In conclusion, no report was overdue on the date of the Commission reply to the written question by the Honourable Member as far as air quality and waste are concerned. The most important reports were received for water-related issues.

(1) OJ L 229, 30.8.1980.
(2) OJ L 378, 31.12.1982.
(3) OJ L 87, 27.3.1985.
(4) OJ L 213, 22.8.1996.
(5) OJ L 296, 21.11.1996.
(6) OJ L 163, 29.6.1999.
(7) OJ L 319, 4.12.2001.
(8) OJ L 365, 31.12.1994.
(9) OJ L 67, 7.3.1998.
(10) OJ L 194, 25.7.1975.
(11) OJ L 78, 26.3.1991.
(12) OJ L 377, 31.12.1991.
(13) OJ L 194, 25.7.1975, as amended by Directive 87/101/EEC of 22 December 1986, OJ L 42, 12.2.1987.
(14) OJ L 181, 4.7.1986.
(15) OJ L 365, 31.12.1994.
(16) OJ L 129, 18.5.1976.
(17) OJ L 229, 30.8.1980.
(18) OJ L 31, 5.2.1976.
(19) OJ L 330, 5.12.1998.
(20) OJ L 327, 22.12.2000.

(2003/C 268 E/092)

## WRITTEN QUESTION E-0316/03

### by Chris Davies (ELDR) to the Commission

*(10 February 2003)*

*Subject:* Validation studies of non-animal tests

In July 2002, ECVAM (1) identified the 13 non-animal tests listed below as being technically ready to complete prevalidation or validation studies by 2003:

— Human skin reconstructed skin model;

— Skin-integrity function test;

— Eye irritation QSAR or ESR;

— Acute systemic toxicity QSAR/DEREK;

— Biokinetics in vitro screens for metabolism;

— Biokinetics human liver cell sandwich culture;

— Target organ/system toxicity (neurotoxicity) 3D brain cell cultures and neuroblastoma cell line;

— Target organ/neurotocicity Glial and neuronal cell cultures;

— Genotoxicity/genotoxic carcinogens in vitro micronucleus test;

— Reproductive toxicity (male fertility) Leydig cell line test;

— Endocrine disruption cell systems for receptor binding;

— Endocrine disruption QSAR to predict receptor binding.

Can the Commission confirm that a pre-validation or validation study for each of these tests is now under way? If this is not the case, can the Commission explain why particular studies are delayed and when they can be expected to begin?

(1) European Centre for the Validation of Alternative Methods, in its report 'Alternative (Non-animal) Methods for Chemicals Testing: Current Status and Future Prospects'.

**Answer given by Mr Busquin on behalf of the Commission**

*(27 February 2003)*

In July 2002, ECVAM (1) identified the 13 non-animal tests listed below as being technically ready to complete prevalidation or validation studies by 2003.

The current status is as follows:

— *human skin reconstructed skin model*

— *skin-integrity function test*

On-going validation of reconstructed human epidermis (Epiderm and Episkin). Assays and Skin integrity function test (SIFT) for acute skin irritation; the project is delayed by the administrative procedure (call for tender).

— *acute systemic toxicity other than QSAR/DEREK*

In 2002 ECVAM started a joint validation study together with ICCVAM (American Interagency Coordinating Committee on the Validation of Alternative Methods).

The primary goal of this study is to evaluate the relevance of two basal cytotoxicity assays named the BALB/c 3T3 Neutral Red Uptake Cytotoxicity Assay and the Normal Human Keratinocyte Neutral Red Uptake Cytotoxicity Assay for refining and reducing animal use for acute oral toxicity testing.

The study is scheduled to be completed by end 2003 beginning 2004.

— *Biokinetics in vitro screens for metabolism*

Phase I Prevalidation studies using subcellular fractions from human hepatocytes or from genetically engineered cell lines expressing human genes to determine metabolism-mediated effects are starting in 2003.

Phase II Prevalidation of in vitro models for evaluating the effects of enzyme polymorphism on metabolism is completed.

— *Biokinetics human liver cell sandwich culture*

Phase II Prevalidation of human liver sandwich cultures for evaluating induction of key biotransformation enzymes is initiated in 2003.

— *Target organ/system toxicity (neurotoxicity) 3D-brain cell cultures and*

Phase I Prevalidation studies using 3D-brain cell cultures (aggregates) are initiated in 2003. The model has been established.

— *Neuroblastoma cell line*

Currently the model is evaluated at ECVAM. Phase I Prevalidation of neuroblastoma cell lines is initiated in 2003.

— *Target organ/neurotocicity Glial and neuronal cell cultures*

Currently the model is evaluated at ECVAM. Phase I Prevalidation studies using mixed cultures of neuronal and glial cells are initiated in 2003.

— *Genotoxicity/genotoxic carcinogens in vitro micronucleus test*

The test has been extensively used by ECVAMs partners (University Autonoma Barcelone and University of Pisa) in the context of the contract study on Cell Transformation Assay. The contract ends this month and a final meeting with such partners will be held in ECVAM on 26 February 2003. A possible validation will be discussed.

— *Reproductive toxicity (male fertility) Leydig cell line test*

Contract negotiated could not be financed in 2002, foreseen for 2003. To be integrated in a planned Integrated Project on Reproductive Toxicity managed by ECVAM.

— *Endocrine disruption cell systems for receptor binding*

— *Endocrine disruption QSAR to predict receptor binding*

ECVAM has joined a validation initiative of the Organisation for Economic Co-operation and Development (OECD), first meeting in March 2003.

— *Acute systemic toxicity QSAR/DEREK*

— *Eye irritation QSAR or ESR*

Through the joint efforts of the European Chemicals bureau (ECB) and ECVAM, the Joint Research Centre (JRC) plans to initiate the validation of QSARs for certain endpoints later this year. However, the detailed planning of QSAR validation studies is currently awaiting discussions at the OECD level on internationally-recognised acceptability criteria for QSARs. It is foreseen that there will be a minimal set of criteria to judge the readiness of QSARs for validation (equivalent to ECVAM's test development criteria for the entry of in vitro tests into prevalidation), and a set of additional criteria that are applied at the end of the QSAR validation process, to judge the scientific validity of QSARs. Therefore, the QSARs selected for validation will need to take account of certain acceptability criteria. For this reason, it is likely that the time-frame for the validation of QSARs will be revised in accordance with an in-depth evaluation of specific QSARs, which was not performed during the preparation of the ECVAM report.

(1) European Centre for the Validation of Alternative Methods, in its report 'Alternative (Non-animal) Methods for Chemicals Testing: Current Status and Future Prospects'.

(2003/C 268 E/093)

## WRITTEN QUESTION P-0322/03

**by Karla Peijs (PPE-DE) to the Commission**

*(4 February 2003)*

*Subject:* Guyana Shield Initiative

Is the Commission aware of the importance of the Guyana Shield for the conservation of the global biodiversity, its importance as a global $CO_2$ sink and as one of the major freshwater reservoirs in the world, and its importance for the many indigenous peoples living in this area?

The EU is a party to the international environmental treaties like the Biodiversity Convention, the Climate Change Treaty and the Desertification Convention and therefore bound to implement the objectives of these conventions. Its Water Initiative has become a central element in the programme for sustainable development. The Guyana Shield is one of the most important regions of the world with regard to these objectives. Taking these objectives into account, what measures has the Commission taken to safeguard the natural and environmental values of the Guyana Shield for posterity?

What are the objectives of the ACP and ALA development aid programmes for the Guyana Shield countries and what activities with regard to safeguarding the natural and environmental values of these countries are financed by these programmes?