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Regulation 1107/2009

Industry feedback

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CEUREG, 10th October 2016

Experience with the zonal system

- **Member State capacity limitations**
  - Delays in evaluation by zRMS, and application refusals by MSs
- **National data requirements**
  - Review and harmonise or remove national requirements and guidance, including national efficacy needs
- **Good intentions to manage Art 43 renewals**
  - Optimise use of resources; better use of mutual recognition; early zRMS designation & pre-submission meetings
- **Threats to innovation**
  - Dossiers should remain in the queue where an updated dossier is provided 3 months after AS renewal

Are the 1107/2009 timelines achievable ?

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- **With the current implementation ? – No !**
  - Renewal processes do not make use of previous evaluations and do not take sufficient account of risk managers needs
  - Inefficiency from sub-optimal cooperation between MSs and zones
  - Poorly managed development of risk assessment guidance
- **With a reformed implementation ? – Yes !**
  - AS renewal focussed on specific areas of concern
  - Make best use of current evaluation of existing studies
  - Focus on single safe use AS (re)approval exam question
  - Zonal secretariat to support more efficient use of resources
  - Embrace zonal as a risk assessment workshare and focus on national risk management

What lessons have been learnt ?

- **Disproportionate resource demand on authorities & industry**
- **Not efficient, not predictable & negatively impacting innovation**
  - Europe's share of PPP R&D innovation is much reduced
- **PPP attrition rate is faster than the innovation rate**
- **Growers increasingly forced to rely on emergency uses**
  - This is a real threat to the sustainability of EU agriculture
  - Sends the wrong message about EU food safety

EU growers need 1107/2009 to give a regulated supply of PPPs

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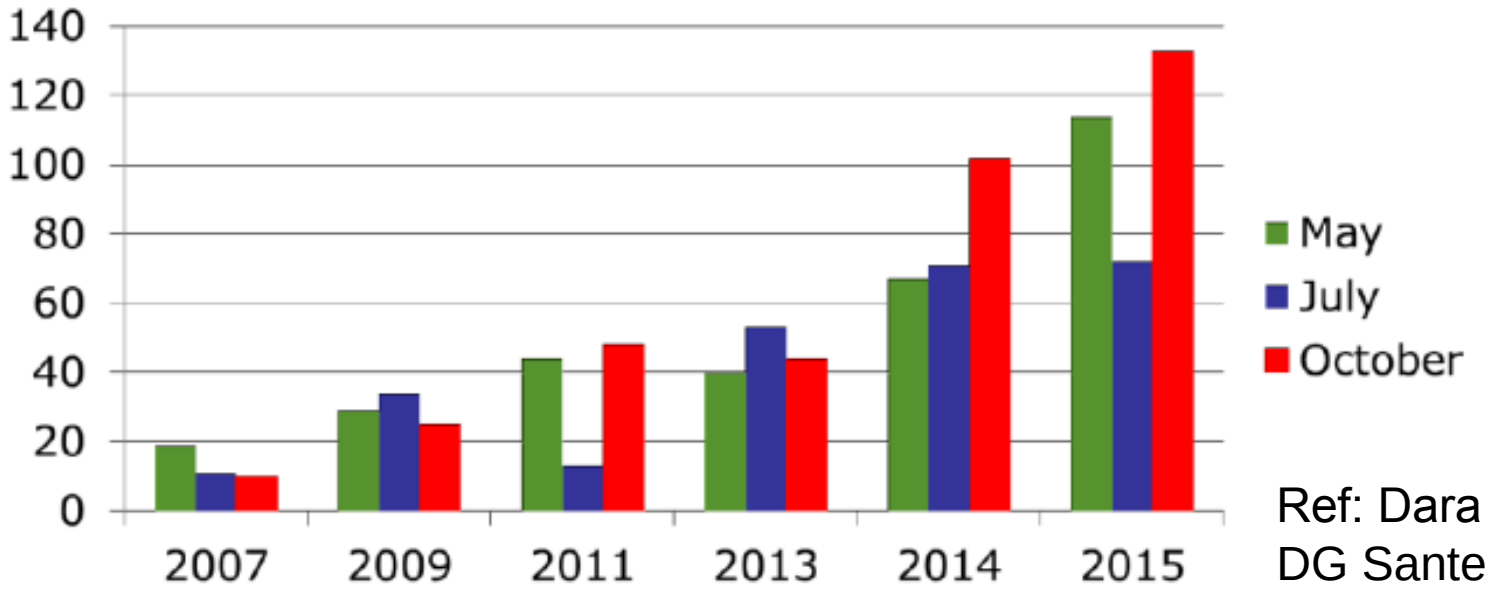
Numbers of emergency authorisations notified at PAFF meetings



Ref: Dara O'Shea
DG Sante
March 2016

What lessons have been learnt ?

- **There is currently insufficient attention to some key 1107/2009 policy goals**
  - To improve agricultural production and at the same time to safeguard the competitiveness of EU agriculture
  - Remove obstacles to trade in PPPs
  - Increase the free movement of PPPs
  - Increase the availability of PPPs in the Member States

Is the amendment of 1107/2009 necessary ?

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- **Assume legislative revision will not really help before 2025**
- **So the urgent priority is to reform 1107/2009 implementation**
  - The Member States, Commission, EFSA and industry should work together with an open mind to explore what could be helpfully reformed now, without the need for legislative revision
  - Preserve / enhance COM/MS AS risk management space
    - Avoid excessive conservatism, provide options to risk managers
  - Improvement in zonal delivery and efficiency
  - Scientific dialogue with EFSA and managed GD development
  - Data call-in, Task force study & cost sharing
  - Faster and more efficient MRL setting, single evaluating MS
  - Evaluate co-formulants under REACH don't add complexity & work

EU growers need it to work !

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Plant Protection Products regulation 1107/2009

MRL regulation 396/2005

Classification Labelling and Packaging CLP regulation 1272/2008

Renewal of AS approval

New Active Substance

Rapporteur Member State
Renewal Assessment Report (RAR) Draft Assessment Report (DAR)

EFSA opinion on setting Maximum Residue Levels

European Food Safety Authority EFSA conclusion on whether AS meets approval criteria

European Chemicals Agency ECHA Risk Assessment Committee RAC opinion for harmonised classification & labelling

Commission review report & draft approval regulation

Commission draft regulation on MRLs

Commission draft regulation on Adaptation to Technical Progress to the CLP regulation

Standing Committee for Plants Animals Food and Feed vote

Standing Committee for Plants, Animals, Food and Feed vote

Low risk or regular substance	15 years
Candidate for substitution	7 years
Article 4.7 approval	5 years
Fail cut-off criteria	No approval

Basic substance	Indefinite
Low risk substance	15 years
Regular substance	10 years
Candidate for substitution	7 years
Article 4.7 approval	5 years
Fail cut-off criteria	No approval

cMS product authorisation ← Northern zone zRMS product authorisation

cMS product authorisation ← Central zone zRMS product authorisation

cMS product authorisation ← Southern zone zRMS product authorisation

Registration, Evaluation, Authorization and Restriction of Chemicals REACH Committee vote

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Thank you !