



# Plant protection product regulations in the EU – an overview

252nd ACS National Meeting & Exposition, Philadelphia  
AGRO Session: Who Should Regulate Pesticides in Our Food  
24th August 2016, Monika Richter, BASF SE


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**Consumer Safety**  
safe use – safe food

# Outline

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- Regulation (EC) No 1107/2009
  - Regulation (EC) No 396/2005
  - Planned review of 1107/2009 and 396/2005
  - Monitoring of plant protection residues in the EU
  - Challenges and Outlook

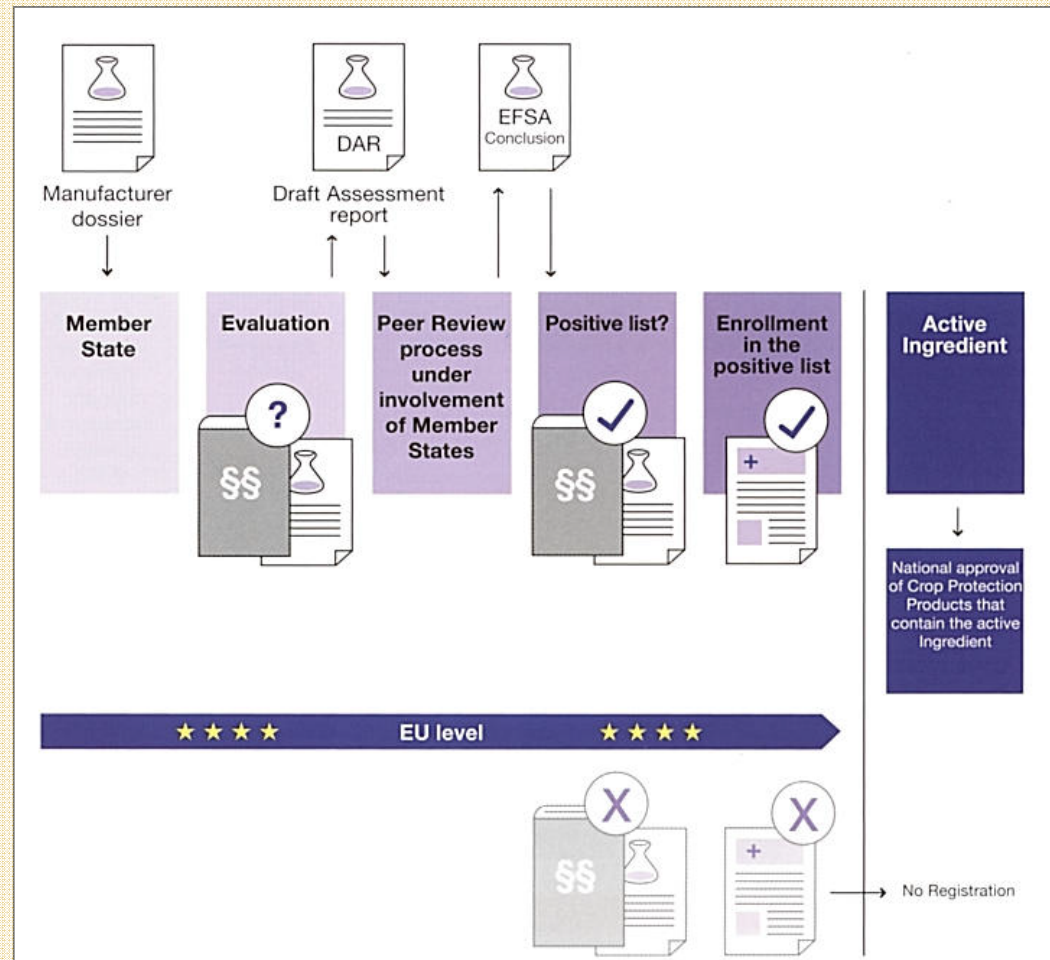


# Regulation (EC) No 1107/2009 – Regulation on placing of Plant Protection Products on the market

**Basic Regulation for plant protection products in the European Union is Regulation (EC) No 1107/2009**

Active ingredients are registered on EU level

Products are registered on country level



# Regulation (EC) No 1107/2009 – News (1)

## Hazard based criteria

An active substance, safener or synergist shall only be approved if it is

- not considered to be a persistent, bioaccumulative and toxic (PBT) substance
- not considered to be a very persistent and very bioaccumulative substance (vPvB)
- not to be classified (...) as mutagen category 1A or 1B
- not to be classified (...) as carcinogen category 1A or 1B or as toxic for reproduction category 1A or 1B, unless the exposure of humans (...) under realistic proposed conditions of use, is negligible
- not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans (...) under realistic proposed conditions of use, is negligible



# Regulation (EC) No 1107/2009 – News (2)

## Candidate for substitution (CfS)

An active substance shall be approved as a candidate for substitution if

- ADI, ARfD or AOEL is significantly lower than those of the majority of the approved A.S.
- It meets two of the criteria to be considered as a PBT substance
- It contains a significant proportion of non-active isomers
- ...

### Consequences:

An active substance identified as candidate for substitution shall be approved for 7 years.

Plant protection products containing such active substances identified as CfS should regularly be examined with the aim of replacing them by plant protection products containing active substances which require less risk mitigation or by non-chemical control or prevention methods.

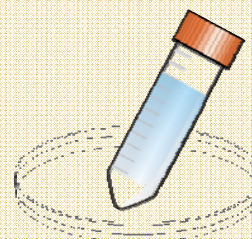
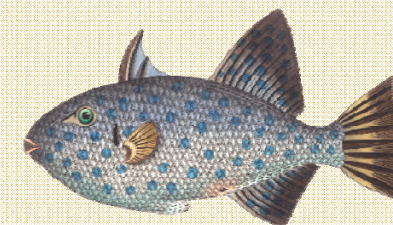


# Regulation (EC) No 1107/2009 – News (3)

## New data requirements

New data requirements in the sector of consumer safety were introduced

- Metabolism study on fish
- Feeding study for fish
- Comparative in vitro metabolism studies
- Residue levels in pollen and bee products
- Methods for analysis of body fluids and tissues
- Commercial availability of analytical standards

