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

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SUMMARY RECORD

3rd Meeting of Competent Authorities for REACH and CLP

12-13 October 2009

Centre A. Borschette,
Rue Froissart, 36, BE-1040 Brussels, Belgium
Room 1-C (12 October) & 1-D (13 October)

Introduction:
The Commission (COM) apologised for the limited space in the room and invited Member States (MS) to consider this in future when putting their delegation together.

1. Adoption of the draft agenda

The agenda was adopted with the following changes:
- In relation to intermediates, agenda point 5.1 covers strictly controlled conditions rather than the interpretation of the definition.
- Agenda points 7.2, 7.3, 7.4 will be discussed at the end of the REACH section of the agenda.
- Agenda points regarding restrictions should also cover compliance check at customs.

One MS asked that even preparatory documents related to information points should be sent timely before the meeting. It was also commented by one MS that for future meetings technical issues should be discussed at technical meetings, while CARACAL would focus on policy issues. COM will consider the use of sub-groups for technical discussions.

COM reminded that changes to the agenda, including moving information points to the core agenda should be requested by participants 1 week before the meeting, however leaving flexibility to have changes requested at the meeting itself if others agree and if it can be accommodated.

2. Follow-up of the 2nd meeting of CARACAL

2.1. Draft summary record

The draft summary record (DSR) of the 2nd meeting of CARACAL was adopted, subject to the edition of the following sections:

- Section 4.5 on Notification of New Substances (NoNS), adding that registration dossier should be updated at 1t rather than 10t.
- Section 6.4, adding: One MS, with support from some others, expressed that the COM proposal on promotion of PBT classification and labelling is too vague and there is need for a specific classification category for PBT/vPvB, leading to specific harmonised labelling.
- Section 8, adding that the Classification and Labelling (C&L) of Plant Protection Products and Biocides should be given by the MS.

It was also noted that the invitation for a presentation of the Voluntary Emissions Control Action Programme was missing from the action list, though present on the DSR (section 4, AOB)

2.2. Actions from the meeting

It was mentioned that OECD had started work on cumulative effects and that they would happily share their progress as they get along.

It was acknowledged that fast action on Genetically Modified Organisms (GMOs) is required. COM would need coordinated views from the Competent Authorities (CAs) for both REACH and GMOs on this. A commenting procedure should be launched with clear timelines.

3. REACH

3.1. Update on REACH Annexes and Implementing Legislation

a) Update

Annex IV and V: A corrigendum is needed in relation to languages issues and typographic errors. COM was still analysing the way forward and was hoping to be able to finalise the discussion soon and inform MS as soon as possible.

Annex II: A vote is foreseen at the REACH comitology meeting on 9 November, in order to amend Annex II on the following two aspects:

- Alignment of Annex II with the CLP Regulation:

2 expert meetings took place in May and June. The interservice consultation was finalised and sent to MS and notified to WTO on 19 August. Comments were received from MS, while none from WTO until now (deadline for comments 19 Oct. 2009).

- Last 4 digits of the registration numbers on the SDSs:

COM proposed that every supplier of SDS needs to agree that he will provide the full registration number on request, or that he will pass on the relevant information up the supply chain, copying the original actor. Thus, if an actor cannot provide the full registration number to e.g. an inspector, he can meet his obligations by indicating who did not provide the full registration number. This is to avoid that an actor would be penalised if an actor up his supply chain fails to supply a registration number.
As this proposal was criticised, arguing that it should only apply for enforcement purposes, COM proposes to clarify that such a request can only be made for enforcement authorities, and to allow alternative ways of communicating with the enforcement authorities, as long as this is within the deadline: e.g. the supplier of the supplier communicates directly with enforcement authorities without the other actors in the supply chain seeing. There is, however, widespread willing among MS to address the confidentiality problems raised by industry.
Several MS feared that the proposal was not yet ready to enable a Committee vote rather soon, and that further discussions were needed as the matter is very complex and technical.

One Member State asked for a further meeting of the working group on registration numbers, to prepare the vote. In particular COM promised to provide supporting documentation on Article 39 shortly, on request from two MS.
CEFIC and AISE stressed the importance of protecting confidentiality in the supply chain, and the workability of meeting the requirements of Article 39, especially in terms of setting the deadlines for actors in the supply chain to respond.
COM agreed to verify whether it was possible to set up another working group meeting but stressed the limited time until Nov 9 and hoped that it would still be possible to have a vote on that day.

Annex XIV
COM is working on the finalisation of the guidance on authorisation and committed to make a proposal as soon as possible. They indicated that the guidance will be faithful to the legal text and keep the two routes of adequate control on the one hand, and risks outweighed by benefits on the other hand.
On requests from three Member States, COM agreed to forward a planning document indicating timelines endorsement of the guidance, and for legislative (comitology) work on Annex XIV.

b) Annex XIII

On a request about the status of the proposal for amendment of Annex XIII, COM indicated that the above-mentioned planning document (see item 3.1.a) would also cover Annex XIII, and confirmed that it would take into account the current and new experience on the identification of PBT/vPvB substances.

3.2. Unsolved interpretations questions

Notification of New Substances (NoNS)
The work on this is being finalised, and ECHA implemented the comments in their strategy on NoNS. COM failed, however, to update the 2 related documents in accordance with the comments received, and will do so as soon as possible. This will include legal issues regarding update of the registration dossiers.
Regarding payment of fee when a dossier is updated, it was clarified that if a notification below one tonne was submitted before 1st June 2008 and was being updated to the 1-10 t tonnage band after 1 June 2008, no fee needs to be paid. This will also be clarified in the Fee Regulation when it will be updated next.

Substance identity and SIEF formation (the role of EINECS)
COM explained that no paper could be produced timely for this meeting because of a misunderstanding of some of the implications of the issue. COM nevertheless outlined its position on the root issue: as there are quite a few mistakes in EINECS, we have to leave room to accommodate for this and allow that one former EINECS entry is dealt with by more than one SIEF even if this should be avoided as much as possible. This is why the pre-SIEF discussion had been introduced in the guidance. In fact the concern was not so much the principle (which is agreed), but what happens if this is done in a uncontrolled way, e.g. due to disagreement between two companies in a SIEF, or if a SME for example feels excluded from a SIEF by an artificial definition of the substance. A discussion is needed on this, we plan to have a paper on this for the next CARACAL. COM will try to come back with information on this ASAP, if possible before the next meeting.

One Member State stressed the urgency of coming forward with clear guidance on this for industry, and agreed strongly that the splitting of SIEFs should only be allowed in very exceptional cases and should be duly justified.
Addressing a request from two Member States to solve this issue swiftly, COM proposed to come forward with a paper in the following 1 to 3 weeks, to be first commented in written and then endorsed via written procedure.

3.3. Data sharing and Joint Submission (Outcome of the Workshop for lead registrants)

COM outlined the current issues and questions in relation to the operation of SIEFs, as well as the communication activities that are planned in the framework of the SIEF awareness campaign. MS were invited to speak at the first of the series of webinars organised as a continuation to the Lead Registrants Workshop of 11 September. One MS welcomed this initiative, however warning that ECHA should take a further look at how webinars are broadcast, as they had accessibility problems.
Participants will also be invited to distribute a leaflet that COM will produce to provide tips to companies, especially SMEs, on SIEFs and on the CLP notification deadline. This leaflet should be available in English by the end of the year, while translations are expected to be available a month later.

