Notes on CARACAL meeting
26-28 November 2013

1. REACH Review follow up (CA/66/2013 & presentation)

The Commission summarizes the main activities following up the Commission's communication on the REACH Review, such as Council discussion (Competitiveness & ENVI Council), EP Intergroup (4 June 2013) and ENVI Committee meetings (29 May 2013), the Commission workshop (June 2013) and the upcoming workshop on SME & registration (9 &10 June 2013). The Commission has also received position papers from stakeholders, including Orgalime. The industry focuses on registration issues and asks for better feedback from ECHA, better coherence with sector specific legislation and increase focus and consideration for SMEs. The NGOs request the registration dossiers improvements, easier access and more practical information (SDS, ECHA website), more application of precautionary principle and better support to SMEs to cope with the requirement.
The Commission launched actions on various issues (see details in the document), including general objectives (i.e. minimizing overlaps with sector specific law by dialogue with other services), supply chain communication (i.e. infringement proceedings launched for dissenting interpretation of article 33) and risk management (i.e. SVHC Roadmap, fast track restriction procedure).
As regards next actions, the Commission will follow up with reporting template based on review recommendations addressed to MS, ECHA & Industry (to be sent in December). The contributions (to be provided by end January / early February) will be gathered in an overview report.

2. Update on Nanomaterial Review

Transparency measures (CA/14/2013)

The Commission launched an impact assessment to identify most adequate means to increase transparency and ensure regulatory oversight on nanomaterials (and assess whether new measures are necessary, such as a register, amendment of tonnage threshold under REACH). The experience on existing registries need to be studied, especially the French notification system. The contractor for the study has been selected, but the contract has not been signed yet (to be done end November). A public consultation is foreseen in spring 2014 and the final decision is expected in 2015 after further discussion with the European Parliament. Additional meetings will take place in the coming months.
Answering to Denmark and the Netherlands, the Commission confirms that the impact assessment intends to assess the cost for industry, but also benefits for the health and the environment as well as the lack of information is a key aspect. However, it is necessary to know the level of needed information and why we need information: Gathering information should lead to health and environmental benefits.

Modifications of REACH Annexes for nanomaterials: Impact assessment, key issues and timetable (CA/36/2013, CA/53/2013& presentation)

The REACH Regulation is a co-responsibility of DGs ENTR & ENVI. A first Impact Assessment Steering Group meeting took place in January 2013, which involves all Commission's actors (DGs ENTR, ENVI, SG, MARKT, JRC, RTD, SANCO and TRADE). A publication consultation has been carried out between June and September 2013 as well as 2 meetings with Member States (CASG Nano).
The scope is limited to measures that can be proposed via the committee procedure (so called "comitology" procedure), which means only the annexes of REACH. The problem is the lack of clarity of REACH for nanomaterials.

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As main consequences, the industry does not demonstrate enough the safe use of nanomaterials and there is uncertainty on how to comply. At the end, it may generate cost and negative effects on the health and environment. There is a double objective: 1. Ensure adequate demonstration of safe use of NM in the registration dossiers; 2. Clarify the legislative obligations and reduce uncertainties for companies on how to comply with their registration obligations.
The draft timeline for the next steps is announced as follows:

- December 2013: submission to the Impact Assessment Board (IAB)
- January 2014: review by IAB
- February 2014: submission to CASG Nano members & discussion at March meeting
- March 2014: launch of the inter-service consultation (ISC)
- April 2014: Submission of Commission's proposal to REACH Regulatory Committee

There are 6 policy options assessed (see document). 142 answers have been provided in the public consultation, mainly coming from industry associations and companies. As main outcomes, REACH is unclear for nanomaterials, the preferred options are the number 5 for the industry (simplified information requirements) and the number 6 for Member States, NGOs and consumer associations (full information requirements). Now, the Commission will compare the different options in terms of efficiency, safety and costs.
In parallel, the German CA prepared a proposal for changes of the REACH annexes, which has been discussed at the CASG Nano meeting and afterwards: 7 Member States (BE, DE, FI, NL, PL, SE & UK), 4 industry organisation, 2 NGO, 1 social partner provided comments. The main issues are: scope of the registration dossier, testing of NM, water solubility, cancellation of registration exemptions for nanomaterials (annexes III & IV).

