



## **Revision of environmental guidance documents: ongoing work at EFSA**

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## *Acknowledgements:*

- PPR-Panel Members (2006 – 2009)
- PPR-Panel Members (2009 – 2012)
- all the external experts which – so far - have been involved in the Guidance Document mandates

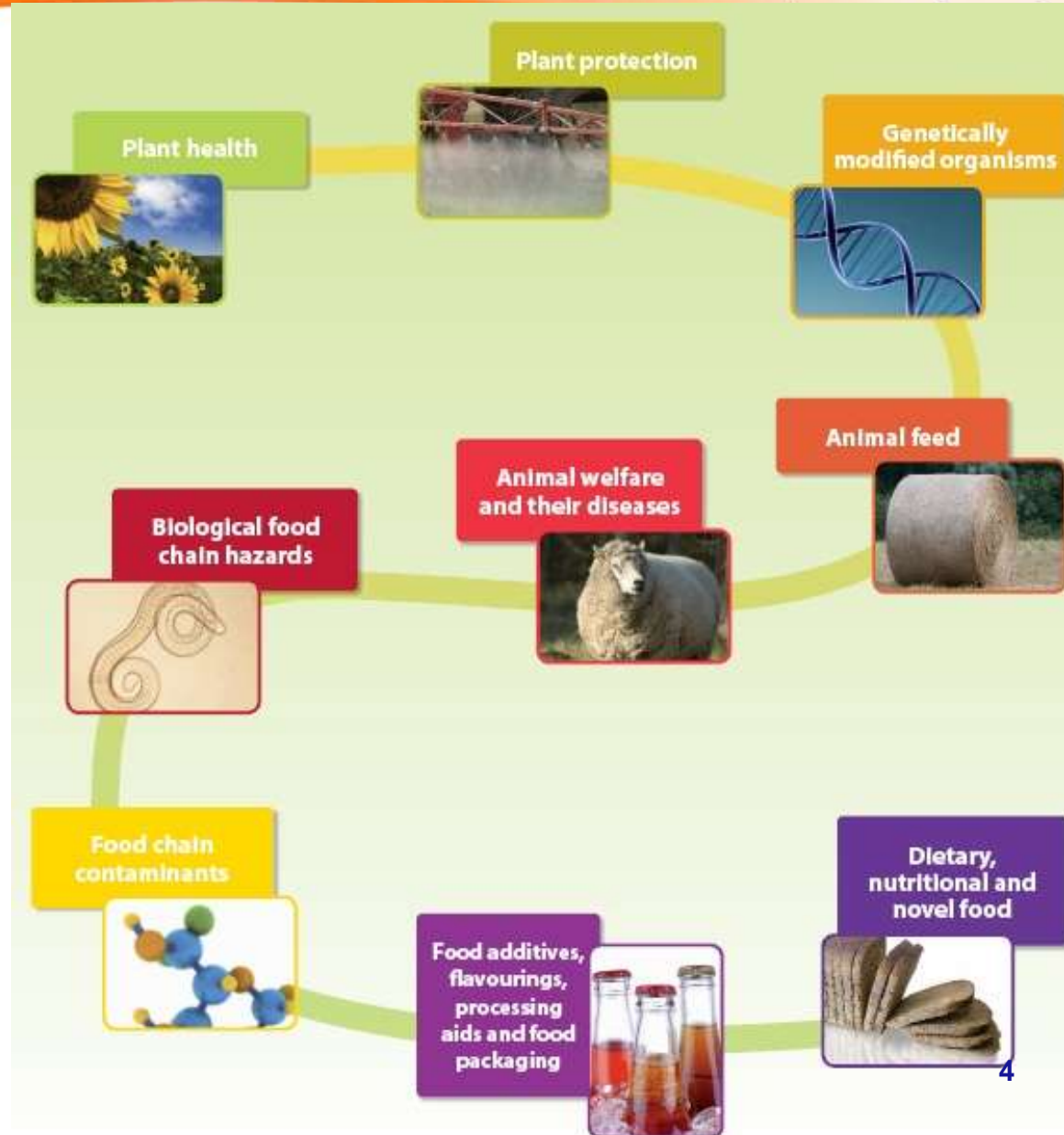
- Introduction about EFSA
- Guidance documents (environment): what is going on?
- Summary on EFSA's working procedures
- outlook

