

**Scientific Committee on Health and Environmental Risks (SCHER)**  
**Scientific Committee on Emerging and newly identified Risks (SCENIHR)**  
**Scientific Committee on Consumer Safety (SCCS)**

**Request for an opinion on the toxicity and the assessment of mixtures<sup>1</sup> of chemicals**

## **1. Background**

EU Chemicals legislation, in common with the situation in other parts of the world, is based predominantly on assessments carried out on individual substances. However, in reality humans are exposed to a wide variety of chemicals throughout their lives as indeed are animals and plants. While current assessment methods incorporate safety factors to take account of a range of uncertainties, the Commission is concerned to ensure that EU chemicals' legislation take proper account of the latest scientific information on mixture toxicity.

In the Council conclusions from 22<sup>nd</sup> December 2009, the Commission was invited, drawing on existing and future research and paying appropriate attention to the costs and benefits, to assess how and whether relevant existing Community legislation adequately addresses risks from exposure to multiple chemicals from different sources and pathways, and on this basis to consider appropriate modifications, guidelines and assessment methods, and report back to the Council by early 2012 at the latest,

## **2. Terms of Reference**

In the light of the above considerations, SCHER/SCCP/SCENIHR are asked to advise the Commission in relation to the following issues:

- 1) Is there scientific evidence that when organisms are exposed to a number of different chemical substances, that these substances may act jointly in a way (addition, antagonism, potentiation, synergies etc) that affects the overall level of toxicity?
- 2) If different chemical substances to which man/environment are exposed can be expected to act jointly in a way which affects their impact/toxicity on/for man and the environment, do the current assessment methods take proper account of these joint actions?
- 3) Several approaches for the assessment of the mixture effects of chemicals already exist such as dose addition and independent action. What are the advantages and disadvantages of the different approaches and is there any particular model that could be considered as sufficiently robust to be used as a default option?
- 4) Given that it is unrealistic to assess every possible combination of chemical substances what is the most effective way to target resources on those combinations of chemicals that constitute the highest risk for man and the environment ?
- 5) Where are the major knowledge gaps with regard to the assessment of the toxicity of chemical mixtures?

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<sup>1</sup> For the purposes of this request, mixtures of chemicals are considered to be:

- Substances that are mixtures themselves (multi-constituent substances, MCS; materials of unknown or variable composition, complex reaction products or biological materials, UVCB)
- Products that contain more than one chemical e.g. cosmetics, plant protection products;
- Chemicals jointly emitted from production sites, during transport processes and consumption or recycling processes;
- Several chemicals that might occur together in environmental media (water, soil, air), food items, biota and humans as a result of emission from various sources and via multiple pathways.

6) Does current knowledge constitute a sufficiently solid foundation upon which to address the toxicity of chemical mixtures in a more systematic way in the context of EU legislations?

In developing its opinion on the questions set out above the Committee is requested to take account of the latest scientific information and to consult with prominent experts and with relevant agencies such as EFSA, EEA, EMEA and ECHA as well as experts and organisations outside the EU.

The Commission services would in particular refer the Committee to the final report of study contract 070307/2007/485103/ETU/D.1 "State of the Art of Mixture Toxicity".

In addition, the EFSA Panel on Plant Protection Products has produced a number of highly relevant opinions on cumulative and synergistic risks from pesticides<sup>2</sup>

### **3. Deadline**

The Commission would ask the Committee to provide its final opinion to the present request by June 2011 at the latest.

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<sup>2</sup> Scientific Opinion of the Panel on Plant Protection Products and their residues (PPR Panel) on a request from the EFSA to evaluate the suitability of existing methodologies and, if appropriate, the identification of new approaches to assess cumulative and synergistic risks from pesticides to human health with a view to set MRLs for those pesticides in the frame of Regulation (EC) 396/2005. The EFSA Journal (2008) 704, 1-85.

EFSA PPR Panel Scientific Opinion on a request from EFSA on risk assessment for a selected group of pesticides from the triazole group to test possible methodologies to assess cumulative effects from exposure through food from these pesticides on human health. The EFSA Journal (2009) 7(9); 1167.