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SUMMARY RECORD

10th Meeting of Competent Authorities for REACH and CLP

21-22-23 March 2012

Berlaymont, Room Walter Hallstein
200, rue de la Loi, 1040 Brussels, Belgium

1. Adoption of Agenda (CA/01/2012 Rev. 2)

At the opening of the session, the Chair welcomed the participants and presented excuses for the change of dates of the meeting due to the unavailability of conference rooms in the Commission buildings and apologised for the late delivery of the minutes of the previous meeting.

The Chair informed the participants about recent staff changes in the two units dealing with REACH in DG ENTR and DG ENV.

The Chair explained that due to an overlap with the meeting of the ECHA Management Board on 22 and 23 March, some of the ECHA points were moved to the first day of CARACAL.

The Chair indicated that the migration from Circa to Circa BC will take place on 10 April 2012. This migration concerns the group CARACAL CA distribution and the Circa site for the open session. The Chair indicated that ECHA is currently collecting feedback from all CIRCA BC users in order to indentify the problems and to improve CIRCA BC performances and therefore invited all participants to participate in this ECHA exercise.

In reply to a comment from one Member State Competent Authority, the Chair reaffirmed that it is not the intention of the Commission to use the information points as a silent procedure for adoption.

At the request of several Member States, a point on the follow-up to the workshop on PAHs was added to AOB. At the request of one Member State, the information point related to doc

20/2012 should be discussed in AOB. In addition, the same Member State wanted to raise the participation of Serbia in CARACAL meetings.

2. Reach Evaluation

2.1 Update on EOGRTS (CA/13/2012)

The Commission presented the last two points of the mandate agreed for the CARACAL ad-hoc expert group on EOGRTS. The information provided was on costs and practicalities related to using this test guideline as compared to those associated with the standard two-generation test method B.35. In addition, the Commission presented its preliminary conclusions on the legal position with regard to the possible use of EOGRTS in REACH and indicated that if EOGRTS were to be implemented in REACH with its full modular capacity, then this would require changing the REACH annexes and also incorporating the test guideline in the Test Method Regulation. Finally, the Commission indicated that it was to request ECHA to ask RAC for an opinion on the utility and applicability of the information generated by EOGRTS for hazard and risk assessment within the regulatory context of REACH and CLP and with recognition of what is currently required to examine reproductive toxicity in REACH. The Commission indicated that with the information currently available, from the points addressed in the EOGRTS expert group mandate, and taking into account the outcome of the request to RAC, it will proceed to consider the implementation of EOGRTS, and the most appropriate test design, for REACH.

Member State Competent Authorities taking the floor again indicated their strong desire for the TG 443 to be incorporated into the Test Methods Regulation and expressed concern about the slowness of the current process urging the Commission to recognise that a policy decision was necessary to move forward.

3. Registration

3.1. ECHA's work on PPORD assessment (CA/04/2012)

ECHA presented the current status of PPORD assessment and the planned next steps. Member States were asked to volunteer to participate in a pilot project aimed at testing and streamlining the interactions between ECHA and the Competent Authorities in the decision-making process on imposing conditions and granting extensions in accordance with REACH, Article 9(8). ECHA also announced that 27 out of 30 Member States and EEA countries had nominated their contact points on 31 January 2012.

Clarification was given on the level of involvement expected from the Competent Authorities (both in terms of workload and type of activities). Upon the comment of one Member State, in relation to the efficiency that national authorities could bring in the phase of asking further information due to their prior knowledge of the companies, the proximity and the language, ECHA explained that the pilot was also aiming at defining roles and responsibilities.

One industry stakeholder, in relation to a concern raised by another Member State on PPORD submitted for high-volume substances, pointed out that this should be assessed on a case-by-case basis, as for the development of certain processes, the size of the installation would

require high volumes. One Member State commented that reasons for requesting exemptions for high volume substances could be checked in the pilot phase.

3.2 ECHA's work to support the functioning of the REACH mechanisms related to Downstream Users (CA/05/2012)

ECHA introduced the document on Downstream Users, making reference to two other documents presented at CARACAL 9, i.e. CSA development programme and launch of the ENES network (Exchange Network on Exposure Scenarios). ECHA has identified the need to develop a long-term roadmap towards relevant and good quality exposure scenario information in the registrant's CSRs and in the extended safety data sheets and invited Competent Authorities to comment proposed steps (in writing by 15 April).

In general, Member States (some of them explicitly) as well as stakeholders and observers reacted positively to the initiative and supported the development of the roadmap. Support to the ENES initiative was also expressed.

One Member State mentioned the need to revisit the Use descriptor Guidance to allow easier reporting of uses by the downstream users; another asked for a preliminary timeframe necessary for the development of the roadmap and highlighted the need to tackle more urgently the issues related to 2013 registrations; a third emphasised that the roadmap discussions must not become an excuse for non-compliance; and a fourth Member State raised the question of the involvement of the Forum. Furthermore, a Member State asked whether the roadmap process could feed into the REACH Review, and another, whether the role of Member States Competent Authorities is now established in ENES. The importance of the issue of scaling was also mentioned by two Member States.

