European Crop Protection

View of the industry concerning PPP authorization

Aurélie Dhaussy

ECPA Senior Manager Regulatory Affairs

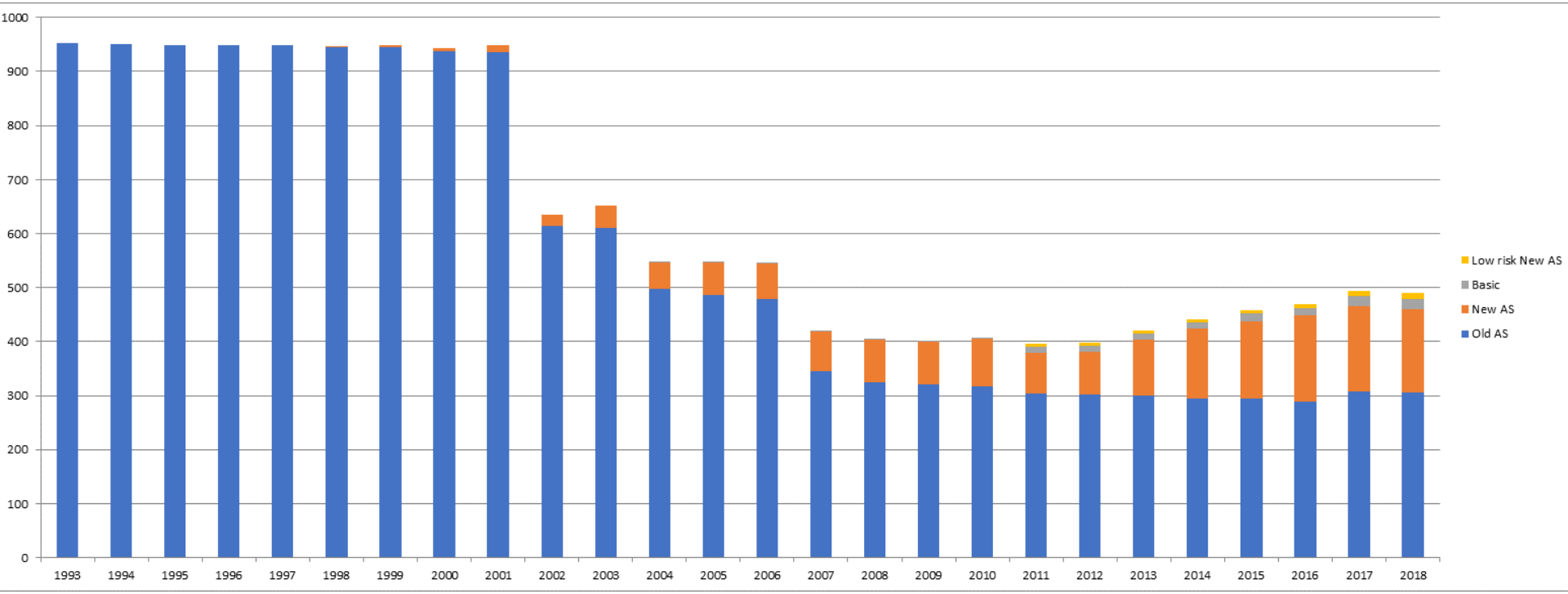
14 October 2019

European
Crop Protection

Authorisations trends

EU Approved active substances

European Crop Protection



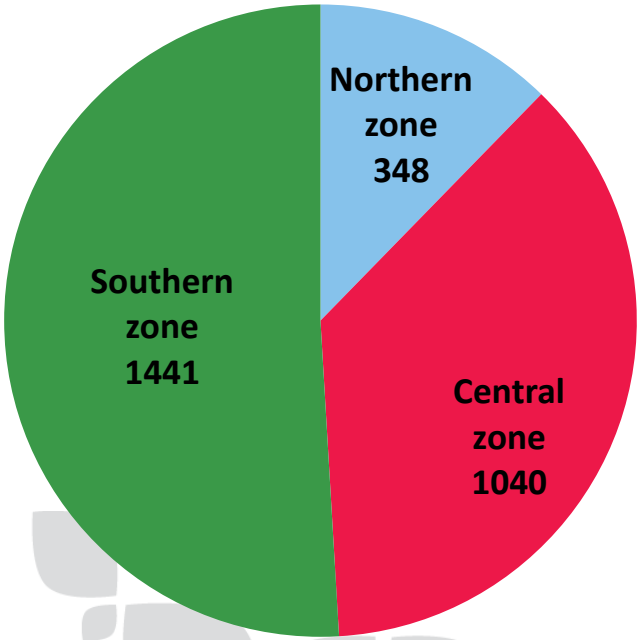
Source: ECPA

Emergency Measures in High Demand due to a system not well implemented?