One MS asked for a timeline of when further analysis on copyright issues would be available, COM explained that questions related to copyright are tricky, and not all of them lie within Community competence, thus requiring very careful drafting.
The MS also felt that the indicated date of the next CARACAL for a document regarding what is available information and whether companies need to pay for it is too remote for industry. COM replied that this also requires cautiousness, therefore it would be unrealistic to expect the analysis to be available before the next CARACAL meeting.

Another MS was surprised that in some exceptional cases some registrants could register before their lead registrant, e.g. in the case of a registrant of a phase-in substance who has not pre-registered. COM explained that this case is described in the guidance on data sharing (“early registrants”). Nevertheless, the early registrant will also under these conditions be part of the joint registration, and this registrant will later need to align his registration with the lead registrant's. ECHA clarified that in REACH-IT, the lead registrant has to submit first when it is within the joint submission. But REACH-IT allows an "early registration" if there is an "early registrant" for the same substance, out of the "pre-SIEF"-SIEF normal route.

The consequences of failure by registrants to put together a complete set of data were also discussed. Though it is clear that there are financial implications (payment of a second fee), it needs to be clearer that it does not imply that the registrant should refrain from manufacturing or importing altogether.

CEFIC disagreed that a confirmation from non-EU customers on strictly controlled conditions should be required in order to allow transported isolated intermediates to be registered with lower information requirements for intermediates. They recalled that this point was originally in the intermediates guidance and that it had been purposely left out in the revised version of this guidance dated February 2008, following a discussion in GRIP. They also referred to similar experience with the PIC Convention of Rotterdam, where many countries refusing to answer, causing difficulties. They underlined that EU does not have enforcement powers beyond its territory. COM recognised practical difficulties but also indicated that the legal text is clear about this matter.

CEFIC also raised the question of a substance being registered both as an intermediate and as a non-intermediate, and whether there should then be only one dossier in this case. They understood there were two possibilities in that case and thought it should remain like this. COM explained that this discussion was not entirely concluded, but that it is clearly recommended to have one joint registration for both non-intermediate and intermediate uses, as this avoids many potential legal and practical problems. In particular, COM reminded that there cannot be two SIEFs for the same substance, as an intermediate and a non-intermediate, because there is no exemption for intermediates for title IV. Moreover, there may be complications where a given company manufactures or imports intermediates both for intermediate and non-intermediates and where not all companies within a SIEF would like to submit separate dossiers, risking violation of either Art 19 or Art 11.

a) GMO

8 Member States expressed their disagreement with the COM opinion stated in March, that oils obtained from genetically modified plants should be exempted from registration. Contrary to COM, these Member States think that these oils are not covered by Annex V(9) because they see them as not qualifying for being obtained from natural sources. The Manual of Decisions to Directive 67/548/EEC was also referred to in that context, several Member States stressed the importance of keeping consistency with former decisions that were taken on substances derived from genetically modified plants. One Member State also called for harmonised answers to GMO-related questions at a more general level and from a broader perspective, looking at whether it is justified to use the experience from the implementation of Directive 67/548/EEC under REACH. One Member State suggested that ane opinion of EFSA could be sought. Another Member State also noted that food and feed are already exempted from REACH, but that on the other hand the discussion should also cover substances obtained from non-plant GMOs, such as bacteria (used for production of different chemicals), which should not be exempted according to them.

4 Member States opposed this view and supported COM, one argument being that EINECS entries are defined by species, thus both GMO and non GMO species are covered by the same EINECS entry without distinction. Some Member States also agreed that in practice it would also be impossible to enforce the position of 8 Member States described above, as it is impossible to distinguish between substances obtained from GMO and non-GMO breeds. One Member State felt that such decisions should be taken on a case by case basis rather than a single decision covering all GMO-related questions.

CEFIC conveyed the views of Fediol, EFEMA, ELMA and COCERAL, and recalled that the issue of GMOs was already discussed under the former regulatory framework and the Manual of Decisions contains some decisions that were taken on this matter. At that time, however, an exemption along the lines of Annex V(9) of REACH did not exist, there was therefore no consistency problem between the two legislative frameworks. In their view, whether obtained from GMOs or not, the substances are, chemically spoken, identical. In addition, the GMO legislation already requires an assessment of the safety of GMOs for the health and the environment so it would be disproportionate to require their registration under REACH too.

COM indicated that they were pursuing internal discussion on this issue, and would ask Member States for input on some more precise questions. Member States will be invited to provide a coordinated view of the REACH and GMO national CAs.

b) Eastern Partnership

On initiative from two Member States, the possible involvement of CARACAL in the Eastern Partnership, a collaboration project between eastern neighbour countries of the EU, was discussed.

One Member State, though valuing such partnership, challenged whether CARACAL is the right forum to use for this partnership, and suggested the Forum would be a better place.

OECD explained that they are carrying out joint activities with eastern countries, specifically on environmental policy transfer, e.g. water management and treatment, environmental policy financing. Some partnership is envisaged with them on chemicals, it might be good that OECD shares their activities on environmental policy transfer.

The COM welcomed the initiative and referred to on-going cooperation within SYCON or TAIEX. Collaboration on chemicals management is good for such countries, though it may be more efficient to focus on specific areas, rather than REACH as a whole, to help getting knowledge of what is on the market, risk management hazard identification.
However, they expressed reservations on the possibility to invite countries Eastern Partnership at CARACAL, given the constraints we have e.g. on the size of the meeting rooms, and questioned the interest for these countries of attending the CARACAL discussions, which are very technical and detailed. Maybe CARACAL observers representing 3rd countries (e.g. US, Switzerland) should liaise with countries of outside interests.

c) State of the Art Report on Mixture Toxicity (update on the ongoing study and its preliminary outcomes)

The study (done by a contractor) was introduced and preliminary findings were presented. The objective is to gather the scientific and regulatory state of the art on how to approach the issue of combined effects of chemicals. The final report is due mid-October.

The Council has been approached on these issues, and the recommendations from the contractor were seen as in line with and complementary to another study that will be shortly presented at the Council, looking at combined exposure for a two-year old child throughout the day. Several Member States invited COM to look further into this area, especially regarding endocrine effects. One Member State questioned whether REACH allows to take these aspects appropriately into account, as it is substance-based and not media-oriented.

The Health and Environment Alliance referred to submissions made by NGOs on prioritisation of chemicals from the candidate list for authorisation, and informed about their publications and a letter concerning a possible action with regard to endocrine disruptors. According to them it should not be possible to pursue the adequate control route for authorisation for some endocrine disruptors that have no threshold values, also because of their cumulative effects.

The COM is awaiting the conclusions of the Council on cumulative effects of chamicals, while ECHA has already started work on a scoping paper which could give a partial REACH answer to the problems that have been identified.

4. Restrictions

4.1. Workplan for Restrictions in the transition phase (update)

COM presented the proposed workplan for restrictions in the transition phase.

Acrylamide: COM explained that it was surprising to find out that the substance has been proposed also as in the candidate list as a very high concern substance. This would mean that 2 risk management options are now under evaluation: restriction and authorisation. However

COM will follow the provisions under the Article 137 of REACH which regard the transitional measure for restrictions. One Member State noticed that the CARACAL may not be the appropriate forum to discuss the most appropriate risk management option.

Cadmium: COM indicated that a study was launched and will end in November 2009. The study will be published on the COM website. An impact assessment will be drafted and a draft amendment to Annex XVII will be presented by COM before 1 June 2010 in accordance with the Article 137 of REACH.