One industry stakeholder welcomed the activity, especially the launch of the ENES network and supported the involvement of enforcement authorities (as mentioned by one Member State). Attention should also be given to mixtures in the near future.

3.3. Strategy for the future development of IUCLID (CA/28/2012)

ECHA presented the strategy for the future development of IUCLID. ECHA is considering specifying a structured data format for the CSR, in order to expand to risk assessment the structured approach followed for hazard assessment and thus improve transparency and consistency of the information reported in the registration. .

The strategy foresees a step-wise approach. The first phase will enable to report in a structured data format in the upcoming version of IUCLID (IUCLID 5.4, June 2012), key information from the CSR that will enable the authorities to process this type of information more easily in their regulatory activities. This will be done on a voluntary basis (i.e. no completeness check applied on the new structured fields), for those registrants who wish to already fill in the structured sections in advance in order to avoid doing so at a later stage, e.g. in case their dossier needs to be updated. The second phase will be completed once 2013 registrations have been processed and registration numbers assigned, i.e. not earlier than 2014. By that time, the format of the CSR will be a mandatory data structure.

Several Member States and one stakeholder supported the proposed approach. Comments included the need to keep flexibility so that additional background information can still be

provided in a free text format. Concerns on the timeline were also expressed (the new format of phase 1 should not be at the detriment of quality).

The same stakeholder confirmed that, although changes would be very helpful to companies, they would require some additional work from the registrants. Therefore the timing of the different steps was critical. For this reason, this stakeholder was glad that the technical completeness check would only be applied in 2014 on the new fields. It was also pointed out that Chesar should in the future cover all types of substances in order to facilitate the work.

Competent Authorities were invited to provide comments by 20 April.

4. REACH Nanomaterials

4.1 Nanomaterials

The Commission gave an overview of its activities since the last CARACAL meeting. Work is progressing in view of the REACH review and on the second Regulatory Review of nanomaterials and its Staff Working Paper on Nanomaterials types and uses, including safety aspects even if with some delays. The JRC study on how nanomaterials have been registered under REACH is almost done as regards Task I and the final report will be made available to CASG Nano shortly. The REACH and Emerging Technologies study is also being finalised.

4.2. Update on work on nanomaterials and report from last CASG Nano
ECHA gave a presentation on its planned activities on nanomaterials, notably the proposal to organise a workshop on nanomaterials on 30 – 31 May in Helsinki that would serve as a platform to start a Working Group on Nanomaterials with a mandate similar to that of the group about to start on PBT. In tandem with this workshop, ECHA has also taken over the responsibility of GAARN (Group Assessing Already Registered Nanomaterials).GAARN had a kick-off meeting in Brussels in mid-February and will have a second meeting prior to the workshop on 29 May, also in Helsinki. The two concurrent activities are designed to support and assist ECHA in its work with nanomaterials, not least on the evaluation processes.

The Commission also gave a summary of discussions at the last CASG Nano meeting in November 2011 (the draft summary record of the meeting is available on Circa). Key issues on the agenda were the definition of nanomaterial and how it will be applied in REACH, GAARN, in-depth discussions on the JRC work on nanomaterials in the REACH registration dossiers, the REACH and emerging technologies study and the results from the study commissioned by CEFIC on impacts assessment of the RIPoN1.

Two Member States asked for a discussion on what subject matters would be covered by CASG Nano and how the complementarity will be ensured with the ECHA Working Group on Nanomaterials. The Commission suggested that it would be useful to outline in a short note to CARACAL how the tasks will be split in the future.

5. Follow-up to the 9th Meeting of CARACAL

5.1 Draft summary record (CA/91/2011)

The DSR was adopted with the suggested modification proposed by a stakeholder. The final version was uploaded to Circa.

5.2 List of Actions (CA/90/2011)

The Commission presented the list of action points and their status.

One Member State asked why the issue of the interface between REACH and Water Framework Directive is not on the agenda.

The Commission indicated that the issue is still under discussion, but this issue should be discussed at the next CARACAL.

In reply to a comment from one Member State related to the Commission's recent letter concerning FAQ to ensure that in CLP the OR is not required to import samples to be able to submit group notifications to the C&L Inventory, ECHA indicated that they received the Commission answer but due to an IT issue, it was not possible to place this answer in the FAQ system.

6. Overall Work plan for CARACAL

6.1 Work plan for CARACAL (Comitology procedures, CARACAL written procedures, subgroup meetings) (CA/02/2012)

Commission presented the Overall Work Plan for CARACAL.

One Member State indicated that as the next CARACAL will take place just before the summer holiday period, we should take this into account when fixing the deadline for follow-up activities.

7. Report from the CA Session

7.1 Reporting on the CA session

During the CA session, Competent Authorities continued the discussion on how to fully implement the framework agreement on Commission expert groups. Then they were informed of the main conclusion of an ECHA evaluation workshop that took place on 31 January. This workshop aimed to support Competent Authorities in their activities in substance evaluation and to agree on a new compliance check strategy. Competent Authorities were also informed of the activities of the RIME meeting in relation with Risk Management Options activities ongoing among Member States and in ECHA. Finally, the Commission presented its view on harmonization efforts of Title VIII and on the application of the re-examination procedure of Art. 69.5. This was followed by a discussion. Today, at the request of some Competent Authorities, the Commission presented its views on the scope of the derogation provided in Annex XIV for the use of DEHP in medical devices. Another discussion took place.