Discussion:

- The UK did not support any of the proposed options, but would prefer a mixed approach. The Commission specifies that the outcomes can be a mix of different options, combining various measures. The Commission will not necessarily follow the options 5 or 6 (the statistic just reflect public preferences).
- Denmark criticises the baseline option (current situation) where industry is supposed complying with REACH requirements, but it does not reflect the reality. Denmark supports the German proposal as a starting point for discussion.
- The Netherlands, Denmark, Germany and NGOs (EEB) raise concerns on the identity of respondents since all stakeholders are not well represented. They point out the low participation rate of NGO and propose to weight the contribution (i.e. EEB represents 50 million citizens vs. one private companies).
- NGOs urge more resources dedicated to measure the benefits to human health (rather than the costs for the industry) and to adopt tonnage threshold (amendment of the REACH Regulation since very few registration done).
- UEAPME requests that information in dossier should be more visible and better communicated through the supply chain. Work should be done on the definition.
- CEFIC (presentation on characterisation of NM based on 5 case studies, including Synthetic Amorphous Silica). CEFIC estimates the cost of characterisation on basis of the German proposal, which vary from 9000 and 15000E (but can be up to 39000E). The cost increases together with the level of the detail information. Moving away from the substance characterisation to individual product grade characterisation makes the joint registration difficult (or even impossible) and will result in the costs increase, especially for SMEs. There are a huge number of organic pigments that fall under the nano definition, but the organic pigment industry does not consider their products as nano.

3. Director Contact Group (DCG) achievements and future

The second mandate of the DCG, which expired in September 2013, focused on the registration. The experience shows that practical solutions have been agreed and the involvement of ECHA increased. As the next registration deadline will impact mainly SMEs and ECHA already gained experience on this matter, it is proposed that the chairmanship and secretariat will be transferred to ECHA for the next mandate. Sherpa are currently working on the draft terms of reference for the next mandate and will come back to the CARACAL.

4. Defence exemption in REACH

The “defence exemption”, included in Article 2.3 REACH, allows exemptions in specific cases for certain substances. However, the criteria are developed at national level. The EU Defence Agency (EDA) took over this matter and built a REACH portal to inform on conditions requested in various Member States to provide an exemption. The sharing of information does not solve main challenges, which are developments of national requirements, the mutual recognition of national exemptions and the harmonisation of information to be provided. The objective is to develop an EU “standard” for the defence exemption to be used as a basis. The first draft has been discussed in September in the EDA. The objective is to finalise this work by the end of 2013. The Commission recommends Member States REACH experts to liaise with national defence representatives / ministries.

UEAPME asks for the legal basis for mutual recognition and whether the criteria are public information. The Commission answers that there is no legal provision to force mutual recognition but the standardisation of the criteria will facilitate the acceptance of national exemptions. The UK welcomes the work for mutual recognition and specified that this is already foreseen in the national law.

5. Evaluation: testing

Extended One-Generation Reproductive Toxicity Study (EOGRTS) (CA/63/2013)

Further to the OECD guideline on EOGRTS (TG 443) adopted in July 2011, the Commission presented a draft proposal for amending the REACH Annexes (Annexes IX & X) to implement EOCRTS. As regards next steps, the draft proposal will be presented to the REACH Regulatory Committee in February 2014 and the vote is expected in April 2014. In addition, the EOGRTS will be introduced in the Commission Regulation 440/2008 on the test methods and the relevant guidance will be updated accordingly.

The REACH Alliance asks whether there will still be room for using the 2nd generation test method. The Commission answers that the test method needs to be mandatory replaced (but, the 2-generation studies submitted before the amendment of the REACH Annexes will be considered as compliant).

Acute toxicity testing (CA/54/2013)

The Commission has received two proposals to modify the REACH information requirements for acute toxicity from European Platform for Alternatives to Animal Testing (EPAA) and the Humane Society International (HSI). This should contribute decreasing animal testing.

The United Kingdom, Austria, Ireland and the Euro-group for Animals support the proposal, while the Netherland and Denmark raise concerns for some analysis.

