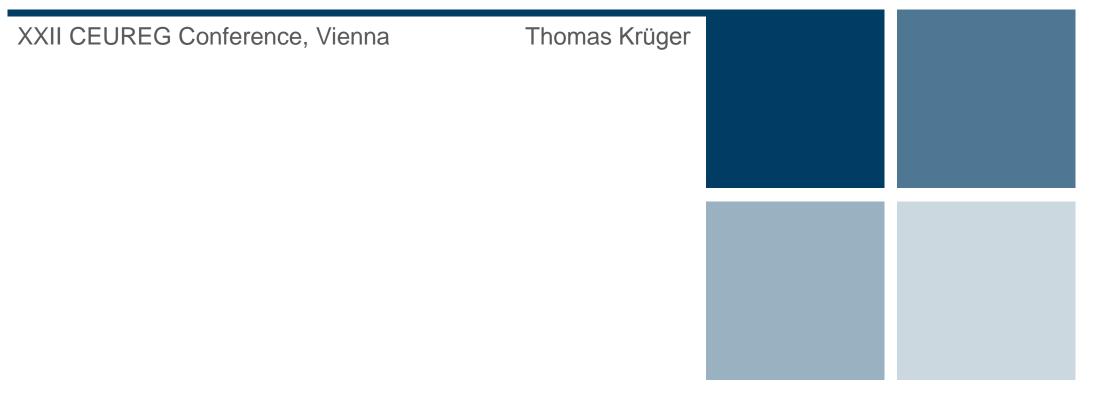
Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues





Structure

Link to our report

https://publications.europa.eu/s/i9z4

REFIT website:

https://ec.europa.eu/food/plant/pesticides/refit_en



Structure

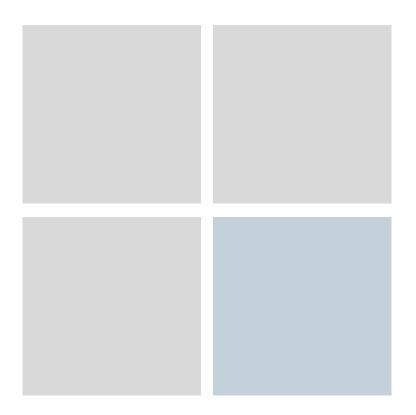
1. Context of the study: REFIT evaluation of the EC

2. Design and implementation of the study: Methodological approach, data collection and analysis

- 3. Structure of the study: The report
- 4. Results of the study: Key findings



Context of the study





Roadmap and timeline

- EC launched evaluation process in 2016
- Regulation (EC) 1107/2009 and Regulation (EC) 396/2005
- REFIT: Regulatory Fitness and Performance programme
- Assessment of implementation and performance
- Supported by an external study



Context of the study

External study

- Five evaluation criteria
- July 2017 until July 2018
- Conclusions, no recommendations
- Final report to be published soon

Effectiveness

Efficiency

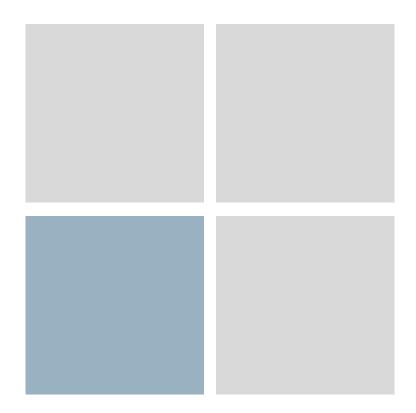
Relevance

Coherence

EU Added Value



Design of the study



Design of the study



- 28 evaluation questions
- Identification of judgement criteria and indicators
- Mixed qualitative and quantitative approach
- Data sources: desk research, consultation activities, case studies



Implementation of the study

Desk research

- Studies and reports
- Academic literature
- Databases
- "Grey" literature

Case studies

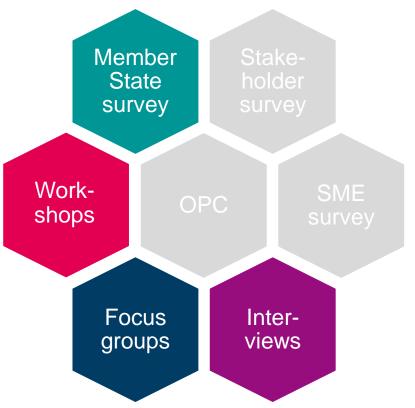
- In-depth assessment of individual cases
- From application to the market
- Impacts on trade
- Candidates for Substitution