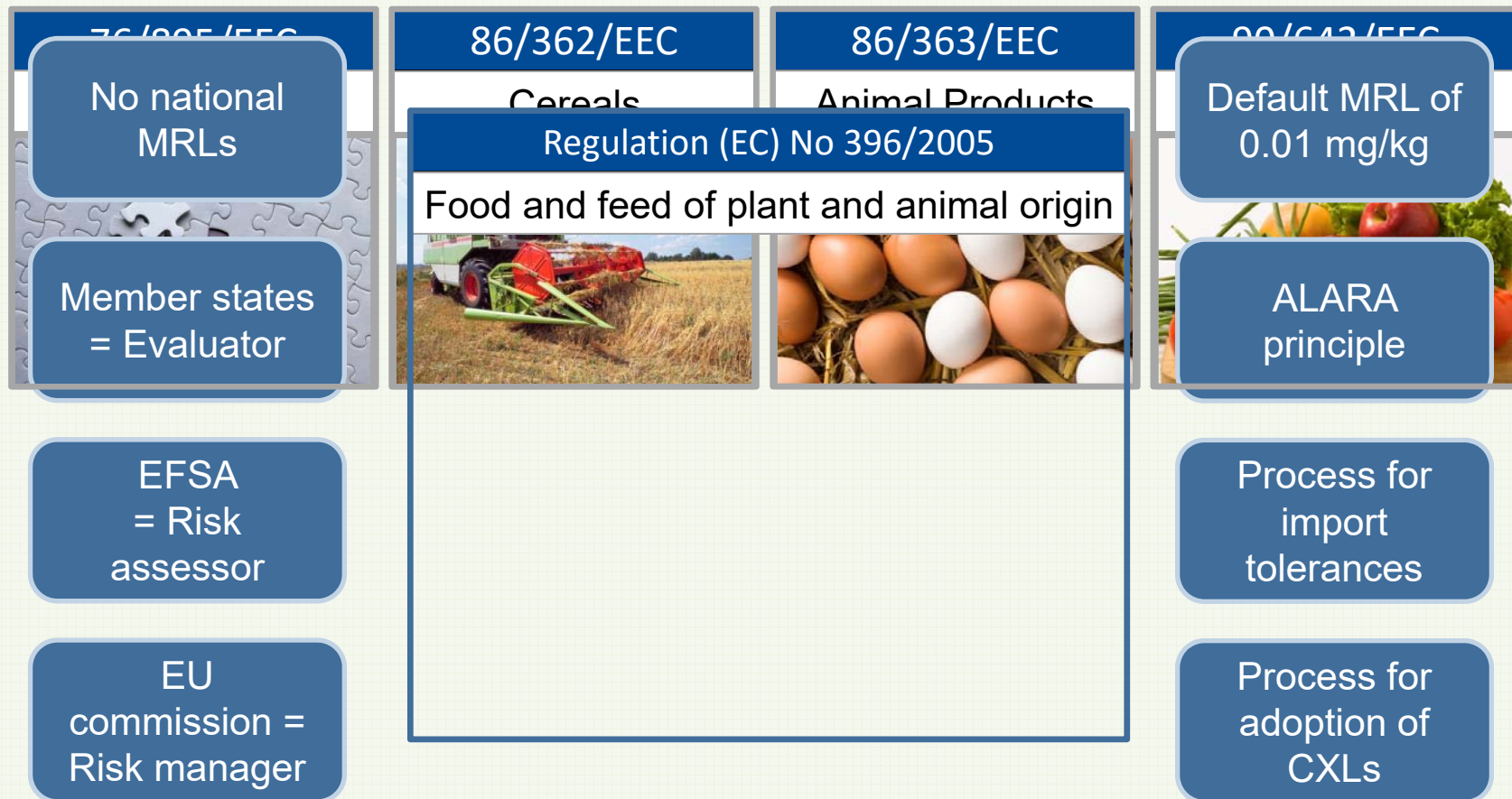


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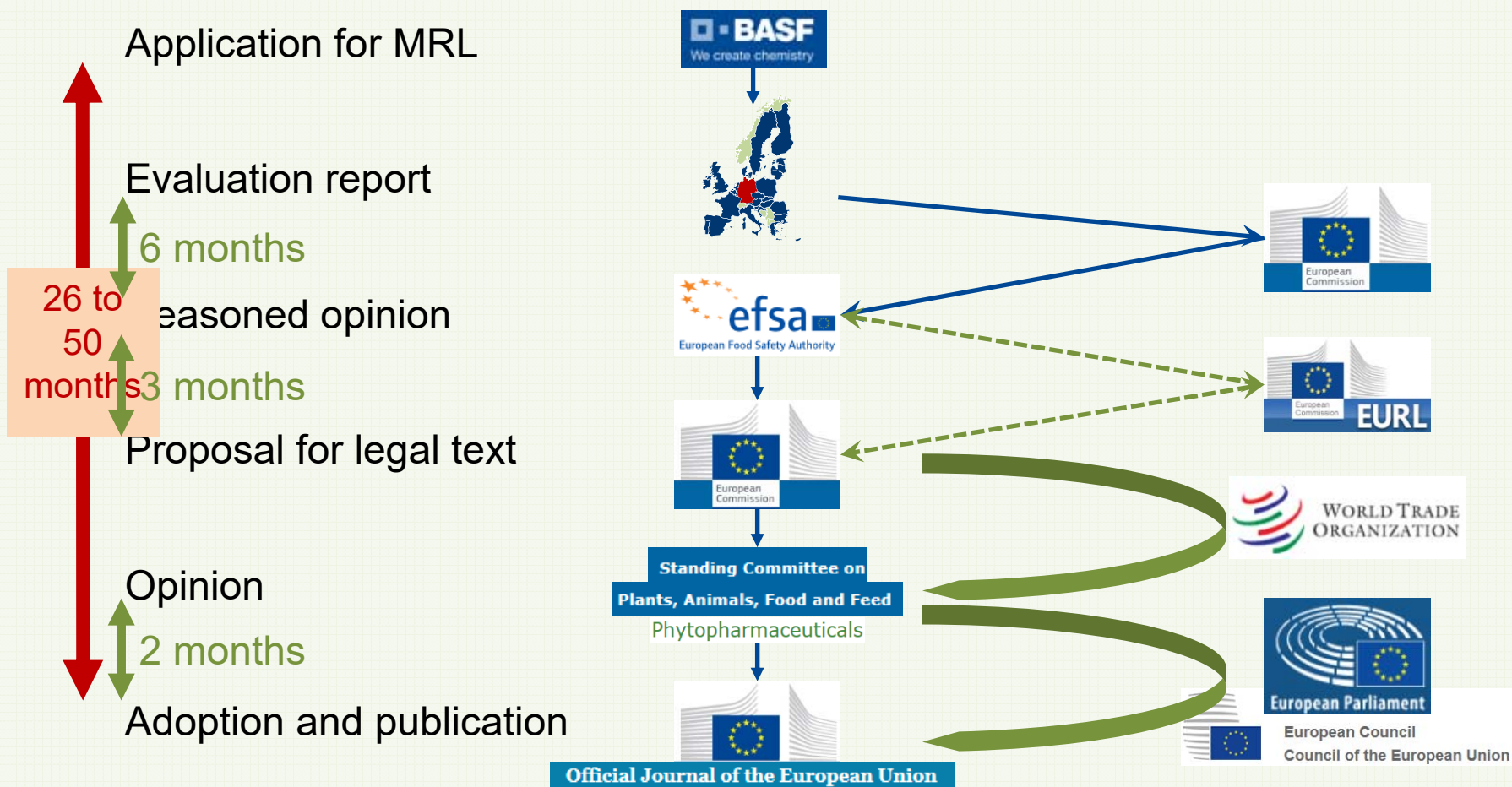
