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ENVIRONMENT DIRECTORATE-GENERAL
Water, Marine Environment & Chemicals
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ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Resources Based, Manufacturing and Consumer Goods Industries
REACH
Chemicals Industry

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SUMMARY RECORD

11th Meeting of Competent Authorities for REACH and CLP

28 - 29 November 2012

Room 2D, Centre Borschette Rue Froissart 36, 1040 Brussels, Belgium

1. Adoption of Agenda (CA/35/2012 Rev. 2)

At the opening of the session the Chair welcomed the participants (other than the Competent Authorities) and explained that CLP points had been transferred to the first day to allow organisation of a back to back meeting of Poison Centres on 29 November.

He also clarified that the agenda had to be adopted at the beginning of that session and that other general issues (follow-up to the last meeting plus other organisational matters) would be dealt with on 29 November at the beginning of the general session.

As the meeting in June had to be cancelled, the draft minutes had already been approved by written procedure.

In addition to the documents distributed via CIRCA, Room documents were made available for agenda items 14, 18, and 19 (from the Commission), as well as agenda item 20 (from one Member State).

Session C: CLP

Sub-session C.1: Commission points

12. Follow-up on review according to Article 45(4) of the CLP Regulation (Poison Centres) (CA/42/2012)

In accordance with its legal obligation according to Article 45(4) of the CLP Regulation, the Commission had submitted a review on 20 January 2012 based on the outcome of two working group meetings. The outcome of the review had been presented and discussed at the meeting of CARACAL in March 2012. Following the positive feedback received and the brought support to continue work in view of harmonisation of the information to be submitted to poison centres, the Commission services had organised a 3rd working group meeting, which would concentrate on the following topics:

1. What should be the exact concentration ranges / bands for information on hazardous ingredients in mixtures to be submitted to Poison Centres?
2. Based on the assumption that non-hazardous ingredients of mixtures should be notified as well, further discussions are needed on the
   - thresholds above which the presence of those non-hazardous ingredients should be notified, and
   - how it can be ensured that confidential business information is not being revealed.
3. Which systems could be used to develop a Unique Product Identifier (UPI), including a company-identifier component?
4. Which Product Categorisation Systems already exist in Europe and how can they be developed further with regard to the needs of Poison Centres?
5. Should specific provisions be foreseen for mixtures exclusively used in an industrial context?

As announced already at the CARACAL meeting in March 2012, the working group meeting was scheduled as a back to back meeting with this CARACAL meeting (29 November), in order to enable C&L experts to participate without additional costs in both meetings.

MSCAs and stakeholders had been requested to nominate participants and to provide feedback / examples for the above mentioned topics. The persons nominated were indicated in the Annex to the Document distributed ahead of the meeting.

The goal of the meeting on 29 November would be to agree on the concentration bands for hazardous ingredients and the threshold for notification of non-hazardous ingredients and to establish smaller working groups on the remaining topics. The next meeting is planned for April 2013. The Commission services would then start preparing a proposal for a new Annex to the CLP Regulation, which could be presented to the REACH Committee in early 2014.

An observer from industry criticised the meetings planning with several overlapping events (CARACAL, Poison Centres Working Group, RAC and Forum) which prevents stakeholders from participating in all of them.

The Commission noted the point, explaining again that the Poison Centre Working Group meeting had been scheduled for 29 November in order to facilitate the participation of experts in both, CARACAL and Working Group. For the future, the Commission and ECHA will strive to avoid organising CARACAL meetings in the same week as meetings in ECHA.

One Member State made the following statements regarding the meeting of the Poison Centre Working Group on 29 November:

- the details of the composition of a mixture should be as precise as possible;
- the concentration ranges should depend on the classification of the ingredients (the more hazardous, the narrower the range);
- no distinctions should be made between industrial and other mixtures;
- Germany is in favour of an UPI in particular in order to identify mixtures in mixtures;
- data amounts and format should be harmonised at EU level, however, the national data bases should be maintained in order to enable quick and precise reaction in case of emergencies.

The Commission informed that it will report back to CARACAL about the outcome of the meeting on 29 November.

One Member State had submitted a document in which it informed CARACAL about a growing number of notifications to Poison Centres of hazardous mixtures by companies, which were established in other EU Member States, which lack in particular data necessary to identify the components of the mixture. The enforcement authorities of that Member State have no legal possibility to force the foreign companies to submit the requested data, and the only way to receive the data is the very cumbersome consultation of enforcement bodies in these other Member States. The Member State requested feedback whether other MSCAs have the same or similar experience.

The Commission replied that the problem raised was a more general enforcement issue that could also concern other obligations under either REACH or CLP and proposed that this question should be discussed at the Forum in ECHA.

13. Stopping the use of DSD classification in future proposals to harmonised C&L (CA/58/2012)

The Commission introduced the document. Several MS indicated their support to the Commission's proposal and one MS suggested stopping activities related to DSD classification before January 2013. However, some MS indicated their wishes to continue to discuss the DSD classification even after January 2013. Other MS indicated that it would be preferable to keep the DSD classification (e.g., a frozen version of table 3.2) in Annex VI to avoid enforcement problems for mixtures already on the market.
COM indicated that if MS wants to continue to include DSD Classification in their dossier for harmonised C&L they can continue to do so but this DSD C&L should not be discussed by RAC that has a very high workload. COM did not support the idea of a frozen version of table 3.2 as it will lead to discrepancies between table 3.1 and table 3.2 as table 3.1 will continue to be updated.

