

**Opinion of the High Level Group (HLG)**  
**Stakeholder Suggestions (“offline consultation”) – VII**

**Topics relative to the European Chemicals Agency**  
**Replies by the ECHA Secretariat**

8) As mentioned by the European Commission, ECHA is this year undertaking a needs and feasibility assessment on improving the accessibility of ECHA’s communication tools in different languages. This investigation in particular responds to observations related to the unilingual REACH-IT tool by which companies successfully submitted their dossiers for over 20,000 registrations for last year’s first REACH registration deadline, whereby they could extensively rely on Industry User Manuals in all official EU languages that facilitated their task. Work on this assessment is currently ongoing. As an activity under ECHA’s 2011 Work Programme, ECHA’s report will be made available later this year.

9) ECHA shares the HLG’s concern regarding the burden of uncertainty on industry that diverging interpretations of duty holder obligations regarding the notification of substances in articles (0.1% threshold) entails. ECHA has undertaken great efforts to promote a consensus between Member States, but to no avail. ECHA has advocated an interpretation based on the European Commission’s legal opinion in direct contacts with dissenting Member States and has addressed their collective formation (CARACAL) in this regard, too. In 2010, ECHA staff participated in a seminar held by countries with dissenting opinions in Stockholm. In February of this year, ECHA convened a technical workshop to elaborate with relevant stakeholders more clearly the consequences of the various interpretations held by Member States. ECHA twice brought the issue to its Management Board, in the context of issuing an updated ECHA Guidance on Substances in Articles. On 1 April 2011, ECHA published an unambiguous Guidance document which industry should be regarding as helpful.

Essentially, the problem arises from the text of the REACH Regulation (Articles 7 and 33) being open to interpretation, combined with the insistence of numerous EU/EEA Member States on their diverging legal views. It does not originate with ECHA creating administrative or regulatory obstacles. To the contrary, as mentioned above, ECHA has made every effort to resolve the issue. Lastly, a definite legal interpretation of the relevant provision of the REACH Regulation may only be found through the European justice system. For the time being, given the stance of Member States, diverging enforcement practices will provide a continued risk to companies operating on the Internal Market which is then a matter for the European Commission.

10) The HLG rightly addresses this issue partly to the European Commission (Fee Regulation). Actually, REACH duty holders – including SMEs – were largely very satisfied with the support and advice that ECHA (through the ECHA Helpdesk) provided in the course of a Special Service for Registrants and proactive direct contacting by ECHA of companies facing submission problems. In late summer 2010, using its network of national helpdesks (HelpNet), ECHA investigated the preparedness of national helpdesks for the 2010 deadline. Commission Vice-President Tajani and Commissioner Potočnik appealed to Member States to ensure sufficient

national resources in autumn 2010. ECHA provided dedicated hands-on training to national helpdesk staff in understanding ECHA processes and relevant IT tools, and continues to do so. The ECHA Helpdesk and the HelpNet are already gearing up for the 2013 deadline.

ECHA is participating in coordinated efforts with stakeholders (European Commission and industry associations) to define recommendations to and support measures for SMEs, drawing on lessons learned from the way industry addressed its REACH and CLP obligations ahead of the 2010 deadline. Even if, strictly speaking, ECHA has no legal obligation to do this (the burden is on industry), ECHA sees this effort as part of its responsibility to make REACH a success and also as part of its corporate value of being a trustworthy partner.

ECHA is furthermore helping SMEs in fulfilling their tasks by making a wide scope of key documents accessible in 22 official EU languages, by providing simplified guidance documents (Guidance in a nutshell, Practical Guides, User Manuals) in the same set of languages, by participating in SME-targeted national events and by coordinating its activities with the European Commission, Member States' Competent Authorities and industry associations.

Based on advice given and their own initiative, SMEs can find various means to optimise their efforts, not least by preparing their registration work early. In the case of joint submissions for registration or a joint application for an authorisation they can share the costs of their data-collecting and reporting work, in addition to the fee reductions from which they profit as an SME.

Whilst the stakeholder observation regarding the extension of the 2010 REACH registration deadline seems obsolete, ECHA does not see any instance that would have justified a stakeholder comment that it would have presented registration tools with delay. To the contrary, the successful registration of submissions for the first REACH registration deadline of 30 November 2010 proved that ECHA had provided all means necessary for this purpose.

**11)** ECHA also recognises the benefits and need of streamlining the implementation of REACH with related EU legislation. As a start-up Agency, ECHA has so far given priority to meeting its initial legal deadlines and to setting up its operations. It has focused on designing and making available to industry the various processes beyond registration (i.e., evaluation, authorisation, the CLP inventory, dissemination, etc.) in which companies and other stakeholders interact with ECHA. As the Agency matures and accumulates detailed experience in the application of REACH and CLP, it is incrementally being put into a position that will enable it to suggest such streamlining to the European Commission and other relevant actors. ECHA is already following such borderline legislation with a view to alerting the European Commission, for instance the Directive on Restriction of Hazardous Substances legislation. Ultimately, any alignment of legislation needs to be left to the Commission's right of initiative and to action taken by the European legislator.

**12)** ECHA notes that the HLG has appropriately addressed its recommendation regarding the review of REACH to the European Commission.

**13)** ECHA shares the HLG's desire for harmonised enforcement. As the implementation of the new REACH and CLP regulatory system progresses, enforcement is deservedly getting more prominent attention. Given the national competence for enforcement and related secondary (implementation) legislation as well as the fact that practical approaches are still being continuously developed to implement REACH and CLP in real life, finding the right enforcement path to identified issues will always face an inherent time-lag. Harmonising enforcement practices of the 30 countries that apply REACH and CLP needs to be seen as a mid- and long-term challenge; it will take time.

ECHA's Forum (on the Exchange of Information on Enforcement) has already harvested initial successes and is currently pursuing numerous important projects (setting minimal requirements for inspection as well as developing strategies for enforcement, implementing so far two joint enforcement projects; identifying in detail the interlinks between ECHA and national authorities required to make REACH and CLP work on the ground; training programmes for inspectors and other trainees with a view of arriving at a common understanding of certain aspects of the REACH and CLP Regulations etc.). Furthermore, next month, ECHA will make operational the RIPE (REACH Information Portal for Enforcement) IT tool which will enable inspectors to have secure access to enforcement-relevant substance and company-specific information held in ECHA's databases.

Within the Agency, ECHA's management has strengthened the staff numbers of the Forum Secretariat. ECHA's reorganisation of January 2011 also allows more corporate management support to be given to the Forum. This increase of personnel resources reflects ECHA's recognition of the importance of harmonised enforcement as a core element of REACH implementation.

The HLG has, in ECHA's view, appropriately addressed its recommendation regarding ex-post evaluation to the European Commission.