# Regulation (EC) No 396/2005 – on maximum residue levels of pesticides in or on food and feed of plant and animal origin



**➔ MRLs are now harmonized within the European Union!**



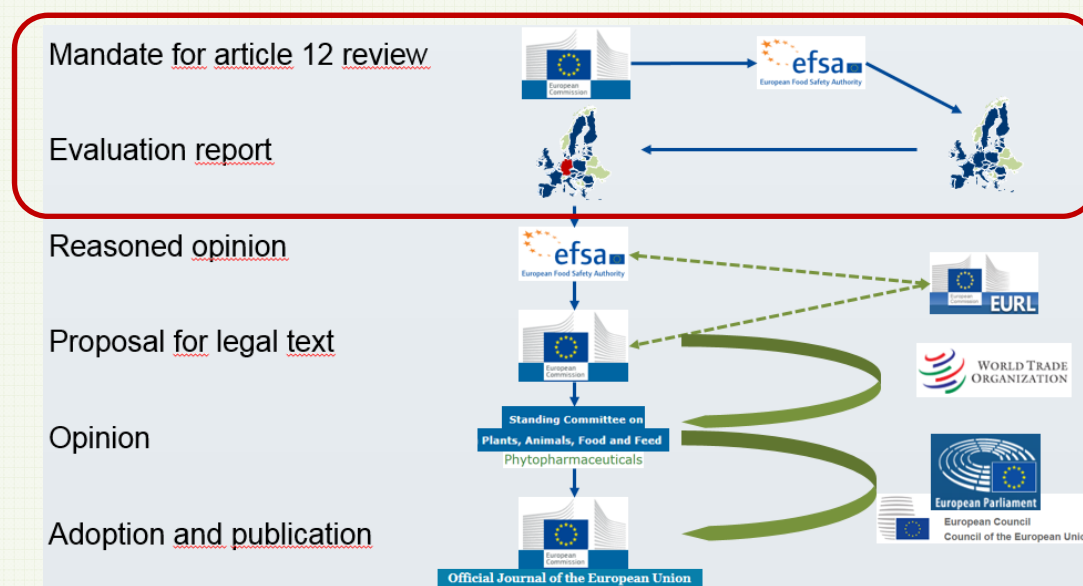
# Regulation (EC) No 396/2005 – MRL setting procedure