14. Outcome of the Report on Safe use of chemicals (Art.34(2) CLP) (COM 630(2012) final)

The Commission presented the main findings of the Report on Communication on the Safe Use of Chemicals[1], drafted according to Article 34 (2) of the CLP Regulation. The report had been established on the basis of the study conducted by ECHA in accordance with Article 34(1) of the CLP Regulation, elaborating the findings of a Europe-wide Eurobarometer survey and of a further, more targeted qualitative study on risk perception.

According to ECHA's study, some new CLP hazard pictograms are well recognised and understood by the general public – in particular certain of those that resemble closely the pictograms used in the context of the Dangerous Substances Directive and Dangerous Preparations Directive. Not surprisingly, the new CLP pictograms, with no similar 'predecessor' under the previous EU legislation, are scarcely known or understood by the general public.

At this point in time, the Commission concluded that a legislative proposal to amend the CLP Regulation would not be justifiable and recommended five actions in order to improve understanding of the communication about the safe use of chemicals by the public:

1. awareness raising activities should be prepared and conducted to enhance safe use of chemicals by EU citizens (to be coordinated by ECHA via the risk communication network);

2. changes to the CLP pictograms are not recommended as it seems more beneficial to allow the general public to get used to the new pictograms introduced via CLP in line with the GHS, and legally binding for substances only since December 2010 and for mixture only in June 2015;

3. consideration should be given to contents simplification and layout improvement on labels;

4. further analysis of the understanding of the communication on the safe use of substances and mixtures should be conducted after 1 June 2015 (sunset date for DPD and when the new pictograms will apply to all hazardous mixtures placed on the market);

5. manufacturers and importers should be encouraged to bring product appearance and packaging more in line with the hazard information communicated on labels.

One Member State supported the need for consumer education but wondered about the right timing. Another Member State considered that the main challenge will be in June 2015 when the classification and labelling of mixtures according to the CLP Regulation will become compulsory. There could be problems for consumers in understanding the new symbols in the correct way after 2015.

The Commission agreed that thinking about the right timing of awareness raising was worthwhile and suggested that the related activities might best take place during the last year

[1] Report COM(2012) 630 final 29 October 2012 is available here http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0630:FIN:EN:PDF

before the sunset date for the DPD (June 2015). ECHA could become the coordinator for awareness raising activities via the Risk Communication Network (RCN). The campaigns should consider cultural differences and to be tailored according to the specific needs of the Member States. The 5th recommendation was rather addressed to industry and could be implemented immediately – for example at the last meeting of the competent authorities for detergents a specific type of products had been discussed where the very positive/animating presentation had been found not to be in line with the hazards of the products.

One Member State welcomed the Commission proposals as sensible. However, the invitation to raise awareness should primarily go to industry as the one responsible for the safety of its products. The Member State also emphasised the importance of the call for label contents simplification - in this context the activities conducted at GHS level on the rationalization of precautionary statements would be important.

The Commission agreed that the simplification of labels could be an important issue to raise comprehension of chemicals hazards by the general public; this could be achieved in a coordinated approach with MSCAs and industry.

An industry representative agreed to engage in such activity. Past experiences had shown that there is no good understanding of certain hazard pictograms and labelling from the consumers.

One Member State reported that teaching of chemicals hazard pictograms is an obligatory activity in primary school, and this had shown to be very effective as among others the children had become messengers to their families. The Commission noted the initiative as an effective method of raising consciousness about the safe use of chemicals that other Member States might wish to implement as well.

15. 5th ATP to CLP

The Commission presented the draft proposal of the 5th ATP by focussing on some substances that required specific attention (epoxiconazole, gallium arsenide, PHMB and coal tar pitch). The Commission indicated that:

- RAC confirmed its previous conclusion with regards the classification of epoxiconazole as reprotoxic cat. 1b. Therefore, the 5th ATP will contain the C&L of epoxiconazole in line with RAC recommendation;

- With regard to the substance gallium arsenide , RAC is in the process of adopting a new opinion for the hazard class 'toxicity to reproduction'. Therefore, this hazard class should not be included in Annex VI to the CLP Regulation until the RAC opinion will be finalised, while all other hazard classes (e.g., carcinogen cat.1 b) covered by the earlier RAC opinion should be included;

- With regard to the substance 'pitch, coal tar, high-temp.; pitch' an extended period of time will be necessary to allow producers and downstream users of the substance to comply with the obligations resulting from the new harmonised classification as very toxic to aquatic organisms, in particular with those set out in Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances and Directive 2008/68/EC on the inland transport of dangerous goods. Therefore, a longer transition time should be foreseen before the harmonised classification has to be applied.

- With regard to the PHMB, new scientific data has been made available for the hazard classes 'acute toxicity (inhalation)' , which suggests that the classification for this hazard class as recommended in the RAC opinion, which is based on older data, might not be appropriate. Therefore, this hazard class should not be included in Annex VI to the CLP Regulation until a new RAC opinion will be available, while all other hazard classes covered by the earlier RAC opinion should be included.

- Some discrepancies have been identified when drafting the 5th ATP between the RAC opinion and the C&L as suggested to be listed by ECHA in the annex VI to CLP (*e.g.*, name of the substances, missing symbol). Corrigendum of RAC opinions will be done by ECHA to ensure full consistency of the RAC opinions and the C&L as published in the OJ.