# What does EFSA?

**Risk assessment** in  
all fields of food and  
feed safety

**From farm to fork**

**RA separated from  
risk management**



# Who can task EFSA?

## Mandate



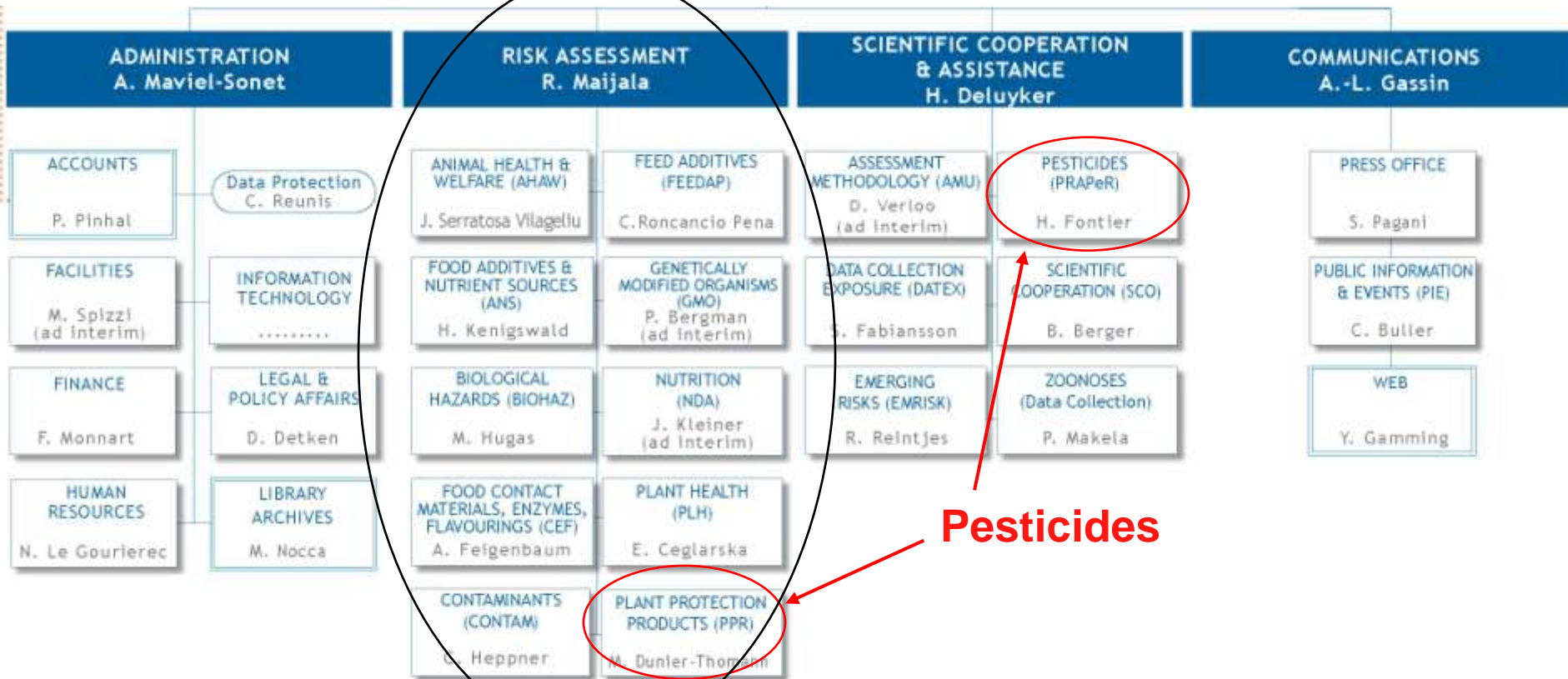
European Commission  
European Parliament  
Member States  
EFSA (self-tasking)

