

## 9.1 Draft Guidance on requirements for substances in Articles (CA/91/2010)

An overview was given by ECHA on the updated version of the Guidance. The aim is to issue the update in December, ideally without the footnote of the dissenting view.

DK, on behalf of MSs with the dissenting view (AT, BE, DE, FR, NO, SE), gave a [presentation](#) of the 0.1% limit value interpretation of candidate list substances in articles: the concept was, in simple terms, 'once an article, always an article'. They believe the original question to COM Legal Services is not any more relevant as it is assumed to be asking about homogenous parts of articles. The MSs having dissenting views have developed their concept and argumentation and they are referring to "articles within articles" and not, as some thought, to homogeneous parts of articles. COM are preparing a request for an opinion on the latest 'dissenting' MS's view of the 0.1% limit for candidate-list substances in articles, but it is very unlikely this will be available for mid November when ECHA would need to finalise the revised guidance so the Executive Director can consult ECHA Management Board (MB). MSs asked for the request to COM Legal Service to be provided to CARACAL, so although COM cannot release complete internal legal service opinions, but will expose all the elements that can be released, they will find out what portion of the question can be released to CARACAL.

There was an extensive discussion. One MS felt great sympathy for the new presented approach without the homogeneous sub-parts of articles from the dissenting MSs and wished this had been addressed in the PEG. They are disappointed that COM did not ask for legal advice earlier. Hence they suggest a road map with the aim of solving the problem without resorting to referral to the MB. Another MS is now more sympathetic with the new dissenting view, but can live with either interpretation so long as it is practical and can be operated by industry and enforced. Their priority is to get agreement for the guidance. They consider the obligations related to imported articles are challenging irrespective of which approach is taken. A further MS is sympathetic to the dissenting view, but had accepted the original COM legal interpretation on the assumption that it was valid, and they are prepared to accept the possible new COM legal interpretation – this was backed by another MS. Yet another MS is sympathetic to the new dissenting view interpretation as they think it would ensure more equal treatment of imported and manufactured articles.

ECHA proposed a way forward. The merits of the revised dissenting view should be further considered from practical point of view and in the case the COM interpretation does not solve the matter it could be clarified in the REACH revision. The guidance will nevertheless be published in December, even without unanimous agreement from MSs as ECHA is committed to publish it well in advance of the June 2010 notification deadline. NL insisted that the letter requesting the legal advice request is provided to CARACAL. COM does not accept that the previous advice is not relevant. COM does not release complete internal legal service opinions, but will expose all the elements that can be released and also what portion of the question can be released to CARACAL.

The discussion on the draft guidance of Substances in Articles continued at the 7th CARACAL meeting in February 2011 when the [Commission's opinion](#) had become available. The record of this discussion will be provided as soon as possible.