- The vote is foreseen to take place in February 2013.

One MS, acting of dossier submitter for PHMB, confirmed their intention to submit a new dossier on acute toxicity very soon but not for carcinogenicity as the new information does not changed the RAC opninion. This will be confirmed by placing this intention in the RoI on ECHA website.

16. Labelling derogation for aerosols and sealed spray attachment (CA/40/2012)

The Commission presented a paper on a request for a possible extension of the existing labelling derogation for aspiration toxicity. Article 23 and Section 1.3.3 of Annex 1 to the CLP Regulation provide for a labelling derogation for aspiration toxicity for *«aerosols and containers fitted with a sealed spray attachment and containing substances or mixtures classified as presenting an aspiration hazard »*. This is based on the fact that a liquid poses an aspiration hazard where it is dispensed into the air in droplets that are large enough to form a pool in the mouth. However, where the droplets of liquid released into the air are so fine that they cannot form a pool in the mouth, then they do not constitute any aspiration hazard. As a consequence, the risk of aspiration toxicity is reduced or removed in the case of a liquid that is dispersed in small droplets from a sealed container.

Air diffusers are a commonly used alternative to aerosols. They disperse liquid into the air in gas form and it could be argued that the probability of a pool forming in the mouth is even lower than for aerosols or sealed sprays. However, the liquid content of the reservoir should not be accessible as such and producers wishing to benefit from the derogation must guarantee the proper sealing of the mentioned device. The Commission distributed a few empty sample air diffusers that had been provided by a manufacturer.

One Member State recognised that the request had some technical merits; however, when manipulating an empty device, it was possible to remove the wick from the bottle without damaging the packaging. Therefore, as long as the sealing was not improved, no exemption could be granted as the liquid would become accessible. In any case, the possibility for a labelling derogation for such devices should be considered first at GHS level before the EU would introduce it in the CLP Regulation.

Several Member State recalled that labelling exemptions in Article 23 of the CLP Regulation should actually remain a very limited derogation and agreed that this request be best considered at the level of the GHS.

Two Member States were in favour to consider an extension of the existing labelling derogation in Article 23 CLP to air diffusers.

The Commission concluded that the majority of MSCA were not fundamentally opposed to examine the possible extension of the labelling exemption; however, interested producers should consider re-engineering the device in such a way as to ensure a comparable degree of safety as a sealed aerosol container. There was also a general preference to consider this issue first at GHS level for establishing a common global approach. Based on the outcome of the above mentioned actions, CARACAL advice could be sought again in the future.

17. Justification for demonstrating the need for action at Community level Art. 36(3) CLP (CA/47/2012)

According to Article 36 (3) CLP Regulation, where a substance fulfils the criteria for other hazard classes than CMRs or respiratory sensitisation (Cat. 1) and the substance is not an active substance under PPP and BP, a proposal for harmonised classification and labelling can be submitted on a case-by-case basis if the dossier submitter provides justification demonstrating the need for such action at Community level. The document presented a list of justifications which can be considered acceptable and how the assessment of those justifications will be enacted.

Several Member States welcomed this proposal and expressed their general agreement with it. One Member State proposed to consider this list as a living document, which might be updated in the future if needed. One Member State proposed to 'tighten' the text in order to enhance the requirements for a valid justification to avoid that RAC will be overloaded by trivial proposals – the CLP Regulation placed the primary responsibility for agreeing classifications on industry itself. Some Member States requested clarification on how ECHA will assess the justifications submitted and whether proposals would actually be refused if ECHA considered the justifications inappropriate.

ECHA confirmed that the assessment of the justifications provided by MSCA will be an open and transparent exercise, providing also the possibility to dossier submitters to improve an initially insufficient justification; when required this will also involve the Commission. A review of the assessments will be made available to all MSCA.

18. Correcting Act of 1st ATP and corrigendum to Annex VI of CLP (CA/66/2012)

The Commission presented the draft proposal of the correcting act to the 1st ATP and indicated that a track change version will be uploaded to CIRCA to facilitate the review by MS CA.

One MS indicated that in recital the word "wrongly" should be removed. The Commission agreed with that proposal.

The Commission indicated that the Secretariat of the Council foresees to develop a corrigendum of the CLP Regulation for the German version during spring 2013 that will be followed by the corrections of the mistakes identified in table 3.1 and 3.2 of Annex VI in all linguistic versions.

19. Preparation of the UN GHS SCE Meeting in December 2012 (CA/67/2012)

COM presented document CA/67/2012, which contained mainly an overview on those topics, for which it was very likely that an agreement will be reached at the forthcoming 24th session

of the UN SCE GHS. For most of the issues, the Commission suggested, and Member States agreed, to support the proposed decisions or continuation of the on-going work.

In relation to the 4th ATP to the CLP Regulation, which had been subject of a vote in the REACH Committee on 22 November 2012, the Commission explained that the draft 4th ATP contains now the special labelling arrangements for substances or mixtures classified as corrosive to metals but not corrosive to skin and / or eye. Those labelling derogations had been agreed in the 4th revision of the GHS as a temporary solution, for which a permanent solution should have been found by the end of this biennium (2011-2012). However, it seems unlikely that a permanent solution will be found at the 24th session of the UNSCE GHS. It was therefore decided to include the temporary solution in the 4th ATP to the CLP.