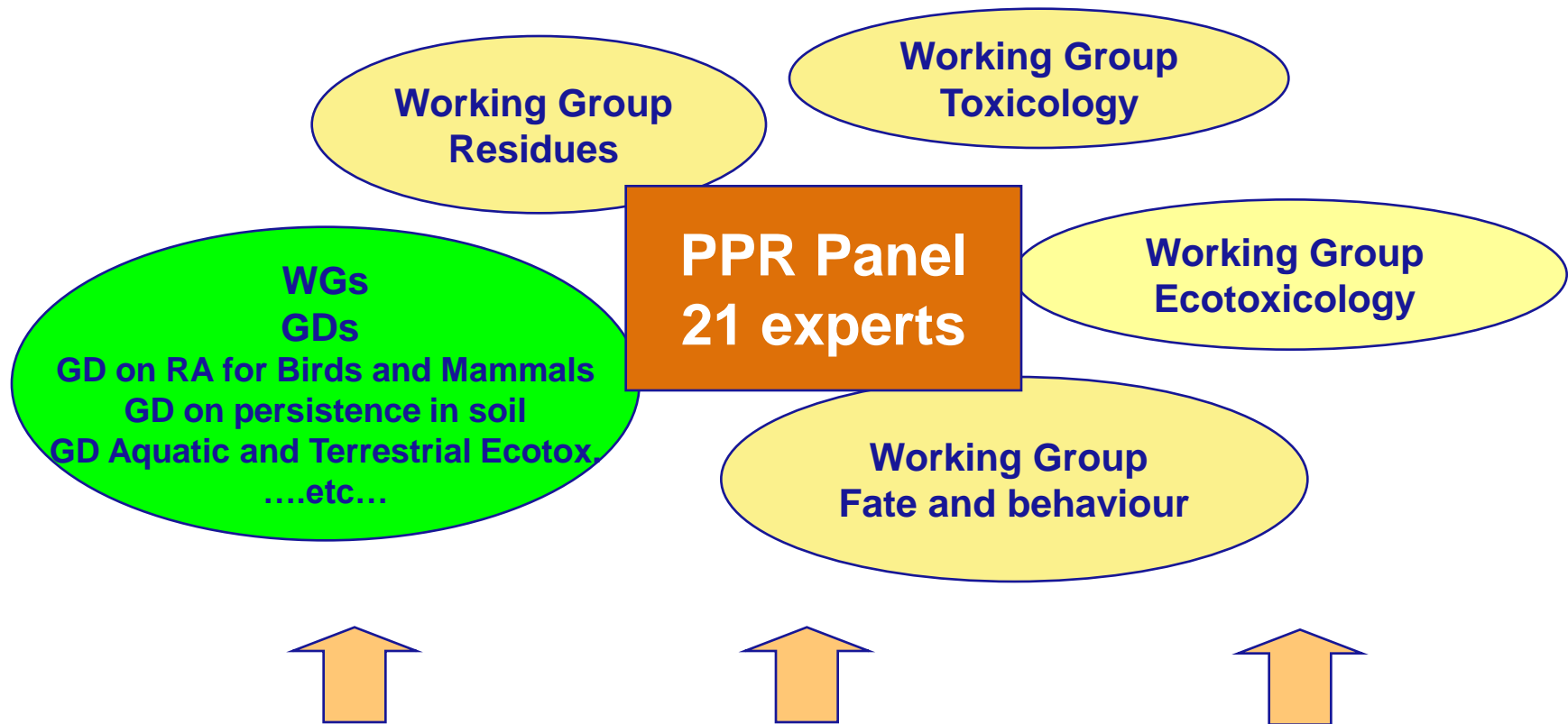
**EFSA-Output**  
(e.g. Scientific Opinion,  
Guidance Document)

# “Panels and Pesticides” at EFSA

**Science**

**Panels**





**Supported by the EFSA Secretariat = PPR Unit**  
(8 scientists + 4 admin)

- Introduction about EFSA
- **Guidance documents (environment): what is going on?**
- Summary on EFSA's working procedures
- outlook



# GDs in pesticide risk assessment: priorities

- 2006: Member States → **priority list** to EFSA for updating/developing GD
- Since end 2008 → **new requests via Pesticide Steering Committee** (EFSA, DG SANCO, MSs, Chair PPR Panel)

# Current GDs timeline

2006	2007	2008	2009	2010	2011
	<b>Birds and Mammals</b>		<b>Joint WG with RM</b>		
			<b>Aquatic Ecotox</b>		
			<b>Terrestrial Ecotox</b>		
		<b>Persistence in Soil / Fate</b>			
		<b>NEW!</b>	<b>Emissions from Greenhouses</b>		

- The opinion on the science behind the **GD on risk assessment for birds and mammals**
  - adopted in June 2008 (*EFSA Journal* (2008) 734: 1-181 + 32 Appendices)
- On-going **Joint WG with EC and MS** for selection of RM options
  - final version of the GD by 30 Oct 2009 to the SCFCAH.
  - The SCFCAH will be kindly requested to take note in their meeting on 26-27 Nov 2009.
  - If the SCFCAH agrees to take note of the GD, it will be published in late 2009/early 2010 with implementation six months later.



