EUROPEAN COMMISSION

ENVIRONMENT DIRECTORATE-GENERAL
Water, Chemicals & Cohesion
Chemicals

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

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SUMMARY RECORD OF THE 2nd Meeting of the Competent Authorities for REACH and CLP (CARACAL)

15-16 June, 2009

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

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

- Welcomed all participants;
- Pointed out that REACH is now completed as Annex XVII entered into force on 1 June 2009;
- Explained the new content and format of the agenda. Discussion points will come first and information points at the end, with the purpose to have a more efficient meeting, spending less time on information issues and more on real discussion. At the request of some MS, several information points were moved forward.

1. ADOPTION OF THE DRAFT AGENDA

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

- Within Item 4, sub-items 4.3 and 4.7 would be treated first

No items were added to the agenda point Any Other Business.

With these changes the agenda was adopted.

2. FOLLOW-UP TO THE FIRST CARACAL MEETING (16 AND 17 MARCH 2009)

2.1. Adoption of the Draft Summary Record

The DSR was presented. Two MS had comments. One MS commented that a phrase was missing under 17.1: *"One MS observed that in the document from the COM the tasks for COM under the CLP regulation were missing and asked for an overview of these tasks*."

Another MS requested the following wording under 17.4: "*In view of the length and complexity of Module 2 one MS asked COM for a significantly extended reviewing period for the final version of the guidance paper*."

With these changes, the DSR was adopted.

2.2. List of Actions, follow-up to 1st meeting of CARACAL 16-17 March

The COM reported that actions 3 and 4 (DSR from closed session of the 6th CA meeting and final summary record from closed session of the 4th CA meeting) would be sent to MS within the coming weeks.

Upon a question from a MS, COM informed the meeting that there would be no paper on substance identification of nanomaterials (Action 12) following discussions at the last two meetings of the CARACAL, where it appeared that MS and stakeholders saw limited value added of such a paper.

The rest of the actions from the 1st CARACAL meeting had either been done or were on the agenda for the 2nd CARACAL meeting.

3. ORGANISATIONAL MATTERS

3.1. Tracking system for conclusions on interpretation questions

The COM explained the new tracking document for interpretation issues on REACH and CLP, discussed at CWG, CA and CARACAL meetings. The purpose of the paper was to be able to trace back discussions on REACH interpretation questions in REACH CA (and, in some cases, CWG) and CARACAL meetings. COM had preferred this format above a "manual of decision" to avoid confusion with other existing documents such as a manual of decisions of the MS Committee, guidance, FAQ's etc. This document provides an overview of the history of relevant discussions. The document contains hyperlinks and references to the relevant CA documents. The document will only be available to CARACAL.

MS welcomed the new tracking system. One MS commented that it would be useful to have the source of the questions recorded. MS were invited to provide further comments in writing until 30 June 2009.

4. REACH

4.1. Update on REACH annexes and implementing legislation

Fee Regulation

The Chair announced that the COM had the duty to review the fees in the Fee Regulations by 1 June 2009, but that the COM had concluded not to increase the fees this year, despite the inflation (3%), because of the economic crisis and taking into account the possibility of a negative inflation next year.

Annex V

The COM considered that a discussion with the experts at the CASG on Nanomaterials is needed to address any possibilities to include carbon in Annex V of REACH. This will therefore be on the Group's agenda for its meeting on 7-8 July. COM also announced that the Commission Communication on the review of Annexes I, IV and V was published on its website in all Community languages together with the related Staff Working Document.

Annex XIII

The COM informed the meeting that it is still discussing the draft proposal for amendment of Annex XIII on the basis of the agreement that it should allow for the use of all relevant information, using a weight of evidence approach, in the identification of PBTs/vPvB substances by comparing this information with the criteria. The draft has been reviewed and the discussion now focuses on the use of information and the legal clarity that can be provided in relation to the bioaccumulation criterion.

Some MS inquired about the expected timeline for the outcome of COM discussions on Annex XIII. COM assured them that it is making progress on this issue.

Annex XVII

The REACH Committee had given a positive opinion on the COM proposal for the revised Annex XVII in February this year, which had subsequently been submitted to Parliament and Council for scrutiny. The period for scrutiny will be expiring soon and then the Commission will adopt the revised Annex. On 1 June 2009, Annex XVII entered into force, i.e., its old version which has been applicable since then. (***Nota bene***: The Commission adopted the revised Annex XVII on 22 June and it entered into force one day after publication in the Official Journal (26 June 2009, ed.).

Test Methods Regulation Process

The COM described the Test Methods Regulation process, by, (1) explaining the issues, (2) describing the National Coordinators' draft mandate, and (3) outlining the process to be followed prior to the inclusion of test methods in the Test Methods Regulation. With regard to the outlining of the issues and the reference to the B46 skin irritation test method, the National Coordinator's input had been taken into account and included.

On the preparation of the 2nd ATP the COM is considering two new alternative methods adopted by the OECD on eye irritation. One of the questions is whether the COM should take over the OECD format directly. ECHA also has a role to play in providing technical advice, but its role still needs to be further defined.

With regards to the adoption of alternative test methods 2 tracks could be followed. Throughout the "standard track" the COM and the National Coordinators pay particular attention to the possibility of there being any "undue delay" within the OECD process. If such "undue delay" is established, the "alternative track" would apply. However, one cannot predict at which point it may become clear when there will be "undue delay". Secondly, the transfer point from OECD to the EU cannot be predicted either. This was for example not clear in the case of the B46 test method. The COM will decide on embarking on the alternative track after consulting the National Coordinators.

The term "undue delay" cannot be defined, but will be decided on a case-by-case basis. This will be possible when there is a full and proper consultation of the National Coordinators.

Some MS supported the changes made by the COM in the process to be followed prior to the inclusion of test methods in the Test Methods Regulation. One MS questioned what undue delay meant, and asked who makes the decision of what is undue delay and how the OECD would be informed? They also wondered what "completed consultation" entailed. COM replied that it is ultimately the COM to decide on "undue delay" whereas focused technical decisions would be taken by CA's.

Before the meeting, the National Coordinators had been asked to comment in writing on the Mandate of the National Coordinators on Test Methods, revised process and on the approach to follow for the 2nd ATP. The COM will modify the documents to take into account the National Coordinators' comments as well as comments made during the meeting and received from CA's during the commenting period thereafter.