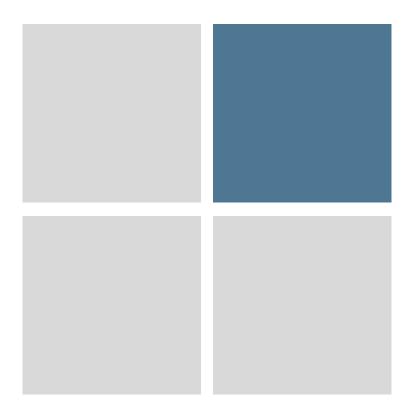
Design of the study

Consultation activities

- Extensive consultation strategy
- High participation rate
- Balanced representation of interests
- Several opportunities to contribute for EU-28, Norway and Iceland

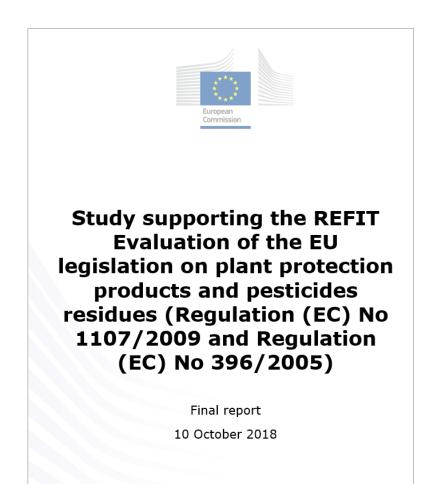


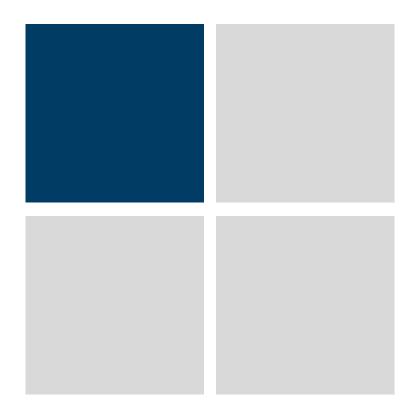
Structure of the study



The report

- Main report
 - Executive Summary
 - Analysis per evaluation question
 - Conclusions
- Appendices and Annexes
- Structured response to evaluation questions





General impression

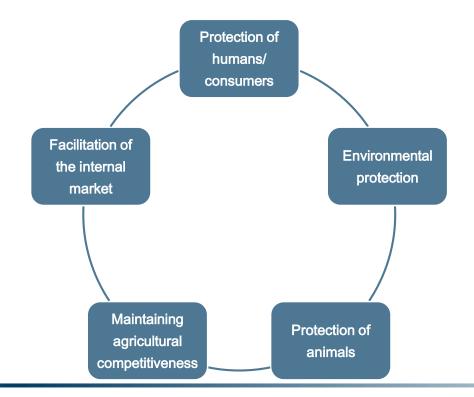
- Fact finding
- Results generally confirm sentiments and beliefs
- Some surprising results
- Comprehensive compilation of different aspects and views



Added value

The two Regulations add great value and enhance the regulatory framework on PPPs and their residues

- Harmonisation of rules
- Enhanced cooperation
- Achieve their objectives



Unanimous agreement





Room to improve

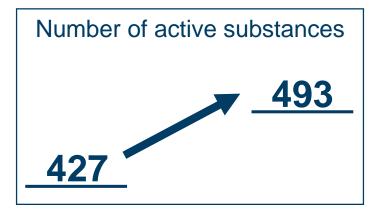
- Challenges remain for different reasons:
 - Non-implementation
 - Lack of resources
 - Delays
 - Scientific development
 - Provisions do not work as intended
 - ...
- For some aspects still too early to judge

Overall, the Regulations are working... but...

Active substances

All fine?

- Number of active substances increased
- 22 new actives, 8 authorised in MS
- Increase partly due to basic and low-risk substances
- No large reduction of active substances due to "cut-off" criteria





Approval of active substances

Not so fast...

- Confirmatory data
- Signalling effect
- Non-approvals:
 - 15 based on environmental
 - 23 based on health concerns
- Delays in (re-)approval procedures

Effects yet to fully materialise?



Approval of active substances

Quick replacements?

- Rate of new approvals per year remains constant
- But: needs to go up (for more targeted solutions)
- Challenging, especially for SMEs, to develop new substances
- Criticism concerns long procedures, delays, etc.