# Revision process



# GD on persistence in soil

- *Start 2008*
- *2 Working Groups*

2008	2009	2010
<b>Persistence in Soil / Fate</b>		
<b>Pers. in Soil / Ecotox (BUGS)</b>		



- Web-consultation (2008)
  - on project plan and current GD
  - Report published February 2009
- Opinion on “*The usefulness of total concentrations and pore water concentrations of pesticides in soil as **metrics for the assessment of ecotoxicological effects***”
  - EFSA Journal, 2009, 922: 1-90
- IRIS Stakeholder Workshop
  - Ispra 12-14 May 2009
  - on ongoing PPR work in soil (combining fate and ecotox)
  - stakeholder report published July 2009



# Persistence in soil GD – what is next...

- Opinion 1 (possible adoption Dec.2009)
  - tiered approach and soil management practises
- Opinion 2 (possible adoption Dec. 2009)
  - tier 1+2+3 with conventional tillage
- Opinion 3 (possible adoption Feb. 2010)
  - Use of field and accumulation studies

# New GD on emissions from protected crops

Aerial view of Almeria (Spain)





# Why is a new GD on emissions from protected crops needed?

- Several Member States asked for the development of a Guidance Document (GD) in this area
- EFSA's PPR Panel was asked to
  1. develop an inventory of protected crop systems
  2. give guidance on potential emissions from these structures to environmental compartments
- New guidance to help risk assessors evaluating PPPs, on when and how emissions to the environment need to be considered

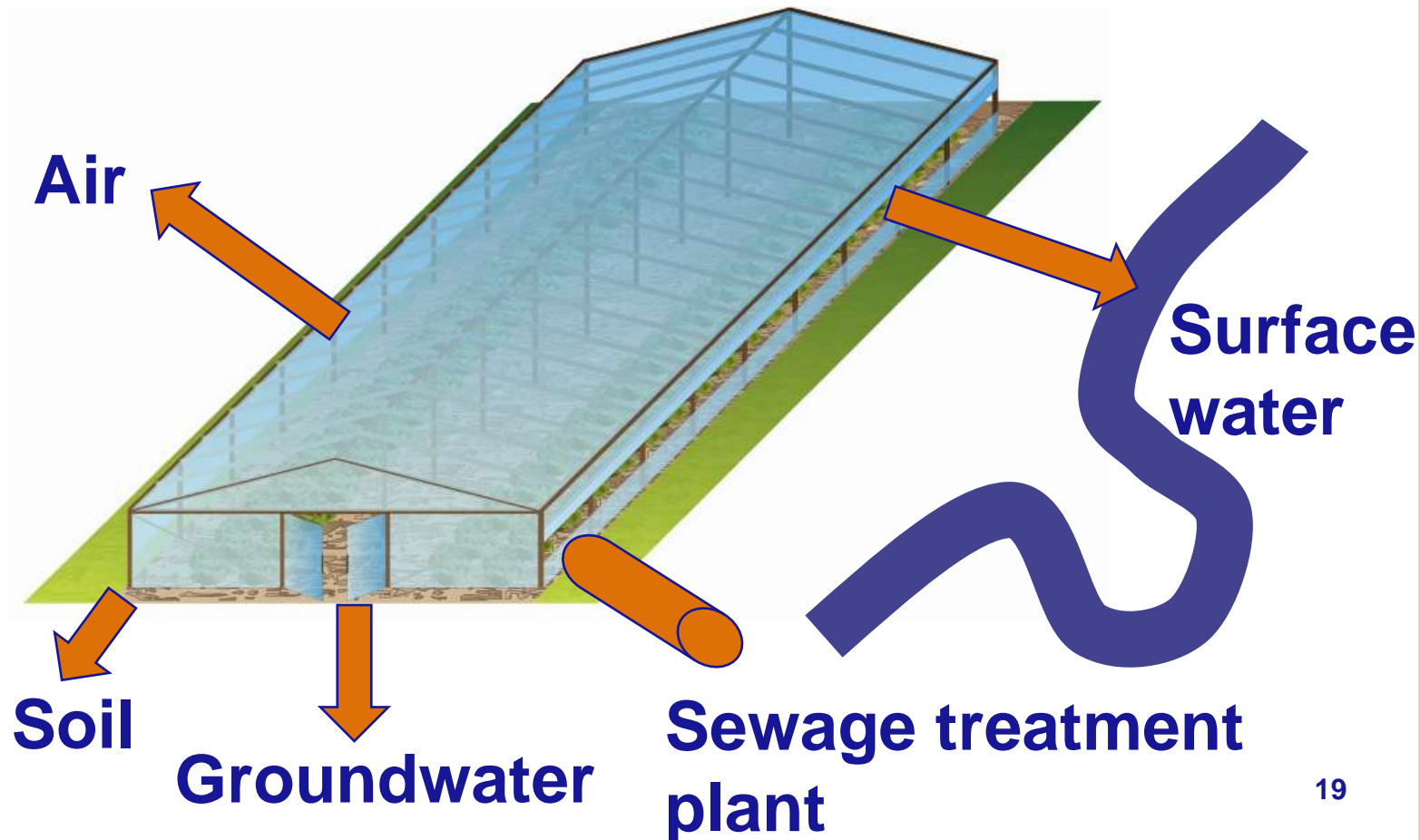
# Protected crop systems in Europe are diverse

