EU Legal framework for pesticides – current isssues and challenges

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Criteria for identifying endocrine disruptors

- 4 July 2017: 21 MS representing 72,35% of the population endorsed the criteria proposed by the Commission for the identification of endocrine disrupting properties in the PPP area
- 25 September 2017: the Council decided not to oppose to these criteria
- 4 October 2017: the European Parliament rejected these criteria – the Commission cannot adopt them and interim criteria remain in force
- The Commission is now reflecting on the next steps

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Renewal of approval for glyphosate

- Proposal for a 10 year renewal of the approval put forward by the Commission in July 2017
- Two rounds of discussions with Member States: on 20 July and 5 October 2017
- Submission of European Citizens Initiative '*Ban glyphosate and Protect People and the Environment from Toxic Pesticides*' on 6 October 2017
- Date for a vote: 25 October 2017
- The "Commission has no intention to reapprove glyphosate without the support of a qualified majority of Member States", adding that "this is and will remain a shared responsibility".

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Neonicotinoids *(clothianidin, thiamethoxam and imidacloprid)*

- 2013: based on EFSA opinion restriction of use by prohibiting all uses on outdoor plants that were considered attractive to bees
- 2016: EFSA identifies further risks to bees from additional data to confirm the safety for bees for the uses still allowed
- 2017: Commission proposals to further restrict the uses
- Date for a vote still to be determined
- Expected end of Nov 2017: EFSA report on review of 2013 restrictions

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Progress with Low risk and basic substances (1)

Sustainable plant protection temporary expert group (NL Council presidency support) composed of 19 Member States delegates, COM and EFSA

- Objective to deliver a plan of actions to accelerate sustainable plant protection, in particular to identify measures to increase low risk products availability and accelerating the implementation of Integrated Pest Management in Member States
- Eight meetings organised since December 2015 including a workshop with MS to provide contributions for ongoing REFIT evaluation
- Council endorsed Implementation plan (40 main actions) in June 2016
- Follow up on actions implementation: aim to finalise an interim report on achievements by end of 2017
- EP adopted a resolution concerning low-risk pesticides of biological origin in February 2017

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Progress with Low risk and basic substances (2)

- Prioritisation of potential low risk active substances under the next renewal process AIR4 through Commission Implementing Decision issued in September 2016 (2016/C 357/05)
- Low risk criteria amended by Reg. (EU) 1432/2017
  - Sets specific criteria **for micro-organisms and for chemicals**
  - Clarifies exclusion from low risk based on hazards categories for chemicals in line with Reg.1272/2008
  - Multiple antimicrobial resistance criteria for micro-organisms
  - Aquatic toxicity to be verified by appropriate standard tests
  - Baculovirus recognised as low risk group
- Guidance in preparation for their implementation with clarification on related provisions for low risk products (e.g. not requiring specific risk mitigation measures)
- Work ongoing on a non-binding list identifying potential low risk active substances which were approved prior to full applicability of Regulation (EC)No 1107/2009

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Progress with Low risk and basic substances (3)

- Continuous development of technical guidance for the assessment of substances:
  - Working document on basic substances - a new revision in preparation to reflect experience gained in these last years
  - Guidance document on secondary metabolites produced by micro-organisms in preparation
  - Update guidance on zonal system and mutual recognition to include accelerated procedure for low risk products.

- Specific focus also on low risk and basic substance issues within the ongoing REFIT evaluation

