Key Points of the Compromise on Registration of Substances (REACH)
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- **Uniform Pre-registration for all substances above 1 t per year after 18 months with at least the following information:**
  - Name and address of the producer
  - Substance name and CAS number (if available)
  - Indication of the existence of own animal test studies
  - First indication of the presumable supported uses respectively as a minimum use and exposure categories

- **Deadlines for Registration**
  - The Registration deadlines remain as proposed by the Commission (3, 6 and 11 years)
  - In addition those substances that fulfil the criteria for long term negative effects in the aquatic environment (R50/53) have to be registered earlier: above 100t/a after 3 years respectively above 1t/a after 6 years

- **Data requirements:**
  - **1 to 10 tonnes per year**
  - Within 11 years physical / chemical data following Annex V as well as any available and for the risk assessment relevant information
  - If risk based screening criteria (i.e. exposure of consumers or professional users) following Annex I c are fulfilled, all data concerning Annex V have to be provided for registration
  - If existing data or the QSRA give reason to the effect that the substance could a CMR or PBT substance, a chemical safety report and a chemical safety assessment have to be provided
  - **Annex V:** in relation to the Commission Proposal the annex is modified by adding the actual toxicity (an intake route) and the ready biodegradability

  - **10 to 100 tonnes per year**
  - Within 11 years certain information following Annex VI have to be provided
  - Annex VI is modified in relation to the Commission Proposal as follows
  - The screening test for the reproduction of the toxicity (test 6.7.1.) is deleted (cost reduction approx. 50.000,- €)
  - The test for the development of the toxicity (test 6.7.2.) is moved to Annex VII (cost reduction approx. 70.000 €)
  - On the basis of exposure oriented criteria (i.e. limitation of the exposure or the risks by risk management measures) the following studies may not be necessary
  - Study for the mutagenicity (tests 6.4.2. and 6.4.3.; cost reduction approx. 15.000,- € respectively 20.000,- €)
  - 28 days test (test 6.6.1., cost reduction approx. 50.000,- €)

- **Waving:**
  - Waving will be possible not only for Annex VII and VIII but as described above for selected studies. Cut-off limits (IMCO, ITRE, COM "Roompaper") are deleted now.

- **Data sharing, "One substance - one registration" - OSOR**
  - The principles of mandatory data sharing and OSOR remain. Yet simple opt-out criteria for certain data or whole data packages are part of the compromise:
  - The costs for data sharing or forming of consortia are not proportional
  - The information are confidential and data sharing would imply economic losses
  - The data are not "transferable" (i.e. different level of contamination)
  - A registrant would like to register early than his competitors
  - (Animal tests may not be repeated (no change to the proposal))

- **Use and exposure categories**
  - Together with the exposure scenario, the respective use and exposure categories have to be defined in the safety data sheet and are therefore elements of communication in the production chain

- **Definition of phase-in substances**
  - All EINECS substances have the phase-in status. The 15 years deadline and the respective evidence has been deleted

- **Good laboratory practice (GLP)**
  - The complex and expensive GLP requirements are only necessary for new vertebral animal tests and not as initially proposed by the Commission for all new tests.

- **Data Protection**
  - The data protection for all studies is set at 15 years rather than 10 years as initially proposed by the Commission.

- **Substances in research and development (PPORD)**
  - Substances in research and development are exempted from registration for 15 years rather than 10 years as initially proposed.

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