- permanent and temporary structures



- covering the crop completely or partly

The EFSA PPR WG considers emissions to the following receptors:



# GD on emissions from protected crops: so far...

- Web-consultation
  - on project plan
  - closed Dec. 2008
  - stakeholder report published
- Stakeholder Workshop
  - PROTEA (17 – 19 Nov. 2009)
- Web-consultation
  - end of guidance (2010)



# GD on emissions from protected crops, next steps...

- Opinions 1 (possible adoption Dec. 2009)
  - focusing on structures/systems and emissions
  - in qualitative way
- Opinion 2 (possible adoption April. 2010)
  - focusing on structures/systems and emissions
  - in a quantitative way

**revision started Dec. 2008:**

- **Terrestrial ecotoxicology**  
(*SANCO/10329/2002-October 2002*)
- **Aquatic ecotoxicology**  
(*SANCO/3268/2001, October 2002*)



# GDs RA on Ecotoxicology: timelines

2008	2009	2010	2011
	<b>Aquatic Ecotox</b>		
	<b>Terrestrial Ecotox</b>		

# GDs RA on Ecotoxicology: Work so far... (2008)

- **Questionnaires to RM** regarding scope & level of protection
- **public consultation** on the existing GDs
  - Report to be published soon
- Procurement on **literature review** ongoing
  - Reptiles (2 lots: exposure + sensitivity)
  - Comparison between Lumbricidae and Enchytraeidae sensitivity
  - Higher tier testing approaches (aquatic + terrestrial)
  - Long term effects in invertebrates
  - Aquatic study protocols other than Crustacea



