**Follow up to the 26th CARACAL:**

- "Phase-In"-Status (AP 5.2)
- Ni-restriction guideline (AP 9.2)
- Registration Deadline 2018 (AP 9.3)
- Classification of TiO2 (AP 13)
- Amendment of Annex VI (AP 14)
- Implementation of Annex VIII (AP 16)

**"Phase-In"-Status (AP 5.2)**

The phase-in-status was a crucial criterion for if a substance could be pre-registered or not. However, the phase-in-status also has other relevance:

- art. 12 (1b): reduced information requirements (no time limitation defined in the legal text);
- art. 43 (2): defines the length of the testing proposal evaluation for phase-in substances (until 1.6.2022).

Although there is a clear connection between the phase-in-status and the transitional registration arrangements, there are also clear separations between those two elements. For example, while the phase-in-definition applied from the day when REACH entered into force on the 1st June 2007, the (pre-)registration obligation only applied one year later from 1st June 2008 on (see article 141).

By abolishing the phase-in-status annex III factually becomes irrelevant. No substance would be entitled to the linked data-reductions. Furthermore, existing registrations would need to be updated, what no one was expecting at the time of registration. Registrants had their legitimate expectations at the time of their registration and calculated based on this expectation based on the pre-assumption of legal-stability.

The Commission now is suggesting to intervene into the core-text of REACH by changing elements in art. 3 (definitions) with an implementing act. In our opinion there is no legal base for such an intervention based on art. 132. A change of the REACH-definitions requires an intervention with the ordinary legislative procedure.

Furthermore, we need to highlight that annex III was one of the main elements in reducing the burden for low-tonnage-substances and finally for SME. Based on the conclusions of the 2nd REACH-review that more needs to be done to support SME, it comes as an even bigger surprise that the Commission now plans to do exactly the opposite. This is even more dazzling, because critical areas like the update of registration-dossiers when changing to a higher tonnage-band in our opinion are not depending on the "per year" nor the "phase-in" definition. For this purpose the legislator took precaution and decided in art. 22 to use the phrase "annual" instead of "per year".

Finally, we see the need to continue the operation of SIEF or SIEF-like structures beyond 1st June 2018. Further cooperation between registrants will be necessary, e.g. in relation to data-sharing, follow-ups of evaluation-processes, dossier-updates etc. In our opinion the existing infrastructure should be exploited for this.

**Ni-restriction guideline (AP 9.2)**

As pointed out in our comments for the 25th CARACAL, we see the urgent need for a more transparent discussion about how examples are chosen. The main difficulty in our opinion is the definition of prolonged skin contact. We are of the opinion that many examples that ECHA wants to include would need a new SEAC and RAC assessment, that means an amendment of the current restriction based on art. 68.

## Registration Deadline 2018 (AP 9.3)

Again we need to stress out our concern about the recent registration status, because:

- The estimations for the 2010 and 2013 registration-deadlines were very accurate.
- Right now we have approx. 137.000 substances in the CLI. Although there are many substances in the CLI that are not relevant for registration, the number is comparable to the sum of the substances listed in EINECS and ELINCS. That means that the overall number of substances placed on the internal market seems to be more or less stable over the years.
- ECHA's estimation for the 2018-deadline stands with 25.000 substances, but we have approx. 5.000 of those registered so far.
- The REACH White Book estimates 30.000 substances (without considering on-site isolated IM).
- The increase of registration dossiers in 14 selected Member States from 2014 until March 2018 varies between a plus of 7 to 55% with an average of 30%. Such a vast difference on the internal market is unusual and should be observed closer.

Overall, the estimations so far were very accurate. Thatfore we do not see a reason, why we should not expect the estimate for 2018 to be correct. Right now we have a big gap of approx. 20.000 substances. That should be worrying. The DCG has developed solutions for exceptional cases. However, those cases in 2010 and 2013 were relatively few. We are sceptical that ECHA will be able to handle a significant number of "exceptional" cases apart from all the other workload related to the 2018-deadline and REACH in general.

We are of the opinion that the recent interpretation of the registrations-status is over-optimistic. So is also the communication strategy. In our opinion we should communicate that there is a large discrepancy between the official estimations and the factual situation. This may have legitimate reasons, but it can also become a problem for individual supply-chains. To avoid disruptions, enterprises should:

- approach their suppliers and ask about the registration-status of their substances;
- start stock-piling;
- start preparing an alternative plan (e.g. alternative source or substitutes).

## Classification of TiO2 (AP 13)

We very much support the Slovene and UK proposal to establish a working group on this topic. A technical meeting like envisaged by the Commission in our opinion will not be enough. We are interested to take part in the working group and nominate [redacted]

We suggest that the technical discussions should include also the identification of the proper RMO, means CLP or worker protection legislation. As an outcome we prefer a final solution, which should also reflect the co-responding substance evaluation results.

## Amendment of Annex VI (AP 14)

Considering the ongoing discussions, TiO2 should be deleted from the current draft.

Concerning Cobalt we share the concerns and views of a number of CARACAL-participants and suggest that this substance is deleted from the current draft until the concerns are clearly analysed.

**Implementation of Annex VIII (AP 16)**

Point 4:

We would like to underline the need for a more pragmatic solution related to MIMs. In some areas like for example cement-mixtures we have observed that the current legal requirements will end up in a very large number of different UFIs for comparable mixtures. This leads to unnecessary administration with no added value. To avoid this, it would require a significant need to disclose mixture-recipes. We suggest instead of indicating a single MIM as a mixture component the submitter may identify a group of MIMs that are comparable. Within such a group a single MIM can be exchanged without the need of an update nor the generation of a new UFI. The approach is similar to the biocidial-family-concept in the BPR.

Point 5:

We agree with the interpretation that a re-brander is not a downstream user. “Re-branding” is not legally defined and in our opinion it must be understood as a synonym for “labelling”. Labelling on the other hand is not a “use” of a mixture/substance. A re-brander, however, must be understood as a “supplier” with all the relevant duties, what also includes correct labelling.

MAISON DE L'ECONOMIE EUROPEENNE - RUE JACQUES DE LALAINGSTRAAT 4 - B-1040 BRUXELLES
TEL +32 (0)2 230 75 99 - FAX +32 (0)2 230 78 61 - E-MAIL info@ueapme.com