8. REACH Review

8.1 Update on REACH Review (CA/14/2012)

The Commission provided a presentation on the content and timelines for the REACH review. Work is progressing well and the official Communication and the accompanying Staff

Working Document are expected to be adopted in June. The Commission has received a lot of input for the Review, but underlined that while finalisation now in the hands of the Commission it was important to see the Commission Communication as a basis for further work. Therefore, to present the Commission's work and to get further input, a workshop has already been scheduled for 24 September.

9. REACH Evaluation - Continued

9.1 Update on OECD test methods (ATP to Test Methods Regulation) (CA/15/2012)

The Commission presented an update on the progress of the 3rd, 4th and 5th ATP to the Test Methods Regulation. The current work plan and timetable for completion of each of the ATPs was presented. The 3rd ATP is currently under EP and Council scrutiny and is scheduled to be completed in June. The test methods for the 4th ATP are being prepared to be sent to the EU National Coordinators for test methods. The test methods for the 5th ATP are currently being reformatted by the EU test methods coordinator. The 4th and 5th ATP has scheduled completion dates of December 2012 and January 2013. CARACAL was informed of upcoming changes in the Commission team dealing with the Test Method Regulation. Based on these changes, the completion date of the 6th ATP will be re-confirmed at the next CARACAL. Overall, the Commission noted that between June 2012 and January 2013 the schedule is to include 52 test methods in the EU Test Method Regulation.

To begin with, Member States pointed out that the paper being discussed was not uploaded on CIRCA prior to the meeting. The Commission apologised and, after this agenda point was discussed, the paper was uploaded. Member States reiterated their view, as expressed when EOGRTS was discussed specifically in a previous agenda point of the meeting, that the EOGRTS test method should be included in the Test Method Regulation. The Member States also insisted that the test method should be included in the 4th ATP and not the 5th ATP. The Commission took note of this request.

10. REACH Authorisation

10.1 State of play of draft Commission Regulation amending Annex XIV for the 3rd time

The Commission explained that, on 20 December 2011, it received the 3rd ECHA Recommendation for inclusion of substances in Annex XIV of REACH. The Commission is currently considering the ECHA recommendation and all the supporting documentation provided by the Agency, including the opinion of the Member States Committee and the contributions submitted by stakeholders during the public consultation. It will then prepare a draft Regulation amending Annex XIV for the third time and, subject to the progress of the internal procedures, will communicate it to the REACH Committee before summer with a view to having a vote in the second half of the year.

11. REACH Restrictions

11.1 Technical Amendment to Annex XVII (CA/16/2012 and CA/29/2012)

The Commission briefly presented document CA/16/2012. Following a comment from one MS, the Commission clarified that the isomers with CAS No 42925-80-4 are not listed in Annex VI to CLP and therefore cannot be in Annex XVII because entry 30 contains only substances having an harmonised classification.

The Commission briefly presented document CA/29/2012.

One Member State pointed out with regards to entry 30 Appendix 6 that both CLP annex VI and REACH annex XVII refer to the same substance but different isomers.

Another Member State thanked the Commission for clarifications on MDI restriction (entry 56). It was glad that the specific CAS numbers for MDI isomers will be added to the text of the restriction and accepted the Commission position with regards to polymeric MDI.

A further Member State asked what would be the next step with regards to technical amendments.

The Commission clarified that it is provisionally scheduled for a vote in the REACH Committee in September. The Commission welcomed comments by 30 April 2012.

11.2 Derogation on dichloromethane – a reminder (CA/12/2012)

The Commission presented the document.

Some Member States indicated that they will not use the derogation and others indicated that they will inform the Commission about their decision.

The Commission requested that all Member States should inform the Commission when they have decided whether to use the derogation or not.

12. REACH AOB

12.1 REACH Article 33

One stakeholder presented the exercise (see full report at http://docshare.beuc.org/docs/1/EBHGGGGCPBMNEJEHAHCHFMEBPDWY9D737K9DW3571KM/BEUC/docs/DLS/2011-09794-01-E.pdf): the awareness and implementation of Article 33 by retailers had been tested by sending letters requesting information on SVHC content for 34 categories of products, then quantifying performance of replies (or lack thereof) against predetermined evaluation benchmarks. Results were disappointing, with performance varying between Member States: one scoring 0/25, and none over 10/25. Often the same company replied very differently in different Member States, indicating a lack of company policy on the subject. Responses would often be meaningless, completely generic or too detailed while not in the language of the request.
This stakeholder presented a list of concrete recommendations and stressed that the evidence from this and other related studies indicates that action is needed now and should not be postponed until after 2108, when the official review would come to the same conclusion.

The Commission thanked the stakeholder for the comprehensive information provided. None of the Member States Competent Authorities made any comment.

