

# Zonal developments & Regulation 1107/2009

*(With a focus on efficacy...)*

**Euros Jones**  
[euros.jones@ecpa.eu](mailto:euros.jones@ecpa.eu)

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# Introduction...

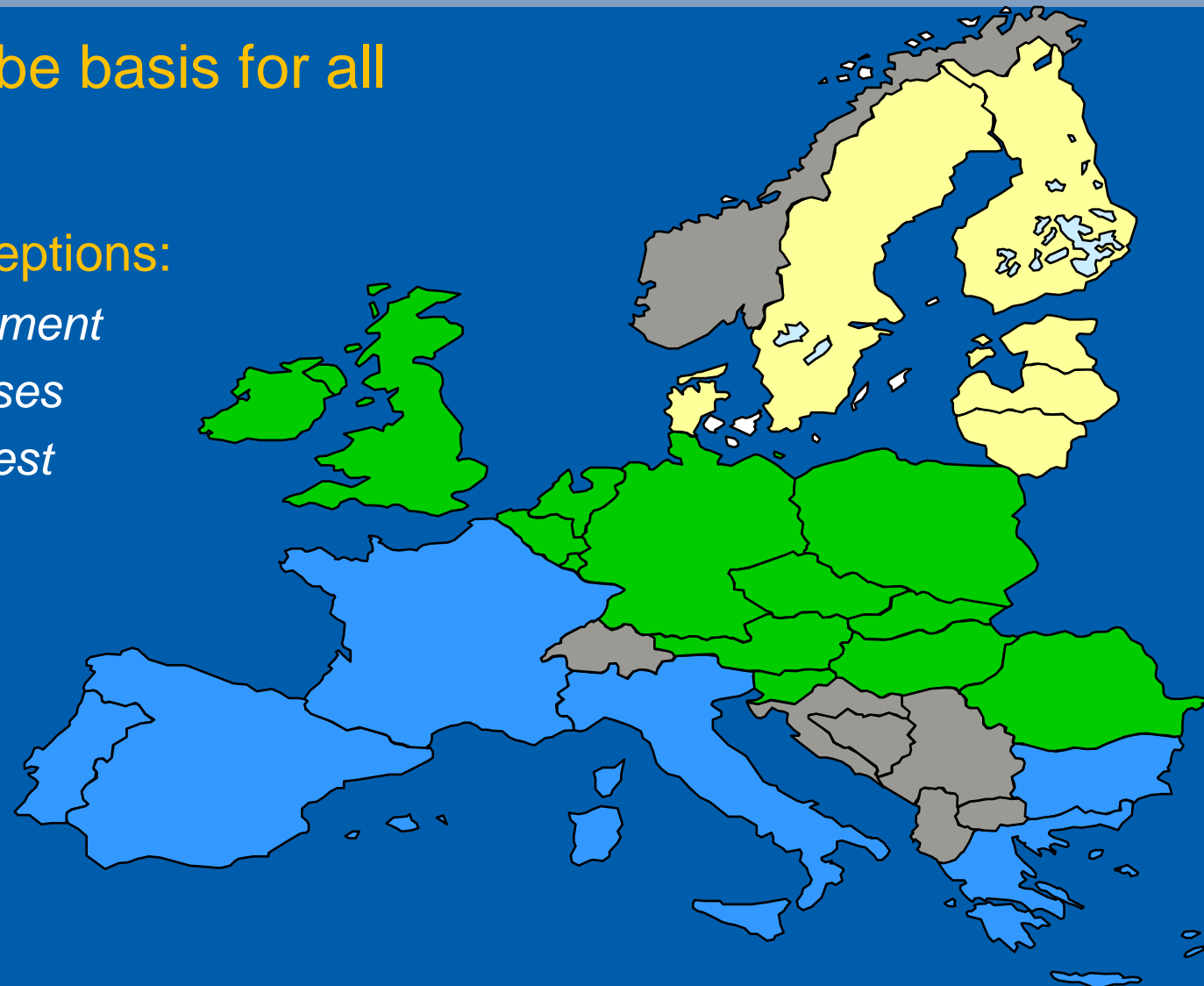
- Zonal approach in Regulation 1107/2009 for the benefit of authorities, agriculture and industry
  - Work sharing will allow faster registrations and free up capacity for new innovations
  - EU/zonal agreements on formats, requirements and methods is a prerequisite to achieve the benefits

