

PLANT PROTECTION PRODUCTS - KEY ISSUES FOR ANIMAL WELFARE

On 12 July 2006 the Commission published a proposal for a Regulation on plant protection products (PPPs) (COM(2006) 388 Final) on the basis of a progress report on the functioning of Directive 91/414/EC¹. The report highlighted a number of areas to be improved and which are now incorporated into the proposal; reinforcement of the protection of public health and the environment, support for sustainable development in agriculture, **reduction of animal testing**, boosting competitiveness for producers and increasing availability of plant protection products to farmers.

The Data Requirements (including the animal tests) fall under the Annexes (II and III) of this Regulation which will only be reviewed at the end of 2007.

Although the proposal requires producers to share data from animal tests in order to **avoid duplicate animal testing**, much more than that is necessary to ensure that animal testing under this Regulation is only undertaken as a last resort. There is no mention of a need or objective to minimise animal testing, ensuring access to relevant information to avoid duplicate animal testing, or **the promotion and use of non-animal test methods and intelligent testing strategies**.

Plant protection products are intended to kill animals which are defined as pests but the Regulation should require that only the **most effective product which causes the least suffering to the animals** are used.

AVOIDING DUPLICATION OF ANIMAL TESTING – OBLIGATORY DATA SHARING

A system needs to be established under the Regulation on PPPs, to ensure producers can find the necessary information about animal tests that have already been carried out by others, possibly by way of a central database so that animal testing can be avoided. The Commission proposal provides only for information and tests and studies on active substances, safeners and synergists to be made publicly available by the European Food Safety Authority (EFSA). However, it does not foresee where producers can find such information about plant protection products, the area most likely to generate duplicate animal testing. Producers only have to request information from the Member State where they intend to make an application for authorisation. Unless they also request information from the other individual Member States, duplicate animal testing is very likely to take place since producers would not be aware of relevant existing data.

There should be a central database to all relevant information on active substances, safeners, synergists and plant protection products in order to ensure that all relevant data is shared and duplicate animal testing does not take place.

DATA REQUIREMENTS - INCLUSION OF NON-ANIMAL TEST METHODS AND “INTELLIGENT”/INTEGRATED TESTING STRATEGIES

The Commission proposal makes no mention of the need to minimise animal testing and to promote the use of alternative test methods. It is therefore vital to include an obligation that animal testing is kept to an absolute minimum. Testing requirements must be in line with actual requirements for each product and not follow a general ‘tick-box’ approach where unnecessary testing on animals takes place.

¹ Council Directive of 15 July 1991 concerning the placing of plant protection products on the market

Briefing on: Plant Protection Products

Under the Regulation, the data requirements for active substances, safeners, synergists and plant protection products will be decided through the comitology procedure, which will exclude thorough discussion in the European Parliament.²

A recent study conducted by the European Crop Protection Association's Toxicology Expert Group (ECPA TEG) estimated that, under the current requirements of Annex II of 91/414, the number of animals needed to generate the human safety information required for registration of a new active ingredient is approximately 6,500. ECPA TEG also estimated that a significant reduction of the number of animals tested could be achieved (to 2,250) by switching from the current test paradigm to the proposed tiered testing approach developed in the framework of the ILSI-HESI-ACSA project³

If tests are performed, they should comply with the relevant requirements for the protection of laboratory animals, set out in Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes⁴. In accordance with the provisions of this Directive, it is necessary to replace, reduce or refine experiments on vertebrate animals. The PPP Regulation should ensure the use of alternative test methods wherever possible. The use of animals should be avoided by recourse to alternative methods validated by the Commission or international bodies, or recognised by the Commission as appropriate to meet the data requirements under this Regulation.

The Regulation should include a provision which ensures that the data requirements are defined with an obligation to minimise animal testing and ensure the application of non-animal test methods and intelligent testing strategies.

With regard to the Testing Requirements outlined in the Annexes, the Commission must perform a retrospective analysis of which endpoints of the testing battery requirements for ingredients and products have turned out to be indispensable.

LIMIT THE SUFFERING FOR THE TARGET ANIMALS

The description of “good plant protection practice” in Article 4 of the revision proposal requires that the product “shall not cause unnecessary suffering and pain to the vertebrates to be controlled” but there is no qualification in the rest of the Regulation. Equally this should be added to the definition of good plant protection practice in Article 3 and as a reason for substituting the product with methods or products which cause less suffering on the vertebrates it aims to control.

The limitation of suffering for the target animals should receive more attention by defining what constitutes unnecessary suffering, including limiting suffering of the target animals in the good plant protection practice and in Article 48 to substitute a product if another method or product exists which causes less harm and suffering to the target animals.

² Having regard to the new Comitology procedure where European Parliament can only reject a Committee decision but not amend it

³ Neil G. Carmichael, Hugh A. Barton, Alan R. Boobis, Ralph L. Cooper, Vicki L. Dellarco, Nancy G. Doerrer, Penelope A. Fenner-Crisp, John E. Doe, James C. Lamb, Timothy P. Pastoor. January 2006. **Agricultural Chemical Safety Assessment: A Multisector Approach to the Modernization of Human Safety Requirements.** *Critical Reviews in Toxicology*. Volume 36, Number 1

⁴ OJ L 358, 18.12.1986, p. 1. Directive as amended by Directive 2003/65/EC of the European Parliament and of the Council (OJ L 230, 16.9.2003, p. 32).

Intelligent Testing Strategies

The way to reduce testing on animals is to apply 'Intelligent Testing Strategies'⁵. Flexible step by step non-animal testing strategies, in which the data collected are evaluated after each step, and decisions on remaining information needs are made based on the results of previous steps.

This would ensure a sensible toxicological approach based on chemical safety assessment, including full use of **all existing data** (including human data), **weight of evidence**, **(Q)SARs**, **grouping of substances** and **read-across**, and all available *in vitro* and other **non-animal test methods**.

The Annexes must include a flexible step-by-step strategy, in which the data collected are evaluated after each step, and decisions on remaining information needs are made based on the results of previous steps.

⁵REACH and the need for Intelligent Testing Strategies, Institute for Health and Consumer Protection, March 2005, European Commission, Joint Research Centre, 21020 Ispra (VA), Italy.

weight of evidence	The comparison of evidence presented by one side as compared to another.
(Q)SARs	(Quantitative) Structure-Activity Relationships are theoretical methods used to predict properties of a molecule.
read-across	The grouping of substances with similar properties or which belong to the same family with structural similarities.