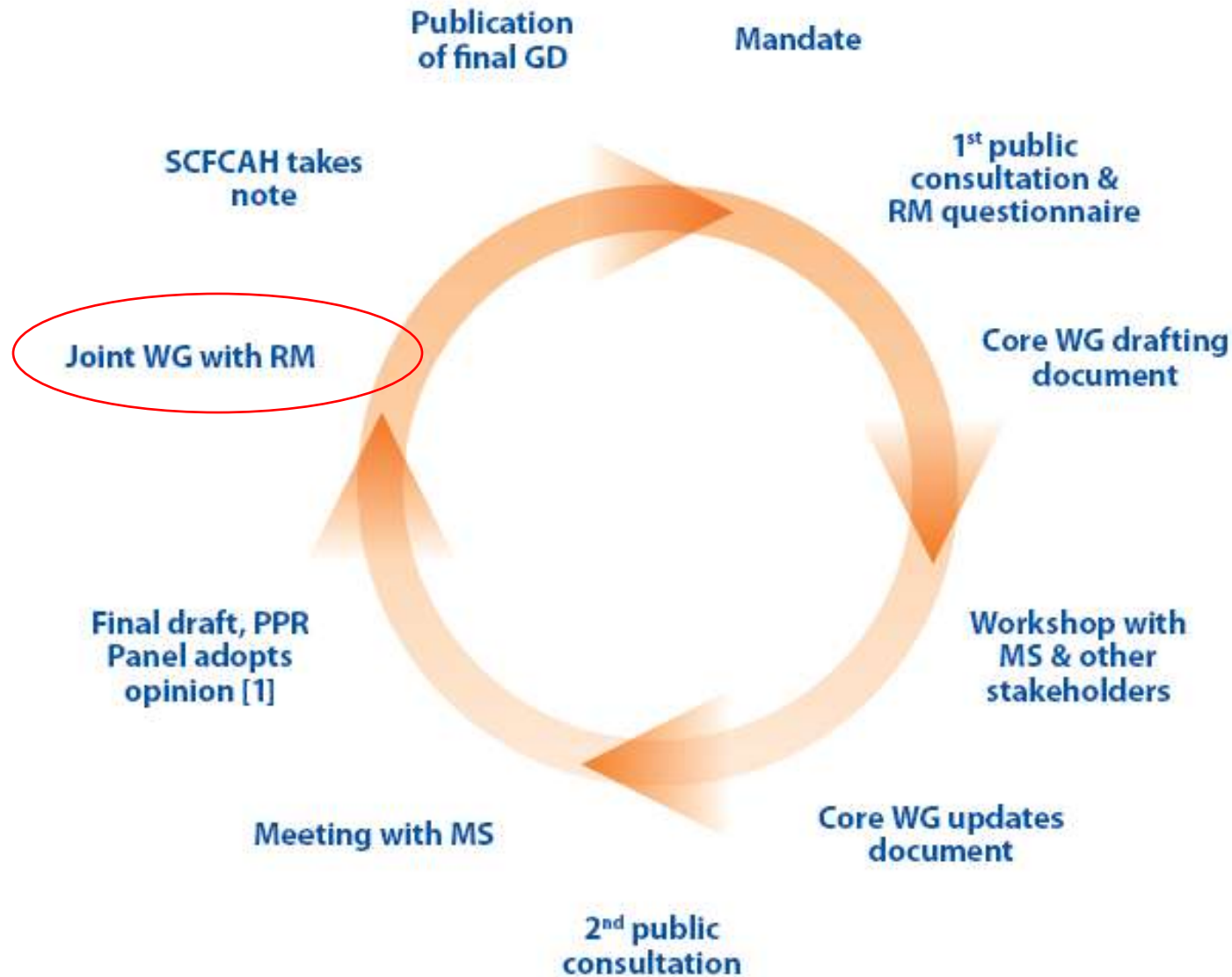
# GDs RA on Ecotoxicology: Work so far... (2009)

- Kick off meetings with Panel members end of 2008
- One **Ecotox Effects Core WG** with the aim
  - of harmonizing RA between compartments
  - Bring together exposure and effects (thus Fate and Ecotox experts)
- Meetings in Jan, March, May, July 2009

# GDs RA on Ecotoxicology: Next steps...

- Dec 2009: **Draft Opinion on protection goal options** ready for consultation (analysis of legislation requirements, proposal of tiered approach, general principles to consider, acceptability criteria, protection goals proposal for each group of organisms)
  - **Consultation with Risk Managers** (back to back SCFCAH, January 2010)
  - **Stakeholder Workshop** on protection goals (March / April 2010)
  - Adoption of Opinion on protection goals (mid 2010)
- ... more specific sub-WGs (to be) created during the process...

# GDs RA on Ecotoxicology: Revision process



# EFSAs working procedures for GDs



- Openness + consultation
  - External experts
  - Public consultations (early and late in the process)
  - Stakeholder workshops
    - Open registration policy
    - Selection of participants based on expertise, affiliation, and geography
  - Risk manager consultations
    - Questionnaires
    - Meetings
  - Stakeholder consultative platform

