

## Preparing for REACH: The Interim Strategy

The European Commission and the European Chemicals Bureau ("ECB") Working Groups are currently working on preparing a plan of action for the so-called "*interim period*" before the new chemicals legislation (REACH) will enter into effect. The interim period would run from November 2003 to March 2006 (forecast date for entry into force of the REACH Regulation). The "*transition period*," during which REACH would be fully implemented, would run from March 2006 to October 2007.

During this interim period, the classification and labeling activities on new and existing substances for inclusion in Annex I to Directive 67/548/EEC will continue, however, using streamlined procedures and formats, which could, according to the European Commission, be easily transferred into REACH. For this purpose, the ECB is already identifying potential substances for the 30th Adaptation to Technical Progress ("ATP") to Directive 67/548/EEC. (The status of the upcoming 29th ATP remains unclear; the draft 29th ATP may be presented to the Technical Progress Committee (TPC) in the coming weeks.)

According to the 2004 Work - Plan,<sup>1</sup> the classification and labeling in 2004 will proceed as follows:

- Classification and labeling activities should concentrate on processing the substance dossiers which would "*significantly induce additional EU risk management*" for so-called "*HEROs*" - *High Expected Regulatory Outcome substances*);
- The following procedure will be applicable to existing and new substances:
  - Member State's (MS) proposal is submitted to the ECB and distributed to Technical Committee (TC) participants for comments;
  - TC/ECB decides if the dossier is sufficiently developed to assure efficient discussions;
  - Comments are sent to MS, copy to ECB;
  - MS adapts its proposal and sends it back to the ECB;
  - ECB places MS proposal on the agenda of the TC "*if the adoption of the proposal will contribute to significant additional risk management*";
  - After discussion in the TC, ECB coordinates obtaining an agreement on the MS proposal;
  - Recommendation is forwarded to the European Commission's Environment Directorate General "*appropriate follow-up*". (Although not

### ■ Contact Info

If you would like more information, please contact any McKenna Long & Aldridge attorney. You may also contact our Brussels attorneys or [brussels@mckennalong.com](mailto:brussels@mckennalong.com):

**Koen Van Maldegem**  
32.2.278.1215

**Robert Matthews**  
202.496.7737 or  
32.2.278.1225

**Ursula Schliessner**  
32.2.278.1224

**Claudio Mereu**  
32.2.278.1265

**Ruxandra Cana**  
32.2.278.1263

*\*Dial the prefix "011" from North America; dial "00" from European countries outside of Belgium.*

specifically indicated in the ECB working document, we assume that the "appropriate follow-up" includes inter-service consultation within the European Commission, presentation of a final proposed ATP to the Technical Progress Committee composed of Member States representatives ("TPC"), voting within the TPC and publication in the Official Journal.)

- Assessment of new information:
  - New information submitted prior to the deadline for final discussion is sent to the MS that prepared the initial proposal, for its own assessment; it will include it in the proposal if deemed appropriate;
  - New information submitted after the deadline is assessed by the MS who submitted the initial proposal, and only brought to the TC if it believes that "new information would likely change the conclusion of the TC".
- For contentious carcinogenic, mutagenic and toxic for reproduction ("CMR") cases: the written round in the TC should, as a standard, consider the need to consult the specialized experts.
- Pesticides and biocides: only those where a harmonized classification gives rise to "significant additional risk management (i.e., beyond Directives 91/414/EEC and 98/8/EEC respectively)" should be processed (such as those that are potentially CMRs or those whose intrinsic properties are of concern and have a use pattern that goes beyond the strict pesticide use); all others should no longer receive a harmonized classification.
- Finally, the classification and labeling of existing substances without CMR concern in cases not leading to considerable risk reduction management should be discontinued (there is no clear indication on what would constitute "considerable risk reduction on management measures").

This interim period plan will be discussed at the ECB CMR Working Group meeting of 18-19 February. If agreed upon, it will be decisive for substances already identified or in the course of being identified for the 29th<sup>2</sup> and 30th ATP (no draft of the 30th ATP is yet available).

[↗Back to top](#)

## Endnotes

1. Ref.: JM/43/2003, ECB Agenda for Commission Working Group on the Classification and Labelling of Dangerous Substances Health Working Group, 18-19 February 2004.

2. Provisional List of Substances for 29th ATP (Revision 18), dated 8 August 2003 and Provisional List of Notified New Substances Proposed for Publication in the 29th ATP (Revision VIII), dated 31 October 2003.

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