European Food Safety Authority

Outcome of the public stakeholder consultation on the CAG opinion

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Info session on Applications – Pesticides
Technical meeting on cumulative risk assessment
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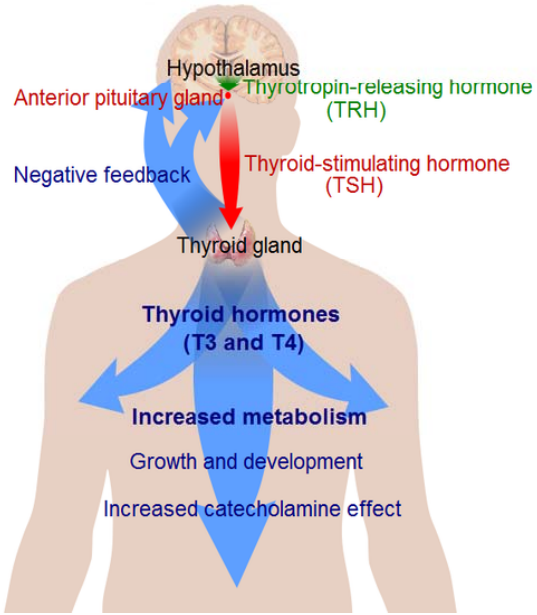
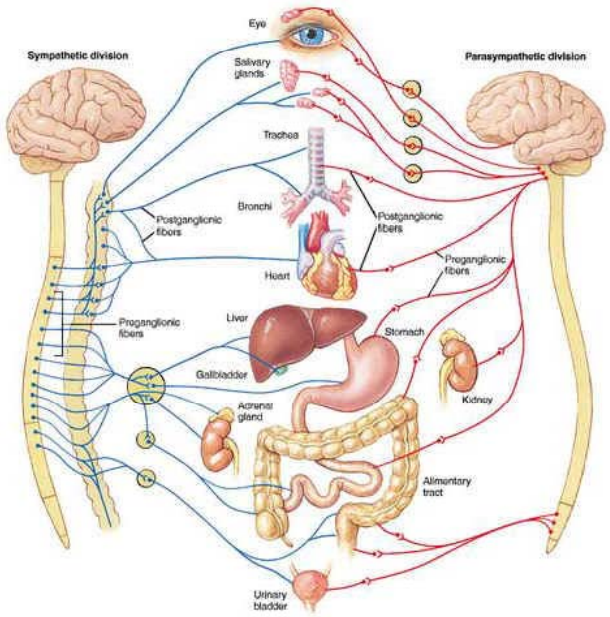
OUTLINE

- Background
- Scope of the consultation
- Overview about comments and how they have been addressed
- Consideration of comments for further activities
- Conclusions

BACKGROUND

The Scientific Opinion presents a general methodology for establishment of cumulative assessment groups (CAGs) for pesticide active substances plus two examples where this methodology has been applied to the **THYROID** and **NERVOUS SYSTEMS**





BACKGROUND

- Opinion published on July 12th 2013:

  “Cumulative assessment groups for pesticides”:

  http://www.efsa.europa.eu/en/efsajournal/pub/3293.htm

- Public consultation: 17th July – 30th September 2013

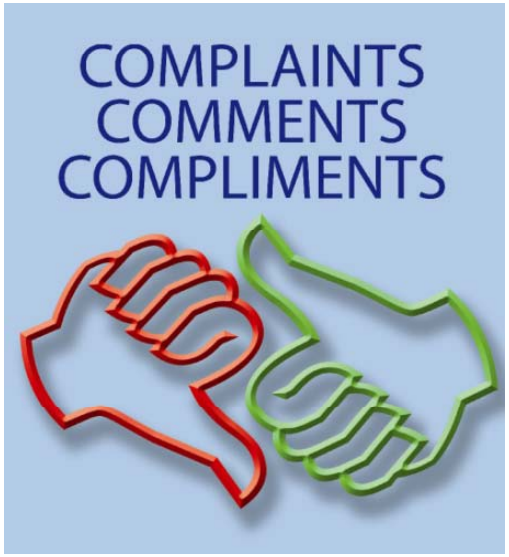
SCOPE OF THE CONSULTATION

Public Consultation performed to:

- get the view of the stakeholders on the methodology used
- identify issues deserving specific considerations in future activities on cumulative risk assessment of pesticides and its implementation