12.2 Update on Mixtures

The Commission provided an update on its follow-up to the Council conclusions on combination effects of chemicals since the last meeting. It explained that it is currently intensively working on its report and its reply to the Council invitation: to analyse how and whether relevant existing EU legislation adequately addresses risks from exposure to multiple chemicals from different sources and pathways, and, on this basis, consider appropriate modifications, guidelines and assessment methods. To a large extent, its analysis and considerations are based on the opinion of three scientific Committees (the Scientific Committee on Health and Environmental Risks (SCHER), Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and Scientific Committee on Consumer Safety (SCCS)). This opinion, "Toxicity and Assessment of Chemicals Mixtures", was adopted in December 2011 and published in the beginning of February 2012. The Commission report has been submitted to an inter-service consultation that should be finalised shortly. It will then be translated in all official languages. Its adoption should take place at the end of April. Once the Commission Report is adopted, CARACAL Members will be informed through the usual channels.

12.3 Update on Endocrine Disruptors

The Commission first recalled the main objectives of its work on endocrine disruptors for the upcoming period, which are to:

- Review and, if appropriate, revise the existing Community Strategy for Endocrine Disruptors by the end of 2012
- Propose scientific criteria for identification of endocrine disruptors by December 2013 as required under the Plant Protection Product Regulation and the Biocidal Products Regulation
- Review how endocrine disruptors are authorised under REACH by 1 June 2013 as required by Article 138 (7) under REACH

The Commission then provided an update on the past and future activities:

- The major study on the State of the Art of the Assessment of Endocrine Disruptors has been finalised and made available on the DG ENV website[1] in February 2012. The study has (I) reviewed the scientific state of the art on EDs for the last 10 years including all EU-funded research projects, (II) reviewed the approaches for assessment of endocrine disruptors in several Member States and non-EU countries and (III) drew conclusions and provided recommendation on policy relevant questions.
- The Commission organised the 3rd Ad hoc meeting of Commission Services, Agencies and Member States and the 1st meeting of the expert subgroup on endocrine disruptors. The meetings took place on the 16th and 17th November 2011. The meetings were dedicated to discussions of the draft final report of the study and of the work programme for these two groups.
- The 2nd meeting of the expert sub-group will take place on 19 and 20 April in Ispra; the discussion will be focused on the first stage of the proposed framework for criteria to identify EDs, at this stage being about adverse effect and mode of action.
- A 4th ad hoc meeting of Commission services, Agencies and Member States is envisaged to take place on 29 May 2012

[1] http://ec.europa.eu/environment/endocrine/documents/studies_en.htm

- The Commission is organising an EU Conference on Endocrine Disruptors: Current challenges in science and policy. It will take place on 11 and 12 June 2012. The objectives of the conference are:
    - To provide input for the shaping of future EU policy on endocrine disruptors (including review and possible revision of the EU strategy for endocrine disruptors)
    - To collect input with regard to the development of the criteria for the identification of endocrine disruptors
    - To increase awareness of the challenge of endocrine disruptors
- Participation to the conference will be by invitation only and will be limited to +/- 300 people:
    - Representatives of international organisations (OECD, UN bodies)
    - Representatives (policy makers and scientific/risk assessment experts) of non-EU countries (US, Japan, China)
    - Representatives (policy makers and scientific/risk assessment experts) of EU Member States
    - Stakeholder representatives (NGOs and Industry)
    - Academics
    - The members of the CARACAL have been invited to participate or to send their representative(s)

12.4. Update on the proposal of Amendment of Annex I of POPs Regulation

The Commission updated the CARACAL on the three-step approach to listing of SCCPs under the POPs Regulation, which was presented by the Commission to CARACAL in February 2011 in paper CA/14/2011.

With regards to the first step a draft Regulation amending Annex I of the POPs Regulation was presented to the relevant comitology committee. The draft Regulation, amongst other things, proposes to lists SCCPs in Annex I for elimination with two exempted uses - as fire retardants in dam sealers and conveyer belts. On 21 February 2012 the vote of the written procedure on the draft regulation was closed. The Committee unanimously adopted a positive opinion on the proposal. Until 21 May2012, the draft Regulation will be under Parliamentary scrutiny. At the end of this period the Regulation will be adopted.

The Commission reminded all that, as announced in the CARACAL paper, following the adoption of the new measure under the POPs Regulation, the Commission will proceed to the second step – the de-listing of SCCPs from Annex XVII in REACH. The Commission will then proceed to the third step – adaptation of the SCCPs entry to technical progress, with a view to deleting the remaining exemptions.

12.5. Announcement of a Workshop: ‘Long Range Transport – New Scientific Findings & Integration into REACH’

One Member State briefly informed CARACAL of the upcoming workshop on ‘Long Range Transport – New Scientific Findings & Integration into REACH’.

12.6. The Commission informed CARACAL members that, in accordance with CARACAL Rules of Procedure, two delegates from Serbia, now candidate country, will be able to

participate in the meetings of CARACAL. The Commission will look into practical arrangements.

12.7 PAHs

The Commission gave an account of the status of tasks resulting from the Expert Meeting on PAHs that took place on last 24 October and indicated it was still considering the way forward in relation to a proposal to restrict certain PAHs in consumer articles.

12.8 Update on ECHA guidance activities

One Member State asked to discuss the Update on ECHA Guidance activities paper (originally an information point).