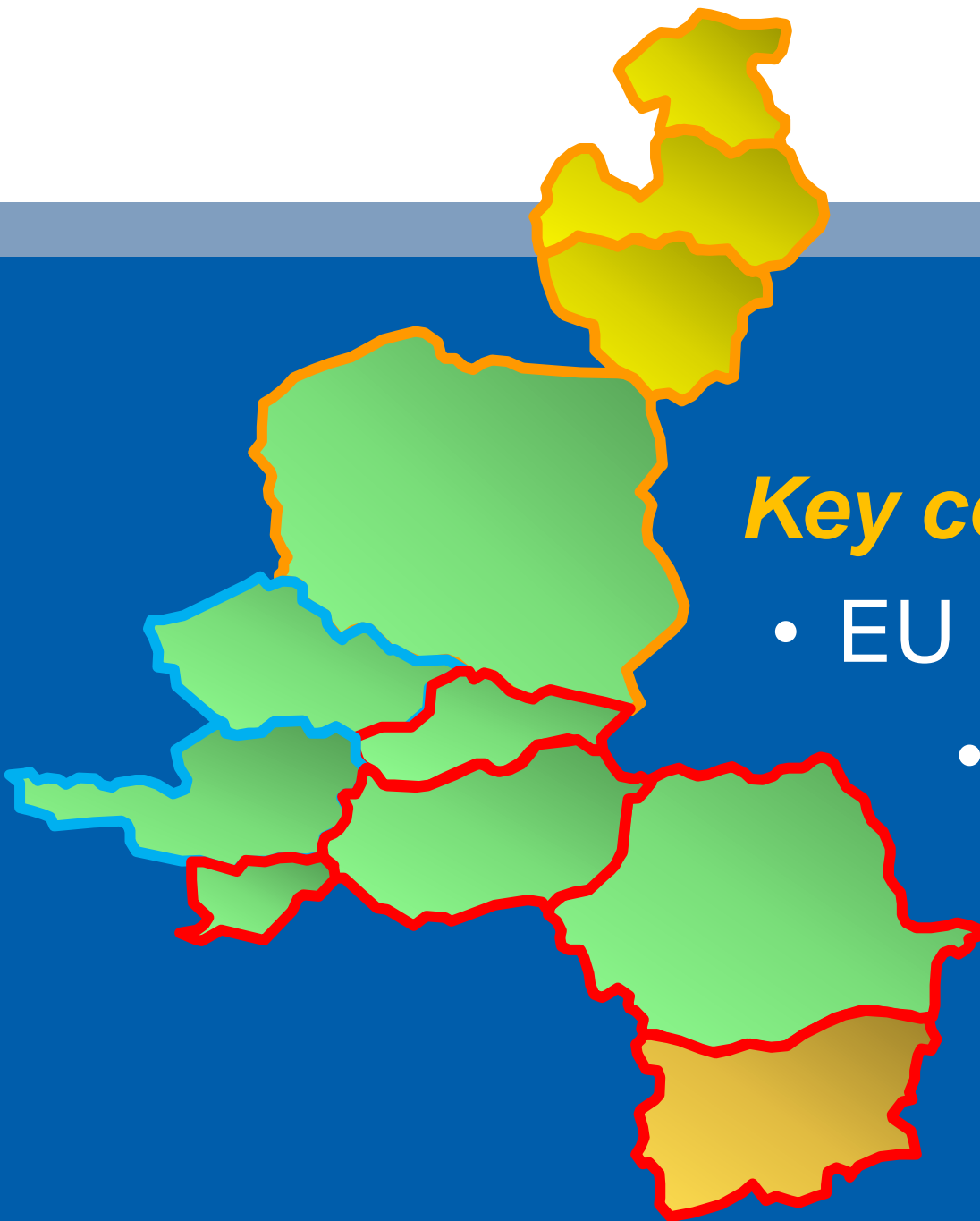
# Administrative Zones in Europe

3 zones should be basis for all developments...

➤ With few exceptions:

- *Seed treatment*
- *Greenhouses*
- *Post-Harvest*





## *Key considerations:*

- EU vs EPPO zones
- Making it work!

# EU zones & EPPO zones

- Zonal approach for Biology should be considered in the same way as other sections of the Dossier.
  - Agronomic practice & climatic condition may vary within EU registration zone, but...

***This is not an opportunity for a particular number of 'standard' trials in each country!!***

# Making zonal work...

## National requirements

- ECPA currently collating a list
- Next step must be to remove as many as possible!

## PPR Panel opinions

- Opinions & GDs must **support (not hinder) zonal process!**
- EFSA has important role to make zonal work

## Guidance documents

- Zonal GD to be agreed in October?
- Risk envelope GD to be agreed in early 2011?
  - Need guidance on efficacy submission in dRR...

