
5. REACH Evaluation			
5.1 OECD Joint Meeting report - extended one generation reprotox study and further work	CA/13/2011	For information and discussion	15:15-15:30

6. REACH Authorisation			
6.1 2nd ECHA recommendation: follow-up		Information	15:30-15:40
6.2 Update on the publication of the first amendment to Annex XIV		Information	15:40-15:45-
Coffee			15:45-16:15
7. REACH Restrictions			
7.1 Entry 56 on Methylenediphenyl diisocyanate (MDI)	CA/22/2011	For discussion	16:15-16:30
7.2 Handover of queries on restrictions in Annex XVII to ECHA		For information	16:30-16:45
7.3 Update on activities related to restrictions on phthalates	CA/23/2011	For information and discussion	16:45-17:00
7.4 SCCP most appropriate risk management options	CA/14/2011	For information and discussion	17:00-17:10-
8. REACH CASG nano			
8.1 Report of CASC Nano meeting		For information	17:10-17:25
8.2 Nanomaterials on the market – preliminary assessment	CA/15/2011	For endorsement	17:25-17:40
9. Report Closed Session			17:40-17:50
REACH AOB			17:50-18:15

Wednesday 9 February **Session B REACH Issues - ECHA points**			
10. REACH			
10.1 Update and follow up first registration deadline (statistics, quality of dossiers)	CA/16/2011	For information and discussion	9:00-9:30
10.2 Update on MS access to REACH–IT	CA/17/2011	For information and discussion	9:30-9:50
10.3 DMEL and the German traffic light model	CA/94/2010	For information and discussion	9:50-10:15
11. Substances in articles: - update COM opinion - report from ECHA workshop		For information	10:15-10.30
Session C: Joint issues REACH/CLP			
11. OECD secretariat: new global portal		Information	10:30-10:45
Coffee			***10:45-11:15***

Session D: CLP – Commission points			
12. Issues related to UN SCE GHS, conclusion and follow-up	CA/28/2011	Information	11:15-11:30
13. Update on CLP cases before ECJ		Information	11:30-11:35
14. Recast of Dir 99/45/EC		Information	11:35-11:40
15. 2nd and 3rd ATP CLP Update		Information	11:40-11:45
16. Ongoing corrigenda CLP and 1st ATP		Information	11:45-11:55
17. Reporting on the workshop on Poison Information Centres of 24 November 2010		Information	11:55-12:05
18. Information on comments received from Member States regarding exemptions for small size packaging		Information	12:05-12:15

END of CLP Open Session			

CLP Closed Session			**12:30-13:00**
END of meetings			

Information Points:

Information Point & Outline	**Document**
1. Update on ECHA guidance activities	CA/18/2011
2. Annex XV dossiers: Submission dates in 2012	CA/19/2011
3. Report on UBA Workshop "Substances of very high concern under REACH – II) Substances with endocrine disrupting properties"	CA/20/2011
4. Member State notifications of the penalties for CLP infringements	CA/21/2011
5. Substances in stock (Rev.)	CA/99/2010
6. Notifications received and update inventory	CA/24/2011
7. Update on CLP guidance	CA/25/2011
8. Regulation of endocrine disrupters under REACH	CA/27/2011

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