Another item on the agenda of the forthcoming meeting of the UN SCE GHS was a proposal of one Member State expert, in which a coding system for pictograms different from the one currently used in the EU had been proposed. The Commission informed that if this proposal was adopted, the downstream consequences for aligning the CLP Regulation to the next revision of the GHS, as well as for ECHA, OECD and other countries outside Europe using the EU coding system would be disproportionate, even though the proposal was following the inner logic of the numbering system used for P- and H-statements in the GHS. This seemed, however, not necessary, as the number of pictograms was much lower than that of the various P- or H- statements. The Commission, therefore, suggested that a new proposal should be submitted based on the existing numbering system in the CLP Regulation.

The Member State expert having made the proposal agreed to prepare an INF paper in co-operation with the Commission which would be submitted to the UN Secretariat at the beginning of December. Other stakeholders and MSCA were invited to provide as soon as possible other examples about the use of the EU coding system outside the EU in order to support such an approach.

Several representatives of industry underlined that the development of a coding system at the international level should follow the already existing approach in the CLP Regulation. Any deviation would lead to significant administrative impacts on companies.

It was agreed that all Member States would inform their experts participating at the UN SCE GHS meeting about the new proposal and that support for this should be confirmed at the co-ordination meeting on the spot, which would take place on the first morning of the meeting.

The Commission suggested that proposals from individual EU Member States experts, which are not discussed in so-called Informal Correspondence Groups of the UNSCE GHS, should be co-ordinated with the other Member States and the Commission before being submitted to the UN Secretariat. To this effect a particular sub-group to CARACAL could be used (e.g. the sub-group dealing with ATPs of the CLP Regulation) or newly created in order to avoid unnecessary and unintentional consequences for the CLP Regulation. Several Member States supported the proposal, while one wondered whether this would be the best procedure given that not all experts participating at the UN SCE GHS meetings were present or involved in CARACAL meetings. The Commission indicated that it would prepare a more elaborate proposal for the next meeting.

Sub-session C.2: ECHA points

20. Follow-up of the CLH process development paper (CA/61/2012 - CA/62/2012 - CA/63/2012)

ECHA introduced document (CA/61/2012) summarising the implementation of the Framework for RAC opinion development on substances for harmonised classification & labelling. The paper was generally welcomed but several Member States recalled that the workload of RAC and dossier submitters should be considered carefully. One Member State suggested that it would be good to involve Member States in the CLH report format discussions. For active substances in PPPs and BPs a set deadline for CLH dossier submission was proposed by one Member State, for example once or twice a year. A concern on assessing CMR RS hazard classes was raised, for example when only environmental hazards are assessed in a dossier. ECHA announced a workshop (16 January 2013) in which these issues may be discussed.

ECHA introduced a paper concerning dossier submitter's (DS) proposal and assessment of hazard classes by RAC (CA/63/2012). Several Member States commented the paper and expressed concerns regarding the possible increase of the workload. One Member State stated that the presented approach (i.e. requirement to always assess CMR RS hazard classes by the Dossier Submitter and RAC) would make sense but there are several problems in it, e.g. the roles of different actors is mixed and as a result RAC would be considered as a body evaluating substances. Two Member States noted that the Dossier Submitter should be in the lead regarding the scope of the assessment. Some comments concerned the possibility of rejecting of a dossier if the CMR RS hazard classes were not addressed. Further clarification on what would really change in the process, also in terms of workload, was requested. Additionally, one MS wanted to know what the additional value is in assessing all CMR RS hazard classes (i.e. would this lead to safer use of chemicals?).

A Member State submitted 2 papers related to Point 20: Follow up of the CLH process development paper and Biocides products classification rules and national authorisations paper. Member States were invited to submit comments. With reference to the second paper, the Commission noted that a similar issue was recently considered for Plant Protection Products. Commission announced that the related note will be uploaded on CIRCABC.

Member States were invited to comment on the ECHA papers and the papers from the Member State by the end of 2012.

2. Follow-up of the 10th meeting of CARACAL

Draft Summary Records and Action list of 10th meeting have been put as information points on the agenda for this meeting.

3. Organisational and Expert groups matters

3.1 Future meetings of CARACAL

The Commission explained the need of reviewing the organisation of the CARACAL meetings. The proposal had been presented and discussed at the CA session, which agreed to the following changes:

- To reduce the frequency and duration of meetings, proposing to hold meetings of two full days twice per year

- No repetition of agenda items covered in other meetings

- Information points only in written form, no information points on the agenda

- All agenda items accompanied by papers

- Proposals for additional agenda points acceptable at the latest two weeks before the meeting

- Dates of the meetings in March and in November

The next meetings are planned for week of 11 March 2013 and week of 25 November 2013, subject to the final confirmation by the Commission services responsible for allocation of conference room.

3.2 Rules of procedure of CARACAL

Following analysis of the new rules on transparency applicable to meetings of Commission's Experts Groups as a result of the inter-institutional agreement between European Parliament and Commission,, their proposed implementation and the RoP, as well as internal consultation within the Commission, the Commission decided to amend the RoP. The amended RoP have been presented to the CAs for consideration and adopted in the CA session.