One MS noted that Cadmium in Fertilisers will be discussed at a workshop on 28 October 2009 (Fertilisers working group).

1,4 dichlorobenzene: COM indicated that a socio economic study is on going on the use of the substance in air fresheners and toilet blocks. It should be finished by the end of February 2010. An impact assessment will be drafted and a draft amendment to Annex XVII will be presented by COM before 1 June 2010 in accordance with Article 137 of REACH.

TCEP: COM explained that the issue concerns the use of TCEP in toys. As the risk management measures refers to lower content of TCEP comparing with the limit of 0.5% it was agreed by the Commission together with the EU Rapporteur under the regulation 793/93 to include TCEP as an example in order to revise the Directive 2009/48/EC on the Safety of toys. . It is planned to revise the Directive on the safety of toys in order to include lower concentrations and the release of substances from toys. In the light of this decision COM will not prepare a proposal amending Annex XVII of REACH for this substance.

PFOA: the Study is ongoing and will be finalised by the end of the year and then will be published on the Commission website A workshop will be possibly organised earlier 2010 to discuss the results and the risk management options with all interested parties.

Phthalates: COM has sent to ECHA new scientific information concerning ***DNOP, DINP, DIDP, DEHP, BBP and DBP*** and has required ECHA to evaluate whether there is evidence that would justify a re-examination of the existing restrictions.

Some MS asked about the timing of the revision: COM and ECHA replied that this was difficult to predict. The first assessment should be completed in 2010.

Mercury:
COM announced that the preparation of the review report (as required under Directive 2007/51/EC) concerning mercury containing devices in healthcare (in particular sphygmomanometers) as well those intended for professional/industrial uses is now completed. By the end of October 2009, the report will have been submitted to ECHA. The report on healthcare sphygmomanometers takes into account the scientific opinion of SCENIHR.

Substances classified as CMR under Commission Regulation 790/2009 (First ATP to 1272/2008): COM indicated that draft amendment to Annex XVII to provide for a ban of the newly classified substances for supply to the general public is being prepared. The ISC has been completed. The draft is providing for 2 exemptions
- perborates in detergents,
- boric acids in photographic applications.

Concerning the photographic applications on the basis of the existing risk assessment COM concluded that the application pose no risk to general public. In order to have a further evaluation, COM has requested ECHA to evaluate the risk to consumers of this application.

One MS asked if the derogation for detergents was for all borates. COM replied that the derogation concerns specifically for perborates.

One MS asked whether for detergents an upper limit should be set. COM replied that this was not necessary as the detergents cannot contain more than a certain percentage of borates.
Concerning the Photographic application COM clarified that it did not see the need for a restriction at this point in time. In addition a further delay will have an impact on the adoption of the restriction for all CMR substances. The draft COM regulation should be soon submitted to the vote of the REACH Committee.
One MS said that it had significant problems with the proposed exemptions for CMR substances based on low-risk arguments.

Dichloromethane, lamp oils and grill lighter fluids and organostannic compounds: COM indicated that it has prepared an amendment to Annex XVII in order to include restrictions adopted under Decisions 455/2009/EC, 2009/424/EC and 2009/425/EC. This falls under the provisions on transitional measures in Article 137 of REACH. The vote of the REACH committee is scheduled on 9 November 2009. The adoption of the amendment by the Commission is scheduled in April 2010. The entry into force will be immediately after the publication and the application of the restrictions will take place at the dates provided in Decisions 455/2009/EC, 2009/424/EC and 2009/425/EC.

4.2 Re-examination of the restrictions pertaining to short chain chlorinated paraffins (SCCPs)

In June 2010 one MS asked COM to re-examine the restriction concerning SCCPs (entry 42 of Annex XVII) following the procedure stated in Article 69-5.

COM indicated that the last addendum of the EU Risk Assessment Report[1] concluded that SCCPs meet the criteria for a persistent, bioaccumulative and toxic (PBT) substance and also identified further environmental risks for backcoating of textiles and for rubber compounding/conversion. SCCPs were identified as Substances of Very High Concern (SVHC) in accordance with Article 59 of the same Regulation.

COM also mentioned that SCCPs are proposed for inclusion into the Protocol on Persistent Organic Pollutants (POPs) (Protocol) in the framework of the UNECE Convention on Long-Range Transboundary Air Transport as well as the Stockholm Convention on Persistant Organic Pollutants (Convention). If the substances are included in the Protocol or the Convention, then Regulation (EC) No 850/2004 on POPs will be amended. That means severe restrictions or the prohibition of the manufacture/placing on the market/use of the substances/in mixtures/in articles.

The REACH Committee will be consulted following the procedure established under article 133(2) of that Regulation (advisory procedure) in December 2009. The adoption by the Commission of this decision is scheduled early 2010.

COM indicated that it agrees to initiate the re-examination of the restriction under REACH. But if SCCPs is included in the Protocol or the Convention, than the re-examination of the restriction concerning SCCPs will become redundant.

One MS suggested that the information on SCCPs should also be provided to the authority which was rapporteur for the dossier on MCCPs under the Regulation 793/93 as in some applications MCCPs could be an alternative to SCCPs. COM agreed.

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[1] The European Union Risk Assessment Report - updated version, August 2008 - is available at: http://ecb.jrc.ec.europa.eu/

One MS asked a clarification concerning the possibility of the inclusion of SCCPs in Annex XIV. COM explained that it was aware that SCCP was included in the candidate list of SVHC, and is considering whether or not it should be listed in Annex XIV.

4.3 Implementation of Restrictions

a) PFOS – Management of stocks

COM presented the result of an enquiry concerning the Member States' inventory on PFOS (CA/79/2009). Directive 2006/122/EC required MS to communicate to the COM an inventory covering (a) processes related to chromium VI electroplating and the amounts of PFOS used in and released from them, (b) existing stocks of fire-fighting foams containing PFOS.

COM indicated that for 4 MS some information was missing. Three MS gave the information required. The other one indicated that it would provide the missing information quickly. COM suggested and MS agreed that the inventory document would be published on the COM website. Two MS suggested that MS should exchange on how to deal with stocks.

b) Interpretation of some Restrictions: Questions and Answers concerning restrictions:

COM presented some questions received and proposed answers concerning the interpretation of the restrictions on phthalates and on PAH in extender oils and in tyres (see document CA/80/2009). MS agreed to these questions and answers and to the inclusion of these in the FAQ (frequently asked question) document which is published on the website of the Commission.

Concerning the question relating to the mattress protector, one MS noted that it was quite clear that these articles are childcare articles as they are intended to facilitate hygiene.

c) Report back from Forum Meeting, Sept. 2009

- Enforcement project

While, within the work of the Forum, "Enforcement I" project is running, plans are being made for "Enforcement II", which will be rolled-out in 2010. COM suggests this would be a good opportunity to focus on restrictions. Some of them have been there for a long time and it would be good to know how they are enforced, what are the difficulties and learn from this.

- Test methods to enforce some of the restrictions

COM indicated that harmonised testing methods exist or are being developed for entries 27 Nickel, 43. Azodyes, 47. Chromium in cement, 50. PAH in tyres and 53. PFOS. The list of harmonised testing methods will be prepared by COM forwarded to the Forum and published on its website. Moreover testing methods were particularly useful when the limit value was very low.

Other restrictions do not have specific test methods to be enforced, so MS should exchange views on such test methods, as it is up to them to find and use these test methods.
There is now a working group of the Forum working on restrictions.