# Overview of the structure / Core / National documents

## Part A: Risk Management

**Part B**  
CORE Risk  
Assessment

**Section 1**  
**Chemistry**  
(doc M)

References  
(doc K)

**Part B**  
CORE Risk  
Assessment

**Section 2**  
**Methods**  
(doc M)

References  
(doc K)

**Part B**  
CORE Risk  
Assessment

**Section 3**  
**Toxicology**  
(doc M)

Country  
Addenda

References  
(doc K)

**Part B**  
CORE Risk  
Assessment

**Section 4**  
**Residues**  
(doc M)

Country  
Addenda

References  
(doc K)

**Part B**  
CORE Risk  
Assessment

**Section 5**  
**E-Fate**  
(doc M)

Country  
Addenda

References  
(doc K)

**Part B**  
CORE Risk  
Assessment

**Section 6**  
**Ecotox**  
(doc M)

Country  
Addenda

References  
(doc K)

**Part B**  
CORE Risk  
Assessment

**Section 7**  
**Efficacy**  
(doc M)

Country  
Addenda

References  
(doc K)

## Part C: Confidential Info.

(to include contents of Documents G,H and J)

# draft Registration Report (dRR) – Part B Section 7. Efficacy

dRR

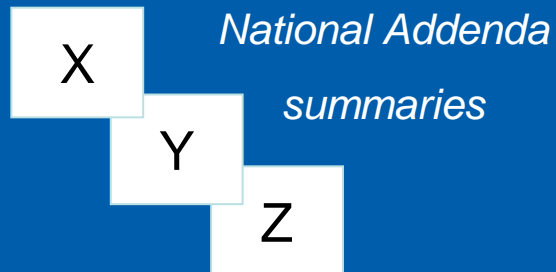
*Zonal summary*

Summary - equivalent to current AIII A-6.6  
plus Appendices 1-2  
(1- list of data, 2 –GAP)

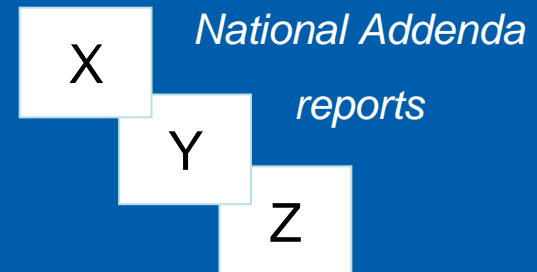
document K

*Zonal BAD*

'Dossier' containing all elements of  
OECD AIII A 6.0 – 6.7  
plus individual study/trial reports



*Public*



*NOT public*



# Zonal Efficacy Workshop

## 23 September 2010

### Key Summary Points



# Efficacy Input into dRR

General agreement to include a 'Summary' from BAD to...

- Provide key summary points only in the dRR
- Avoid duplication of content/detailed evaluation in dossier

There is a need for more clarity/agreement on the level of detail in the 'Summary' section to put in the dRR

## Way forward:

- MSs to provide examples on the preferred level of detail required in the dRR (by end November 2010 )
- ECPA to review Member State responses and suggest a common summary format for inclusion in the dRR guidance

# Core versus National Considerations

Aim should be to include as much information in Core dossiers rather than as National addenda!

- Keep National aspects to a minimum (*e.g. IPM; Convenience Tank Mixes; Local Resistance Management Strategies*).
  - ✓ Encourages work sharing & more efficient use of resource
  - ✓ Better facilitates the process of Mutual Recognition

Would be useful to have common guidance to assist the process.

➤ Guidance will help – but agreement needed for each dossier at the pre-submission meeting with the Z-RMS

## Way forward:

- ECPA to review different views expressed and suggest a way forward in developing common guidance
- French Authorities to propose the development of EU guidance

# Data Generation

## – General Agreement Points

- Acceptance of data according to EPPO zones across regions
- Acceptance of data from other regions/sources as long as relevant scientific justification provided in data package
- Acceptance of data generated according to EPPO guidelines
  - *Less emphasis in future on National guidelines!*

# Conclusion

## Zonal approach is an opportunity...

- *For greater efficiency*

- *To encourage innovation*

- **Cooperation essential**

- EFSA & Commission

- Member States & Zones

- Industry

- **Remove national requirements**

- **Greater MS acceptance of all relevant data**

**□ *Good implementation will benefit authorities, agriculture and industry!!***