

REACH: the start is near...

By Andrew Fasey

'Agreement' REACHed:

The REACH text was informally 'agreed' at a 'trialogue' meeting (Government of Finland as the Presidency of the EU, the European Parliament (EP) and the European Commission) on Thursday 30 November. The 'agreement' reached was endorsed at a COREPER meeting (the meeting of the 'Ambassadors' to the EU from all the Member States) on 5 December.

Next Steps:

1. The legal-linguistic experts in Parliament and Council are currently working on all 20 EU language versions of the text to be adopted;
2. A consolidated version of REACH, with the agreed amendments, will be made available to EU governments in all languages on 8 December 2006 with a request for any comments by 11 December;
3. The European Parliament is expected to vote in Plenary on the 'agreement' on 13 December (all political groups have reservations about the agreement but are expected to support it; a 'classical' compromise. The rapporteur, Guido Sacconi (Italy, PES) has the backing of the shadow rapporteurs from the EPP and ALDE groups (Ria Oomen-Ruijten, Netherlands and Chris Davies, UK). They are expected to persuade their respective groups to support the compromise before the plenary vote on 13 December);



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5. Provided that the EP votes in favour (text must fully correspond to the 'agreement'), COREPER will consider again on 13 December in preparation for final adoption by the Council;
6. The Council is expected to adopt the text at the Environment Council on 18 December;
7. After the Council's adoption, the Regulation will be signed by the Presidents of the Council and of the European Parliament. This will be followed by transmission of the texts to the Publication Office in order to have the text published in the Official Journal before the end of the year.
8. **REACH to enter into force on 1 June 2007.**
9. **Pre-registration deadline 1 December 2008.**
10. **First Registration deadline 1 December 2010.**

What was the basis of the 'agreement'?

Compromises were found on the registration and confidentiality of data, with slightly longer registration periods for higher tonnages (first Registration deadline 3 ½ years after REACH enters into force) and some extensions to the period over which confidential information is protected (12 years for studies, some information protected for 6 years rather than 3). There was agreement not to extend the requirements for smaller tonnages (i.e. a chemical safety assessment (CSA) is still not required for 1 – 10t Registrations and the information requirements remain unchanged). The 'agreement' includes a number of review clauses which could result in recommendations for change in the future; e.g. CSAs for 1 – 10t to be reviewed after 7 years, methods for reproductive toxicity testing to be reviewed after 12 years, and after 6 years whether endocrine disruptors should be added to the group of substances of very high concern for which the adequate control route is not available for the granting of an



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authorisation. The principle of a 'duty of care' is explained and clarified in the recitals without specific requirements being placed on duty holders.

The most problematic area has always been on the authorisation and substitution of substances of very high concern. The 'agreement' makes an authorisation potentially harder to get for substances with certain dangerous properties but does not require mandatory substitution. The possibility for an authorisation on the basis of adequate control is maintained although the scope is not quite as wide as in the Common Position text. An application for authorisation should be accompanied by an analysis of alternative substances - if alternatives are available companies would need to consider how they would move towards them in a substitution plan. If there are no suitable alternatives, companies should make a research and development plan to develop or identify suitable alternatives. If adequate control cannot be demonstrated and no suitable alternatives exist, an authorisation can be granted if the applicant demonstrates that the socio and economic benefits of the use (per substance) are higher than the risks.

The Changes in Detail (N.B. this is not necessarily a definitive and exhaustive list):

The main elements of the compromise package are:

1. A recital on **Duty of care** putting emphasis on industry's "*care*" and "*responsibility*"; no specific new duties;
2. The **promotion of alternative test methods** and their development is emphasised through a detailed European Commission Statement on activities and intentions in this area;
3. The text of the Common Position on the **communication of information** as regards the obligations of a manufacturer, importer or downstream user to complete the chemicals safety report (CSR) for uses identified by the downstream user has been retained despite this being raised strongly by the EP;

4. **Comitology** (the EU rules for taking decisions):

- The publication on the Agency's website of the "*candidate list*" of substances subject to authorisation as set-out in the Common Position has been retained, largely for reasons of practicability;
- When the Commission takes a decision on a draft authorisation the procedure to be followed shall be the (normal) "*regulatory procedure*";
- Concerning qualifications required of members of the Board of Appeal as well as operating procedures of the Board, the procedure to be followed shall be the (normal) "*regulatory procedure*";

5. **European Chemicals Agency:**

- The EP will appoint two independent persons to the Management Board of the Agency;
- The selected candidate for Executive Director of the Agency shall be invited to make a statement before the EP prior to their appointment;

6. **Registration/data-sharing:**

- seven years after the entry into force of REACH, the Commission shall review whether or not CMR (carcinogens, mutagens and reproductive toxicants) substances in the 1-10 tonnes band should be covered by the requirement for a Chemical Safety Assessment (CSA);
- the approach to test methods for reproductive toxicity (Annex VIII, point 8.7), as set-out in the Common Position, has been retained. However, the Commission shall review these testing requirements twelve years after the entry into force of REACH.

7. **Authorisation/substitution:**

- PBT and vPvB substances identified under Article 56(f) have been excluded from the "*adequate control route*" (Article 59.3) of authorisation (i.e. whilst they should not have been able to go through this route anyway this is now made explicit). Six years after the entry into force of REACH, the Commission shall



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review whether or not to extend this exclusion to substances with endocrine disrupting properties (N.B. if a threshold cannot be established for endocrine disruptors they could not follow this route anyway).

- When suitable alternatives are available, taking into account certain elements, a substitution plan shall be a mandatory part of an application for both the "*adequate control*" route and for the "*socio-economic*" route for authorisation;
- The recital (64 in the CP) on methodologies to establish thresholds for CMR substances has been modified slightly with a view to underlining the protection of the environment and human health.

8. **Intellectual property rights** and other issues:

- studies shall be freely available after 12 years rather than 10;
- electronic public access to information, the name in the IUPAC Nomenclature for non-phase-in substances which are dangerous (as defined by Directive 67/548/EEC) may, if justified, be exempted from the requirement to make information available to the public, for a period of six years.