One Member State did not agree with COM that the analytical methods used for enforcement is a matter for MS rather than for the legislator. They explained that MS had to repeal their national legislation because REACH is a Regulation, and this included the test methods for enforcement. According to them the test methods should be part of the legislation, and should be included in Annex XVII. Another Member State found it difficult to embed analytical

methods in the legislation, and noted that it is difficult to get harmonised results in 27 Member States, even with a common analytical method.

COM explained that one possibility is to collect analytical methods and then submit them to CEN for standardisation, so as to have repeatability and reproduceability of the tests. This would save time for harmonisation of the test methods rather than asking CEN to start from scratch. It would be desirable to have test methods in Annex XVII but it is faster to publish the restriction and then catch-up with the test method. COM also noted that this had only been a problem when the thresholds indicated in the restriction were very low, e.g. in the case of azodyes (5ppm). We need to distinguish between restrictions for which a (harmonized) test method is needed or not.

OECD suggested to consider making proposals at OECD level for harmonisation/work on analytical methods, if it is worthwhile having analytical methods harmonised beyond the EU

CEFIC found good that analytical methods are harmonised and known about, this ensures better information of industry to know and harmonised enforcement.

- CrVI in cement

The issue concerns non compliant cement allegedly found in 4 MS. MS have informed the COM about the results of the testing performed and measures taken in case non-compliant cement was found.

One MS noted that all non compliant products found on its territory were imported products. An other MS noted that all cement which were found non compliant was re-exported.
One observer asked whether it was possible for MS to ask certificates from the importers indicating that the product complies with the legislation. COM replied that the enforcement was the responsibility of MS which could choose the way to achieve this, as long as they did not impose disproportionate measures

Several suggestions were made to the Forum by the COM on areas of focus for enforcement: CEFIC also foresaw problems in the harmonisation of enforcement regarding only representatives and registration numbers.

ECHA indicated that this is a matter of setting priorities. The Forum is very grateful for all suggestions, but it will decide itself on its priorities and they have a working group working on these issues. One Member State also noted that many SDSs for mixtures are not compliant, and felt that enforcement authorities should work more closely.

One Member State announced the upcoming Regional meeting for Central and Eastern Europe in framework of SYCON. It will take place on 9-10 December 2009.

DAY 2 - 13 OCTOBER 2009

5. ECHA ACTIVITIES IN RELATION TO REACH

5.1 Interpretation of the intermediates definition

The agenda item was not discussed due to the fact that COM/ECHA had not managed to finalise the related discussion document in time.

Under this agenda Item the French CA explained their note in which they summarised their concerns about the CEFIC, CONCAWE and EFCG guidance on strictly controlled conditions in relation to articles 17.3. and 18.4 of REACH. The French authorities indicated that if there is any ambiguity in the guidance on registration and intermediates that may have led to the interpretation provided in the CEFIC/CONCAWE/EFGC guidance, this would need to be removed as soon as possible.

In the discussion several Member States stated that they agree with the concerns raised by France. CEFIC explained that the current guidance is not suitable to explain to companies how they should interpret strictly controlled conditions but that they were open to further discussions on the issue. ECHA explained that it is working on further guidance for exposure scenarios for strictly controlled conditions and invited industry to play an active role in this development.

In response to a question raised by the Commission CEFIC indicated that it will not publish its guidance in the current state but will develop it further in collaboration with the Commission and ECHA (and interested MSs).

5.2 Report from the dissemination workshop

ECHA outlined their approach to ensuring the public dissemination of non-confidential information on chemicals from the end of 2009 onwards. Information was provided on the progress made on the development of a “filter tool” that, in accordance with Articles 118 & 119 on access to information and together with pre-set criteria defined by ECHA, would allow for the automated dissemination of information available in the IUCLID 5 format, on ECHA’s website. ECHA also reported on the outcome of the round table with representatives from stakeholder organisations held in Brussels on 6 July 2009 where the principles of dissemination were explained and discussed. ECHA reminded the meeting that all the information presented at the round table had been made available to Member States in July 2009. Finally ECHA informed the meeting that at the 14th meeting of September 2009, the Management Board had decided to establish from among its members an advisory group on the public dissemination of information on chemical substances.

Several NGO representatives were of the opinion that other EU legislation such as the Aarhus Convention should be considered in addition to the REACH articles for defining the “filtering” criteria. They objected that no timeline had been announced by ECHA on establishing clear criteria for accepting or rejecting confidentiality requests made by industry in their IUCLID dossiers. However, they welcomed the approach taken by ECHA in publishing sufficient contextual information with the result of a study when confidentiality had been requested by the registrant.

Some Member States stressed the importance of dissemination as one of the cornerstones of the REACH Regulation and expressed their concern over the delay in making the data available on the ECHA web site.

Following an explanation from ECHA that NONS data would not be published before the definition of specific criteria to adapt the "filtering" tool to take into account differences in legal requirements between the NONS and the REACH legislations, some Member States refered to Article 123 under which information could be disseminated by national authorities.

One MS questioned the intended use of the published data and the usefulness to the public.

Following several technical questions, ECHA confirmed that the query function, which in 2009 is limited to chemical identifiers , would later be extended to chemical properties; the detailed list of fields to be published was in the documents available to Member States and that the registrant name would not appear. Finally, enforcement authorities would have access to additional information via the RIPE portal to be developed in 2010.

OECD supported the approach taken by ECHA, which was considered as a good balance between public and industry interests and would enable the use of the published data in eChemPortal (Global Portal to Information on Chemical Substances) and the (Q)SAR Application Toolbox.

5.3. Report from the Workshop on Evaluation

ECHA gave a report from the workshop on evaluation that was held in ECHA premises 22 and 23 September 2009. The workshop was open for Member State authorities, and COM and ECHA representatives. The goal of the workshop was to promote common understanding about the principles, priorities and focus of the evaluation activities. It focussed especially on aim and scope of the compliance check and included a preliminary exchange of views on substance evaluation. As a working method also real registration dossiers were reviewed in break-out groups.

The report highlighted especially the challenges of the compliance check activities, including the foreseen workload, strict deadlines imposed by the legislation, and the importance of the implementation of the mindset change related to the reversed burden of proof as one of key principles of REACH. It clarified the scope of formal decision making under compliance check, i.e. to bring the registration dossiers into compliance by requesting further information, and described how ECHA is planning to deal with other possible shortcomings identified in the dossiers.

ECHA will produce a written workshop report and communicate the conclusions of the workshop, in addition to the CARACAL meeting, to the ECHA Management Board, the Member State Committee, and the Forum. ECHA also announced its intention to arrange further workshops in 2010, parallel to the actual evaluation activities.

One Member State expressed concern about the scope of the decision making under evaluation activities. An NGO representative asked about possible intervention by authorities regarding risk management measures recommended by registrants in their dossiers. ECHA referred to the fact the formal outcome of a compliance check is a request for further information to bring the dossier in compliance with the information requirements in the legislation, and noted that further discussion is still ongoing to clarify the issues.

5.4. Report from the workshop on prioritisation and grouping of SVHCs

The outcome of the workshop on prioritisation and grouping of SVHCs which was held on October 24 2009 in Helsinki was discussed in the closed session. The report from the closed session was provided to the plenary. The following statement was made:

1. Member State Authorities have joined efforts to screen potential SVHCs, in order to share the burden of work on prioritising substances already identified as CMRs and/or PBT/vPvBs.