6. Restrictions

Outcomes of the workshop on the interface between REACH and other legislation (CA/65/2013 & CA/41/2013)

The Commission (DG ENTR/REACH unit) reports that four issues have been tackled at the workshop of 8 November with Member States competent authorities, including the RoHS Directive, the Occupational Health & Safety legislation (worker protection), the Toys Directive and the POP Regulation (Stockholm Convention). The Commission already developed papers for a common understanding on RoHS and the PoP Regulation issues, which are for debate today, and announces the intention to publish other papers on the remaining issues in 2014. These are tabled to CARACAL for debate today. Such work on developing common understandings forms part of the follow up to the REACH Review. Although few cases of actual conflicts were identified so far in the Commission´s view, the potential for incoherence is recognised between REACH and other pieces of legislation. The Commission approach is based on a common understanding and aims to provide guidance on how to proceed when facing such a situation. For the case of RoHS-REACH, three scenarios have been identified: 1. Action already taken in REACH; 2. Substances already in REACH & action envisaged in a sectorial legislation (or the contrary); 3. No action launched under either policy tool.

The main suggestion for the way forward is to “carve out electrical and electronic equipment from REACH where RoHS takes into account the protection of human health and the environment at all

stages". RoHS is dealing with the use of substances in EEE that is also covered under REACH. RoHS is not being limited to waste phase: it is related to environmental protection, but also protects workers (overlap with OSH). A maximum concentration is fixed for the use of a restricted substance in the Annex II and exemptions can be granted under certain conditions.
The POP Regulation has the right to implement the agreement reached under the Stockholm convention. The Commission wants to avoid that substances regulated under the POP convention are placed on the Annex XIV (avoid such a case with the DecaBDE substance). The overall objective is to strengthen the legislation.

Discussion:

- Member States broadly supported the proposal to develop a common understanding on the interface of REACH and sector specific legislation: Especially Sweden, the Netherlands, the United Kingdom and Germany support the Commission paper as a good overview, welcome such common understanding approach to ensure consistency of the different procedures and express a strong support for further meeting on interaction between REACH and other legislation.
- While some Member States support restricting the use of substances in the REACH framework (such the United Kingdom), other reiterate support for the RoHS restriction (i.e. Sweden).
- Main questions / concerns raised: Can we end up in the situation where a REACH authorisation procedure can be undermined by a RoHS exemption? Could RoHS exemption be granted while there is no authorisation given under REACH? What happens if specific sector legislation is less strict compared to REACH? There is need to give certainty to industry.
- CEFIC welcomes the two Commission's documents, but asks why it was a closed workshop since REACH & sector legislation is not a confidential matter. The transparency being a key value for the Agency, such an event should be open. There is not sufficient time in the CARACAL open session for descent discussion. CEFIC raises strong concerns that discussions are taking place behind closed doors.
- Orgalime thanks the Commission for having taken up the work on developing a common understanding, which industry urgently needs considering the increasing overlaps arising between REACH and RoHS, notably in the area of REACH/RoHS implementation activities on 3 phthalates (DEHP, DBP, BBP), lead and cadmium. At initial sight, Orgalime believes that the working document represents a fair picture of the current situation and identifies the remaining challenges. The industry considers its main principle of "carving out EEE from REACH where the risks over the life cycle are addressed" as a welcome, however insufficient step. As long as the RoHS methodology remains focusing on the waste phase, the good intention of the working document would not have impacts in practice. Orgalime calls upon regulators to support the development of this working document and to support shaping the draft RoHS methodology in a way that it fully takes up REACH risk assessment procedures. This should be the way forward considering article 6 RoHS and the recent ECJ ruling.
- The Netherlands and Germany remind that the EU has not made any proposal for the POP convention. They highlight that the POP / REACH processes are overlapping (i.e. HBCDD, which the latest application date is February 2014). Does the Commission want to submit any substances? It is important to give more consideration on substances that can be candidate for the POP convention.
- The Commission reminds that all necessary restrictions can be handled in REACH; however, it should be noted that the European Parliament and the Council recently recasted RoHS and reiterated their wish to have both RoHS and REACH. Today, the objective is to streamline REACH and RoHS restriction procedures and take note of the willingness to continue the discussion. While RoHS cannot be obliged to follow the REACH, the methodology should be coherent with REACH (RoHS should consider all aspects of the life cycle for not being a relaxation of REACH assessment and to get exemptions under REACH).
  As regards the HBCCD, we should make sure that any authorisation is aligned with exemptions foreseen under the POP convention. So far, the Commission did not see any substance to be regulated under the POP convention, but will assess whether there is a new candidate.
  Finally, the Commission noted the interest of Member States and stakeholders to continue the discussion (there will be a follow up discussion at the next CARACAL meeting). CARACAL members and observers can send comments on the working document to the Commission until end of January 2014.

