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Technical stakeholder event on cumulative risk assessment of pesticides in food

Introduction

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Pesticide Residues Unit

Trusted science for safe food

efsa
European Food Safety Authority

Legal context

Legal basis

- Regulation (EC) No 396/2005 (MRLs)
- Regulation (EC) No 1107/2009 (Authorisation of PPPs)

- ❑ Achievement of a high level of protection
- ❑ Application of the precautionary principle when there is scientific uncertainty

When should cumulative risk assessment be conducted?

- Pre-marketing: Applications for MRLs (Article 14 of Reg. 396/2005)

- Post-marketing: Annual assessment of official monitoring data (Article 32 of Reg. 396/2005)

Overall timeline

2007 2009 2011 2013 2015 2017 2019

Methodological development for pesticides

- *Tiered methodology for cumulative risk assessment (PPR, 2009)*
- *Methodology for probabilistic exposure assessment (PPR, 2012)*
- *Methodology for cumulative assessment groups (PPR, 2013)*
- *Opinion on dissimilar mode of action (PPR, 2013)*
- *Monte Carlo Risk Assessment software (ACROPOLIS Project, 2013)*

Pilot for pesticides

- *Effects on the thyroid and the nervous system*
- *Framework partnership agreement with RIVM (MCRA software)*
- *EC Working Group on risk management questions*

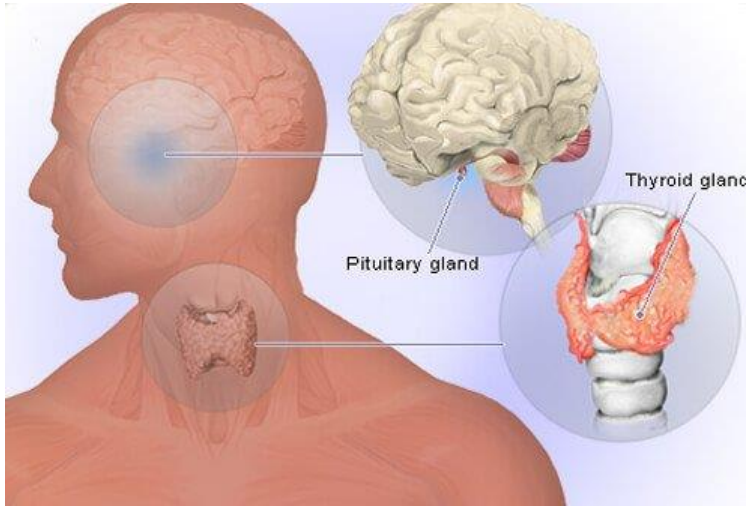
Cross-cutting activities

- *Guidance on risk assessment of combined exposure to multiple chemicals (SC, 2019)*
- *Guidance on uncertainty analysis (SC, 2018)*
- *FoodEx2 (EFSA, 2015)*
- *Raw Primary Commodity (RPC) model (EFSA, 2019)*

Pilot project – Organs and effects considered

Nervous system

- AChE inhibition
- Functional alteration of the motor division



Thyroid

- Hypothyroidism
- C-cell hypertrophy, hyperplasia and neoplasia

Assessment questions

- Nervous system: What was the acute cumulative risk of AChE inhibition and of functional alteration of the motor division for European consumers resulting from dietary exposure to pesticide residues from 2014 to 2016?

- Thyroid: What was the chronic cumulative risk of hypothyroidism and of hypertrophy, hyperplasia and neoplasia of C-cells for European consumers resulting from dietary exposure to pesticide residues from 2014 to 2016?