2. A working group has tried to find pragmatic means to identify potential SVHCs that could be prioritised with respect to the building up of the Candidate list. For this purpose they have grouped prioritised substances in a way that facilitates individual Member States to select which ones they wish to undertake further work on enabling them to decide on whether or not to notify them for inclusion in the Registry of Intentions (ROI).

3. A simple, manageable process on the prioritisation of substances of very high concern, using the results from a previous Commission Working Group on PBTs has been followed, and using the substances already known to fulfil the SVHC criteria, based on the harmonized classification in Annex VI of the CLP-regulation (1272/2008/EC), i.e. the project did not aim to identify potential new SVHCs. At the June 2009 meeting of CARACAL the method used has been explained[2] .

4. After de-selection of petroleum substances, information on exposure, use and volumes have been collected for 478 substances, which have been fed into the prioritisation process. For the process of prioritisation simple indicators based on the information collected have been applied to these substances. The result can be used by Member States as a starting point for the preparation of Annex XV dossiers, in the understanding that more detailed investigation and expert judgment in line with the recommendations of the ECHA Workshop of January 2009 may be necessary to come to a decision for each substance.

5. Sometimes available data was ambiguous and in other cases further data needs to be collected. Had "full" information been available, some substances with low priority scores could have got a higher ranking. Since MS will need to do further work based on the results of the working group in prioritising substances, no final conclusions can be drawn from these results regarding the potential regulatory fate of prioritised substances. Nevertheless, all-in-all it is believed that the accomplished prioritisation exercise helped Member States to focus on further work to identify candidates for the Candidate list.

6. Member States felt that CARACAL should not be the forum to disseminate the priority setting results achieved so far on the substances they screened. They also felt that the dissemination of their work on priority setting at this stage could result in premature conclusions. They emphasize that individual Member States may need to collect more information before being able to conclude that appropriate action should be taken as set out in point 9 below.

7. Member states recognise their individual discretion on whether and how to share the results in their communications and consultations with stakeholders on national strategies for priority setting. The CARACAL meeting encouraged Member States to explain to stakeholders the status of the results and in particular the aspects set out in point 6 above.

[2] CA/41/2009 ***Results of an informal expert group, 2 June 2009***

8. As this is a working list with no legal standing, it should not be taken to imply that an Annex XV dossier will be brought forward for any substance. Whether priority setting will in fact result in a Member State's decision to prepare and submit (an) Annex XV dossier can easily be followed by stakeholders and other interested parties by checking the updates of the ROI. Where an Annex XV dossier has been submitted, REACH provides a consultation procedure for stakeholders to provide their views.

9. The working group now invites each individual MSCA and the Commission to consider its involvement in this on-going work, to make use of the knowledge gained in this project for developing and implementing its national strategy for priority setting and identifying potential SVHC's and eventually deciding on the appropriate RMO for the substances concerned. The Commission has offered to arrange further closed sessions of CARACAL to help coordinate the work of MS in this regard.

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Report from closed session regarding the outcome of the working group on identification of SVHCs: the following statement was made is in Annex II at the end.

5.5 Status report on SVHC Identification

ECHA introduced the subject and in particular invited the CA's to provide comments to the Risk management Options (RMO) format by the end of October. ECHA furthermore stressed that for those substances for which it has received Annex XV dossiers with little or no information on uses, exposure and alternatives and risks, it may be problematic to close these information gaps in time for the next prioritisation round.

In the discussion, ECHA was requested to provide more clarity on the exact type of information that it considers necessary to include in the Annex XV dossier as gathering information on use and exposure by the MSs in the preparatory phase is considered rather difficult. ECHA responded that the further discussions on the priority setting mechanism would take place at the upcoming MSC meetings on the basis of which further clarity could hopefully be provided. ECHA furthermore clarified that it had no legal basis to reject dossiers that lacked information on use and exposure.

5.6 Report back to CARACAL on discussion in Management Board on REACH-IT access for MS CA's – Security policy

ECHA informed that a revised version of the declaration of commitment to be signed by for getting access to REACH-IT had been submitted to the Management Board at its last meeting of September 2009. The final version will be adopted by written procedure. MSs were advised to further channel their questions through their Management Board's or Security Officer Network's members. Technical problems would be addressed at the next SON meeting.

Guidance updates

NONS

One MS observed that the registration guidance was in the process of being updated regarding the already notified substances and requested explanation on the procedure that had been followed.

ECHA explained that COM had revised – as explained in the previous CARACAL-meeting - the legal interpretation of Article 135 of the REACH Regulation. This revision provided further clarification of the information needs to be submitted when updating dossiers of previously notified substances in the different cases as defined in Article 22 of the REACH Regulation.

In order to minimise the time period that incorrect guidance would lead to wrong activities the relevant sections of the Guidance on Registration were updated according to a fast-track procedure. As the update was considered as a legal issue with minor technical implications only the COM and MSCAs were consulted via the CARACAL via a written procedure. The procedure was launched on 18 September and a 3 week deadline was given (9 October 2009). Only one MS provided comments.
In response to a question by one of the MSs ECHA agreed to take some late comment on board on the condition that they would be submitted the next day.

Annex V
One MS requested additional information on the status of the Guidance for Annex V as the document should be made available as soon as possible to stakeholders for clarifying their registration duties. ECHA explained that the consultation of the Partner Expert Group (PEG) took more time than initially forecasted because of the different views but still targetted for consultation of the Forum by the end of October, consultation of the CARACAL by the end of December (via a written procedure) and publication of the document in early 2010.

Alcohol test
Several MSs questioned the handling of the alcohol test in the Guidance on requirements for substances in articles and preferred discussion of this issue in the CARACAL meeting. One MSs explained that whether the alcohol test will be considered as an article or as a substance in a container will have consequences for consumer use.

ECHA clarified that MSCAs are invited to submit their views on this issue to the functional mailbox as indicated in paper CA/103/2009 and that the alcohol test is one of the examples of borderline cases in the Guidance on requirements for substances in articles. The CARACAL will be consulted later on in the process as for any other guidance document that will be updated and can still have its final say on it.

Composition of the PEG

Two MSs asked whether the names of the PEG-members could be released. ECHA referred to document CA/52/2008 where a promise had been made to release the identity of the members of the PEG. So far ECHA interpreted this as communicating how many and which MSCAs, NGOs and other stakeholder organisations are represented. In the overview of comments on a particular guidance document, the names of the organisation/MSCAs are released but not the names of the individual experts in order to avoid that PEG-members are lobbied. Additionally, when publishing the names of individual experts there is an issue of protection of personal data.

MSCAs asked whether the names could be provided to MSCAs only. ECHA promised to explore whether there are any legal objections to do so and act accordingly.

PEG-consultation process

One MS observed a number of difficulties on the occasion of the consultation on the Guidance on requirements for substances in articles. Experts participating in the PEG would like to be informed earlier that guidance documents will arrive for consultation. Experts get to know that they are member of the PEG at the same time when they get the documents for commenting. At that stage is very difficult to make other arrangements if needed as the time frame for providing comments is very short. Furthermore some representatives asked for more transparency regarding the changes in updated guidance documents submitted for

consultation. Two MSs pointed out that against this background the guidance consultation procedure should be revised.

ECHA explained that it is permanently looking for ways to improve its way of working. An invitation to nominate experts and a planning was provided on 27/03/2009 and updated on 29/09/2009. ECHA will in future inform experts in advance that they are part of the PEG and indicate when distribution of the documents for commenting is foreseen. ECHA will see how these concerns can be accommodated for the ongoing updates.