The most significant changes, based on the rules introduced by the Framework Agreement and the recent budgetary exercise are included in Articles 5 (documents) and 13 (transparency). The latter provision outlines the rules on the involvement of the European Parliament and publication of CARACAL documents. The former provision deals with the practical implementation (i.e. how the Members of this group should mark their documents).
Furthermore a separate provision on access to documents was added – Article 14 and the term "closed session" has been replaced by "Competent Authorities session" throughout the document.

Article 2(e) gives a new definition of observers appointed as stakeholder representatives. In the same article, an emphasis is made on balanced representation as opposed to simply broad representation.

Additional minor changes include clarification in Article 2(b), on ECHA leading this meeting, where word 'consultation with the Commission' has been replaced with the term 'agreement with the Commission'. Article 3, where it regulates convening of a meeting of this group following a request of the majority of its members, makes such convocation subject to the agreement of the Commission services. Finally, Article 12 on prevention of conflicts of interests now clarifies that deliberations taken in the written procedure are also subject to the relevant rules on prevention of conflicts of interests.

During the budgetary exercise, which resulted in the decision to publish Commission Expert Groups documents and which was described during the last CARACAL, the Commission also took upon itself to undertake the review of the composition of all of its expert groups. Following the review of CARACAL and some internal discussions, four industry and environmental associations have been added and invited to the open session of this meeting:
(i) Client Earth;
(ii) International Chemical Secretariat (ChemSec);
(iii) Two organisations working on animal welfare to share one seat - The European Coalition to End Animal Experiments (ECEAE) and Eurogroup for Animals;
(iv) industriAll

4. Report from CA session

4.1 Report from the CA session

The report was presented as bullet points and was distributed as a room document during the meeting. It is also uploaded on CIRCABC.

- Organisational matters: two short points are foreseen in the agenda of the open session concerning RoP and future meetings of CARACAL. Brief report under those points.
- EPG group: update on new mandate for the main group, to cover also SME policy. Thus, an extended mandate for the REACH sub-group, which becomes working group under the name "ESPG working group on REACH and CLP". There was also agreement on mutual access to documents (EPG to CARACAL and vice versa).
- Registration part
    - Question on registration of chromium trioxide and chromic acid was discussed. As next step, ECHA will prepare a FAQ on this matter.
    - ECHA presented objectives and tentative agenda for a workshop on Substance ID that will take place in Helsinki on 13/14 February 2013. This workshop is seen as a first step (with MS CA) and could probably be followed by a second workshop with stakeholders.
- Authorisation
    - RiME meeting in a MS: that MS summarised the meeting organised last October and the planning for next meetings to take place 3/year.
    - Candidate list and roadmap: There was unanimous agreement to develop a Roadmap but further work is necessary. Further details to follow under relevant point of the agenda for the open session.
    - Sensitizers: ECHA presented a paper for endorsement. The paper was considered a good starting point for a broader assessment of how to deal with sensitizers. There is a specific point on the agenda of the open session to deal with this topic.
    - A MS presented their approach to propose UVCBs containing Benzo(a)pyrene as SVHC and the general concept of Substances in Substances to be identified as SVHC.
- Restrictions

    - The Commission presented a paper taking into account the reactions of MS on harmonization effects related to restrictions, restating its view on harmonization effects of Title VIII and on the application of Art. 69 (4). This was followed by an exchange of views with MS.
    - Scope of entry 43 (azo-dyes): COM presented a paper in which the general issue of second-hand market articles was evaluated as related to the restrictions. The azo-dyes restriction was taken as example after a suggestion of a MS at the REACH Committee meeting. General agreement that second-hand market articles are covered by that restriction.
    - A MS requested from the other MS information concerning any current restrictions on the manufacture, import and sale of matches which contain white (yellow) phosphorus, implementing the Bern Convention.
- AOB: derogation for use of dichloromethane – a MS requested to the other MS information concerning a professional application on the use of dichloromethane as paint stripper, in order to allow a possible derogation for this use.
- Evaluation (These points are developed as separate points further on in the current Summary record)
    - EOGRTS – co-financing aspects
    - Compliance check: planning for 2013 to 2018
    - Follow-up on dossier evaluation
    - Updates in IUCLID during substance evaluation

Session B: REACH

Sub-session B.1: Commission points

5. Update REACH review and nanomaterials

5.1 REACH review: state of play

The chairman informed the meeting of the progress of the REACH Review that was expected to be adopted early after New Year. A MS requested that COM ensured sufficient time between the adoption and the planned stakeholder conference on 14 February 2013.

5.2a Nanomaterials review

COM presented the main findings in the Commission Communication on "Second Regulatory Review on Nanomaterials" and the accompanying SWD.

A number of MS expressed doubts as to whether changes to REACH Annexes would suffice. Some argued for a need to introduce a firm legal definition and that the volume based registration triggers also would need a downwards adjustment for nanomaterials. A few MS called for action at the EU level on a nano registry. Several MS regretted that COM had not responded more substantially to the letter sent to COM by NL in July with the support of 9 other MS.

Three observers found that COM was unambitious in its approach; that the SWD was biased by leaving out important scientific evidence and that it also was erroneous in some places leading to faulty conclusions.

Two other observers appreciated the work of COM and underlined that REACH was appropriate even if it was obvious that more work was needed also on the side of industry.

ECHA outline some of the key activities already undertaken with respect to nanomaterials such as update of IUCLID and Guidance, activities in evaluation and issuing of the so-called Art. 36 letters.