As regards Guidance for Annex V genetically modified plants that may benefit from exemption from registration according to entry 9 in Annex V to REACH – ECHA clarified that it will host a workshop to discuss the technical matters on GMOs (provisional date 19 April 2012). The intention is to see whether a consensus on the scientific basis needed for a guidance update can be achieved. A GMO expert was requested to address a number of key scientific questions. The background report on oils and waxes derived from genetically modified plants that may benefit from exemption from registration according to entry 9 in Annex V to REACH has been made available to the participants of the Workshop.

Only if a consensus on the science can be achieved, guidance update will be launched preferably via fast-track procedure.

Regarding the Guidance on monomers and polymers, ECHA clarified that its intention is to tackle only the court case and some editorial corrections via a fast-track procedure. Technical issues that require in-depth discussions (e.g. the need of CSA for the monomer) will be tackled in a separate update when they are ripe for inclusion in the guidance.

13. Review according to Article 45(5) of the CLP Regulation (Poison Centres) (CA/17/2012)

The report summarising the Commission review on the possibility of harmonising the information requirements and formats for notifications to Poison Centres had been made available to CARACAL on 20 January 2012. The Commission introduced the report, including background information, explanations on how the review had been performed, topics discussed, main conclusions from the Commission's perspective and possible follow-up. The Commission highlighted that in particular the question of whether notifications should be submitted to one European database (as had been decided for cosmetic products) or to national databases in the Member States would still have to be examined further. However, the actual format for data submission and the content of the notifications would need to be fully harmonised.

The Commission thanked especially the European Association of Poison Centres and Clinical Toxicologists (EAPCCT) for their input in the process. The Commission concluded that it seemed possible to proceed with further work along the lines outlined in the conclusions of

the report including also for the controversial points identified, provided there was support from Member States and stakeholders.

All the Member States who took the floor welcomed the report, were satisfied with the work already done, stressed that the conclusions were a good starting point and supported the continuation of the process towards harmonisation of information. Several Member States were in favour of a decentralised system of databases for submitting notifications rather than a single European database.

On the other hand, one Member State supported a centralised system and explained that it was also using the information gathered for enforcement purposes. Another Member State did not exclude the possibility of a centralised system but stressed that it could be the end of a long process. One Member State also stressed the importance of languages and another one raised the issue of possible legal implications for the CLP Regulation (possible need for an amendment if a central data base were to be set up), which also needed to be discussed.

The Commission confirmed that the report is the starting point for further work (e.g. also to define the concentration bands for ingredients in mixtures). Languages could be a particular problem for SMEs and they should have the possibility to submit the information in their national language. The Commission noted that, on the other hand, EAPCCT had confirmed that notifications in English would be acceptable everywhere. The Commission repeated that views with regard to the centralisation or non-centralisation of the database for notification were not yet finalised. A hybrid system could also be possible – as long as formats and contents are harmonised and information exchange possible.

Upon request of a Member State, the Commission confirmed that the notifications to Poison Centres would be independent of the submission of information to product registers in some Member States, which has a different purpose.

Several representatives from industry associations welcomed the Commission report and confirmed that they were willing to continue to work together on the remaining issues. Industry representatives in general favoured a central database. One industry representative noted that the proposed unique product identifier (UPI) number, as well as the submission of information on non-hazardous ingredients, could both become problematic. He also contended that in the current system, only information on consumer products was required to be notified to poison centres, whilst the Commission review indicated that, in the future, notifications would have to be made for all products (including for professional and industrial use). The Commission, supported by several Member States, disagreed and explained that, in its understanding of Directive 1999/45/EC, the submission of information to poison centres was not limited to consumer products. Furthermore, the review had revealed that poison centres did actually receive many enquiries from SMEs who had no in-house expertise in case of poisoning incidents. With regard to the UPI, the Commission explained that the model given in the review (based on a proposal from one poison centres) was only an example and that how such a number could be developed and added to the label of products was a matter that could still be discussed further– .

The Commission presented the cosmetics products notification portal, a centralised system for information on cosmetic products, which had recently become operational[2]. Until the date of

[2] http://ec.europa.eu/consumers/sectors/cosmetics/cpnp/index_en.htm

CARACAL, about 2000 notifications had been made and so far no particular problems had been signalled by notifiers or Member States. Following the request from some Member States, the Commission conceded that the approach from the cosmetic products legislation might not be fully transferable to the gathering of information for poison centres on all mixtures,. The CPNP works with highly standardised data (e.g. INCI names, drop down menus, accepted frame formulations) that would not be applicable to all chemical mixtures for which information would have to be notified under the CLP Regulation.

In conclusion, the Commission thanked Member States and stakeholders for their clear support for continuing the work. The Commission will strive to find solutions that satisfy the needs of poison centres while seeking to reduce the burden for companies. The Commission will prepare a work plan on how to move things forward for the next CARACAL.

14. 5th ATP CLP Regulation (CA/18/2012)

The Commission gave an update on the current procedure for the adoption of the 5th ATP to CLP (i.e. for inclusion of the next batch of substances into Annex VI to the CLP Regulation). A very first version of the list of substances had been distributed to CARACAL and included all substances for which RAC opinions had been delivered from 24 May 2011, as well as the two substances, gallium arsenide and epoxiconazole, which had eventually not been included in the 3rd ATP. The vote is tentatively foreseen for November 2012.