Major interim documents of the consultation process are published on ECHA's website so that those that are not directly involved in the consultation process can follow the process and provide comments where appropriate. The upcoming updates of guidance documents such as the Guidance on requirements for substances in articles are usually announced in the CARACAL (Update on guidance publication and further development).

Where feasible, the documents for consultation will be provided in track changes mode. However there may be cases such as for the Guidance on requirements for substances in articles where hardly anything of the original structure is left. In such cases an introductory note highlighting the major changes and why they have been made will accompany the document. An overview of all comments and how they have been handled will be provided at each stage of the consultation process.

Regarding an update of the guidance consultation process, ECHA suggests to wait until more experience is available.

5.7. Interface REACH/CLP and OECD

COM explained the interlinks between the CLP Regulation and GHS, outlined the latest UN developments related to CLP and described how this work is carried out in practice.

6. REGULATION ON CLASSIFICATION, LABELLING AND PACKAGING

6.1. Issues raised at ECHA Committee Meetings

- Scope of proposals for harmonised C&L

COM presented their proposal on this, it relates to classification& labelling triggered by a CMR impurity. The problem arose from RAC, which has a mandate to bring back policy issues to this forum.

Following the intervention of a Member State, COM explained that the petroleum streams examples is to illustrate that classification of mixtures or substances on the basis of markers are outside the scope of the document. It was agreed that the Member State would make a proposal on how to draft this, that COM would revise their proposal & upload it on Circa ASAP.

Several Member States intervened and asked for specific clarification or changes of the wording of the proposal, which COM promised to make. It was also questioned whether it is legal to test a substance with impurity. COM explained that when for instance the carcinogenic end point is tested, the study needs to be evaluated, but it brings data for that substance with this impurity. For mixtures this is not the case, as one cannot test for CMR endpoints. But his level of detail is being elaborated further in the guidance. This is expert judgment depending on how the study looks like for you and on what one wants to base one's judgment.

2 Member States thought that classification should be performed on the CMR impurity, otherwise there is a risk not to see any effect due to dilution. It was also proposed that the classification of the impurity should be harmonised, and then only the impurity would be found in annex VI. If then a substance in the market contains this impurity this substance should not be on annex VI, but a statement in the annex be made that classification of substances containing impurities only applies if the concentration is above a certain limit.

CEFIC noted that the COM proposal did not address complex substances such as oil and coke products, and asked whether ores and concentrates could be considered as being covered by the document, as well as why there was no mention of art.12 in this doc.
COM explained that the intention was rather to draw general rules, recognizing that a marker approach was taken for some examples, without intending to be comprehensive on other examples, e.g. UVCBs or complex substances are not covered here. Other approaches could be valid.

According to REACH alliance, substances with impurities should appear in annex VI and should be notified. If it is needed to notify all the different substances with all different impurity levels, then we'd have very split entries with the same base substance. For COM, this goes somewhat beyond the scope of the document. One should notify the classification of the substance but indicate that the classification is based on the impurity.

6.2. Follow up of Article 53(2)

COM introduced the subject: as a follow-up from a previous CARACAL meting, DG ENTR and DG ENV have revised their proposal for harmonisation of PBT/vPvB criteria at UN level, based on comments received. The proposal will be made in the form of an information document for the December meeting.

The procedure and mandate of COM in this context were discussed, it was clarified that following common practice for GHS-related matters, COM presents the document to the UN on behalf of the 2 Directorate Generals concerned, rather than that of the European Community. This means that COM, which has an observer status in UN ECOSOC, does not intervene on behalf of the MS, which act in their role and could still adopt a different position at the UN meeting.

However, though this is clear on the heading of the draft document that would be sent to the UN, some phrasing in the body of the text introduce confusion about on which behalf COM is acting here. Thus COM agreed to revise point 9 of the document accordingly.

One MS felt that the document was not advocating further labelling requirements strongly enough, and rather saying that we need to wait until more experience is gained and then consider whether such requirements would add value. This MS is of the view that PBT/vPvB information should be clearly communicated to the users, which the present lacks. 2 MS agreed that unlike COM, they saw this issue as related to risk rather than hazard.

Overall it was thought that this was a good first step. One MS also felt that some preparation would be needed prior to the meeting, for example at the informal MS co-ordination meeting prior to the UN meeting.

6.3. Interim solutions for proposals for harmonised C&L for pesticides and biocides

MSCAs for biocides and pesticides have requested an interim solution to be found on that subject, as dossiers were submitted in different formats than IUCLID in the past, and RSS were not compulsory. As there is no tracking system for applicants' contact details, companies

may have disappeared or merge, and they cannot be asked to resubmit the file in a different format. They would not have an obligation to provide RSS anyway.

An agreement is emerging on this issue. It will probably take the form of a Memorandum of Understanding between ECHA and COM. The deadline by which the biocides and pesticides CAs will be asked to make proposals including the RSS, in IUCLID5, would probably be 1st Jan 2011. Until then the dossiers have to be submitted in IUCLID but RSS can be provided in different formats. ECHA is also requested to provide guidance and training to CAs so we can implement this agreement. This intends to help CAs to meet their duties as speedily as possible, though it is recognized that this may be quite a heavy task for MSCAs to undertake.

OECD underlined that industry prefers to use a single format that can also be used for other purposes, also at international level.

ECHA reminded that the dossiers need to contain information on substance ID and classification, and they have the obligation to publish proposal for harmonised classification on their internet site. Therefore they need a report, and a stand alone risk assessment report for a pesticide is not adequate. To the question whether RSS should be provided in IUCLID format or other formats were acceptable, they said it is better to use IUCLID, for dissemination purposes. ECHA also challenged the amount of time it takes to complete a dossier, as described by one MS, but would welcome any additional information on this.

ECHA also reminded that they are part of the pesticide working group of OECD for formats, where there is strong interest to use IUCLID 5 especially for the RSS. New templates for pesticides are being developed for that purpose. MS should bear in mind the long-term benefits of using harmonized templates. Annex VI or annex XV dossiers could be used for other purposes later on.

6.4. Fee Regulation relating to the CLP Regulation

COM presented progress to date on the CLP Fee Regulation proposal. The legal basis of this Regulation is not REACH but CLP. Two of its articles mention it: Art .24 requires that a fee is paid when requesting use of alternative name. Art 37.(3) foresees a fee in the procedure for harmonisation of C&L for a substance in accordance with Art 36(3).

The proposal is being developed based on the general principles that the costs incurred by ECHA should be covered by these fees, and that request are considered complete upon receipt of payment.

The first draft should be ready by end November. It will then undergo interservice consultation and be submitted to the MS. A Committee meeting is planned to discuss this January 2010.

One MS asked whether the proposal foresees the reimbursement of expenses of rapporteurs for C&L dossiers in the RAC, as the REACH fee Regulation does not foresee this. COM promised to answer this question by the end of October.

Another MS, disliking the principle of paying fees for these purposes, asked that the fees should be moderate, unlike for REACH.

6.5. C&L awareness campaign

As a follow up to ECHA's call in June 2009 for a virtual network of communication specialists in the Member States the Agency presented the feedback it had received from MSCAs and the REHCORN network. It also informed the meeting about the progress made in ECHA in preparing CLP awareness raising material and further developing the CLP communication plan. The second part of the presentation informed the participants of the CLP study that ECHA will carry out in 2011. The first part of the presentation is summarised in CA/89/2009 and the second in CA/89/2009 ADD 1.