COM referred to the Communication as a substantial reply to the external requests also contained in the Dutch letter. REACH could be changed in co-decision but it would be very time consuming while Annex changes can be made swiftly and are currently considered sufficient to deliver the needs identified. A web portal will be established with parallel impact assessment on a possible EU level registry. A stakeholder conference will be organised on 30 January 2013 but otherwise COM was not informed if other EU institutions would pick up the file.

5.2b Possible modifications of REACH Annexes for nanomaterials

COM gave a brief introduction to the content and timetable of work related to changes to the REACH Annexes that will be guided by an impact assessment. The principal options in the assessment were presented and the milestones.

5.3 Member State actions on registry of nanomaterials

No discussion under this item.

5.4 CASG nano meeting report and the new mandate (CA/39/2012)

COM gave a short oral briefing of the main agenda items and conclusions from the CASG Nano meeting held on 20 November. Flowing from that CARACAL was requested to endorse the revised mandate of the CASG Nano as presented in CA/39/2012.

One MS argued that there was no need to continue CASG Nano due to the newly established NMWG in ECHA.

Four MS and an observer actively supported the continuation of CASG Nano based on the new mandate with the proviso that a clear division of tasks between the two groups was respected. COM assured that it was the intention. Moreover, the CASG Nano would operate with a sunset date after which it would seize to exist unless CARACAL decided otherwise. On that basis there was unanimous support to the revised mandate.

6. Registration

6.1 REACH awareness-raising for SMEs (CA/41/2012)

The Commission (ENTR) gave a presentation of the SME awareness paper. It emphasised that 20 million of SMEs operate in the EU, many of them being downstream users or distributors. Only 10% of registrants in 2010 were SMEs, so more are expected to be concerned for 2013 and 2018. In order to increase their awareness, the Commission emphasised the need to use existing tools. So far, tools to assist registrants have not been entirely thought with a focus on SMEs but it must be stressed that the HelpNet and the Directors Contact Group have already been very helpful. Tools designed by ECHA to support SMEs have also been well received. However, new issues will come up for SMEs as the first applications for authorisation will have to be submitted.

The Commission also outlined the important work carried out at Member State level and notably through local chambers of commerce. The paper presented by the Commission made a distinction between two categories of SMES: SMEs-IN and SMEs-OUT. While the former category describes SMEs that are relatively well aware of their obligations under REACH, the latter was to distinguish those with poor awareness and presenting a risk of being in breach of the Regulation. Another conclusion of the SME awareness paper was that the level of information for SMEs needed to be short and synthetic in order to avoid confusion.
One Member State expressed its support for the Commission paper and its findings. However, it emphasised that attempts at organising training conferences had been successful with stakeholders answering they were already trained and not in need of such information sessions. The Chamber of Commerce in this Member State is also not involved in REACH at all. However a survey carried out there showed that there is still a 20% of SMEs who are unaware of REACH. Some work has started on communication about authorisation. There are no new methods to spread information; experience is that one just needs to keep on the effort.

Another Member State reminded the CARACAL that it had been interviewed by ECHA in the summer in order to describe SMEs activities in the country. This information can be found in the ECHA Newsletter for August. The Member State has however sent an update and would be grateful for the Commission to upload it.

Another Member State expressed support for the paper and especially the distinction between SME-in and SME-out. In that country, the experience has been that actors in the supply chain however pay more attention to what is said within the supply chain than by authorities. Also, feedback on level of awareness in the MS's industry has shown that some actors are well aware of what was relevant in 2008 but not necessarily what is relevant for 2013 and 2018. Authorities thus need to recontact businesses and make sure they are aware of their obligations.

Another Member State expressed support and inquired whether there was an overview of answers from the questionnaire it had to send in the autumn to the Commission. This Member State organised an event with 200 participants and requested its consultant to see what could be done in addition to approach SMEs. As outlined by the other Member State,

letters need to be sent to those who have submitted dossiers in the past not that SIEFs are not active anymore in order to remind them to register.

Another Member State expressed support for the paper and wondered whether other Member States had ideas to support SMEs-OUT.

ECHA expressed support for the SME-in/ SME-out distinction and stressed that it often had requests for more information and guidance. This is a sign that we need to build on the network that is in place and that the Commission has to identify the weakest links.

One observer explained that although not focussed on SMEs, some of its member national associations covered some SMEs. For 2013, the observer does not see any problems looming but it is likely that 2018 will be much more difficult to tackle. For sure, these small companies will need information and the question is about how to get more with less. The observer deems the dichotomy between SME-in and SME-out useful; it is indeed very hard to interact with SMEs-out that are way down in the supply chains.

Another observer indicated that trade unions are to raise awareness in collaboration with ECHA. An initiative by two trade unions and the Bilbao Agency is to have trade unions leaders as REACH ambassadors.

A Member State emphasised its work through the chambers of commerce.
The Commission answered that indeed solutions could not be one size fits all. In some Member States, chambers of commerce are indeed very strong but in some others it is not the case. The Europe Enterprise Network can be a solution outside the chambers. In answer to one of the Member States, the Commission answered that an overview of the answers was indeed needed in order to develop best practices. Also the paper is on REACH but it will be necessary in the future to also address CLP, Biocides and authorisation. For ECHA, the Commission emphasized that the priority was to make information that is easy for companies, better guidance is not enough and 2013 should be our immediate focus.