Several Member States indicated that they had been approached by industry with regard to the PHMB substance., In industry's view, the relevant RAC opinion was not properly derived as the relevant information had not all been taken into account. These Member States addedthat they were currently analysing the dossier. The Commission stated that industry had indeed brought forward these concerns and that the Commission had requested clarification from ECHA, who had confirmed that the procedures were followed properly when RAC discussed this substance and that all evidence submitted by industry had been examined by RAC. The Commission considered that the real problem was not a procedural issue but rather a difference in scientific views between RAC and industry on how to interpret the available data.

One Member State mentioned that the next ATP may not need to include the old DSD classification anymore, because of the expiry of the transitional period in CLP. The Commission replied that it was aware of the transitional periods but that the DSD classification would still be relevant for other legislation, which had not yet been aligned to CLP.

Several Member States asked for further clarification on the procedure with regard to epoxiconazole. One Member State mentioned that it had understood that ECHA did not want to follow up on the request from the Commission for a new opinion, and another one wondered whether there was a "plan B", if ECHA would not follow the mandate.

The Commission explained that, in line with what had been decided at the last REACH Committee, the company concerned had submitted the additional data on 1 March 2012 and the Commission had sent the data and a request for opinion to ECHA on 6 March. ECHA added that it was looking at the Commission request and considering the procedural aspects, where the workload of the RAC should also be taken into account. The Commission and

several Member States stressed that everyone was interested in concluding the evaluation of the additional data very quickly so that a decision on the classification of the substance could be taken as soon as possible.

The Commission invited Member States to submit comments on the substances provisionally listed for the 5th ATP by 30 April 2012 and a new version will be available before the June CARACAL meeting.

15. Update of Annex VI when new classification criteria are adopted (CA/25/2012)

The Commission stated that the document on this issue, with its 3 different options, was presented at the last meeting. Since then Member States have provided comments.

One Member State asked for a clarification on the concept of "new information" and whether this really included the change of classification criteria. The Commission replied that one of the possible interpretations of Article 37(6) is that, if existing information was insufficient for classification under the old criteria but is relevant for classification under the new criteria (and in that sense "new" for the purpose of CLP), it could be considered as "new information".

Two Member States would be in favour of acting on sensitisers only.

One Member State pointed out that Annex VI reflected the criteria at the time of adoption of a classification and supported option 3 in the document. The same Member State also stated that it was not necessary to have the same approach in each case and suggested using the procedure specified in Article 53 CLP for updating Annex VI, thus not involving RAC. The Commission considered that the proposed procedure needed to be analysed and assessed from a legal point of view – it would however still require a review of the data for each substance to see whether the new criteria did actually lead to a different classification. Another Member State also supported option 3 with some modifications, i.e. to define a prioritisation process for when action would be required.

Industry representatives replied that there were no exact figures available at the moment on how many substances would be affected, but they would continue to investigate it, in particular also by assessing the modifications of the self-classification for substances not listed in Annex VI that would be induced by the new criteria.

One Member State considered that Annex VI CLP should not be made more complicated. In its view, options 1 and 3 did not differ so much. If option 3 were to be followed, the related workload could be reduced if very targeted CLH proposals were made and ECHA subsequently to "run them through" quickly.

The Commission concluded that there was a general interest for an option 3 with some modifications and that prioritisation was needed. Member States and stakeholders were invited to submit any further comments before 6 April 2012 (Easter).

16. Article 46(2) on Enforcement

The Commission stressed the importance of enforcement, outlined the current status of Member States reporting on CLP enforcement and explained the next steps. Several Member

States sent only partial information and they were asked to update their reports as soon as possible.

ECHA gave a preliminary overview and assessment of the information provided. Upon request of one Member State, ECHA confirmed that all Member States having sent no or only partial reports had been informed.

Two Member States stressed that the template for reporting should have been provided earlier and that it might need adaptation. The involved Authorities would then be in a position to collect the required data. ECHA indicated that this had indeed been the first reporting round and the FORUM had probably agreed on the template a bit late. The situation would be improved for the next reporting round.

17. C&L Inventory

ECHA gave a presentation on the launch of version 1.0 of the Inventory in February this year and on future related activities.

In general, Member States Competent Authorities were very positive towards the Inventory and found it a useful tool. The following aspects were further highlighted in the discussion:

- One Member State raised a question regarding the role of ECHA in helping Competent Authorities to identify wrong notifications.
- Another Member State announced that it will provide written comments (as they have received feedback from industry) and proposed an additional disclaimer to be added explicitly saying that the content is not the official classification of ECHA. Also it would be useful to flag whether classification is due to the pure substance or due to an impurity. The question of limitation of potential abuses of the Inventory was raised.
- Several Member States raised questions on further steps (both on industry and Competent Authorities / ECHA part) to support the harmonisation process. One Member State announced that they initiated a project on data mining of the information in the Inventory to identify potential candidates for harmonised C&L. Some Member States showed interest in participating to this project and ECHA also expressed its interest in a potential collaboration in order to avoid double work.
- One industry stakeholder asked how updated versions of the Inventory would be marked so that it is clear where exactly updates are made.