4.2. Implications of the Market Surveillance Regulation on REACH enforcement

The COM gave a brief presentation on Regulation 765/2008 which sets out the requirements for accreditation and market surveillance relating to the marketing of products. Some elements of this Regulation have REACH relevance, in particular the market surveillance, and possibly the financing elements.

Substances, mixtures and articles under REACH are defined as "products" under MSR, which applies to both industrial and consumer products. MSR provisions apply only in so far as there are no specific provisions with the same objective, nature or effect in REACH (lex generalis vs. lex specialis). Its provisions aim at complementing and enhancing market surveillance.

The MSR applies as of 1 January 2010 provides that market surveillance programmes must be submitted by that date. These programmes can be either general or specific for each sector covered by the Regulation. The Forum is to be asked to discuss how to make RAPEX operational for REACH products and to look at the electronic information exchange system (in a Forum Working Group). There are few provisions in REACH about enforcement, therefore the Market Surveillance enforcement rules will apply to REACH. In the ensuing discussion one MS said it had many problems and questions with REACH products falling under the Market Surveillance Regulation – the REACH

products market is different to the consumer products market, and manufacturers and DU have many other obligations. All chemicals pose serious risks. It will be very difficult for authorities to report to the COM with a 1.1.2010 deadline.

The Market Surveillance Regulation will also be discussed at the Forum during its next meeting.

The COM clarified that under the MSR the concept of "products presenting a serious risk to be recalled, withdrawn or their prohibition to be made available on the market" is different and relates to situations requiring rapid intervention.

MS were invited to comment on the paper on implications of the Market Surveillance Regulation on REACH enforcement. COM will then revise the paper based on MS comments.

4.3. Format/constitution of Registration number on Safety Data Sheets (SDS)

The COM presented the background and the current state of play of the discussion on the format or constitution of a registration number on SDS.

Annex II section 1.1 (for substances) and 3.5 (for mixtures) provide that registration numbers must be indicated on SDS. However, these provisions cause workability as well as confidentiality concerns for industry. The issue was already discussed at the CA meetings in September and December 2008, where industry was invited to come forward with proposed solutions. During the CARACAL meeting in March, written comments were asked, and it was decided to set up a working group to discuss this issue further. The working group first met on 8 May 2009. It discussed the viability of the proposed solutions: (1) to change the registration number to random numbers and to integrate registration numbers of different suppliers into an annex; (2) to create a tracing mechanism outside SDS; (3) to remove the last 4 digits in SDS. It was concluded that the track to follow was to investigate the feasibility of omitting the four last digits under certain conditions. However, this requires an adaptation of Annex II. The COM had put forward a proposal for a rewording of the relevant paragraphs of Annex II and had invited the CARACAL to comment. The intention is to submit amendments on these paragraphs of Annex II at the same time as its revision to adapt it to the CLP Regulation (scheduled for early autumn).

Some MS agreed that the 4 last digits are not needed for enforcement purposes; others still want reassurance that such changes would be legally sound. Two MS proposed changes the COM proposal, another MS expressed some detailed concerns to the discussion, such as, if the MS (in the REACH Committee) would vote in favour of the changes, can it be challenged by Parliament or the DU? Does it need an adaptation of Art. 39? Changing the registration number format touches on the REACH core elements of no data/no market: can DU still fully comply with Art. 5 if there are no full numbers as verification from further up the supply chain? Will DU duties be triggered at all, or before there are registrations/scenarios from up the supply chain? Another consideration is the SIEF formation – omission of the 4 last digits may make it more difficult to keep track of waiving conditions; it may disturb competition; may increase misuse (free riders). This MS also saw problems for enforcement authorities if the last 4 numbers of the registration number would be dropped; it suggested an alternative possibility to request information assembled according to Art. 36, but only MSCA and ECHA can request this.

An industry observer commented that the full registration number on a SDS is not per se a proof of registration for the DU. There is still a need for other means for demonstrating REACH compliance. The observer suggested a practical solution to enforcement concerns, namely to provide the registration number when requested by an authority. For example a model letter or e-mail to be sent by DU to his supplier asking to provide the full number by a specified deadline; this letter can be forwarded upstream if supplier is a DU/distributor himself. There are examples of such letters under the Detergent Directive. Industry needs clarification under Annex II of REACH as a matter of urgency; an amendment of Annex II would bring this clarification.

The COM stated that a review of Annex II is not to be taken lightly, but it should be done if the seriousness of the problem justifies such a revision. Hence the question for discussion remains: should Annex II be revised or not?

Six CA and one observer expressed their support for the COM conclusions; some other MS supported the MS which presented the most detailed concerns, and were reluctant to remove the 4 last digits from the registration number on the SDS.

Some MS questioned the usefulness of the 4 last digits for enforcement purposes. They also asked for a definition of "enforcement authorities".

The COM concluded the discussion by inviting MS to provide further comments (if there were any new ones) by 30 June. The matter would then go to the REACH Committee during its Annex II discussions.

4.4. Restriction Issues

Work Plan for Restrictions

The COM presented a work plan for restrictions. The purpose of this work plan was to keep the CA's and ECHA informed about actions in the near future. There are a few remnants from the work under the existing substances regulation, where risk assessments and risk reduction strategies had been completed (**Acrylamide**, **Cadmium** and **1,4-dichlorobenzene**). For these three substances the COM will prepare draft amendments to Annex XVII by 1 June 2010 in accordance with Article 137 – 1(a) of REACH.

The amendment of Annex XVII for prohibiting the sale to consumers of substances newly classified as CMR 1A and 1B under the 1st ATP of the CLP Regulation (and of mixtures containing them) will include nickel compounds and borates. COM had conducted a specific study on possible risks to consumers from mixtures containing borates – as no risks had been identified, COM will propose to exempt them from the ban.

PFOA and **ammonium salt**: following the obligation from the existing restriction to keep these substances under review, COM has launched a study to evaluate possible risks to human health and the environment. A MS had in the meantime prepared a chemical safety assessment (together with industry) and had announced earlier that it might submit an Annex XV dossier for restrictions to ECHA. The MS clarified in the meeting that it has not yet decided whether this would become a restriction dossier or rather a dossier for establishing that PFOA and its salts are PBTs.