Pilot project – Work packages

3 work packages

- Hazard identification and characterisation
- Cumulative exposure assessment
- Risk characterisation and uncertainty analysis

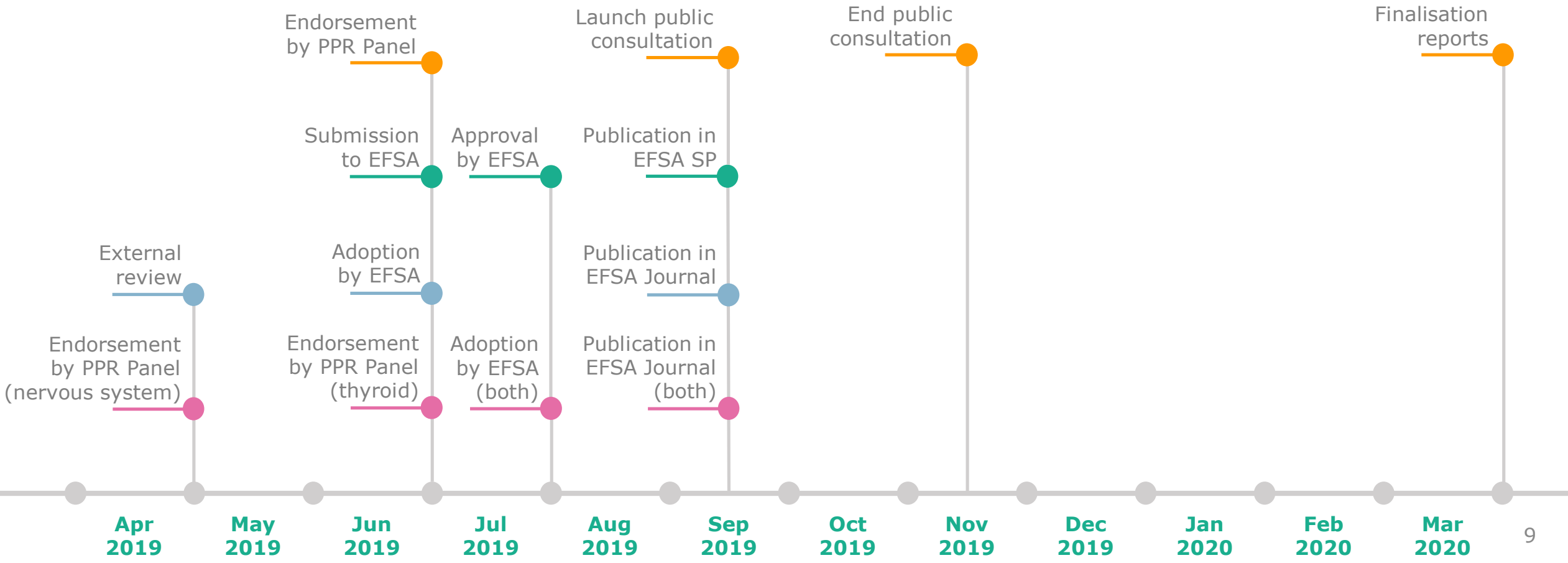
- ❑ 420 active substances considered
- ❑ Official pesticide monitoring data from 2014, 2015 and 2016
- ❑ 10 population groups
  - ➢ Adults (BE, CZ, DE, IT)
  - ➢ Children (BG, FR, NL)
  - ➢ Toddlers (DK, NL, UK)
- ❑ 30 raw primary commodities, food for infant and children, water
- ❑ Assumptions and thresholds of regulatory consideration defined by EC and Member States
- ❑ 2 probabilistic software: MCRA and SAS®

Pilot project – Scientific reports

Target organ	Author	Subject
Thyroid	EFSA	Establishment of **cumulative assessment groups**
Thyroid	RIVM	Cumulative dietary **exposure assessment using MCRA software**
Thyroid	EFSA	Cumulative dietary **exposure assessment using SAS® software**
Thyroid	EFSA	Cumulative dietary **risk characterisation**
Nervous system	EFSA	Establishment of **cumulative assessment groups**
Nervous system	RIVM	Cumulative dietary **exposure assessment using MCRA software**
Nervous system	EFSA	Cumulative dietary **exposure assessment using SAS® software**
Nervous system	EFSA	Cumulative dietary **risk characterisation**

Pilot project – Timelines for finalisation

- Scientific reports on the risk characterisations
- Scientific reports on the exposure (MCRA)
- Scientific reports on the exposure (SAS)
- Scientific reports on the CAGs



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