In response to comments, ECHA clarified that:

- Future further collaboration would be very much welcomed (project of a Member State on data mining);
- As to further indications/flagging of the reasons for different classifications (e.g. impurity flag) and marking of updated notifications – this would be further discussed and possibilities explored (post meeting comment: updated notifications cannot be specifically flagged because the notifications that are classified in the same way are aggregated for display purposes. A clarifying sentence has been added on the inventory search page on 29 March);
- As to a system to avoid potential abuse – possible tools will have to be explored from a technical point of view;
- The aim is to refresh the Inventory every second month (next refresh foreseen for June 2012);

- Language versions for names of substances included in Annex VI are at the moment available in the Classlab database (until June 2012), appropriate measures after phase out of that database are being discussed.

18 CLH Process

ECHA presented the main aspects of the planned revision of the RAC opinion-forming process, stressing that the paper submitted should be seen as an initial step: the revision of this process will be further developed.

The Commission supported the initiative, especially in the context of some difficult cases that RAC has faced so far, and as a follow-up to the workshop organised by ECHA in February 2011.

In general, delegations responded positively to the paper and welcomed this initiative to improve the CLH process and opinion-forming in RAC. One Member State, however, expressed concern that the document showed too strong an emphasis on procedural issues, indicating that ECHA should be mindful of the fact that, for some specific dossiers, there will always be extensive scientific debate which simply will take a lot of time and active involvement of many parties in the different steps of the process. The issue of how to handle and take into account new data was seen as crucial. As a necessary next step (supported by several Member States), the development of concrete criteria for when to accept new information after the closure of the public consultation was highlighted. One Member State offered to actively contribute to the further elaboration of specific criteria. The concept of 'expert meetings'/'hearings' was generally supported and mainly regarded as complementary to existing procedures and aiming at better structuring of the whole process. One Member State queried whether these meetings were consistent with other ECHA processes and another one expressed its concern that these meetings could cause information to be held back during PC.
The responsibility of dossier submitters was seen as not having been sufficiently addressed in the paper; two Member States stressed that the scope of the discussion should be widened and include potential dossier submitters (i.e. Member States) and called for involvement of interested parties already at the stage before the preparation of the dossier (after the intention has been reported in the RoI).
In reaction to comments that the approach was too process-oriented, ECHA pointed out activities that were occurring in parallel (including the RAC boxes approach). ECHA and a number of Member States also noted the need to define procedures that improved efficiency and allowed for the required flexibility of its processes.

19. The Outcome/Results of the Study/Report on Risk Communication (Article 34(1) CLP)

ECHA gave a brief presentation of the findings of the study on risk communication it carried out in accordance with Art. 34(1) of the CLP Regulation[3]. The study has notably identified the need for awareness-raising campaigns to familiarise consumers with the CLP pictograms and that a further study should be conducted after June 2015 (i.e. when CLP would be fully applicable to mixtures). ECHA did not recommend changes to the CLP pictograms for the time being.

[3] The report is available at: http://echa.europa.eu/documents/10162/13597/pr_12_01_clp_report_en.pdf

The Commission informed that in line with Article 34 of the CLP Regulation, it would prepare a report to the European Parliament and the Council on the basis of ECHA's study.

12. CLP AOB

Recast of the DPD.

The Commission recalled the reasons for this proposal and indicated that the text of the recast adopted by the Commission had been sent to the Council and to the European Parliament. Discussions had already taken place in the inter-institutional consultative Working Party, composed of officials from the Legal Services of the Commission, European Parliament and Council. In the European Parliament, there will be a report from the Environment Committee (Rapporteur: Ms Korhola) and an Opinion from the JURI Committee. The responsible working party in the Council has not been yet confirmed.

EUROPEAN COMMISSION

ENVIRONMENT DIRECTORATE-GENERAL
Water, Marine Environment & Chemicals
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ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Chemicals, metals, mechanical, electrical and construction industries; Raw materials
Chemicals – REACH
Chemicals - Classification & Labelling, Specific Products, Competitiveness

Brussels, 15/03/2012
Doc. CA/01/2012 Rev.3

FINAL DRAFT AGENDA
10th Meeting of Competent Authorities for REACH and CLP

21-22-23 March 2012

Room: Walter Hallstein (WHALL)

Berlaymont Building
Rue de la Loi 200, 1040 Brussels, Belgium

Discussion Points:

21 MARCH 2012		**14:00**
AGENDA ITEM	**ACTION**	**TIME (APPROX.)**
SESSION A: GENERAL ISSUES		**14:00 – 14:10**
1. ADOPTION OF AGENDA	Discussion/Adoption CA/01/2012 Rev. 2	14:00 – 14:10
SESSION B: REACH		**14:10 – 17:30**
SUB-SESSION B.1: ECHA AND COMMISSION POINTS		**14:10- 17:30**
2. REACH EVALUATION		
2.1. Update on EOGRTS	Information CA/13/2012	14:10 – 14:55
3. REGISTRATION		
3.1. ECHA's work on PPORD assessment	Discussion CA/04/2012	14:55 – 15:25
3.2 ECHA's work to support the functioning of the REACH mechanisms related to Downstream Users	Discussion CA/05/2012	15:25 – 15:50
3.3 Strategy for the future development of IUCLID	Discussion CA/28/2012	15:50 – 16:10
Coffee Break		***16:10 – 16:30***
4. REACH NANOMATERIALS		
4.1 Nanomaterials	Information/discussion	16:30 – 16:55

