Resolution on the draft Commission Regulation laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

2008/2577(RSP) - 22/05/2008 - Text adopted by Parliament, topical subjects

Following the debate which took place during the sitting of 21 May 2008, the European Parliament adopted, by 508 votes to 6 with 8 abstentions, a resolution on the draft Commission Regulation laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). The resolution had been tabled for consideration in plenary by the Committee on the Environment, Public Health and Food Safety.

The draft Commission Regulation is also of particular importance for legislation on other sectors, such as cosmetics and pesticides, since the acts relating to them refer to test methods included in chemicals legislation, Parliament examines the rules on testing on animals and points out that the European Centre for the Validation of Alternative Methods (ECVAM) **validated a number of alternative methods to animal testing** in 2006/2007 which are, however, not included in the draft Commission Regulation. Furthermore, the draft Commission Regulation contains one animal testing method which is obsolete, as the same draft Regulation also contains an alternative method for the same endpoint. The Commission justifies the non-inclusion of the validated alternative tests by stating that the tests have not yet been approved for regulatory purposes. It defers to the OECD with regard to the regulatory acceptance procedure for three of the five tests. Parliament points out that the development and publication of an OECD Test Guideline generally takes a minimum of 3 years. The Commission has made it clear that it always tries to proceed first **within the OECD framework**. Parliament states that this is **contrary to EU legislation** and the spirit of the cosmetics directive, which gives priority to the EU process.

It goes on to point out that there do not seem to be sufficient rules for an efficient preliminary analysis of regulatory relevance before ECVAM scientifically validates an alternative test. Furthermore, the basic concepts of validation and legal acceptance are not used in a uniform manner at national, Community and international level and EU legislation does not provide any definition of 'validation' (or criteria for validators) or 'regulatory (or legal) acceptance. Members feel that the conditions by which potentially far-reaching decisions under this procedure, such as questioning scientific validation by ECVAM or transferring validation and regulatory acceptance to the OECD level, should be decided case by case in a transparent and accountable manner at political level. It is not acceptable that timely inclusion of new validated alternative methods by ECVAM in the draft Commission Proposal is not yet possible due to delays brought about by the opaque, slow, cumbersome and partly inappropriate procedures for the regulatory acceptance of validated alternative methods to animal testing. On a general point, the problems identified in the area of chemicals legislation concerning validation and regulatory acceptance of alternative test methods might even have a larger dimension when other industrial sectors are taken into account.

In view of these considerations, Parliament refrains from opposing the adoption of the draft Commission Regulation laying down test methods pursuant to Regulation (EC) No 1907/2006 on REACH in the light of the formal commitment received from the Commission in its letter of 5 May 2008 to make the following arrangements to streamline and speed up the Commission's internal procedures for the validation and regulatory acceptance of new alternative test methods:

-the Commission will introduce a 'preliminary analysis of regulatory relevance' in all cases to ensure that subsequent scientific validation focuses on test methods that have the best potential to be considered suitable for clearly identified regulatory purposes;

-it will reduce the number of steps and establish new deadlines to accelerate the current process, insofar as the role of advisory committees and consultation with Member States is concerned;

-all important procedural decisions to be taken by the Commission will be taken at Director-General level;

-the current reorganisation of the JRC Institute for Health and Consumer Protection (IHCP) will make an important contribution to accelerating the on-going efforts to advance alternative methods, including their validation, via the European Centre for Validation of Alternative Methods (ECVAM). This will involve reinforcement of ECVAM's work through support by other IHCP teams. The IHCP is also developing an integrated testing strategy which will leverage the synergies of many complementary activities within the IHCP and allow a more holistic and effective approach to the question of risk assessment;

-the revised process will be more transparent. The procedures for regulatory acceptance of new test methods will be published on the Commission's website once the current review is formalised. The current status of proposed alternative methods will be posted on a website to be set up by the JRC allowing interested parties to track progress. The information will be regularly updated. The website will also include an indication of decisions not to proceed with a particular test method and the reasons why such decisions are taken;

-in line with the REACH Regulation, the Commission will provide for a more transparent process involving consultation of stakeholders in the run-up to any proposal for an Adaptation to Technical Progress of the Test Methods Regulation;

-the Commission will make the necessary resources available to ensure that these result in real improvements, in particular by inviting applications from qualified staff with the relevant expertise to be seconded to the OECD Test Guidelines Programme (TGP) in the near future. It will look into possibilities of providing financial support to the OECD TGP Secretariat, concentrating specifically on regulatory acceptance of alternative test methods;

-the Commission will monitor the OECD process closely in each individual case to make sure that following this route does not entail undue delays. This will include systematic stocktaking of the progress of each alternative method at regular intervals. Any unreasonable delays in relation to a particular method will result in the Commission launching the EU process for regulatory approval for the method in question.

The Commission is asked to report to Parliament by the end of 2008 on the implementation of these commitments. Parliament states that it understands that the streamlining and acceleration of the internal procedures apply to the entire process from validation to regulatory acceptance with no gaps. It calls on the Commission to ensure full stakeholder participation throughout the process from validation to regulatory approval.

Lastly, the Commission is urged to come forward with a proposal for the first adaptation to technical progress of this Regulation by the end of 2008 as the litmus test for the implementation of the above commitments.