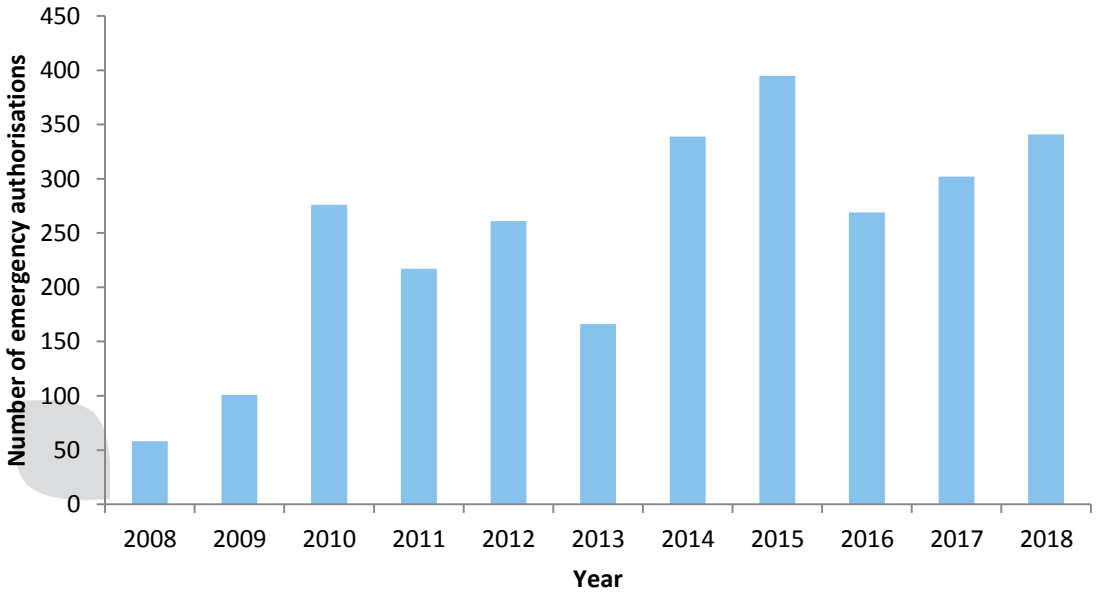
European Crop Protection

- 2717 Emergency Derogations given by all MS from 2008-2018
- 5 MS (ES, PT, FR, EL, IT make up for 47% of all EU Derogations
- Specialty crops (fruits and vegetables) at risk

Emergency authorizations per zone (2008-2018)



EU total emergency authorizations per year



Source: ECPA

Products evaluation

- **Member States capacity limitations**
  - Delays
  - Use GD available at the time of submission and EU endpoints
  - Publish agreements reached
- **Support cooperation between MSs and zones**
  - Minimize national data requirements
  - Zonal secretariat created in Central Zone, need to be a-extended to all zones
  - Cooperation between zones

Article 43 re-authorisations

European Crop Protection

- **Some improvement in Guidance document**
  - Regularly updated
- **Remaining, main difficulties**
  - Planning post AIR
  - Timelines of zRMS Allocation
  - Record Cat 4 decisions in the zone
  - Timing of Category 4 studies decisions: only 1 submission
  - Mixtures: avoid *multiple* dossiers/timelines
  - Pending evaluations new products: allow update to new endpoints

European
Crop Protection

Refit

Review reports

European Crop Protection

Commission

Consultant report
Jun/Oct

Refit COM working doc
Q1 2020?