6.6. C&L of nanomaterials

COM explained the objectives of the advice on classification and labelling of nanomaterials that had been discussed in CASG Nano and revised according to their comments. A first revised version had been circulated to MS within timings in accordance with the Rules of Procedure of CARACAL. This had triggered comments from one MS and COM had accommodated them in the revised version submitted on the 1st day of the CARACAL meeting as a paper copy to the meeting room and uploaded in CIRCA.

COM emphasized the importance to endorse the advice on classification and labelling of nanomaterials as the issue is currently being discussed in SIEFs. The comments received from one MS relate to the absence of requirements in CLP for (eco)toxicity testing and they have been added to the revised version. As CLP does not require above mentioned testing, the 'available' data must come from REACH registrations, scientific literature, OECD or from elsewhere. The OECD Working Party for Manufactured Nanomaterials has made a preliminary review of the current test guidelines and concluded them usually appropriate for human health endpoints, but more problematic for environmental ones.

Several MS criticized the proposal of mentioning of the absence of testing requirements in the advice. It is too early to discourage testing, and OECD is working on further adjustments of the current test guidelines for nanomaterials. REACH Alliance found problematic that the proposal covers both REACH and CLP, as this could undermine testing proposals under REACH. Some MS found the document was not containing much information, and some challenged its usefulness. One Member State considered useful to "take stock" of the progress done in the sub-group Another one thought, on the contrary, that this reflected the (low) level of current knowledge on nanomaterials that could be useful for SIEFs. Therefore a written procedure was proposed for the endorsement of the document.

COM found useful to go ahead with the proposal, as it records current understanding and agreements. The revised proposal reflecting the discussion in CARACAL and adding testing requirement on physico-chemical properties will be produced for the written procedure. A document on the actions taken and further plans will be prepared for the next CARACAL.

6.7. Proposals for amendments to Annex VI

There can be group entries in Annex VI, covering different substances, and CLP introduces harmonised classification only for some end points. Thus it is possible to have harmonised classification possible for some end-points and self-classification for other end points. One MS makes a proposal on how to address this.

COM and 2 MS prefer harmonised classification of a substance for all endpoints in the group entry, and would like this rule to be generalised. If there is a proposal for a revised classification, e.g. of 2 end points, other end points should be copied from the original dossier. This would fall under adaptation to technical progress.

When preparing an Annex VI dossier, one should think which end points should be harmonised. For those endpoints not included in the dossier but for which there is harmonised C&L, they should be copied from the original dossier.

7. AOB and information points on ECHA and CLP

7.1 Feedback of the UN SCE GHS meeting (Information on UN developments related to CLP, GHS)

COM outlined the UNSCE GHS work programme for the next two years and the links between CLP and GHS. The CLP EU Regulation will need to be adapted to adapt to the 3rd revision of GHS (version of 2009). This 3rd revision adds the following hazard categories: hazardous to the ozone layer, chronic toxicity for the aquatic environment, strong or other sensitisers. At the occasion of adapting CLP, we should also change the unclear items in CLP we recognized in the meantime.

COM presented the working procedures of the UNSCE GHS, including frequency of meetings and decision-making procedure, and asked how best to do upfront coordination before the UN meetings, e.g. if we want to start a discussion to develop new criteria or change criteria, etc. In the past some coordination was done by the informal MS coordination meeting organised just before the UN meetings and by the TC C&L.

It was agreed that coordination is needed before these meetings. One MS also found that a technical group is needed to discuss PBT/vPvB matters, and this cannot be done just before these meetings. They would happily participate if COM could organize such technical meetings. COM showed openness to this, but expressed the view that a meeting just before the UN meeting remains necessary, as a lot of information comes the day before the meeting.

The importance of the UN work was stressed. Such issues may be discussed increasingly in CARACAL, and a community approach would be beneficial, if not necessary on some issues.

7.2 Data requirements for registration of substances manufactured/imported at quantities over 100 t/a or 1000 t/a: repeated dose toxicity and reproductive toxicity. (ECHA informs about a press release)

ECHA informed the meeting about a press release that was issued on September 15, 2009 in which it has provided clarification to companies manufacturing or importing substances at quantities greater than or equal to 100 tonnes (and 1000 tonnes) per year who need to provide information in their registration dossiers on the repeated dose toxicity or reproductive toxicity of their substance.

7.3 Action paper on transitional measures for the evaluation of previously notified substances

ECHA gave a short progress report on the implementation of the transitional measures for the evaluation of previously notified substances. This included the finalisation of an Action Plan and its publication on the Circa Evaluation Interest Group, and the start of the three evaluation activities included in the Action Plan. A revision of a Q&A document on previously notified substances and Data Submission Manual 5 had been published in October on ECHA website. Also the NONS related parts of the guidance on registration had been updated and uploaded on Circa for commenting.

7.4 MS Reporting Format

A common reporting format and electronic tool for MS reporting under Article 117, REACH Regulation, is being developed and should be finalised early December 09. After rounds of

comments from several MS, the contractor is working on a revised version of the questionnaire. MS were invited to volunteer to test the questionnaire prototype by beginning of November, and to discuss how to proceed with the endorsement of the questionnaire, as the first MS reporting deadline is June 2010. One possibility would be that MS work with draft questionnaire or proceed with adoption via written procedure.

It was clarified that the technical basis foreseen for the questionnaire would be the IPM tool (Interactive Policy Making tool), already used for the construction and management of questionnaires under some EU Directives..

4 MS volunteered to participate in the test, one additional one held their response. It was agreed that the adoption of the reporting format and electronic tool would be done via written procedure. The tool should be finalised by the end of the year.

8. Next meeting and closure

The dates of next meetings were indicated, in particular the next meeting is tentatively planned to start on February 2nd, and MS were invited to reflect upon the proposals made regarding the organisation of CARACAL meetings, as well as on the nanomaterials CASG.

ANNEX I – Adopted agenda

EUROPEAN COMMISSION
ENVIRONMENT DIRECTORATE-GENERAL
Water, Chemicals & Cohesion
Chemicals
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Chemicals, Metals, Forest-based & Textile Industries
REACH

Brussels, 12 October 2009

FINAL AGENDA
3rd Meeting of Competent Authorities for REACH and CLP
12-13 October 2009

Centre A. Borschette,
Rue Froissart, 36, BE-1040 Brussels, Belgium
Room 1-C (12 October) & 1-D (13 October)

Discussion Points:

12 OCTOBER	**REGISTRATION**	**09:00 – 09:30**
AGENDA ITEM	**ACTION**	**TIME (APPROX.)**
1. ADOPTION OF THE DRAFT AGENDA	Discussion/ Adoption	**09:30 – 09:45**
2. FOLLOW-UP OF THE 2ND MEETING OF CARACAL		09:45 – 10:10
2.1. DRAFT SUMMARY RECORD	Discussion/ Adoption	
2.2. ACTIONS FROM THE MEETING	Discussion	
3. REACH		
3.1. Update on REACH Annexes and Implementing Legislation **a) Update** **b) Annex XIII**	Information/ Discussion	10:10–10:45
Coffee Break		***10:45-11:15***