7. Evaluation

7.1 Update on EOGRTS (CA/57/2012)

The Commission outlined the proposed approach to introduce EOGRTS into the REACH regulatory framework.
The approach involves inclusion of TG 443 in the TMR via the 5th ATP, modification of the REACH Annexes IX and X to include a "core" EOGRTS as the standard information requirement under point 8.7.3, and a 5y review phase. The proposed review phase involves performing the 2nd generation for a limited number of substances, selected based on exposure-proxy trigger accompanied by low-toxicity waiver (exact trigger tbd.). The Commission considers options for funding in the review phase the additional cost for the 2nd generation in cases where it is triggered, which is the prerequisite to implement the approach. The most promising financing instrument appears to be the Life+ programme; use would require project application and management by one or several MSCA jointly.

Stakeholders welcomed the progress in adapting the REACH Annexes to the advances in science and inquired about the timing of the proposed steps. Commission clarified that timing will depend on agreements reached on the different aspects of the proposed package. In addition, the inclusion in the TMR and the REACH annexes involve changes in legislation which need time to be adopted and enter into force. One stakeholder proposed that CARACAL should (at some point in the future) reflect on general issue how new science is addressed in REACH; Commission noted the proposal.

8. Authorisation

8.1 SVHC: candidate list state of play

The COM explained the recent developments in the SVHC area. In August a letter was sent to Member State Ministers informing that the COM asked ECHA to develop Annex XV (SVHC) dossiers for 37 substances and announced its intention to start working together with Member States and ECHA on a roadmap for SVHCs until 2020. ECHA has started work on the risk Management Option Analysis (RMOAs) for the 37 substances.
The work on the roadmap has started and a number of elements and factors for consideration in the roadmap and other useful input were provided by Member States in the workshop organised by Denmark. The draft roadmap was further developed and discussed in the CA session, with a general agreement that there is the need to develop such a roadmap. At the same time, it is necessary to continue discussion and to develop the roadmap document further, based on further commenting by Member States. The Commissioner's target date to have the roadmap by the end of 2012 however does not seem to be unrealistic. The document once finalised should then be discussed with MS Ministers in the beginning of next year.
ECHA informed that in the last SVHC identification round, it has processed 54 dossiers, finalised the public consultation in October and is carefully scrutinising the comments received. For 31 substances, no comments were received challenging their hazard properties or substance identification, for other substances, there were comments justifying referral to the Member States Committee. How many substances will be included in the candidate list in the end of December will depend on the outcome of the forthcoming Member State Committee.

9. Restrictions

9.1 New CEN test method for PAHs in extender oils (CA/38/2012)

COM presented the document CA/38/2012. Deadline for comments was set for 15 January 2013. A MS informed CARACAL about a launch of national research activities related to test methods on PAHs. Once the results will be available the MS will present them to the Group.

9.2 Criteria for use of Article 68 (2) with respect to articles

The Commission (ENTR) briefly informed about launching a scoping study for the application of Article 68(2) of REACH to CMR substances that require priority action. A

contract is to be signed by the end of 2012 and will firstly elaborate on collecting and analysing information (e.g, uses and functions of CMR substances in articles, market information on articles, market players, identification and initial assessment of possible alternatives to CMRs) on a list of CMR substances that are likely to be found in articles and that are to be identified by the ECHA's project dealing with screening of CMRs in articles. Then, socio-economic impact aspects will be investigated for a shorter list of substances identified by the COM and ECHA on the basis of the data collected in the initial phase, resulting in a scoring given to each substance in the shorter list. Finally, on the basis of socio-economic impact indicators developed in the previous task, the contractor will propose criteria for prioritisation of CMR substances for use of Article 68(2). The criteria should be based on the potential impact that restriction measures would have on the market linked with uses of the substances in articles vis-à-vis the effects on and benefits for human health and the environment.
To the question of one Member State on whether and when the Commission is planning to consult Member States on this issue, the COM answered that it will do it towards the end of the study, in the criteria development phase.

Sub-session B.2: ECHA points

10.1 Update on CSR/CSA programme and ENES (CA/48/2012)

ECHA updated CARACAL on the outcome of the recent meeting of the Exchange Network on Exposure Scenarios (ENES) which focussed in particular on the handling of exposure scenario related information for mixtures. Whereas good progress was made with discussing the main concepts and problems it was concluded that further work will be needed in the area of methods development, by further exemplification with best practices and by possibly developing a common format for communicating the results of a mixture risk assessment in the SDS. More in general ECHA concluded that there is a general recognition of the importance of the topic of Exposure Scenarios and value of the co-operation between the different actors in the supply-chains, MS competent and enforcement authorities and ECHA to further support the implementation. While currently more activities have been carried out related to the upper part of the supply chain there is clearly a need for intensifying the work to support the implementation further down in the supply chain.
ECHA has prepared a “Discussion document” on how to improve the quality of CSR and ES, providing a starting point for a coordination group with industry, MSs and ECHA which will develop a CSA roadmap until 2018. Further discussion on this CSA roadmap is foreseen to take place at the next CARACAL meeting.

