



EUROPEAN COMMISSION
DIRECTORATE GENERAL JRC
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
European Centre for the Validation of Alternative Methods (ECVAM)

STATEMENT ON DOG TOXICITY STUDIES

At its 25th Meeting, held on 16-17 November 2006 at the European Centre for the Validation of Alternative Methods (ECVAM), Ispra, Italy, the non-Commission members of the ECVAM Scientific Advisory Committee (ESAC)¹ unanimously endorsed the following statement:

Extension of a dog toxicity study beyond a 13-week duration does not provide additional essential information and reliance on the chronic rodent and 13-week dog studies would provide an adequate basis for chronic RfD derivation in pesticide risk assessment.

There is no further need to require a one year dog study for the evaluation of repeated dose toxicity of pesticides. The short-term oral toxicity of the active substance to non rodents must always be reported only in a 90-day study, usually in dogs.

Data requirements to the chronic dog studies should be harmonized between the European and North American (as well as other) regulatory agencies to avoid unnecessary testing of dogs in different time frames.

The statement is mainly based on retrospective analyses of data used for the authorisation of pesticides performed by the Federal Institute for Risk Assessment (BfR)^{2,3,4} as well as further retrospective analyses⁵.

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Ispra

17 November 2006

1. The ESAC was established by the European Commission, and is composed of nominees from the EU Members States, industry, academia and animal welfare, together with representatives of the relevant Commission services.

This statement was endorsed by the following members of the ESAC:

Mr Walter Pfaller (Austria)
Ms Sonja Beken (Belgium)
Ms Dagmar Jírová (Czech Republic)
Ms Elisabeth Knudsen (Denmark)
Mr Tõnu Püssa (Estonia)
Mr Timo Ylikomi (Finland)
Mr Manfred Liebsch (Germany)
Mr Efstathios Nikolaidis (Greece)
Ms Katalin Horvath (Hungary)
Ms Annalaura Stamatii (Italy)
Ms Maija Dambrova (Latvia)
Mr Jan van der Valk (The Netherlands)
Mr Dariusz Sladowski (Poland)
Mr Albert Breier (Slovakia)
Mr Jon Richmond (UK)
Ms Odile de Silva (COLIPA)
Ms Julia Fentem (ECETOC)
Ms Nathalie Alépée (EFPIA)
Mr Robert Combes (ESTIV)
Ms Maggy Jennings (Eurogroup for Animal Welfare)
Mr Roman Kolar (Eurogroup for Animal Welfare)

The following Commission Services and Observer Organisations were involved in the consultation process, but not in the endorsement process itself.

Mr Thomas Hartung (ECVAM; chairman)
Mr Jens Linge (ECVAM; ESAC secretary)
Ms Elke Anklam (Director of IHCP)
Mr Juan Riego Sintes (ECB)
Mr Siegfried Breier (DG Enterprise, Unit F.3)
Ms Susanna Louhimies (DG Environment, Unit C.3)
Ms Beatrice Lucaroni (DG Research, Unit F.5)
Mr Christian Wimmer (DG Research)
Mr Constantin Mircioiu (Romania)
Mr Len Schechtman (ICCVAM, USA)
Mr William Stokes (NICEATM, USA)
Ms Vera Rogiers (ECOPA)
Mr Hasso Seibert (European Science Foundation)

2. Gerbracht, U. and Spielmann, H.
The use of dogs as second species in regulatory testing of pesticides. Part I:
Interspecies comparison.
Arch. Toxicol. 72, 319-329, 1998
3. Spielmann H. and Gerbracht U.
The use of dogs as second species in regulatory testing of pesticides. Part II.
Subacute, subchronic and chronic studies in the dog.
Arch Toxicol 75, 1-21, 2001
4. Box, R.J., and Spielmann H.
Use of the dog as non-rodent test species in the safety testing schedule
associated with the registration of crop and plant protection products
(pesticides): present status.
Archives of Toxicology 79, 615-626, 2005
5. Doe, J.E., Boobis, A.R., Blacker, A., Dellarco, V., Doerrler, N.G., Franklin, C.,
Goodman, J.I., Kronenberg, J.M., Lewis, R., McConnell, E.E., Mercier, T.,
Moretto, A., Nolan, C., Padilla, S., Phang, W., Solecki, R., Tilbury, L., van
Ravenzwaay, B. and Wolf, D.C.
A tiered approach to systemic toxicity testing for agricultural chemical safety
assessment.
Critical Reviews in Toxicology 36: 37-68, 2006