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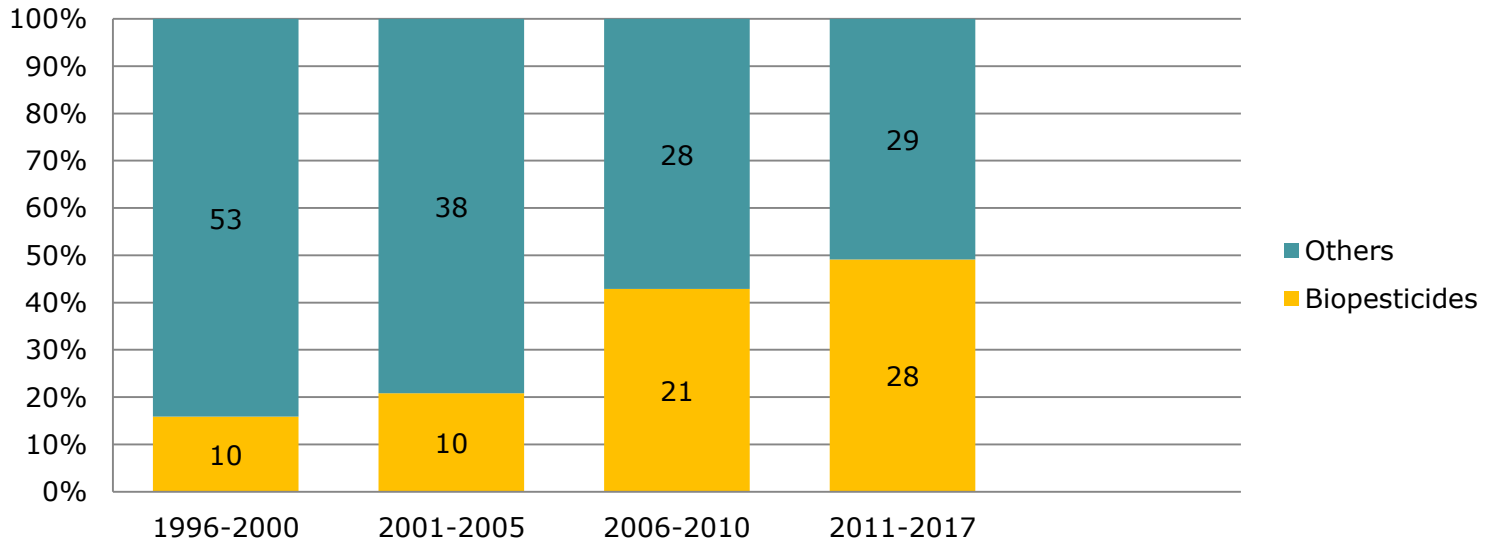
Increase in new applications for "biopesticides" since 1996

Application for new active substances since 1996



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Basic substances since 2012

Type of basic substances:

Foodstuff (37)
Traditional medicine (1)
Biocide (2)
Mineral (4)
Other (7)

Main issues:

- **No product with basic substances can be a PPP**
- **Basic substances must be available on the market for other purposes e.g. foodstuff, cosmetics, etc ….**

Basic substance applications	
Approved	18
Non-approved	10
Pending	12
Extensions	
- approved	3
- non approved	-
- pending	4
Withdrawn / non-admissible	6
Total applications	**53**