OVERVIEW ABOUT COMMENTS

69 feedbacks received



analysed by EFSA with consultation with some Panel Experts when dealing with specific issues

EFSA thanks all stakeholders for their valuable contributions

OVERVIEW ABOUT COMMENTS-STAKEHOLDERS

Organisation	Country	Number
European Crop Protection Association (ECPA)	Belgium	24
BAYER CropScience	Germany	20
The Chemical Company (BASF)	Germany	13
Netherlands Organisation for Applied Scientific Research (TNO)	The Netherlands	6
Board for the Authorisation of Plant Protection Products and Biocides (CTGB)	The Netherlands	3
Swedish Chemicals Agency (KEMI)	Sweden	1
French Agency for Food, Environmental and Occupational Health & Safety (ANSES)	France	1
World Health Organisation (WHO)	Switzerland	1

OVERVIEW ABOUT COMMENTS –BY CHAPTER

Chapters	Number of comments
General comments	4
Abstract	2
Summary	11
1. Interpretation of the Terms of Reference by the PPR Panel	2
2. Introduction	1
3.5. The grouping approach adopted by the PPR Panel	1
6. Grouping methodology	2
6.1.2 Step 1.2: Exclusion of non-adverse effects	4
6.1.3 Step 1.3: Exclusion of effects non relevant for human risk assessment	1
7.1 Hazard identification and characterisation for neurotoxicity (Step 1 and 2)	1
8.3 CAGs for the thyroid system (Step 4)	1
9. Considerations on potency during conduct of cumulative risk assessment (CRA)	3
10. Uncertainties and limitations	2
11. Conclusions	1
12. Recommendations	2
Appendix B. Data collection for effects on the nervous system	5
Appendix C. Acute CAGs for the nervous system	3
Appendix D. Chronic CAGs for the nervous system	4
Appendix F. Data collection for effects on the thyroid system	10
Appendix G. CAGs for the thyroid system	8
Appendix H. List of examined substances in the data collection (step 3) and those selected for CAGs (step 4)	1

MAIN COMMENTS ON:

- Lack of consideration on exposure and potency in the methodology (the approach taken is different from the one used by other regulatory authorities - e.g. USEPA)

- Grouping criteria:

    1. considered a conservative approach (large CAGs)
    2. the assumption that chemicals with the same phenomenological effect may have a similar mode of action considered overly conservative and precautionary

- Use of non-specific endpoints for the effect (particularly for step 1 and 2 for neurotoxicity)

- Information reported in data collection (e.g. treatment-relationship of some of the effects reported, NOAEL/LOAEL values) and consequent inclusion criteria of substances in the CAGs

HOW THE COMMENTS HAVE BEEN ADDRESSED

- The Opinion was focused on the identification of pesticides to be included in CAGs on the basis of their toxicological profile (phenomenological effect only) and was therefore confined solely to hazard assessment

- Potency and exposure were not criteria considered in the inclusion of substances in CAGs since outside the scope of the Opinion

- The application of dose addition as a default concept in cumulative risk assessment for substances producing the same adverse outcome is not considered unnecessarily precautionary and conservative

- Harmonisation in the field at the international levels is desiderable but not possible due to the different legal framework

- NOAEL/LOAEL values were double checked and changes, when necessary, will be considered for future activities

CONSIDERATIONS OF COMMENTS FOR FURTHER ACTIVITIES

- Report on Public Consultation published on January 7th, 2014

  "Public consultation on cumulative assessment groups"

  http://www.efsa.europa.eu/en/supporting/pub/538e.htm

Next steps:

- Changes will be taken into account for future activities related to cumulative risk assessment

CONCLUSIONS

- Stakeholders have broadly welcomed EFSA's CAG opinion as an important contribution to implementing cumulative risk assessment of pesticides in the EU
- Following feedback from stakeholders, EFSA considers the methodology set out in the opinion to identify CAGs to be valid
- The Authority notes stakeholders concerns about the methodology but considers the approach delivers the necessary level of consumer protection
- EFSA is now taking steps to implement the methodology developed by the PPR Panel to evaluate exposure to multiple pesticide residues in cooperation with European Commission and MSs and continues its work on the establishment of further CAGs for other organs and systems

THANK YOU FOR YOUR ATTENTION