SAM report
4 June

SAPEA

2018					2019		
Feb	March	July	Sept	Dec	Feb	June	Nov

Parliament

EPRS report
Apr

Poc report
10 Jul

Plenary vote
13 Sep

ECA report
15 Jan

PEST report
16 Jan

SUD report
12 Feb

GFL
Sept 19

Convergent conclusions

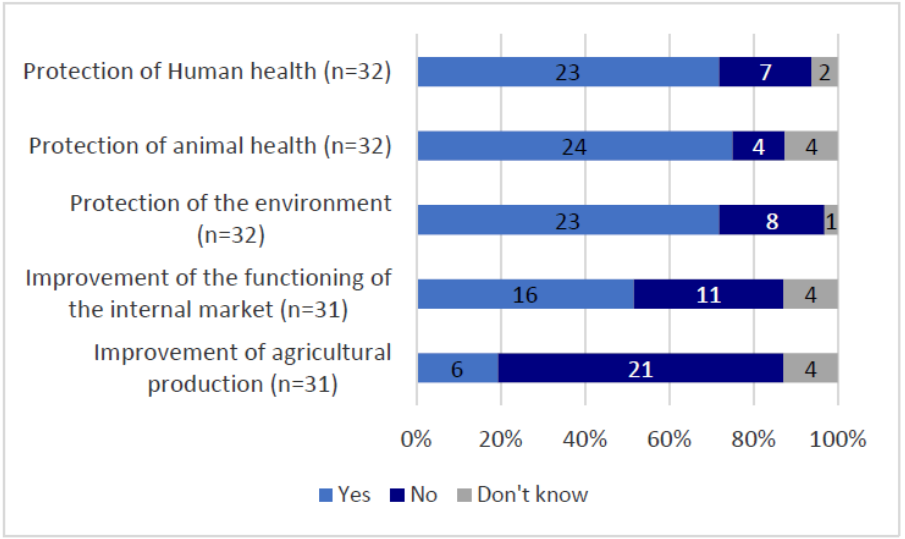
European Crop Protection

- Need to **improve implementation** of the current provisions
- **Delays** in process
  - Cause for increased use of emergency authorisations
- Insufficient **work sharing** (zonal, mutual recognition)
- Guidance documents **complexity**

”Stakeholders (across all categories with the exception of environment/health NGOs, organic food and farming, and the biopesticides industry), consider that the health and environment objectives of the regulation have been met.”

EPRS report PE 615,668, page 64

Figure 13: Do you think that the objectives of the PPPR are being met?



EPRS report PE 615,668, page I-110

Ecorys report: key findings

European Crop Protection

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

Issue	Report findings: Reg 1107/2009
Availability	- Number of active substances stable - Number of PPPs increasing, but number of uses decreasing
Protection health/environment	- Reg 1107/2009 contributes, but some failures
Hazard cut-off	- Strictest system - Majority say should be less strict
Timelines	- Largely exceeded
Zonal authorisation & mutual recognition	- Insufficiently working - Obstacle to LR, minor uses
Comparative assessment	- Inefficient: no substitution, burdensome
Latest science	- Limited flexibility to consider latest science
Guidance documents	- Bring harmonisation - But too complex and constantly modified
Article 53 (Emergency authorisations)	- Often used but necessary due to lack of PPPs and delays - Undermine NNI restrictions - Used to fast track decisions
Alternatives	- Unsufficiently available
Anti-counterfeit	- Lack of effectiveness and harmonization regarding control enforcement - Too low levels of sanctions to incentivize compliance

Ecorys report: key findings

European Crop Protection

Issue	Report findings: Reg 396/2005
Timelines	- Largely exceeded, especially in MRL reviews (Article12) – note there is no timeline for the EMS in Reg 396/2005
Protection health/environment	- Consumer safety objectives met
Import tolerances (IT)	- Setting ITs for cut-off substances: impact on global trade
Article 12	- Important delays in MRL reviews has led to conflicting processes with Reg 1107/2009
Multiple uses	- For substances used as pesticide, biocide and veterinary drug the process to reach a harmonized level of MRL is unclear (chlorate case)
Latest science	- Limited flexibility to consider latest science
Cumulative risk assessment	- Methodology is missing to evaluate CRA for MRLs
MRLs for feed and processed products	- No MRL for feed items and no processing factors published for the processed products

ECPA view

European Crop Protection

Focus : improve implementation of current provisions

AS evaluation

- Guidance document development
- Dialogue

PPPs

- Increased cooperation
- Improved process for renewals
- Anti-counterfeit

MRL evaluation

- Improve MRL review
- Single Evaluating Member State
- Transparent setting of import tolerances

European
Crop Protection

THANK YOU

aurelie.dhaussy@ecpa.eu