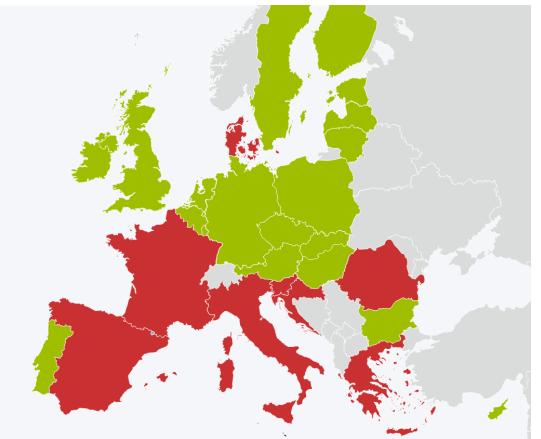


Plant Protection Products

- The number of PPPs increased over the last 7 years
- Finding also valid when looking at different types of PPPs
- Decrease mostly in Southern Zone
 - Consolidation?
 - More affected by non-approvals?
 - ..

But: PPPs ≠ Uses

• Still, number of actives approved in PPPs also increased

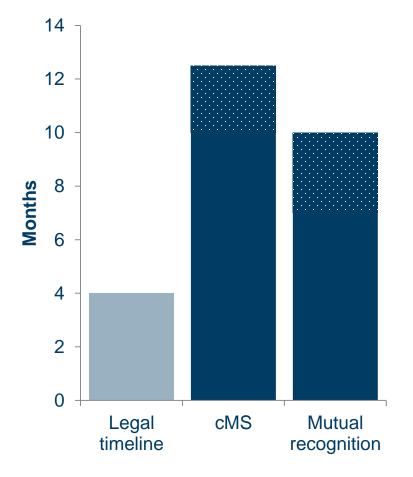


PPP authorisation

Zonal system and mutual recognition

- Not working as well as hoped for
- Challenge: national and zonal requirements
- E.g. delays for authorisations in cMS/ via MR

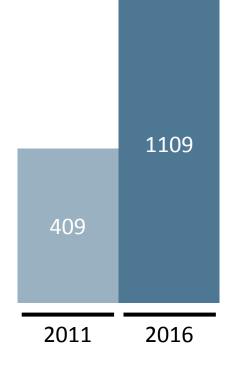
So is there any improvement?



PPP authorisation

Yes!

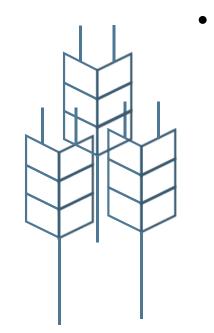
- Number of mutual recognitions more than doubled:
- Duration for authorisation decreased
- Harmonisation of requirements (at least within zones)





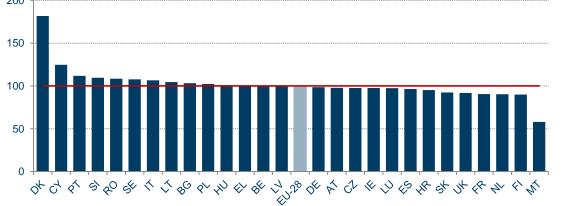
Agriculture

- Great concerns that competitiveness of EU farmers deteriorates
 - Lack of products available
 - Increased costs



- Evidence does not support these concerns
 - No clear evidence on products lost (exception: neonics)
 - Costs remained relatively stable 200

Future development?



Comparative assessment

- No substitution of PPP yet
- Several reasons:
 - Minor uses
 - No replacement available
 - Alternatives not as efficient

As of now: only adds burden, no benefit

But: "Signalling effect"







MRLs

- Generally more positive views on 396/2009
- Procedures more efficient compared to before implementation
- Similar challenges as 1107/2009:
 - Delays
 - Capacity
 - Scientific progress
- Particular challenges
 - Cumulative risk assessment
 - Art. 12

Only **1.6%** of samples not compliant with MRLs in 2015



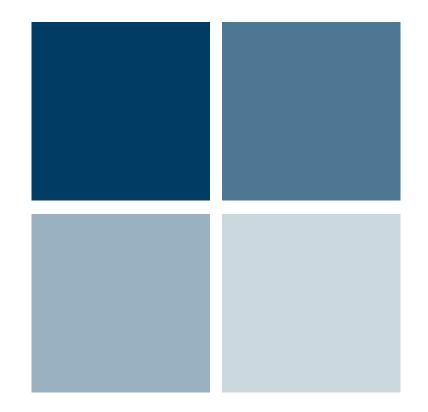
Summary/ Key points for attention

• Capacity issues

- Work sharing already in place, but not enough?
- Too strict deadlines? Or not strict enough?
- Coordination and knowledge management
 - Sharing of information?
 - Approaches across zones?
- Relevance in light of science and society
 - Adaptation to "new" substances?
 - Adaptation to changing societal demands?
 - Adaptation to farmers' demands?



Thank you



thomas.kruger@ecorys.com