# Regulation (EC) No 396/2005 – Review of all existing MRLs

Article 12 of Regulation (EC) 396/2005 is to review all existing MRLs. This review process has been on-going since 2008.

The current list with all active ingredients to be evaluated can be found at <http://www.efsa.europa.eu/en/events/event/140619>



# Regulation (EC) No 396/2005 – Review of all existing MRLs

In June 2016, WTO published a communication from the European Union on how non-EU countries may submit additional data to the EU risk assessors.

[http://ec.europa.eu/food/plant/docs/pesticides\\_mrl\\_guidelines\\_mrl-review\\_en.pdf](http://ec.europa.eu/food/plant/docs/pesticides_mrl_guidelines_mrl-review_en.pdf)

## 1) At an early stage, via the Rapporteur Member State (RMS):

(..) before the risk assessment is carried out by EFSA. Non-EU countries should first contact the manufacturer of the active substance concerned.

## 2) During the WTO/SPS consultation procedure:

WTO members have 60 calendar days to send their comments to the WTO notification



# Regulation (EC) No 396/2005 – Adoption of CXLs

In accordance with Article 43 of Regulation (EC) 396/2005, EFSA receives request from the European Commission to provide support for the preparation of the EU position for next year's session of the Codex Committee on Pesticide Residues (CCPR).

This request is usually made after the JMPR evaluation meeting, taking place in September.

EU will adopt CXLs to EU-MRLs if EU requirements with regard to

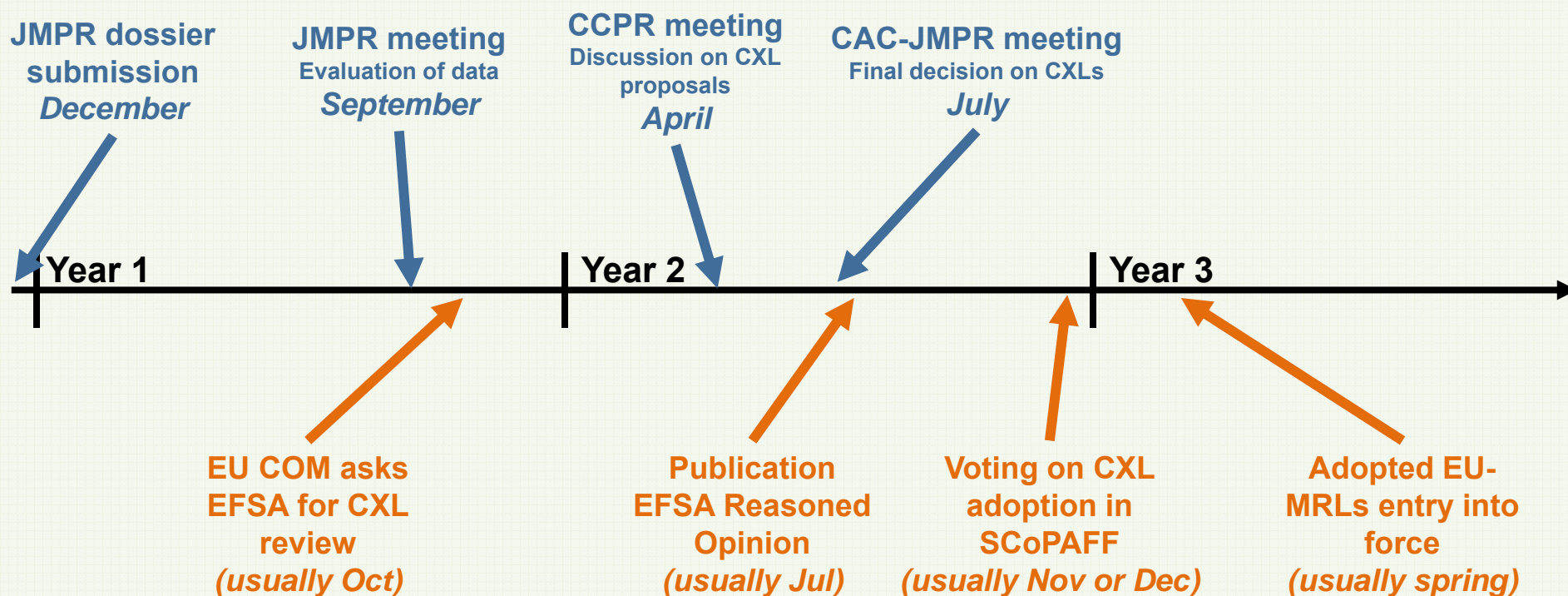
- number of required field trials
- acute and chronic dietary risk assessment with EFSA PRIMO model
- matching residue definitions