Phtalates: COM will ask ECHA in July 2009 to review all new scientific information (including opinions by SCHER) and to evaluate in accordance with Article 69 (5)

whether there is evidence that would justify an amendment of the existing restrictions for phtalates (DEHP, DBP, DBB, DNOP, DINP and DIDP, and focusing for DEHP, DBP, and DBB in particular on possible risks from their use in articles as they have been recommended for inclusion into Annex XIV.) COM had invited all MS and stakeholders to submit any new scientific information that they were aware of by 30 June 2009.

In the light of the review obligation in the restrictions for mercury in measuring devices, COM had consulted stakeholders extensively and had held a specific workshop on 28 April. Measuring applications and different industries may be affected. COM had also requested an opinion of the Scientific Committee on New and Emerging Health Risks on the need for mercury-containing sphygmomanometers in healthcare. COM will then summarise all information received and will request ECHA in October to evaluate in accordance with Article 69 (5) whether there is evidence that would justify an amendment of the existing restrictions.

A MS raised his concerns about the lengthy process around acrylamide in the limitations working group. This substance is still used in industry. COM confirmed that it is still used in small-scale grouting and that it has had contacts with the industry members in question in the particular MS. Another MS asked what happened to the cadmium risk reduction strategy, and the intention to set limit values for cadmium in phosphate fertilisers. COM answered that it is working on an impact assessment on the latter, but this is a different issue to the one of cadmium in solders and jewellery.

Future amendments to Annex XVII: 3 substances (Organotins, Dichloromethane and lamp oils and grill lighters) and newly classified CMRs

COM informed the meeting that the decision to amend Council Directive 76/769/EEC as regards restrictions on the marketing and use of certain dangerous substances and preparations concerning Dichloromethane in paint strippers (had been adopted by the European Parliament and the Council on 6 May 2009.

COM also adopted on 28 May 2009 two adaptations to technical progress of existing restrictions of certain organostannic compounds in articles, and restrictions for lamp oils and grill lighter fluids. As Directive 76/769/EEC and all its amendments and adaptations have now been repealed, COM will prepare proposals to include the agreed restrictions into Annex XVII of REACH and will present these to the REACH Committee in the second semester of 2009.

Cement containing Chromium VI imported from third countries

A discussion took place on the levels of Chromium VI in cement imported from a third country. The Association of the Cement Industry in one MS informed COM that imports of cement from a third country did not comply with the existing restriction. COM had contacted the MS about its enforcement activities. This MS informed that it had taken several enforcement actions: sometimes restraining the use of the cement with the too high Chromium VI content, other times re-exporting the cement. Another action could be to redirect the cement to end uses in a closed system (e.g. automated bulk systems and no human handling). The customs of two other MS had also found cement with high Chromium VI contents but had not yet taken any action.

During the 28 April limitations working group, the third country from which the cement had been exported was represented. The observer in the CA meeting reported that the

country is in the process of harmonising its laws with the EU, and that its cement industry had been informed of the EU rules on Chromium VI in cement.

The question was raised how to enforce the existing derogation in the restriction that if such cement is used in a closed system the limit value for chromium VI not apply. COM confirmed that the derogation indeed applied for use in closed, automated systems. It was rather clear that packaged cement was not intended to be used in such automated closed systems.

MS were asked to provide feedback to the COM on enforcement actions regarding the restriction on Chromium VI in cement for the next CARACAL meeting. This issue can also be discussed further at the Forum, if MS so desire.

Amending existing restrictions

The procedure described in document CA 38 was presented by COM and discussed. The procedure implies that either ECHA or a MS provide evidence that an existing restriction be re-examined, then COM has to adopt a Decision to do so – following an advisory Committee procedure, which means that at least a simply majority of MS has to agree, then an Annex XV dossier is prepared, followed by the normal process with opinions by RAC and SEAC. The process is rather long. One way to gain time would be to provide the evidence requested by Art. 69.5 already in a form of a (partial) Annex XV dossier.

In the discussion, several MS asked questions about the length of the procedure; what kind of evidence would be needed under Art. 69.5? Could the timing between step 3 and 4 be shortened? What exactly is the role of the Registry of intent? Should the Forum be involved? How far does the socio-economic analysis need to go?

It was noted that the guidance on the revision of restrictions is not yet developed, and the process is "learning by doing". The process for adopting the initial COM Decision to actually start the process to review a restriction could be made faster by a written procedure in the REACH Committee if all CA's agree that it should be sped up. The role of the Forum has not been specified and will have to be discussed by ECHA.

4.5. Unsolved interpretation questions

Yeast

A debate on yeast and yeast extract had been held in the framework of REHCORN. Some MS defended the idea that yeast extract is a naturally occurring substance and therefore does not need to be registered. Other MS were of the opinion that yeast extract and vinasses should be considered as substances, which are produced in manufacturing processes. From there, the matter had been referred to the COM for its opinion. The COM opinion was presented at the meeting. COM’s conclusion is that yeast extract, vinasses solution, vevomix and kalimix are not naturally occurring substances and therefore cannot benefit from the exemption under Annex V point 8. Additionally, COM believes that yeast extract cannot benefit from the exemption under Annex V point 9, as it is not one of the substances listed.

One MS insisted that yeast extract is the result of a natural, be it optimised, process. Optimising natural processes is extremely common practice in agriculture.

An industry observer commented that it had been pleased with the paper that one MS had prepared on this issue (concluding yeast extract was a naturally occurring substance hence no registration needed). When REACH was conceived companies using fermentation in their processes were not its target. Whereas the chemical sector prepared itself for REACH, fermentation companies would now be operating illegally due to this interpretation.

It was also underlined that Annex V point 9 is a closed list of substances. Yeast was not discussed at the time of its revision.

NONS

COM stated that a notification before June 2008 is to be seen as a complete registration and is subject to evaluation and a standard compliance check. It also discussed what happens if a MS did not finalise its evaluation for lack of time. When the registration dossier is updated, and this should be the case at 1 t rather than 10 t, the dossier needs to be REACH compliant. When a 10-1000 kg substance reaches the one tonne threshold, companies need to provide an update.