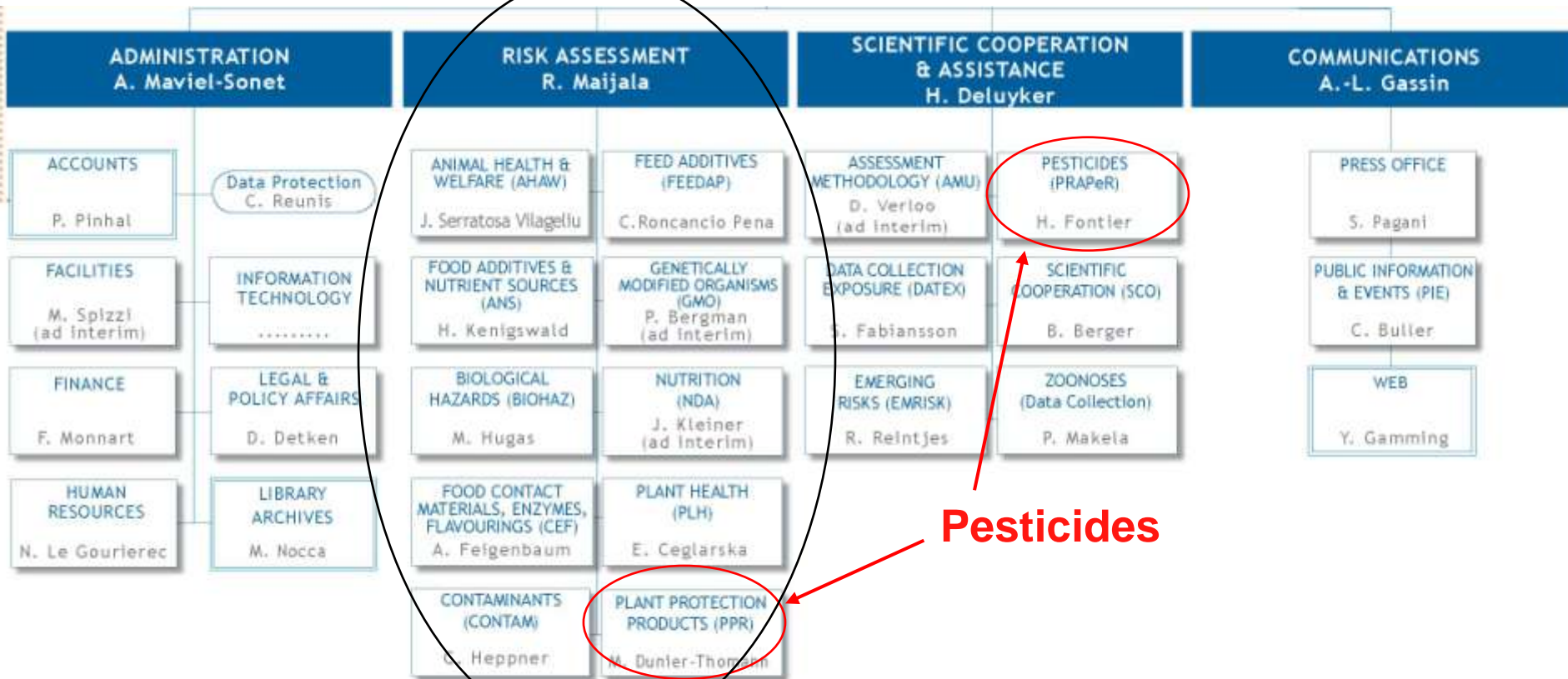
- Transparency
  - Declaration of interest policy
    - Experts declare interests in DOIs
    - DOIs are assessed by EFSA according to rules
    - DOIs are published
  - Reports and opinions published
  - public consultations reported and published
  - Minutes of WGs published
  - [www.efsa.europa.eu](http://www.efsa.europa.eu)

# Outlook...



**Science**

**Panels**



**Pesticides**



- Emergency in PRAPeR unit in 2010
- Decision of the Executive Director to transfer part of PPR unit staff to PRAPeR unit in 2010 for 6 to 9 months
- Sectors: Residues:100%, **Ecotox 100%**, Tox 50%, **Fate 50%**
- Consequences on the 2010 Workplan for GDs

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		<b>Emissions from Greenhouses</b>			

# Current GDs timeline

*Finalisation by end of 2009, new follow up questions postponed*

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		<b>Emissions from Greenhouses</b>			

*Part of the activities (1 GD) frozen for 9 months in 2010*

*Finalisation in 2010 will be a priority, delay foreseen*

*Any additional mandates postponed*

# Outlook...



# Thank you!

