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*Vice-President of the European Commission
Enterprise and Industry*

JANEZ POTOČNIK
*Member of the European Commission
Science and Research*

STAVROS DIMAS
*Member of the European Commission
Environment*

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Dear Chairman,

Vice-President Verheugen, Commissioner Potočnik and myself have followed closely the debates in your Committee with regard to the draft Commission Regulation laying down test methods pursuant to Regulation 1907/2006 (REACH). This letter represents our shared views on the issues raised at this occasion and is therefore, and because of the particular urgency of this matter, also sent on their behalf.

We share the Parliament's concern that the limited number of valid alternative tests that are available so far is disappointing, that further research and scientific progress are necessary, and that greater focus is needed to achieve more rapid results.

The debates that have taken place, together with an informal exchange of views between representatives of the Commission Services and the Parliament's Environment Committee rapporteur Mr. Sacconi on 23 April, have allowed us to better understand the particular elements of concern on the Parliament's side as regards the EU's procedures for approving alternative test methods. In this regard we would like to restate the Commission's full commitment to fostering the development and use of alternatives to animal testing and to provide for procedures that would allow the use of alternative test methods within the shortest possible deadlines.

Accordingly, following an extensive review of current procedures, which has included discussions with Member States and with representatives of the OECD, we have decided to put into effect new streamlined procedures which we believe constitute a substantive response to the concerns of the Parliament. This letter is to provide the necessary confirmation of the arrangements to streamline and speed up the Commission's internal procedures for the validation and regulatory acceptance of new alternative test methods where available. Transparency throughout the procedures is a key feature of these proposals.

The key changes, set out in more detail in the Annex, to this letter are as follows.

- 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.

Mr Miroslav Ouzký
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- we will reduce the number of steps and establish new and clear deadlines to streamline and accelerate the current process, insofar as the role of advisory committees and consultation with Member States is concerned.
- all important procedural decisions where they are to be taken by the Commission services, 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, which is central to the regulatory process, thus avoiding unnecessary internal transmission delays. The integrated testing team will, in 2009, consist of about 85 staff members (including the present 62 ECVAM staff members). As part of its contribution to streamlining the process from scientific validation to regulatory acceptance, IHCP will ensure close and consistent follow up of the regulatory acceptance process both within the Commission and at the level of the OECD.
- the revised process will be more transparent. More specifically the current status of proposed alternative methods will be posted on a specific website to be set up by the JRC allowing interested parties to track the state of progress; the information will be regularly updated. This will happen from the moment any proposed new alternative method undergoes a preliminary regulatory analysis. 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.

The new procedures will be kept under continual review with a view to identifying and introducing any further improvements that may be necessary.

A number of questions have been raised within the ENVI Committee about the risk of serious delays arising from the Commission's traditional practice of submitting new test methods to the OECD process in the first instance. This is an approach that has been followed for good reason and is one which Member States and industry strongly support. The considerations that underpin this approach are, from a) the policy perspective, that the OECD is the essential forum for international cooperation on chemicals, within which the EU is an active player and as such has the opportunity of influencing global policy developments and b) at the practical level, data generated by OECD Test Guidelines are accepted worldwide, thus avoiding double testing and saving animals and resources.

We are, therefore, convinced that the solution is not to abandon the OECD process, but rather to make it work more efficiently. Our services have recently discussed with the Secretariat practical ways in which the OECD can make the approval of alternative methods a key priority. In response, the OECD has indicated a willingness to improve the speed and transparency of its process and will put forward practical proposals to its members to that effect over the coming months.

The Commission for its part 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 detached to the OECD Test Guidelines Programme (TGP) in the near future. We are also looking into possibilities of providing financial support to the OECD TGP Secretariat, concentrating specifically on regulatory acceptance of alternative test methods.

In addition we 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 stock-taking 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 above reflects the Commission's commitment to making accepted alternative test methods available for REACH and for other regulatory purposes as quickly as possible. To conclude, we wish to stress the importance of a timely adoption of the draft Commission Regulation on test methods, which is essential for the effective operation of both the REACH Regulation and other important sectoral legislation.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Stavros Dimas', is written in a cursive style.

Stavros DIMAS

Annex to letter on test methods

1. Preliminary Regulatory Analysis

Systematic preliminary regulatory analysis will take place before a specific test method undergoes scientific validation. Such analysis will become part of the process for all new tests methods before scientific validation begins. This will allow us to focus on those methods that have more potential to have a real impact on the reduction of animal testing.

In relation to the preliminary regulatory analysis, under the activities of the European Partnership on Alternative Approaches to Animal Testing (EPAA), the Commission is hosting a Workshop in May on the subject of overcoming barriers to validation. As one of the items on the agenda, a group of experts, including a number of stakeholders, are invited to find practical solutions for an early and dynamic regulatory involvement. It is important that this "pre-screening" allows the necessary input from all sectors of potential end-users of the method, while at the same time ensuring that its implementation will not create a new, additional bottleneck but rather speed up the overall process.

The Commission will take account of the results of this Workshop in putting in place the mechanism for the practical implementation of this element of the process as soon as is practicably possible.

2. Proposed Streamlined Procedure for Approval of Alternative Test Methods for Regulatory Purposes

Stage 1 Launch of process

The EU test guidelines Coordinator (within JRC) sends the complete set of documentation concerning a new scientifically validated alternative test method, including a test protocol, to the Member States' National Coordinators by e-mail, giving them a deadline of **two months** within which to provide comments and give their positions *[the NCs need to send the documentation to their networks of experts, then gather and summarise comments and possibly organise a meeting to agree on a position]*.

At the same time, the EU Coordinator sends the documentation to ECHA and to other Commission services as appropriate, which may provide comments within the same time frame.



Stage 2

The EU Coordinator (1) compiles and summarises all the comments (2) makes the necessary changes to the draft test method guideline; and (3) prepares a recommendation on whether to move forward with the test method guideline. This step should be completed within **three weeks**. In cases where further information is required, a further deadline shall be set on an ad-hoc basis, depending on the complexity of the issues. If there is a risk of undue delay, a meeting of the National Coordinators may be arranged to discuss difficult issues.



Stage 3

As soon as the consultation with the National Coordinators is completed, the EU Coordinator forwards the recommendation to DG ENV. DG ENV seeks the advice of the Member States' Competent Authorities by means of a "silent consent" written procedure, with a deadline of **two weeks**. It also ensures that stakeholders are consulted.



Stage 4

DG ENV includes the draft test method guideline (as provided by the EU Coordinator) in a proposed adaptation to technical progress of the Test Methods Regulation. The proposed measure goes through Inter Service consultation and is translated in all required languages. This part of the process should take from **six to eight weeks**. The proposed measure then goes through the regulatory procedure with scrutiny.

3. Transparency

Several documents will be published on the Commission's web site:

- The revised procedures for regulatory acceptance of new test methods, once the current review is finalised.
- The status of all alternative test methods going through the process. This will cover the status of a method from the moment it undergoes a preliminary regulatory analysis, through the various stages, to the moment of inclusion in the Test Methods Regulation. This information will be updated on a regular basis
- Information on individual test methods. This will include decisions not to proceed with adoption of a test method, following scientific validation of that method.

As stated above, stakeholders are involved in the EPAA initiative designed to find practical solutions for an early and dynamic preliminary regulatory analysis.

In addition, stakeholders have the opportunity to intervene, as observers, in Competent Authorities' meetings and in Committees of the European Chemicals Agency (for industrial chemicals) when matters relating to validation of non animal tests are concerned..

Furthermore, in line with Article 13(2) of the REACH Regulation, we 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.