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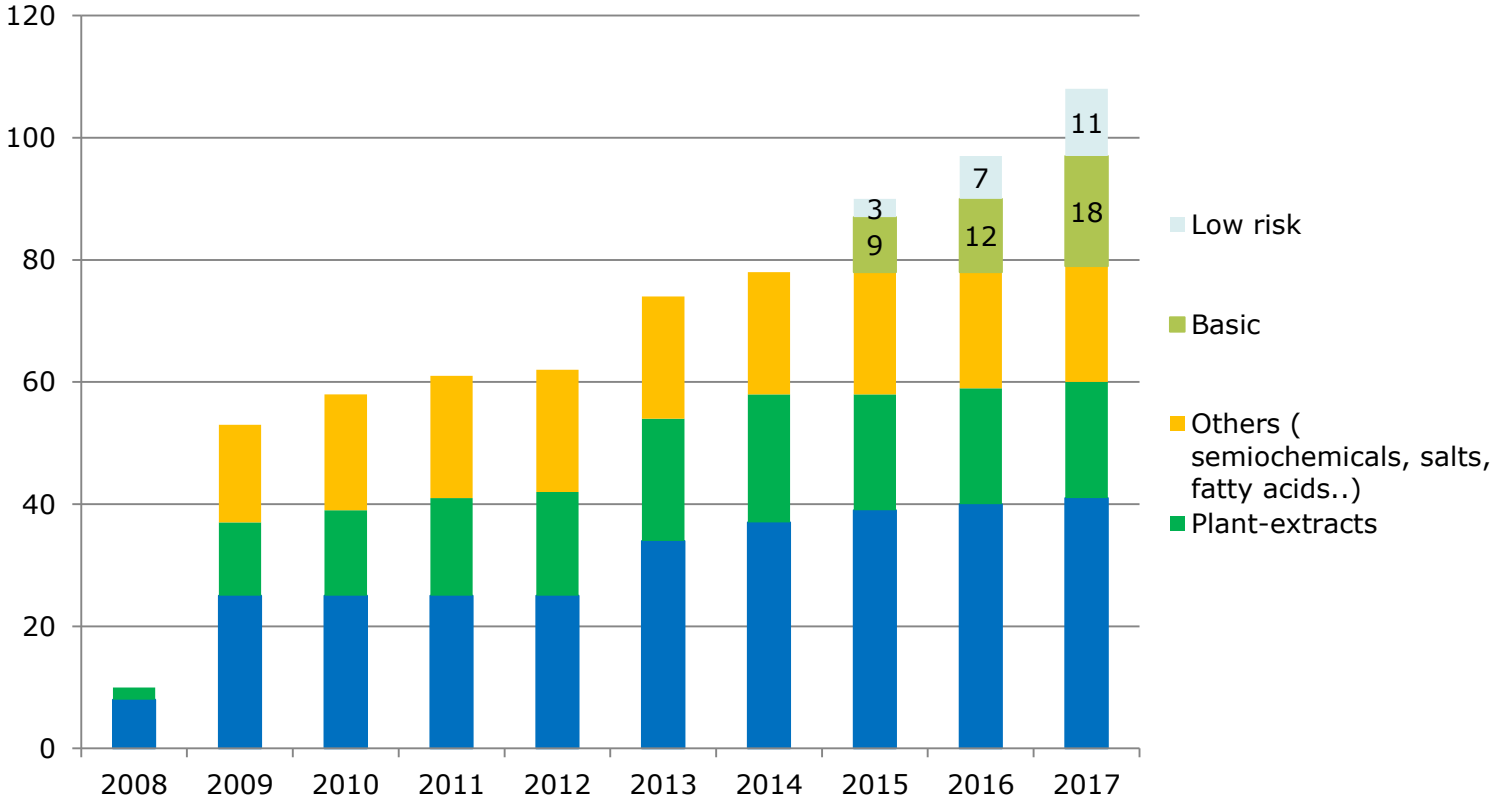
Approved low risk and basic substances



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Cut-off criteria and their impact on MRLs

- **Regulation(EC) No 1107/2009 includes hazard based criteria for human health: active substances cannot be approved if classified under Regulation (EC) No 1272/2008 as:**

Mutagen 1A or 1B	Carcinogen 1A or 1B	Toxic for reproduction 1A or 1B	Endocrine disruptors