ECHA reported that there were 250 cases of finished decisions, and 120 unfinished ones. ECHA is also starting to update the NONS related sections of the registration guidance. As for the unfinished decisions and communication to industry a number of deadlines were passed. ECHA will contact the CA's on this.

A detailed discussion followed. Further comments on the paper from MS and observers were invited by 7 July and the Commission will finalise the paper based on the discussion and written comments.

4.6. Update on the guidance on application for authorisations

The COM reported that its respective internal services had had intense discussions on this topic, including at Commissioner level and that their positions had moved closer. Therefore the paper that had been promised to the CA's, outlining the diverging internal views would no longer make sense. Instead, COM was hopeful to be presenting a shared interpretation in the near future.

An NGO observer questioned why this guidance was not put before CARACAL for discussion, unlike other guidances. COM reassured them that the guidance would indeed be made available.

An industry observer deplored that no document has yet been made available to clarify the substitution plan and requested that a paper be made available ASAP.

4.7. Data sharing and Joint Submission

The COM introduced the subject. The main issue is: Must registration dossiers (lead registrant, subsequent registrants) de facto be submitted before the relevant registration deadline, in order to respect the waiting periods for the completeness check? The COM proposed to give the following replies: (1) the registration date is the date of the submission of the registration dossier. Consequently, registrations for the first registration deadline can be submitted until 30 November 2010, 24 hrs. (2) Registrants can continue manufacturing or importing their substance during the completeness check unless their registration has been rejected by ECHA. The legal text of Art. 21 requires

interpretation. In the understanding of the COM, the intention of the legislator was not to stop manufacturing or importing of substances already on the market during the completeness check. This corresponds to the interpretation in the Guidance on Data Sharing as endorsed by the REACH CA. (3) As for the deadline for ECHA to finalise the completeness check: this would be 3 weeks, if the dossier is submitted by 30 September 2010 at the latest, or 28 February 2011, if the dossier is submitted between 1 October 2010 and 30 November 2010. (4) Results of the first completeness check can be: dossier is complete, Agency assigns registration number and registration date; dossier is incomplete, Agency sets reasonable deadline to complete dossier. In both cases, registrants can continue manufacturing or importing if there is no indication to the contrary from the Agency. (5) Results of the second completeness check can be: dossier is complete, Agency assigns registration number and registration date; dossier is incomplete or the deadline is missed by the registrant: the Agency rejects the registration and the registrant must stop manufacturing or importing the substance; in case of rejection, manufacturing or importing can only resume after a new registration dossier has been submitted (in this case the waiting periods apply and the fee must be paid again). (6) In case of joint submission, when does the lead registrant have to submit his dossier? Art. 21(3) could be interpreted as saying that if lead registrant submits the dossier between 1 October and 30 November 2010, subsequent registrants have to stop manufacturing or importing until 1 March 2011. However, COM proposes to take a wider interpretation, allowing the continuation of manufacturing or importing during that time. Nevertheless, it might be useful for a lead registrant to submit the registration dossier before 30 September, to avoid any doubts and to give sufficient time for subsequent registrants to submit their dossiers.

MS and Observers welcomed the flexible approach. It was agreed that an interruption of business was not the intention of the legislator.

One MS mentioned *en passant* that the translation (of REACH?) into its national language is incorrect with regard to deadlines and asked whether an amendment of the wrong translation was forthcoming.

One industry observer said they advise lead registrants to submit before the end of June 2010. Answering the question whether individual registrants can submit their dossiers at the same time, in parallel, ECHA said that REACH-IT does not allow this at the moment - SIEF members can only submit after the lead registrant. However in 2010 this would be possible.

COM concluded the discussion by repeating that it is recommending lead registrant to submit by 30 September 2010, but that it continues its reflection on the subject. The 11 September workshop for lead registrants could be used to discuss any open questions. MS were invited to submit their comments in writing by 7 July 2009.

4.8. Interface REACH/CLP and OECD

COM introduced a proposal on how the work carried out by MS, ECHA and COM for implementing REACH could contribute to the OECD co-operative work on the assessment of chemicals. In this way the benefits from the OECD cooperation could be maximised and it could contribute to the goals of WSSD and SAICM.

It was suggested that ECHA should develop a proposal on exchanging information aiming at reducing double work within the mandate of OECD Hazard Assessment

programme. ECHA should also be asked to report regularly to CARACAL and OECD on progress. Where necessary they should prepare proposals to be considered by CARACAL and thereafter by OECD. It is essential to have a complete co-ordination between the work of MS, ECHA and COM within the OECD Task Force on Hazard Assessment.

MS and other participants supported these proposals. However, several MS were concerned about the possible extra burden on MS and they underlined that such an extra burden must be avoided. One MS informed that they could not commit themselves to follow up automatically. During the discussion it was also stated/noted that MS stand for themselves within OECD.

ECHA was invited to further develop the details for implementing the proposal from COM. ECHA asked MS that are already planning to send dossiers to OECD to inform ECHA about their experience.

4.9. Exemptions in the Interest of Defence

This discussion was a follow up of the discussion at the 1st CARACAL meeting. One important item during the previous discussion had been the possibility of having a mutual recognition of exemptions. However, the discussions had already shown that mutual recognition might not be an option. One MS underlined that their system had been set up to handle confidentiality and not to circumvent the REACH requirements. Several MS explained that they had set up systems to handle these exemptions. These systems and how they are handled obviously differ a lot from one MS to another. MS experiences with contact with the defence authorities within their own country were also mixed.
A representative from the European Defence Agency (EDA), who had been invited to participate in the meeting under this agenda item, informed about the recent developments regarding REACH within EDA. This Agency was established by the Council in 2004 to facilitate intergovernmental co-operation of Member States in defence related issues. One of the four long term strategies of the EDA is to work to strengthen the European Defence Technological and Industrial Base (the EDTIB). Ono of the main goals of this EDTIB Strategy is to establish a more level playing field in this segment of the European Market.
Due to their mandate, EDA had been approached by a couple of member states in course of the latest Steering Board to investigate the issue of REACH and the possibility for national defence exemptions and its defence implications. In a series of subsequent bilateral talks, a substantive number of member states had indicated that they could envisage the EDA to play a role in this field, particularly in the area of harmonisation of national approaches towards defence exemptions.
However, EDA also learned during these talks that national views differ significantly. EDA were now in the process of assessing if and how EDA, given its intergovernmental status, actually can add something to the current situation. EDA plans to report back to their Steering Board in early autumn this year and it will be up to the Steering Board to decide on any further steps.
After listening to the interventions from different MS and EDA, one MS suggested waiting for the conclusion from EDA before eventually continuing these discussions within other forums. COM did not want to draw any conclusions, but it will listen to MS advice if time is needed for discussion within CARACAL and/or Forum.

