

European Parliament REACH Hearing Breaks New Ground

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On 19 January, the European Parliament launched the first phase of its legislative review of the Commission's REACH proposal with a full-day public Hearing. The Hearing was organized jointly by the three Committees¹ sharing responsibility for formulating the Parliament's opinion. The Hearing drew one of the largest audiences ever attracted by such an event at the Parliament, including presentations from the past Dutch and current Luxembourg Presidencies of the Council, the Enterprise and Environment Commissioners and responsible services of the European Commission, a range of industry representatives, environment/health NGOs and various other experts. The turnout confirmed REACH as one of the most important legislative initiatives undertaken by the EU. From the perspective of an observer at numerous Parliament Hearings over the years, this Hearing also was notable because the debate was highly substantive, testifying to an underlying current of commitment to making REACH a reality. The hearing also revealed that the current proposal is likely to undergo important amendments before finally being considered for joint adoption by the Council and Parliament.

There are several developments to highlight.

Prospect of Amendments to Avoid Undue Impacts on Industry

European Commissioner Verheugen (Enterprise, Competitiveness) personally confirmed that the Commission is open to making changes in REACH, will take full account of impact assessments and related studies that are still being carried out (principally those focusing on industry costs and impacts on competition to be concluded over the next few months) and will introduce appropriate amendments to the current proposal. Both Commissioner Verheugen and Environment Commissioner Dimas emphasized the importance of further studies and the need to understand the real burdens that would be placed by the current proposal on industry, particularly on small and medium-sized enterprises (SMEs). They pledged to developing appropriate solutions while still maintaining the proposal's environmental and health objectives. Commissioner Verheugen, however, suggested a greater need for amendments than did Commissioner Dimas.

The Commission's views on openness to changes were largely supported by the representatives of the Luxembourg Presidency, who intend to put the theory of "better regulation" into practice. The representatives confirmed that the Presidency would organize a stakeholders Workshop this May and welcome "practical" proposals to make REACH more workable (real improvements) without imposing undue costs. They appealed for "creative" proposals to this end. We would note that the Presidency is fully open to consideration of "alternative proposals" on key issues (see analysis of REACH's unresolved issues in "[Excessive Costs or Crying Wolf](#)" in this issue of *Chemical Regulation Alert*) and openly mentioned at the Hearing, as did the Commission, the prospect of introducing, at least in part, the "one substance one registration" ([OSOR](#)) proposal of the U.K./Hungary.

Interestingly, Parliamentary reaction to these comments was one of initial surprise followed by some alarm. Some Members of the European Parliament ("MEPs") directly questioned Commission representatives why its Committees should spend time studying the current

¹ Committee for the Environment, Public Health and Food Safety; Committee on Industry, Research and Energy; Committee on Internal Market and Consumer Protection.

proposal over the next months if the Commission was already intending to introduce major changes. MEPs also asked whether the Commission was intending to draft the amendments itself (with the knowledge that changes in one chapter could require a number of related amendments in other chapters and in the annexes) or if the Commission would rely on the Parliament to draft the changes. The Commission responded carefully (!), indicating that it would introduce amendments to its proposal in the normal legislative sequence, i.e. following the Parliament's first reading and taking account of the Parliament's requests for amendments. While this position does not undercut Parliament's right to propose amendments, neither does it preclude the possibility of the Commission formally tabling amendments not addressed by the Parliament.

Key Substantive Issues

Apart from the standard disputing of views on the cost impact of REACH, there was a good, substantive exchange of opinions regarding how REACH's impact on industry might be lessened while still fulfilling its high environmental and health objectives. Several substantive questions areas were addressed.

Is REACH duplicating vertical legislation?

Commissioner Verheugen confirmed that the operative principle for REACH is "no duplication." If there is duplication with vertical legislation that adequately regulates the product (question raised by a MEP concerned the EU cosmetics legislation), then this is a basis for amending the REACH proposal.

Is a volume-based approach alone the most effective approach for registration requirements? Should the EU give priority to risk assessment?

Commissioner Verheugen indicated that there is "broad consensus" that the substances of greatest risk should be assessed first. A representative of SME chemical suppliers confirmed that a volume-only approach is wrong and would not be bearable for SMEs - volume bands must be combined with prioritization-based on risk assessment (see also CEFIC's alternative proposal). A retailer panellist, responding to a question whether Article 6 (registration / notification of substances released from articles) is workable, suggested that it is not and should be restricted to only priority chemicals. The Volvo representative confirmed the need to restrict Article 6 to only a very few, hazardous substances (the RoHS Directive was mentioned several times as an appropriate model).

How to protect proprietary data, share other data and also share consortia costs ?

Through much of the day there were repeated references to data confidentiality issues, often in the context of questions on the OSOR proposal. Reflecting on the comments registered at the hearing, from the institutions and industry alike, there appeared to develop a general appreciation that OSOR will eventually become part of REACH, bringing about a substantial sharing of data beyond animal tests and a consequent reduction of registration costs. However, the details of the data sharing arrangement still need to be worked out carefully. One role of OSOR that was presented involved using the proposal as a means to help protect SMEs [SMEs, comprising a major segment of the chemicals industry, were frequently cited as on an "endangered list" due to REACH costs], enabling them to join consortia and share data with larger registrants whereas they could be squeezed out of purely voluntary registration consortia. On the other hand, broad support for OSOR was conditioned on the possibility of

an opt-out when properly justified, allowing for individual submission of proprietary data (considered to include specific/detailed use data).

To the extent that data is shared or submitted on behalf of other companies, compensation systems are clearly a major issue of concern. Indeed the issue of data compensation was cited by Commissioner Dimas as one of the current workability problems with OSOR. He noted that the current proposal would rely on cost sharing guidelines to be provided by industry, but that, so far, the industry guidelines do not yet exist. The U.K. environmental agency (DEFRA) representative, explaining OSOR and the complications of cost-sharing (noting that different companies have different volumes, different available data, etc.), indicated that the OSOR proposal provides provisionally for an ombudsman to resolve cost disputes but confirmed that industry guidelines are needed and that there are also other ways to deal with disputes.

Conclusions

The Parliament's Hearing significantly advanced an understanding of the EU institutions' collective planning concerning REACH. While the Luxembourg Presidency had earlier outlined its work plan, the new components from the Commission and Parliament help complete a picture that is largely positive and progressive. For industry, the Hearing confirmed for many participants that the institutions, notably including the Commission which has until now been very protective of its original proposal, are very open to consideration of specific amendments that will improve the workability of REACH. Thus, the hearing made it abundantly clear that REACH will not go away, but with real work and - as the Luxembourg Presidency put it - creativity, it can still be amended in important ways so as to enhance all three pillars of sustainability, including economic.