- **Limited derogations to comply with these criteria are provided:**

serious danger to plant health	negligible human exposure

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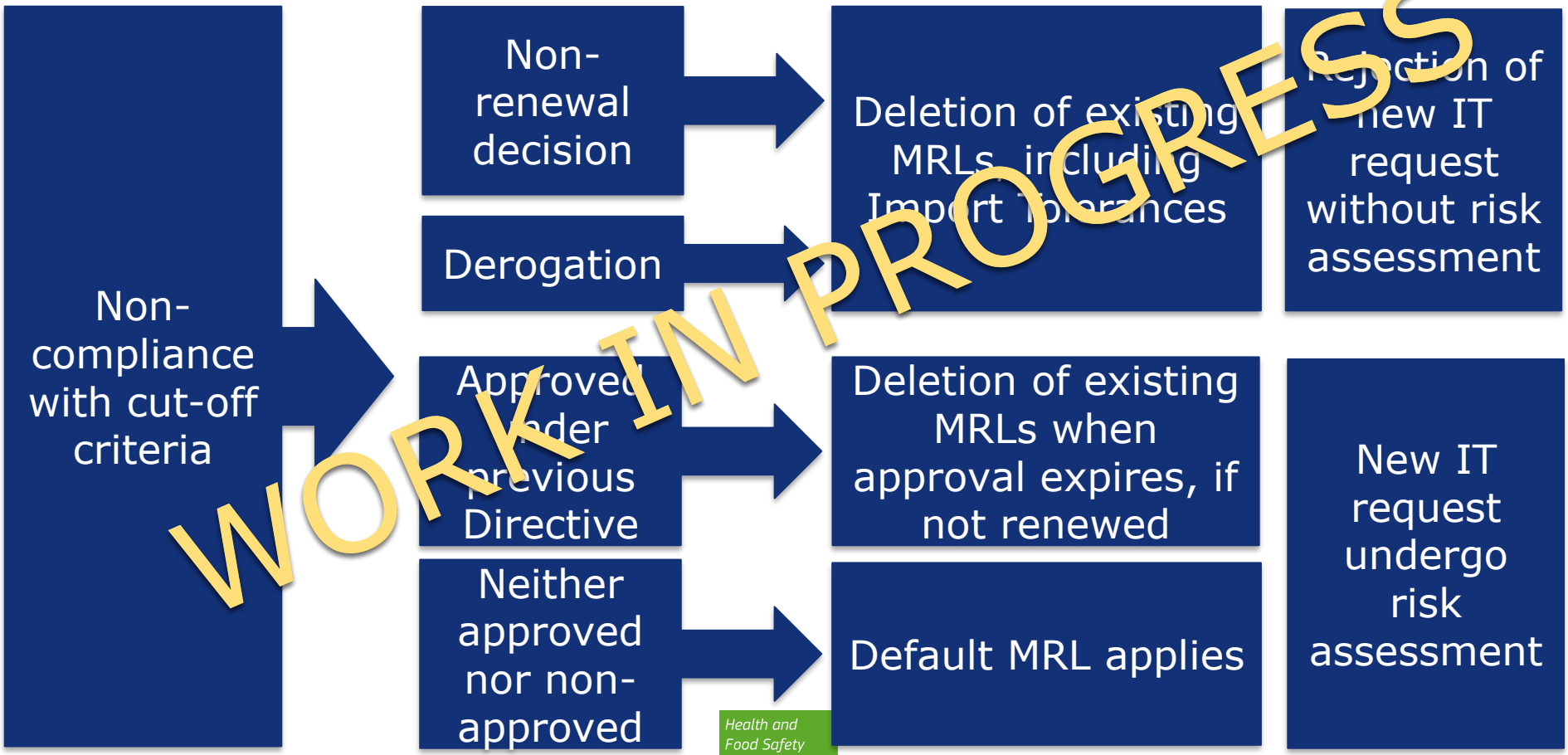
Impact of cut-off criteria on MRLs



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Overview Report on Audits by SANTE in MS

- SANTE carried out a first series of audits on the authorisation of PPP in 2016 and 2017 in seven MS (DE, UK, LU, PT, FR, LT, ES)

- Objectives: - Check authorisation systems in place
  - Co-ordination within and co-operation between authorities
  - Inform EU policy makers

- Some good practices were detected in most or all MS, including:
  - Fee reduction for potential low risk products
  - Incoming fees are retained by the authorities
  - Enhance degree of scrutiny vis a vis repeated applications for authorisation under Article 53 for the same use

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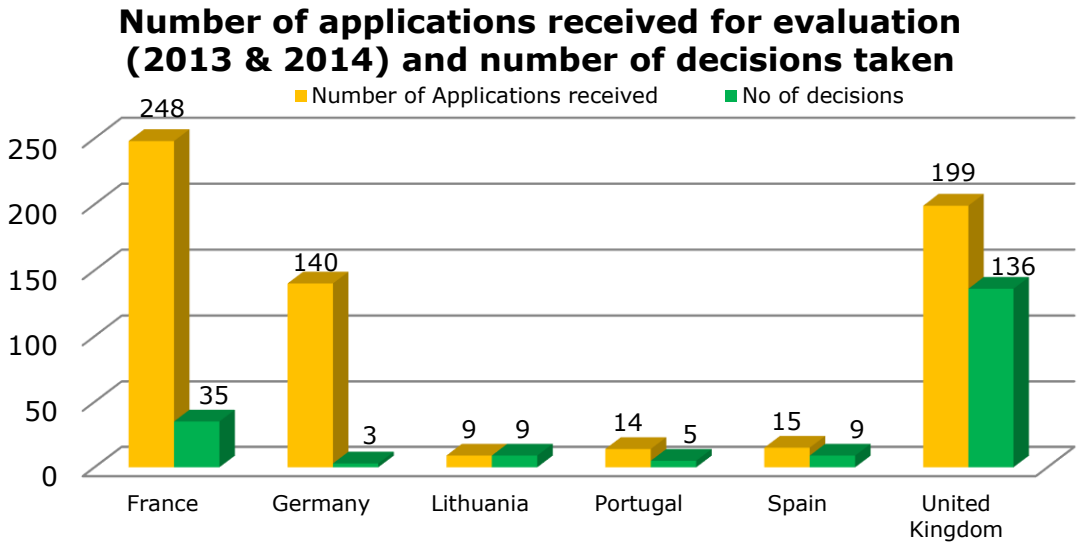
Overview Report on Audits by SANTE in MS: Delays



