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Committee on the Environment, Public Health and Food Safety

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NOTICE TO MEMBERS

(0005/2008)

Question for Question Time in committee 0005/2008
under Rule 187 of the Rules of Procedure
by Mojca Drčar Murko and Chris Davies

Subject: Revision of toxicological data requirements for agrochemicals under Council Directive 91/414/EEC

Development and registration of a new agricultural pesticide can cost as much as 120 million Euros and use upwards of 12,000 animals in dozens of separate and often overlapping tests. Inefficiencies associated requirements specified in Annexes II and III of Council Directive 91/414/EEC have prompted calls for more flexible regulations and approaches to testing. In January 2007, the European Food Safety Authority's PPR Panel published an opinion stating:

- "In general, the PPR panel believes there should be a drive towards use of fewer but more informative studies in toxicological risk assessment...."
- "The value of several individual tests that currently form part of the standard data package for plant protection products – in particular, the 1-year dog study and the mouse carcinogenicity study – is questionable."

Other animal reduction opportunities identified by stakeholders include:

- Substance- and exposure-tailored data requirements, as provided for under REACH, to allow flexible testing for substances of lower toxicity, such as biochemical pesticides and non-active ingredients in a product formulation.
- Limiting acute lethality testing to (i) a single exposure route, instead of the current three routes, and (ii) active ingredients, instead of both ingredients and formulated

products.

- Ending the requirement for the use of two or more species in tests such as acute and repeated dose toxicity, developmental toxicity, and carcinogenicity.

The Commission is requested to (i) report on the status and timetable for completion of revisions to EU data requirements for agrochemicals, and (ii) provide a detailed response for each of the above points as to how these considerations will be reflected in the revised data requirements.

In addition, will the Commission include the following ECVAM-endorsed/OECD-accepted alternative methods in the revised EU data requirements:

- EPISKIN skin irritation test;
- *in vitro* skin absorption test;
- *in vitro* micronucleus test;
- limit dose local lymph node assay;
- and step-down approach for acute fish toxicity?