4.10. AOB and information points concerning REACH

The intention with this agenda point was to introduce different items that MS had specifically requested. However, there was not foreseen time at this meeting for a real discussion. MS were asked to comment orally at the meeting and/or send written comments after the meeting. If needed, COM will put these items on the agenda for the 3rd meeting of CARACAL.

GMOs

Several MS had sent written comments concerning the reply COM had given at the meeting of REHCORN in March. They did not agree with the answer that had been given and wanted to discuss the item further.

MS were asked to send written comments by 30 June 2009 to the MS who requested the item to be put on the agenda.

Progress report on registration and IT support tools

Several MS asked questions about how ECHA can contribute to facilitate SIEF formation and operation, in light of the first months' experience of difficulties in this area for industry. ECHA explained that it considers that SIEFs should be formed and Lead Registrants nominated by the end of this summer. Lead Registrants should submit their dossiers as early as possible and with a high quality. This will help subsequent registrants to submit all their dossiers before the deadline as they will have a complete dossier to refer to. ECHA also informed about their campaign "the clock is ticking". It contains of the following three elements: 1) try to remove the barriers to effective SIEF working, 2) to raise the awareness of the urgency of the need for action and 3) to support the Lead Registrants. ECHA was also of the opinion that SIEF members can work around an inactive Lead Registrants. However, it is important that these members then document what they have done. This means to work outside REACH-IT, but within the SIEF.

ECHA welcomed written comments by 30 June.

Progress report on guidance

One MS wanted to know who from the nominated parties in the ECHA database are to be invited to participate in different PEGs (Partner Expert Group). The projects that are going to be started in June were of particular interest. ECHA responded that they needed to clarify some legal issues before they soon will be sending out information to MS.

Proposal for an interim strategy to identify and prioritise substances of very high concern (SVHC) according to environmental risk criteria of REACH

The proposal an interim strategy to identify and prioritise substances of very high concern (SVHC) according to environmental risk criteria of REACH was presented by one MS. They suggest considering already existing evaluations of substances and information on intrinsic substance properties for an interim period until a lager number of registration dossier become available.

MS were asked to send written comments to MS presenting the proposal and COM before 30 June.

AOB

COM intends to come back on the issues of tobacco and sea and sea going vessels at the 3rd meeting of CARACAL.

On request it was decided that a representative from the brominates industry should be invited to the 3rd meeting of CARACAL to present the development of VECAP (Voluntary Emissions Control Action Program).

One MS informed about the ongoing work concerning the EU initiated Eastern Partnership. They will prepare a document before the next meeting of CARACAL and asked for a discussion at this meeting.

5. ECHA ACTIVITIES IN RELATION TO REACH

5.1. REACH-IT access for MSCAs – security policy

ECHA presented the main elements of the draft decision proposed to its Management Board allowing the ECHA secretariat to give access to REACH-IT for MS Competent Authorities, and in particular the amendments to the declaration of commitment to be signed by the legal representatives of the MSCA, and the Standard Security Requirements prepared with the support of the Security officer Network (SON).

Eight Member States expressed their views on the draft decision. They generally were satisfied about the additional flexibility in the security requirements. However, a number a points were mentioned as problematic, such as the lack of clear written procedures for requiring an access to REACH-IT, the use of REACH data for other purposes than the REACH implementation, the impact of confidentiality requirements on employment contracts, the potential conflicts between the confidentiality requirements in the declaration and national and European legislation on access to documents, and the necessity of a video-surveillance system. Moreover, many participants expressed that ECHA should take into account the fact that the MSCAs are used to dealing with confidential data and should be trusted.

5.2. Workshop on Evaluation

ECHA presented the draft agenda for the Workshop on Evaluation which is planned to take place on 22 and 23 September, 2009, in Helsinki. MSCAs and MSC members were kindly invited to participate in this meeting.

5.3. Authorisation

Progress on Annex XIV recommendation

ECHA summarised the process that has been followed for the development of ECHA's first recommendation for substances to be included in Annex XIV of REACH. The document particularly invited MSCAs to reflect on a number of policy related issues that the MSC had raised in its opinion on ECHA's draft recommendation, notably SCCPs/MCCPs, concerns through import of articles containing SVHCs, combined effects and grouping of arsenates and chromates.

In terms of the risks of SVHCs in imported articles most MS could agree to ECHAs proposal not to treat this issue with high priority given the specific requirements of article

69(2) although some expressed doubts whether there's indeed no urgency to look into this matter. ECHA noted that due to the revision clause for phtalates in Annex XVII for these substances this discussion may anyway come back on the table earlier.

In the discussion on combined effects of substances several MSs and NGOs showed clear interest in the subject. ECHA's proposal to develop a paper scoping the legal, scientific and technical boundaries of this issue for the next CARACAL meeting was agreed.

MS also agreed to the proposal by ECHA that further analysis of the need for grouping for arsenates and chromates should be carried out by those MS (or COM) that eventually will decide to develop such dossiers. The meeting was informed by one MS that they have launched a project to look into the potential grouping of arsenic acid and its salts.

The COM informed the meeting that good progress was made on preparing the Annex XIV proposal. A committee vote was planned for the autumn which would allow entry into force of the Annex early 2010.

Report from MS Working Group on Candidate List Preparation

The work of the informal expert group on pre-screening of SVHCs for potential future inclusion in the Candidate List was presented. It was stressed that the draft table provided to the MS should be seen as a working list that is under development. MS were asked to indicate their interest in participating in a further expert meeting that could potentially decide on the proposed grouping of substances and in the end decide on how to share the burden of preparing SVHCs for the years to come. The outcome of such a meeting would be reported to the next CARACAL meeting and the results could then be included in the Registry of Intent, taking into account the analysis of the best risk management option as was agreed to be performed in the January workshop. One MS furthermore informed the meeting that it plans to develop 5-10 SVHC dossiers per year.

