

# *Dealing with chemical mixtures*

## *Activities of DG ENV*

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# Background

- EU chemicals' legislation – assessment of individual substances
- Combination Effects in current legislation:
  - **CLP Regulation**
  - **New PPP Regulation**
  - **Cosmetics Directive**
  - **Directive on Chemical Agents at Work**
  - **New Biocides Regulation in adoption**
  
- Real life scenario – many different chemicals from different sources and pathways
  - ***Potential adverse combination effects***

# Combination Effects and Plant Protection Products (1)

- Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (Text with EEA relevance)
- Recital #6

*“It is also important to carry out further work to develop a methodology to take into account cumulative and synergistic effects. In view of human exposure to combinations of active substances and their cumulative and possible aggregate and synergistic effects on human health, MRLs should be set after consultation of the European Food Safety Authority ---”*

# Combination Effects and Plant Protection Products (2)

- Opinion 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 - Published: 10 September 2009
- Opinion 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 - Published: 30 May 2009
- EFSA's 7th Scientific Colloquium - Cumulative Risk Assessment of Pesticides to Human Health: the Way forward - Parma , 28 November 2006

# Combination Effects and Biocides.

- Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the placing on the market and use of biocidal products
- **Article 8- Evaluation of applications**
- *“Para 3. Where the evaluating competent authority considers that there are concerns with regard to the cumulative effects from the use of biocidal products containing the same active substance, it shall document its concerns-----”*

# *Council Conclusions 17820/09 of 22 December 2009* - **Combination effects of chemicals**

## **Commission was invited:**

- 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,

# Council Conclusions 17820/09 of 22 December 2009 - **Combination effects of chemicals** ...cont'd

## Example - Endocrine disruptors

- Commission was invited:

- to make recommendations as to how exposure to multiple **endocrine disruptors** should be further addressed within relevant existing Community legislation, *inter alia* in the context of its forthcoming report on the **implementation of the Community strategy on endocrine disruptors** to be completed by 2010.

# Council Conclusions 17820/09 of 22 December 2009 - **Combination effects of chemicals** ...cont'd

## Commission was invited:

- to pay appropriate attention to the **precautionary principle** and the potential risks of chemical combination effects when drawing up future proposals, *inter alia* by assessing the need for risk management measures to protect the environment and human health.



# DG ENV activities

- contract to gather and summarise knowledge (awarded end of 2007)
- Final report **State of the Art Report on Mixture Toxicity** (Febr 2010)
- Report dissemination
- DG ENV web-site ***Combination effects of chemicals***

*<http://ec.europa.eu/environment/chemicals/effects.htm>*

- **consultations** - COM, MS and other stakeholders
- **a workshop** organised in June 2010

- Request for opinion by the SANCO Scientific Committees
- Mandate – to advise the Commission on:
  - Scientific evidence - when organisms are exposed to different chemicals, substances may act jointly so that the overall toxicity level is affected; do the current assessment methods take proper account of these joint actions?
  - Analyse the existing approaches for mixture effect assessment – advantages/disadvantages
  - Effective way to target the combinations of chemicals with the highest risk for man and the environment
  - Where are major knowledge gaps, is the current knowledge sufficiently solid to address mixtures toxicity in a more systematic way (within the context of the EU legislation)
- a WG in place – draft opinion - summer 2011

## Preparatory work – Report to the Council

■ Analysis of the existing EU ENV legislation (*REACH, CLP, WFD, IPPC, Marine Strategy Directive...*)

- ***Gaps? Possible solutions?***

■ *What is still missing ? - research ? development ? methods?*

■ Increase integration of health and environmental monitoring data –  
*How it can be used for addressing combination effects?*

# Emerging Challenges

- **Definitions-** number of chemicals, number of exposure routes and the time dimension;
- **Low dose issue-** definition and experimental evidence.
- **Integrated assessments** –are they needed? How to do them? How to do them effectively?
- **Legislative compartmentalisation**
- **Liability**
- **Assessing combination effects in a regulatory context**

# International fora

## WHO IPCS

- March 2007 – Washington, Workshop: Aggregate/Cumulative Risk Assessment (Combined Exposures to Multiple Chemicals)
- **2009 – Draft framework for Risk Assessment of Combined Exposures to Multiple Chemicals** – comments by 30 October 2009
  - Two case studies – **polybrominated diphenyl ethers (PBDES)**
    - carbamates
  - currently work in progress

## OECD

- Joint meeting
- 15-16 February 2011 - WHO OECD ILSI/HESI **International Workshop on Risk Assessment of Combined Exposures to Multiple Chemicals**

*<https://community.oecd.org/community/envworkshops2>*

# Next steps

- Report to the Council due **early 2012**
- Commission Communication
- Identify relevant existing EU legislation
- Analysis of the existing relevant EU legislation
  - **are risks adequately addresses?**
  - **ideas for possible modifications, guidelines and risk assessment methods**
- Opinion of the Scientific Committees
- Precautionary principle

# Next steps – discussion and co-ordination

## ■ Approach :

*General and stock taking ?*

*Horizontal technical criteria and principles applied through all sectors?*

## ■ Target date: *end of 2011*

# Thank you

**European Commission**

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