10.2 Substance evaluation – update (CA/49/2012)

ECHA presented the update for 2013-2015. The improved collaboration with Member States in the manual screening of the substances for inclusion in the CoRAP led to a high number of candidate substances and increased efficiency, avoiding overlaps of MS with interest for the same substance. ECHA renewed the invitation to MSs to support the manual screening also in 2013. Among the challenges for 2014, ECHA will put forward a proposal on how to handle structural related substances under substance evaluation.

A MS pointed out that the published draft CoRAP list does not include the relevant concerns. Another MS volunteered to take part of the manual screening. The grouping of substances was considered of special interest by a Stakeholder.
ECHA clarified that the draft CoRAP list is considered work in progress; therefore the initial concern is not included in the published version, while it will be in the final CoRAP. On the other hand, the draft CoRAP includes the contacts of the evaluating MSs to allow for early contacts between the registrant and the MS, where the initial concern can be discussed.
A deadline in mid-December is set to comment on this paper and to volunteer for contributing to the manual screening in 2013.

10.3 Follow-up on dossier evaluation (CA/50/2012)

ECHA explained that the draft strategy has been supported in other fora and refined taking into account the comments received.
Some stakeholders requested more transparency in the process, as according to REACH Art. 42(2), the follow-up conclusions are not communicated to the registrants. One MS raised questions related to enforcement mentioning that it should be a last resort tool, and possibly ECHA should preliminary deal with the communication of delays.
Upon request, ECHA clarified that the evaluation is deemed as concluded when the requested information is provided. In principle there could be another parallel or following evaluation process on-going on the same dossier, but this would be dealt separately with respect to the obligation of Art. 42.2.
As far delays, slight delays may not be captured in the follow up evaluation. When a communication of delay or a request for extension of deadline is received, ECHA would include such information in the statement of non-compliance sent to the related MS.

10.4 Sensitizers under Article 57(f)

ECHA presented a document describing a generic approach which can be applied when considering on a case-by-case basis whether certain sensitisers can be identified as SVHCs under the ‘equivalent level of concern route (art 57(f) of REACH) (CACS/25/2012). This document had been developed in co-operation with MSCAs and the Commission, and had been presented and discussed in RiME meetings, in the ad hoc CA meeting in June 2012 and in ECHA’s Member State Committee.
ECHA stressed that this document only covers the step where the level of concern related to a sensitiser is compared to CMRs. The steps preceding and following the possible identification have to be carried out as for any other substance. In other words, the paper does not cover how to conclude whether there is a need for further regulatory action for a certain sensitiser and, if yes, which would be the most appropriate risk management instrument to be used (RMO analysis), nor does it cover whether a certain substance would have priority for inclusion in Annex XIV after the substance is included in the Candidate List. Furthermore it was stressed that the identification of substances in accordance with Art 57(f) always requires case-by-case justification showing that the conditions set out in this article are fulfilled. For sensitisers the fact that the substance is classified in accordance with the CLP Regulation is not alone sufficient justification for inclusion in the Candidate List. The document does not aim to present clear cut criteria for the potential identification of substances as SVHCs but presents which factors could be considered to support the identification. It was stressed that these factors should be considered as a whole rather than one by one.

While the document was in general welcomed and considered as a useful summary of the considerations and development so far, some MSs raised concern that all sensitisers would be identified based on the approach presented. Furthermore, some MSs raised concerns related to the socio-economic benefits associated with the use of some substances with sensitising properties which may be compromised if they would be included in the Candidate List.
It was stressed that this paper is a living document which can be updated based on experience gained with concrete examples. Further comments were invited by the end of the year. The aim is to publish the document on ECHA's website in early 2013.

Sub-session B.3: REACH AOB

11. REACH AOB

11.1 Animal tests without testing proposal (CA/52/2012)

ECHA informs about the issue of registrants which conducted testing without the necessary testing proposal, including how ECHA communicates with the registrant and the MSCAs in these cases. In CEFIC's opinion these cases a rare. Furthermore global companies are confronted with different legislations outside the EU, demanding similar information requirements but with tighter deadlines. ECHA acknowledges the challenge and therefore requests the registrants to inform as soon as possible in their dossier about this situation.

11.2 Combination effects

As a follow up of the Commission Communication on chemical mixtures (COM(2012)252final) adopted on 31 May 2012, the Commission is in the process of establishing the ad hoc working group of relevant Commission services and associated agencies as outlined in the Commission Communication (publically available at http://ec.europa.eu/environment/chemicals/effects.htm).

The Commission services and agencies have nominated their representatives over the Summer and the first meeting of the ad hoc WG took place in October to discuss the appropriate follow up to the Commission Communication on mixtures, and the actions and tasks outlined there (including, e.g., the modalities, method of work, need and ways of engagement of MS and stakeholders for individual tasks).

The initial discussions in the first meeting indicate a general agreement to organise the work along the following lines:

To have the ad hoc working group as an internal interservice working group that will be supported by:

(i) a scientific advisory group to advise on technical and scientific issues, such as the guidance development that should be chaired by Dg JRC, and

(ii) a stakeholder advisory group to provide a support and orientation to the ad hoc group on general and policy-related issues. Both advisory groups would have the status of a Commission expert group, involving the representatives nominated by Member States, industry, NGOs and other stakeholders.

Further details and exact modalities are to be discussed in the next meeting at the end of January/beginning of February next year. COM will communicate on the outcomes through usual channels and expects to be able to send invitations to Member States and other stakeholders for nominations of their representatives for the two advisory groups shortly after.