3.2. Unsolved interpretations questions		
- NONS	Progress Report	11:15-11:30
- Substance identity and SIEF formation (the role of EINECS)	Information	11:30-12:00
3.3. Data sharing and Joint Submission (Outcome of the Workshop for lead registrants)	Information/ Discussion	12:00-12:15
3.4. AOB and information points concerning REACH		12:15 – 13:00 (for all)
a) GMO	Information/ Discussion	
b) Eastern Partnership	Presentation by PL/ Discussion	
d) State of the Art Report on Mixture Toxicity (update on the ongoing study and its preliminary outcomes)	Information/ Discussion	
7.2 Data requirements for registration of substances manufactured/imported at quantities over 100 t/a or 1000 t/a: repeated dose toxicity and reproductive toxicity. **(ECHA informs about a press release)**	Information/ Discussion	
7.3 Action paper on transitional measures for the evaluation of previously notified substances	Information/ Discussion	
7.4 MS Reporting Format	Information/ Discussion	
Lunch		***13:00– 14:00***
4. RESTRICTIONS		**14:00-18:00**
4.1. Workplan for Restrictions in the transition phase (update)	Information/ Discussion	14:00-15:30
4.2. Re-examination of the restrictions pertaining short chain chlorinated paraffins (SCCPs) – Article 69 (5)	Information	15:30-15:45
Coffee break		***15:45 -16:15***

4.3. Implementation of Restrictions **a) Implementation of the restriction on PFOS - Management of stocks**	Information/ Discussion	16:15 -17:00
b) Interpretation of some restrictions; Questions and Answers on restrictions	Information/ Discussion	
c) Report back from Forum Meeting, Sept. 2009	Information	
CLOSED SESSION **(Outcome of the SVHC subgroup on Annex I)**		17:00-18:00

13 OCTOBER 2009		**0 9:00**
AGENDA ITEM	**ACTION**	**TIME (APPROX.)**
5. ECHA ACTIVITIES IN RELATION TO REACH		09:00 -12:30
5.1 Interpretation of the intermediates definition	Discussion	09:00 – 09:30
5.2 Report from the dissemination workshop	Information/ Discussion	09:30-10:00
5.3. Report from the Workshop on Evaluation	Oral report/ Discussion	10:00 -10:20
Coffee break		***10:20 – 10:50***
5.4. Report from the workshop on prioritisation and grouping of SVHCs	Oral report by the chairman of the workshop	10:50-11:30
5.5. Status report on SVHC Identification	Information/ Discussion	11:30-11:45
5.6 Report back to CARACAL on discussion in Management Board on REACH-IT access for MS CA's – Security policy	Information/ discussion	11:45-12:15
5.7. Interface REACH/CLP and OECD	Information	12:15 -12:30
Lunch		***12:30-13:30***
6. REGULATION ON CLASSIFICATION, LABELLING		13:30- 15:30

AND PACKAGING		
6.1. Issues raised at ECHA Committee Meetings **- Scope of proposals for harmonised C&L**	Information/Discussion	13:30 – 14:00
6.2. Follow up of Article 53(2)	Information/ Discussion	14:00-14:25
6.3. Interim solutions for proposals for harmonised C&L for pesticides and biocides	Information/ Discussion	14:25 - 14:40
6.4. Fee Regulation relating to the CLP Regulation	Information/ Discussion	14:40 – 14:55
6.5. C&L awareness campaign	Progress report/ Discussion	14:55 – 15:10
6.6. C&L of nanomaterials	Endorsement	15:10-15.30
6.7. DE proposals for amendments to Annex VI		
7. AOB AND INFORMATION POINTS ON ECHA AND CLP		15:30-15:45
7.1 Feedback of the UN SCE GHS meeting (Information on UN developments related to CLP, GHS)	Information/ Discussion	
8. NEXT MEETING AND CLOSURE		15:45 - 16:00

Information Points:

AGENDA ITEM
1. REACH
1.1. Tracking system for conclusions on interpretation questions
1.2. Test Methods Regulation process
1.3. Tobacco
1.4. Implications of the Market Surveillance Regulation on REACH

Enforcement
2. CLP
2.1. CLP Info on ATP to CLP
2.2. Status report on proposals for harmonised C&L
2.3. Use of Robust Study Summaries from registration dossiers for preparing proposals for harmonised C&L
3. Other items
3.1. Nanomaterials **(Report from CASG Nano of 7-8/09/09)**
3.2. Sea and seagoing vessels
3.3 Breath Alcohol Tester
3.4. Progress report on registration
3.5. Progress report on guidance development
3.6. Metals workshop
3.7. Substances of very high concern

Annex II. - Key messages from Closed Session CARACAL 3 (13 October)

10. Member State Authorities have joined efforts to screen potential SVHCs, in order to share the burden of work on prioritising substances already identified as CMRs and/or PBT/vPvBs.

11. A working group has tried to find pragmatic means to identify potential SVHCs that could be prioritised with respect to the building up of the Candidate list. For this purpose they have grouped prioritised substances in a way that facilitates individual Member States to select which ones they wish to undertake further work on enabling them to decide on whether or not to notify them for inclusion in the Registry of Intentions (ROI).

12. A simple, manageable process on the prioritisation of substances of very high concern, using the results from a previous Commission Working Group on PBTs has been followed, and using the substances already known to fulfil the SVHC criteria, based on the harmonized classification in Annex VI of the CLP-regulation (1272/2008/EC), i.e. the project did not aim to identify potential new SVHCs. At the June 2009 meeting of CARACAL the method used has been explained[3] .

13. After deselection of petroleum substances, information on exposure, use and volumes have been collected for 478 substances, which have been fed into the prioritisation process. For the process of prioritisation simple indicators based on the information collected have been applied to these substances. The result can be used by Member States as a starting point for the preparation of Annex XV dossiers, in the understanding that more detailed investigation and expert judgment in line with the recommendations of the ECHA Workshop of January 2009 may be necessary to come to a decision for each substance.

14. Sometimes available data was ambiguous and in other cases further data needs to be collected. Had "full" information been available, some substances with low priority scores could have got a higher ranking. Since MS will need to do further work based on the results of the working group in prioritising substances, no final conclusions can be drawn from these results regarding the potential regulatory fate of prioritised substances. Nevertheless, all-in-all it is believed that the accomplished prioritisation exercise helped Member States to focus on further work to identify candidates for the Candidate list.

15. Member States felt that CARACAL should not be the forum to disseminate the priority setting results achieved so far on the substances they screened. They also felt that the dissemination of their work on priority setting at this stage could result in premature conclusions. They

[3] CA/41/2009 ***Results of an informal expert group, 2 June 2009***

emphasize that individual Member States may need to collect more information before being able to concludethat appropriate action should be taken as set out in point 9 below.

16. Member states recognise their individual discretion on whether and how to share the results in their communications and consultations with stakeholders on national strategies for priority setting. The CARACAL meeting encouraged Member States to explain to stakeholders the status of the results and in particular the aspects set out in point 6 above.

17. As this is a working list with no legal standing, it should not be taken to imply that an Annex XV dossier will be brought forward for any substance. Whether priority setting will in fact result in a Member State's decision to prepare and submit (an) Annex XV dossier can easily be followed by stakeholders and other interested parties by checking the updates of the ROI. Where an Annex XV dossier has been submitted, REACH provides a consultation procedure for stakeholders to provide their views.

18. The working group now invites each individual MSCA and the Commission to consider its involvement in this on-going work, to make use of the knowledge gained in this project for developing and implementing its national strategy for priority setting and identifying potential SVHC's and eventually deciding on the appropriate RMO for the substances concerned. The Commission has offered to arrange further closed sessions of CARACAL to help coordinate the work of MS in this regard.