- The vast majority of applications is made to only few MS, whereas the output does not necessarily correspond to the input
- Delays and deficiencies in the authorisation process (including minor uses) are one of the main reasons for the high number of emergency authorisations

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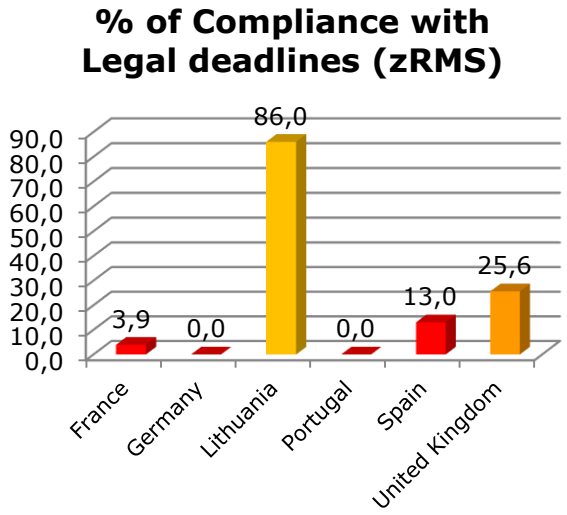
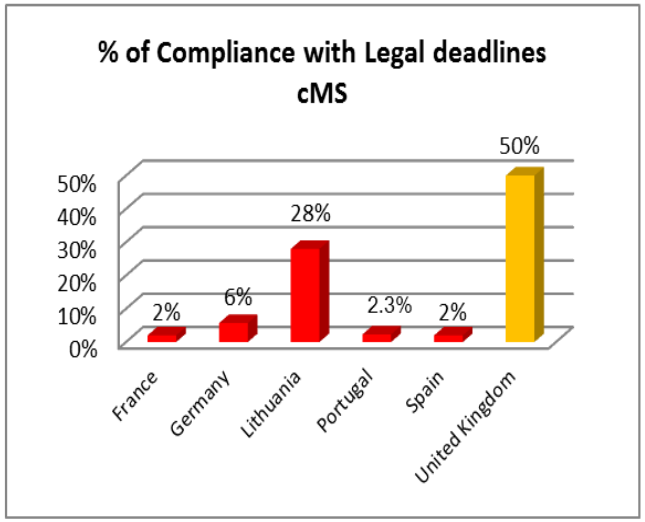
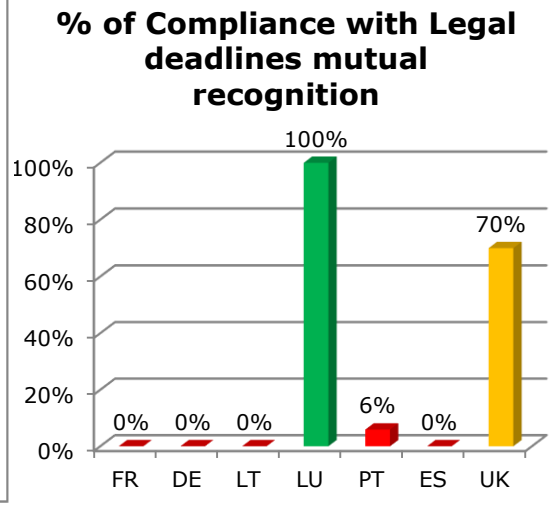
Overview Report on Audits by SANTE in MS: Delays