Review of the existing restriction on Phthalates (CA/44/2013)
The restriction of the use of 3 Phthalates (DINP, DIDP & DNOP) in toys and childcare articles (Annex XVII, Entry 52) has been reviewed between 2010 and 2013, mainly by ECHA. On basis of this extensive review, the Commission comes to the conclusion that the existing restriction should be maintained and no unacceptable risk has been characterised in any other articles than the ones restricted on basis of available information. As regards next steps, comments can be provided by 20 December to the Commission. Then, the Commission will finalise the review clause and publish its opinion on its website.

Lamp oils & grill lighter fluids (CA/39/2013)
In the context of the existing restriction (Annex XVII REACH, Entry 3), the Commission shall request ECHA to prepare a dossier to ban, if appropriate, grill lighter fluids and fuel for decorative lamps intended for supply to the general public. While some alternatives have been tried without any commercial success, no suitable alternative have been identified so far. In order to gather as much useful information, a questionnaire will be distributed to Member States (via ECHA weblink) on products placed on the market and related accidents.
Cyprus and Greece report on the use of such products for religious & traditional purpose (currently exempted) and raise concerns that further restriction may not be accepted by consumers.

CMR study (AMEC / ICF presentation)
Started in December 2013, the study was carried out in 2 steps: 1. Gathering evidences on a large number of substances and 2. Socio-economic analysis of 13 substances. The study is not a full SEA but takes into account a baseline scenario (use of substances and presence in different types of articles) and expected non-use scenario. As a main outcome, the consultant assesses different considerations whether the Article 68.2 procedure (fast track) is appropriate or not (such as evidence of ongoing harm to EU citizens from the substance in the consumer article, potential exposure of consumers, threshold…). The study has also identified some socio-economic considerations to be taken into account, such as the complexity of the supply chain, SMEs, quick innovative market, availability of alternatives, substances due to recycled materials, and compliance of a possible restriction. In conclusion, the study proposes a decision tree whether the Article 68.2 procedure or the Article 69 procedure is appropriate. As regards next steps, the final results will be published and the Commission will draft criteria for the use of the Article 68.2 procedure, early 2014, on basis of the results of the study.

Nickel: definition of prolonged contact with the skin (CA/37/2013)
The nickel restriction (Annex XVII REACH, Entry 27) does not define the term: “prolonged contact with the skin”, leaving room for different approaches. The proposed definition does not intend to amend the limit provided in the Annex XVII but provide a better clarity. This issue has not been addressed to the Forum, but this paper can be discussed with the enforcement authorities at national level. On basis of comments received (by end January 2014) and ECHA recommendations, the Commission will consider issuing a Q&A paper (or other format) to be discussed at the next CARACAL meeting. The coherence with other restriction using the same wording need be ensured.

7. Update on the CSR/ES Roadmap (CA/57/2013)
The summary paper lists actions launched and upcoming ones to implement the Chemical Safety Report & Exposure Scenario (CSR/ES) Roadmap. Progresses have been made; further information is available on the Roadmap web pages.
CEFIC underlines the importance for the industry to work together with the Commission, ECHA, trade unions & NGO to solve existing problems.

8. Substance Evaluation
Interaction with Member States CAs and registrant during substance evaluation (CA/58/2013)
A working group (composed of industry and Member States) set up conclusions on the first substance evaluation and drafted recommendations based on the best practices for registrants.

Competent authorities express support and endorse the draft document. Then, ECHA will publish the document on its website and will issue general recommendations for registrants.
CEFIC informs that a guideline for their constituencies will be published together with Eurometaux. DUCC asks whether the interaction with DUs is considered. ECHA answers that it was not in the scope since first contacts are limited to registrants; however, it does not prevent registrants to exchange information with its DUs.