are met



# Regulation (EC) No 396/2005 – Adoption of CXLs

## Process of CXL setting by JMPR (WHO and FAO experts)



## EU process for adoption of CXLs

**Only CXLs which pass the EU requirements will be adopted!!!**



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# Planned review of 396/2005 and 1107/2009

- Revision of regulation (EC) No 396/2005 planned jointly with regulation (EC) No 1107/2009
- Currently a road map for public consultation is being drafted
- Evaluation study by an external contractor is planned for 2016/2017
- Reports to Council and Parliament: 2017/2018
- Alignment with Reg. 1107/2009, e.g. cut-off criteria, procedural alignments
- Biocides
- Clarifications and addressing legal gaps e.g. dual use substances, presence of residues from other sources than PPP use



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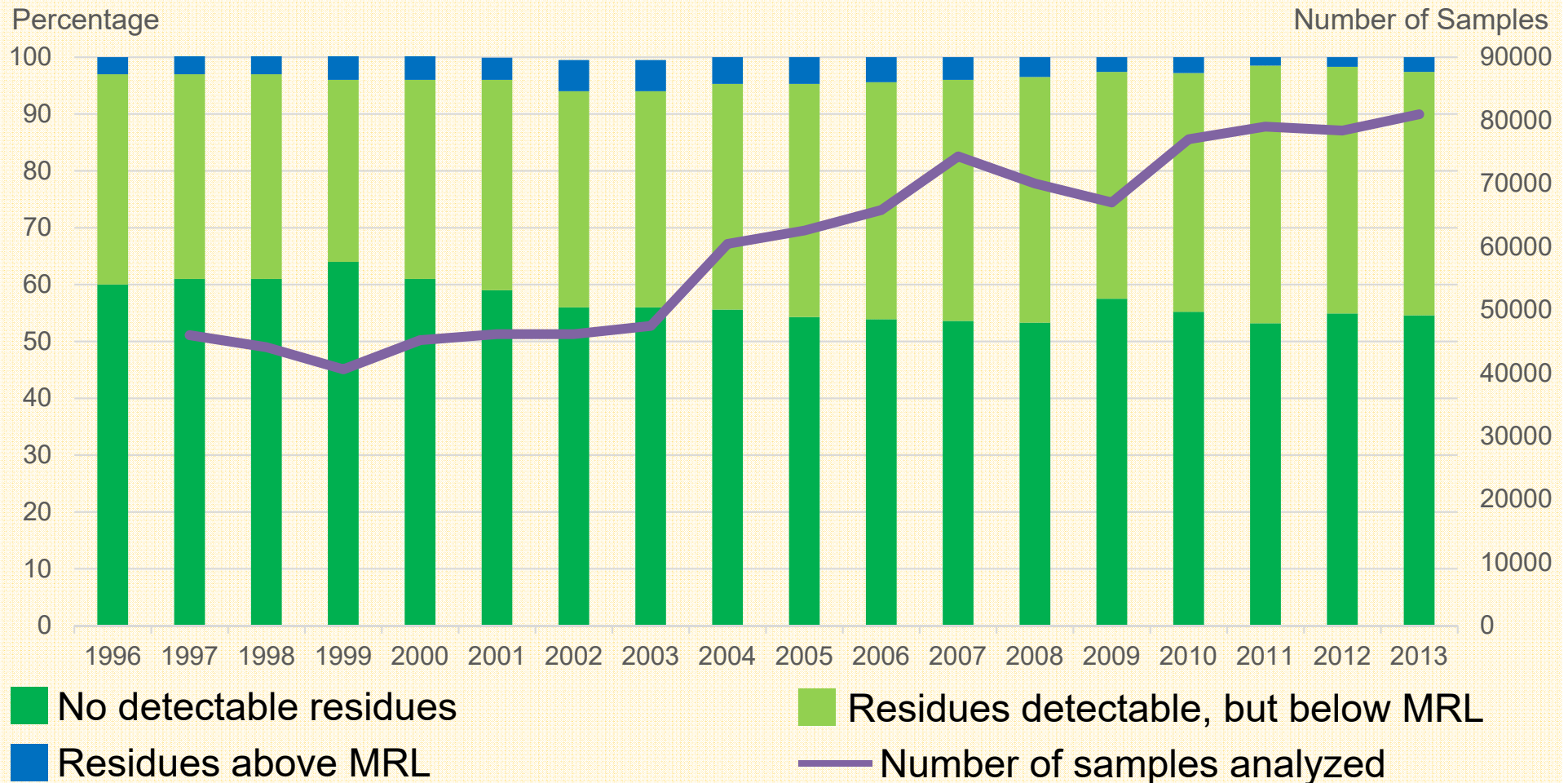