In the discussion another MS informed the meeting that they were also planning to develop 8-10 dossiers per year and would also be interested to work together with other MS. In response to questions raised, one MS further clarified that the list will be made publicly available once further clean-up has been established but stressed again the fact that the list should not be seen as decisive on whether for a substance an annex XV dossier should be prepared in the future, but rather as a first step in identifying potential candidates.

5.4. Restriction process and timelines

ECHA explained the background for the suggested submission dates for Annex XV dossiers with proposals for restrictions and the need to have the dossier submitter involved in the RAC/SEAC working procedures. After a discussion in which MS expressed in particular their concern about the workload and short timelines for preparing responses to comments, it was agreed that the proposed process should be tried out in practice with the first restriction dossiers. It was suggested to add to the table in Annex I of the document also the timelines for the Forum's advice on the enforceability of the proposals.

6. REGULATION ON CLASSIFICATION, LABELLING AND PACKAGING

6.1. Update of REACH Annexes due to CLP

This item became an information point without discussion.

6.2. Implementation of CLP

The COM clarified the 1 December 2010 deadline for notification to the classification and labelling inventory. The original provision containing a deadline for notification to the inventory in Art. 116 of REACH, was interpreted by the COM as meaning that the notifications had to be submitted by 1 December 2010, but the COM was aware that the wording was not very clear. Hence the COM proposal for the CLP Regulation contained wording expressing the deadline of 1 December 2010 in very clear terms.

CLP entered into force in January 2009 and repealed Art 116 of REACH. The wording of Article 40(3) CLP, which resulted as a compromise from extensive discussions in the Council Working Group, provides that "substances placed on the market on or after 1 December 2010 shall be notified in accordance with paragraph 1 within one month after their placing on the market. Substances placed on the market before 1 December 2010 may be notified in accordance with paragraph 1 before that date". In other words, notification before 1 December 2010 is encouraged but voluntary, and the other deadline, one month after placing on the market is an obligation and has to be calculated on a case-by-case basis. The COM added that it had examined, at ECHA's suggestion, whether a corrigendum could be initiated in order for the text to provide an obligatory notification deadline of 1 December 2010, but had concluded that such use of a corrigendum would fall outside the conditions and rules for a corrigendum as contained in the Joint Declaration of European Parliament, Council and COM on the co-decision procedure.

ECHA added that the CLP Module 1 guidance refers to the 1 December 2010 as the deadline so any change to this deadline is not a mere editorial change. As the authority that will receive the notifications, ECHA is quite apprehensive about the number of notifications that will come in during the Christmas period when ECHA, like all other EU institutions, will remain closed. Similar to the situation with the pre-registrations, it is impossible to predict this number.

MS were invited to comment. Several Member States confirmed that the provision had been discussed at length in the Council Working Group and supported the Commission interpretation of Article 40(3) CLP, but at the same time expressed sympathy for the difficulties and uncertainty thus created for ECHA. They agreed that a change to the deadline fell outside the conditions and rules for a corrigendum. Some Member States suggested that ECHA raise awareness of operators on end-of-year arrangements and recommend notification well before the deadline while another pleaded for pragmatic dealing with notifications arriving between 1 December 2010 and 1 January 2011. This was echoed by one observer who stressed the importance of awareness raising on the deadline and pragmatic solutions for particular cases.

ECHA concluded the discussion on this issue by confirming that the wording regarding the deadline should be clarified in the guidance and that the revised Module 1 would be circulated to CARACAL for information. The final copy will be handed over to ECHA, to be integrated in ECHA's guidance documents.

Some CAs inquired about the previously announced general corrigendum to the CLP Regulation. COM explained that such a corrigendum has to be processed by the Council which had already taken some steps, but COM suspected that due to the urgency of some legislative files linked to the European Parliament elections, the CLP corrigendum might have received lower priority treatment. The COM undertook to contact the Council Secretariat and report back to CAs; the COM also invited CAs to submit any suggestions for the corrigendum to the Council Secretariat as quickly as possible in order for them to be considered.

6.3. Issues raised at ECHA Committee Meetings – Scope of Annex VI dossiers

The COM presented how to classify a mixture that contains a CMR impurity. Annex VI Article 10 provides that if a substance contains a CMR impurity above the generic or specific concentration limit, this substance will be classified as a CMR. If then such a substance classified as CMR because of the impurity, is incorporated in another mixture, and the CMR component is now present in a lower concentration, the CMR classification may not be scientifically justified. As an alternative, it should be possible to assess the concentration of the CMR impurity in the mixture as a whole and compare that to the relevant concentration limits and thus determine the classification of the mixture as a CMR.

The discussion highlighted the difficulties of the paper in case of complex substances, for example oil substances, and the risk of overlooking other substances in the mixtures. Another comment was that the cut-off levels are not reflected in the paper, could they be looked at? Another question was: how does one recognise an impurity or additive in a substance, considering CMR are banned to the public.

It was concluded that if the constituent is classified as CMR and already included in Annex VI, there is no need to include substances classified due to the presence of this constituent in Annex VI as the obligation to classify is clear. Classification of complex substances needs further thoughts and the COM will redraft the paper on classification of substances containing an identified impurity, additive or individual constituent as a CMR at a concentration above its specific or generic concentration limit.

6.4. Follow-up of Article 53(2)

The COM reminded the meeting that during co-decision a few MS at the Council WP and some political groups of the Parliament had pleaded for labelling of PBT/vPvB substances. As a compromise, Article 53(2) in the CLP Regulation had been formulated as follows: "*Member States and the Commission shall, in the manner appropriate to their role in the relevant UN fora, promote the harmonisation of the criteria for classification and labelling of persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances at the level of the UN*".

Currently different jurisdictions and intergovernmental organisations have schemes to screen for persistent, bioaccumulative and/or toxic properties of substances in order to manage the risk. There are criteria for C&L in UN GHS and CLP: (1) based on UN GHS rev2/CLP most substances meeting REACH PBT/vPvB are classified and labelled for environmental hazard and in certain cases for human toxicity; (2) the few PBT that are not classified (no or low acute toxicity to aquatic organisms) will fall under UN GHS/CLP by the criteria laid down in rev3 UN GHS; (3) only the few vPvB with NOEC above water solubility limit would not be classified.