Update on the Substance Evaluation & CoRAP (CA/59/2013)
ECHA is already working on the next CoRAP (2015-2018), which will have to take into consideration the ongoing work on the SVHC Roadmap. The criteria for selecting substances for evaluation will be updated in 2014 (any suggestions to improve substance evaluation can be communicated to ECHA). The first substances evaluated in 2012 are slowly following the process (i.e. Member States agreement on the first request for further information). A workshop on the Evaluation process is foreseen in May 2014 and ECHA calls for volunteers to prepare the workshop. ECHA wants to create a network between ECHA & Member States lawyers, which are working on the substance evaluation (that can also be extended to other legal issues).
The Netherlands specifies that, if there is a conclusion on the substance evaluation, the scope should be made clear. The Commission agrees that the substance evaluation is not a complete risk assessment.

Contracts between ECHA & MSCAs (CA/60/2013)
ECHA proposes to simplify the procedure for payments to Member States CAs for the works done under substance evaluation, restrictions and applications for authorisation.

9. Member State Committee
The current Chairman of the ECHA MS Committee, Mrs. Anna-Liisa Sundquist, will be replaced in 2014 by Mr. Watze De wolf (who is currently head of unit in the Directorate of evaluation).

10. Endocrine disruptors: REACH Review (presentation)
According to Article 138.7 REACH, the Commission is required to review, by June 2013, whether there is need to extend the scope of the Article 60 to endocrine disruptor substances. It is difficult to implement the legal text for substances having agreed threshold. An assessment has been carried out by DG ENVI, in cooperation with JRC ED experts, Member States and stakeholders. The review is not ready because the workload is too high, but it is progressing. The review report is expected to be provided to CARACAL members in Q1 2014. This matter will be further discussed at the next meeting. Although the Commission is still working on the appropriate wording, the main conclusions have been agreed:
- Where a threshold can be proven, the adequate control route should be possible for granting an authorisation
- Applicants should demonstrate the existence of the threshold (evidences based is necessary)
- The Commission will not propose any change to the current legislation

The United Kingdom and Denmark support main preliminary conclusions of the Commission, but point out a lack of clarity on EDs, in particular whether the industry will be able to demonstrate the existence of a threshold. NGOs (HEAL, EEB) & ETUC raise concerns on the Risk Assessment Committee activities to develop DNELs, i.e. on Chromium (it is up industry to provide DNELs), which lead to incoherencies with other substances.

11. Cadmium Court case
The European Court of Justice partially annulled the Cadmium Regulation on the restriction of cadmium in plastics. The Commission adopted a new regulation in 2012 (Regulation 835/2012) with retroactive effect to ensure statut quo. Therefore, there is no need for to act further since the issue was already remediated with the Regulation adopted in 2012.
The Court concluded that the Commission made a major error of assessment. It stated that all measures, even preventive measures, should be based on strong evidences and a scientific evaluation of the risks. The Commission does not intend to make an appeal for this judgment. It shows that the Commission and Member States CAs should be very careful with the last minutes changes and the need to have a proper justification.

Sweden highlights that this judgment demonstrates the difficulties to phase out some substances even there is a political agreement.

12. Discussions held in closed CARACAL session

- CLP: Classification of liquid / soluble packaging (different views whether a soluble packaging is considered as packaging or not, and covered by the CLP),
- UN GHS: classification of Nanomaterials (to be discussed in Geneva early December 2013), updating of Annexes 9 &10 of the GHS related to metals classification, the global list of chemical (no discussion)
- Recycling & REACH (CA/28/2013): Member States welcome in general the Commission position but it is up to waste legislators to decide what is waste or recycled or not. The discussion will continue at the next CARACAL
- SVHC roadmap: the implementation plan endorsed and to be discussed at the workshop
- Authorization: Exemption for PPORD (exemptions to be granted on case by case according to Article 56; need for guidance for industry?), application of the authorization requirements for legacy spare parts (introduction of a similar mechanism to ELV?)
- Restriction:
    - Dichloromethane: UK presentation on derogation, scope cover paint strippers, lacquer and varnish removers (other strippers not covered, but the scope of the Restriction could be reviewed)
    - CMRs for tattoos: Article 68.2 procedure can be considered
    - Streamline restriction process: industry, ECHA, Commission and Member States will meet to propose a way to streamline the process (Annex XV & RAC / SEAC opinion)
- Safeguard clause: document prepared and endorsed for discussion
- TTIP: update on trade negotiation with US (no lowering of the level of protection set by REACH)
- OELs vs. DNELs to be discussed at the next CARACAL meeting

13. Next CARACAL meetings are scheduled on 2&3 April 2014 and 11-13 June 2014.