# Monitoring of pesticide residues in the EU 1996 - 2013



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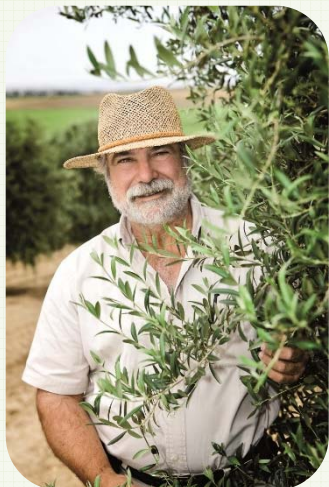
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# Challenges and Outlook Plant Protection Products in the EU



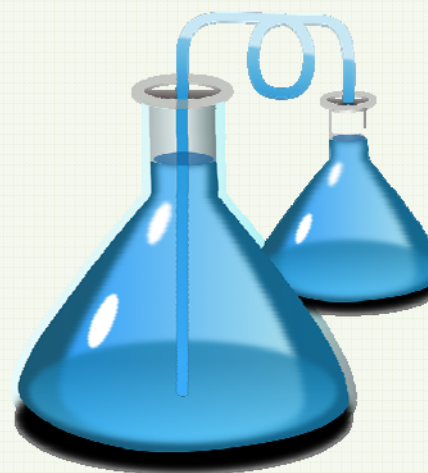
- Good efficacy
- Good resistance profile



- Low application rates
- Minimal effect on environment



- No harmful effect on consumers
- Low / no residues



- Simple MRLs and easy analytical methods for monitoring



A close-up photograph of a basket filled with numerous red and green peppers. The peppers are vibrant and glossy, with some showing signs of ripening or slight bruising. The basket is dark, and the lighting highlights the texture of the peppers.

**Thanks a lot for your attention!  
Any questions?**



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