CLP requires promoting the harmonisation of C&L criteria for PBT and vPvB substances at UN level, therefore COM and MS should bring the issue to the attention of the UN and seek their views. However, the effect on labelling due to the introduction of Rev3 UN GHS should be monitored. Based on that experience, the added value of further labelling requirements might need further consideration.

One MS, supported by some others, expressed that the Commission proposal on promotion of PBT classification and labelling (Doc. CA/51/2009) is too vague, and that there is need for a specific PBT/vPvB classification category leading to harmonized labelling reflecting the hazard, so that users get informed about it.

It was concluded that the COM should prepare a document for the next UN GHS meeting. The document should seek to strike the right balance on the best way to promote development of criteria.

6.5. Guidance (RIP 3.6)

COM (JRC) presented the finalised Guidance Module 2, as developed under RIP 3.6 by four expert working groups from September 2007 until February 2009. It was approved by a stakeholder expert group during March-April 2009. It was presented to CARACAL with a view to obtaining its endorsement. Finally, the Guidance will be handed over to ECHA to become an integral part of all its Guidance documents.

The Guidance consists of 5 parts: (1) General Introduction, (2) Physical Hazards, (3) Health Hazards, (4) Environmental Hazards, (5) Labelling.

COM reported that editorial and reference errors present in the version distributed in May had meanwhile been corrected. Some MS had sent detailed written comments – COM will consider how to take them into account. MS welcomed the work done but felt they had to work with the document for some more time before they could endorse it.

A round of comments was taken per chapter: Chapter 1 – none. Chapter 2 Physical Hazards – flammability: a MS made a specific comment on oil and diesel and references to 55° to be deleted. He was asked to provide the comment in writing. Chapter 3 Health Hazards – Austria already commented in writing on in vivo testing of corrosives. Sweden commented on “human health” chapter 3.2.6 – does this not take into account animal welfare? Sweden was asked to propose a text. An industry observer said the example about skin irritation should not be deleted. Chapter 4 – none. Chapter 5 Labelling – This chapter is to be considered work in progress. Some MS commented that they had problems with the sizes of the pictogrammes and the sizes of the labels. MS were invited to provide further (editorial) comments in writing to COM within three weeks. The final guidance document will be circulated to CARACAL. The final document will also be handed over to ECHA, to be integrated in ECHA’s guidance documents and for future processing.

6.6. Implementation of the declaration regarding languages

This agenda item follows on from the previous CARACAL meeting. As an outcome of the CLP negotiations and on the basis of substantive input from MS and COM ECHA is to make available over the internet the chemical names corresponding to the International Chemical Identifications in Tables 3.1 and 3.2 of Annex VI in EU languages,. The public

part of the C&L inventory will be the main tool for ECHA to make the substance names available in EU languages. However, this tool will not be available before mid 2010.

Therefore, to avoid delay, ECHA is currently preparing an arrangement with JRC, to ensure that ClassLab will remain open, and maintained, until all the information in ClassLab can be transferred to the C&L inventory when it is ready.

MS said that they have been contributing chemical names already. However, the major lack of names in the database is in the new MS languages. MS confirmed they have all the names available and that they are keen to transfer the information, as soon as they will receive the requirements from ECHA.

ECHA, together with ex-ECB, will contact MS in writing with the exact requirements and formats to fill in, and will inform CARACAL when this communication can be expected.

7. ECHA ACTIVITIES IN RELATION TO CLP

7.1. Transitional arrangements for PPP and biocides on format for proposals for harmonised C&L

This item became an information point under 2.6 and was not discussed.

7.2. Communications strategy on CLP

ECHA presented the document outlining the first thoughts for communication about the CLP Regulation. The intention is that communications should focus on the obligations of industry to classify their substances in accordance with the new CLP criteria from 1 December 2010 and to notify the classification & labelling within the deadline specified. The communication should be targeted towards companies that have registration obligations under REACH, companies that do not have registration obligations but nevertheless have to classify & label their substances and to notify this to ECHA, and to non-EU trade partners. Finally, ECHA invited the Commission, Member State Competent Authorities, and other potential partners and stakeholders to work with ECHA to develop a plan that will ensure that the CLP communication activities effectively reach the target audiences.

MS and observers expressed their willingness to work with ECHA on developing the communication strategy and would also provide examples of their information material.

ECHA asked the MS and observers to send available information material as well as ideas to ECHA.

8. AOB AND INFORMATION POINTS CONCERNING CLP

- Information about the list of entries concluded by TC C&L but not included in the 1st ATP

The list of entries agreed for the 31st ATP to the 67 Directive (now included in Annex VI to the CLP Regulation through the draft 1st ATP) was closed by the May 2006 meeting of the Technical Committee on the Classification and Labelling (TC C&L) at JRC in Ispra. However, the TC C&L continued its activities for an additional year and its last meeting

took place in September 2007. During this time, the TC C&L concluded the classification proposals of a list of more than 50 substances; the information on the substances not concluded was forwarded for continuous discussions at the Risk Assessment Committee at ECHA.

The outcome of the internal discussions at the COM level concerning this topic can be summarised as follows: MS are to prepare Annex VI dossiers for classification and labelling of these substances and submit the dossiers to ECHA. ECHA and RAC will then see how to move forward. Altogether it concerns some 50 substances "pending".

A MS asked for a simplified format for Annex VI dossiers, and expressed a concern that also PPP and Biocides would cause additional work. Could there utmost flexibility in terms of deadlines? This was supported by other MS.

COM replied that in the framework of REACH and CLP Commission services are preparing a paper on PPP and biocides, which will be brought to the attention of the CAs for PPP and biocides and also to CARACAL.

ECHA added that for biocides, PPP, and the 50 substances, MS would in any case need to submit the proposal for harmonised C&L to ECHA who will have to publish the proposal for commenting by parties concerned, and RAC would need to give an opinion. ECHA will explore possibilities for reducing the level of documentation in the dossiers and whether a lighter procedure could be implemented leading to the RAC opinion.