- Legal deadlines are hardly respected by any MS, regardless of the process
- With the consequences of delaying market access of products and availability of appropriate tools for farmers

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Overview Report on Audits by SANTE in MS: Reasons for delays:

- National requirements:
  - Requested in 6 out of 7 MS
  - Not foreseen in the legislation
  - Additional burden for dossier submitters
  - Hamper co-operation between MS and recognition of authorisations
  - Lead to duplication of work

- Re-evaluation by the cRMS instead of recognition:
  - Leads to duplication of work
  - Ignores the existence of Uniform Principles
  - Is not a lawful practice
  - undermines the credibility of the work of the zRMS

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Overview Report on Audits by SANTE in MS: Reasons for delays (2)

- Use of guidance documents which entered into force after application:
  - applicants have to generate and submit additional ("confirmatory") information
  - Authorities must evaluate the information
  - Leads to delays
  - Hampers mutual recognition
  - Locks out generic producers
  - No legal basis in Regulation (EC) No 1107/2009

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Renewal of authorisations (Article 43)

- Application (incl. RR) 3 months after Commission decision to renew the approval of the active substance to each zone
- Compliance check (by all MS) within 3 months and Assessment by zRMS to be completed in 6 months
- Decision on renewal of product authorisation by all concerned Member States in the zone after a further 3 months
- No application then product authorisation withdrawn
- Application must not contain new uses (for the zone)

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Renewal of authorisations (Article 43)

- Difficult to prepare a dossier incl. risk assessments for product re-authorisation before the active substance endpoints are finalised
- Choice of zonal rapporteurs
- Capacity issues
- Products containing mixtures of active substances will trigger multiple Article 43 submissions and reviews

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Renewal of authorisations (Article 43)

Article 43(6): 'reasons beyond the control of the authorisation holder'

- If it is not possible for the applicant to provide studies in time due to a new endpoint
- Applicant has to justify the lack of data
- Member States may find it appropriate to apply Article 43(6) and delay re-authorisation of the product
- Member States have the responsibility to ensure the appropriate protection standards are respected

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Exemption from submission of studies (Art. 34)

- Tests and study protocols in possession of the authorities shall not be submitted if
  - data sharing was agreed; or
  - negotiations for data sharing have been initiated for studies involving vertebrates; or
  - data protection expired
- This measure is intended to minimise duplication of tests and studies and a lock-out of generic applicants
- As exemption, authorities may request the submission of some types of test and study protocols (e.g. identity, efficacy)

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Exemption from submission of studies (Art. 34)

- The ongoing revision of the zonal guidance document will address some of the issues
- However, no agreement about applicability of guidance documents to submissions under Article 34
- Application of most recent guidance may leverage the intention of the legislator (avoidance of duplication of studies)
- As authorisations must be renewed after renewal of approval the active substance, new guidance will apply anyway at that point in the process

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REFIT - Evaluation of EU pesticide legislation

- **Objective:** to assess if the needs of citizens, businesses and public institutions are met in an efficient manner, legislation should be fit for purpose

- **Ex-post evaluation** - BACKWARD LOOKING!

- **Reporting obligations to Council and Parliament :**

  i) Articles 62(5) and 82 of Reg. (EC) No 1107/2009

  ii) Article 47 of Reg. (EC) No 396/2005

➢ Commission Staff Working Document and Report: first half of 2019

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REFIT – State of play

- Refit **Roadmap** published on 17 November 2016: purpose, content and scope of the evaluation plus main evaluation criteria
- **Feedback** received was reflected in the **Terms of Reference** for an evaluation study
- Evaluation study carried out by **external contractor** from July 2017 until June 2018
- **First workshop** with a limited group of Member States and stakeholders held in September 2017
- **Consultations** to start end of October / early November

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REFIT – Next steps

- Launch of surveys planned by end October 2017

  i) Open public consultation

  ii) Stakeholder survey

  iii) Member State Competent Authorities survey

  iv) Small and Medium Enterprises (SME) survey

- Future consultations (after surveys):

  Focus groups, in-depth interviews, Workshop (2)

- Commission website on the evaluation:

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

Thank you for your attention!

For further information:

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

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