4.2. Update on work on nanomaterials and report from last CASG Nano	Information/ discussion	16:55 – 17:30
22 MARCH 2012		**09:30**
AGENDA ITEM	**ACTION**	**TIME (APPROX.)**
SESSION A: GENERAL ISSUES - CONTINUED		**09:30 – 10:00**
5. FOLLOW UP OF THE 9TH MEETING OF CARACAL		
5.1 Draft summary record	Information/ Discussion CA/91/2011	09:30 – 09:40
5.2 List of Actions	Information CA/90/2011	09:40 – 09:50
6. OVERALL WORKPLAN FOR CARACAL		
6.1 Work plan for CARACAL (Comitology procedures, CARACAL written procedures, subgroup meetings)	Information CA/02/2012	09:50 – 10:00
7. REPORT FROM THE CA SESSION		
7.1. Reporting on the CA session	Information	10:00 – 10:05
SESSION B: REACH - CONTINUED		**10:05 – 15:00**
SUB-SESSION B.2: COMMISSION POINTS		
8. REACH REVIEW		
8.1. Update on REACH review	Information / discussion CA/14/2012	10:05 – 10:50
9. REACH EVALUATION - CONTINUED		
9.1. Update on OECD test methods	Information / discussion	10:50 - 11:15

	CA/15/2012	

Coffee Break		***11:15 – 11:45***
10. REACH AUTHORISATION		
10.1. State of play of draft Commission Regulation amending Annex XIV for the 3rd time	Information	11:45 – 12:00
11. REACH RESTRICTIONS		
11.1. Technical Amendment to Annex XVII	Information / Discussion CA/16/2012 CA/29/2012	12:00 – 12:45
Lunch		***12:45 – 13:45***
11.2. Derogation on dichloromethane – a reminder	Information / Discussion CA/12/2012	13:45 – 14:00
12. REACH AOB		
12.1. REACH Article 33	Information / discussion Presentation by BEUC	14:00 – 14:30
12.2. Update on Mixtures	Information	14:30 – 14:35
12.3. Update on Endocrine Disruptors	Information	14:35 – 14:55
12.4. Update on the proposal of Amendment of Annex I of POPs Regulation	Information	14:55 – 15:00
12.5. Announcement of a Workshop: 'Long Range Transport – New Scientific Findings & Integration into REACH'	Information by DE CA	15:00 – 15:05

AGENDA ITEM	ACTION	TIME (APPROX.)
SESSION C: CLP		**09:00 – 14:00**
SUB-SESSION C.1: COMMISSION POINTS		
13. REVIEW ACCORDING TO ARTICLE 45(5) OF THE CLP REGULATION (POISON CENTRES)	Information / discussion CA/17/2012	09:00– 10:00
14. 5TH ATP CLP REGULATION	Information / discussion CA/18/2012	10:00 – 10:30
15. UPDATE OF ANNEX VI WHEN NEW CRITERIA ARE ADOPTED	Discussion CA/25/2012	10:30 – 11:00
Coffee break		***11:00– 11:30***
16. ARTICLE 46(2) ON ENFORCEMENT	Information	11:30 – 12:00
SUB-SESSION C.2: ECHA POINTS		
17. C&L INVENTORY	Information/Discussion	12:00 – 12:45
18. CLH PROCESS	Information/Discussion	12:45 – 13:40
19. THE OUTCOME / RESULTS OF THE STUDY / REPORT ON RISK COMMUNICATION (ARTICLE 34(1) CLP)	Information	13:40 – 13:55
SESSION D: CLOSE OF MEETING		13:55 – 14:00

Information Points:

INFORMATION POINT & OUTLINE	
1. Tracking document	CA/19/2011
2. OR clarification note for CARACAL	CA/03/2012
3. Clarification of the concept of placing on the market	CA/20/2012
4. Reporting obligations on lamp oils and grill lighters	CA/11/2012
5. Substance evaluation state of play	CA/06/2012
6. SVHC submission dates	CA/07/2012
7. Conference on Enforcement – Feedback	CA/21/2012
8. Corrigendum to CLP and correcting act to the 1st ATP	CA/22/2012
9. Outcome of the Milieu study on enforcement	CA/23/2012
10. Report on the Forum WG on Interlinks	CA/08/2012
11. 3rd ATP CLP Regulation	CA/10/2012
12. 4th ATP CLP Regulation	CA/26/2012
13. Update on ECHA Guidance activities	CA/27/2012
14. Status report on proposals for harmonised classification and labelling of substances (CLH proposals).	CA/09/20012

Rules for information points:

- Information points and accompanying documents are not allocated a specific agenda time but the documents are available on circa before the meeting;

- Information points can be prepared by COM, ECHA or MS and these documents are included in the draft agenda;

- Information points should have a title and a short outline of the main issues discussed in the document;

- Based on the outline referred to above, if any MS considers that information point may merit a specific agenda point, they should inform COM by sending an email to env-caracal@ec.europa.eu and entr-caracal@ec.europa.eu at the latest 10 days before the meeting.