- *Information about a future ATP to the CLP"*

This item was not discussed. MS were asked to send suggestions about possible items to be included in future ATPs to the CLP Regulation.

9. NEXT MEETING AND CLOSURE

The next meeting will be held on 12 and 13 October 2009 in Brussels.

The meeting closed at 15h30.

EUROPEAN COMMISSION

ENVIRONMENT DIRECTORATE-GENERAL
Water, Chemicals & Cohesion
Chemicals

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

Brussels, 12 June 2009
Doc. **CA/29/2009 - Rev. 3**

2nd Meeting of Competent Authorities for REACH and CLP

15-16 June 2009

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

AGENDA

Discussion Points:

AGENDA ITEM	ACTION	TIME (APPROX.)
1. ADOPTION OF THE DRAFT AGENDA	Discussion, adoption	**09:30 – 09:45**
2. FOLLOW-UP OF THE 1ST CARACAL MEETING		09:45 – 10:10
2.1. Draft Summary Record	Discussion, adoption	
2.2. Actions from the meeting	Discussion	
3. ORGANISATIONAL MATTERS	Discussion	10:10 – 10:30
3.1. Tracking system for conclusions on interpretation questions		
4. REACH		
4.1. Update on REACH Annexes and Implementing Legislation - Fee Regulation - Annex V	Information and Discussion	10:30 – 11:00
- Annex XIII		
- Annex XVII		
Coffee break		***11:00 – 11:30***

AGENDA ITEM	ACTION	TIME (APPROX.)
Continue item 4.1. - Test Methods Regulation Process	Discussion	11:30 – 12:30
4.2. Implications of the Market Surveillance Regulation on REACH Enforcement	Information and discussion	12:30 – 12:50
4.3. Format/constitution of Registration number on SDS	Discussion	12:50 – 13:15
Lunch		***13:15 – 14:15***
4.4. Restriction issues - Work plan for restrictions	Discussion	14.15 – 15:00
- Future amendments to Annex XVII : 3 substances (Organotins, Dichloromethane and Lamp oils and grill lighters) and newly classified CMRs	Discussion	
- Cement containing Chromium VI imported from third countries	Discussion	
- Article 69(5) of REACH: procedure to amend existing restrictions	Discussion	
4.5. Interpretation issues - Yeast	Discussion	15:00 – 15:40
- NONS	Discussion	
4.6. Update on the guidance on application for authorisations	Discussion	15:40 – 16:00
Coffee break		***16:00 – 16:30***

AGENDA ITEM	ACTION	TIME (APPROX.)
4.7. Data sharing and Joint Submission	Discussion	16:30 – 16:50
4.8. Interface REACH/CLP and OECD	Discussion	16:50 – 17:10
4.9. Exemptions in the Interest of Defence	Discussion	17:10 – 17:30
4.10. AOB and information points concerning REACH [1]		17:30 – 18:15
- GMOs		
- Progress report on registration and IT support tools (Information point 1.3)		
- Progress report on guidance (Information point 1.6)		
- Proposal for an interim strategy to identify and prioritise substances of very high concern (SVHV) according to environ-mental risk criteria of REACH		
- AOB		

[1] Information points will not be addressed orally, unless this is specifically requested; see last page of the PDA

AGENDA ITEM	ACTION	TIME (APPROX.)
5. ECHA ACTIVITIES IN RELATION TO REACH		**09:00 – 12:00**
5.1. REACH-IT access for MS CAs - security policy	Discussion	09:00 – 09:30
5.2. Evaluation - Workshop on evaluation	Information & discussion	09:30 – 10:10
5.3. Authorisation – Progress on Annex XIV recommendation – Report from MS Working Group on Candidate list preparation	Information & discussion	10:10 – 11:00
Coffee break		***11:00 – 11:30***
5.4. Restriction process and timelines	Discussion	11:30 – 12:00
6. REGULATION ON CLASSIFICATION, LABELLING AND PACKAGING		
6.1. Update of REACH Annexes due to CLP – *moved to information point 2.8*		
6.2. Implementation of CLP - notification deadline	Information & Discussion	12:00 – 12:20
6.3. Issues raised at ECHA Committee Meetings - Scope of Annex VI dossiers		12:20 – 12:40
6.4. Follow up of Article 53(2)	Discussion	12:40 – 13:00
Lunch		***13:00 – 14:00***
6.5. Guidance (RIP 3.6) - Module 2	Discussion & Endorsement	14:00 – 14:45
6.6. Implementation of the declaration regarding languages	Input from MS about the issues	14:45 – 15:15
7. ECHA ACTIVITIES IN RELATION TO CLP		
7.1. Transitional arrangements for PPP and biocides on format for proposals for harmonised C&L – *moved to information point 2.6*		

AGENDA ITEM	ACTION	TIME (APPROX.)
7.2. Communications strategy on CLP	Information & discussion	15:15 – 15:45
Coffee break		***15:45 – 16:15***
8. AOB AND INFORMATION POINTS CONCERNING CLP[2] - Information about the list of entries concluded by TC C& L but not included in the 1st ATP (Information point 2.1)		16:15 – 16:45
- Information about a future ATP to the CLP (Information point 2.2)		
9. NEXT MEETING AND CLOSURE		16:45 - 17:00

[2] Information points will not be addressed orally, unless this is specifically requested; see last page of the PDA

Information Points[3]:

1. REACH
1.1. MS Reporting
1.2. Study "Penalties applicable for infringement of the REACH Regulation in the MS"
1.5. Procedure for RoI
1.7. REACH Implementation projects on Nanomaterials
2. CLP
2.3. Relationship of requests for use of an alternative chemical name under DPD or CLP
2.4. Progress report on proposals for harmonised classifications
2.5. Report from REHCORN Workshop on CLP
2.6. Transitional arrangements for PPP and biocides on format for proposals for harmonised C&L
2.7. Issues to be considered for further development of Guidance under CLP
2.8. Update of REACH Annexes due to CLP Annex II – report from CASC Annexes meeting 27 May 2009

[3] Information items are not allocated a specific agenda time. If delegates wish to raise an issue which may merit further consideration, please signal this by sending an email to Solvar.hardeng@ec.europa.eu and Christine.wistuba@ec.europa.eu by 10 June 2009.