Current Developments under the PPP Regulation

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Health and Food Safety

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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 Report and accompanying Staff Working Document will be adopted under the new Commission

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REFIT – Evaluation Steps

- Refit **Roadmap** published on 17 November 2016: purpose, content and scope of the evaluation + main evaluation criteria
- Evaluation study carried out by **external contractor** from July 2017 until June 2018
- **Workshops on specific topics** with a limited group of Member States and stakeholders in 9/2017 + 5/2018
- **Consultations:** general public, Member States, stakeholders and SMEs
- Other information sources: reports from the Commission on **audits** in Member States, 2 reports and studies from the European Parliament, Scientific advice mechanism, …
- Commission website on the evaluation: *http://ec.europa.eu/food/plant/pesticides/refit_en*

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Applications for new active substances

Year	2011	2012	2013	2014	2015	2016	2017	2018
New active substance applications	4	8	12	6	15	10	4	10

Information from the summary reports from the Standing Committee on Plants, Animals, Food and Feed.

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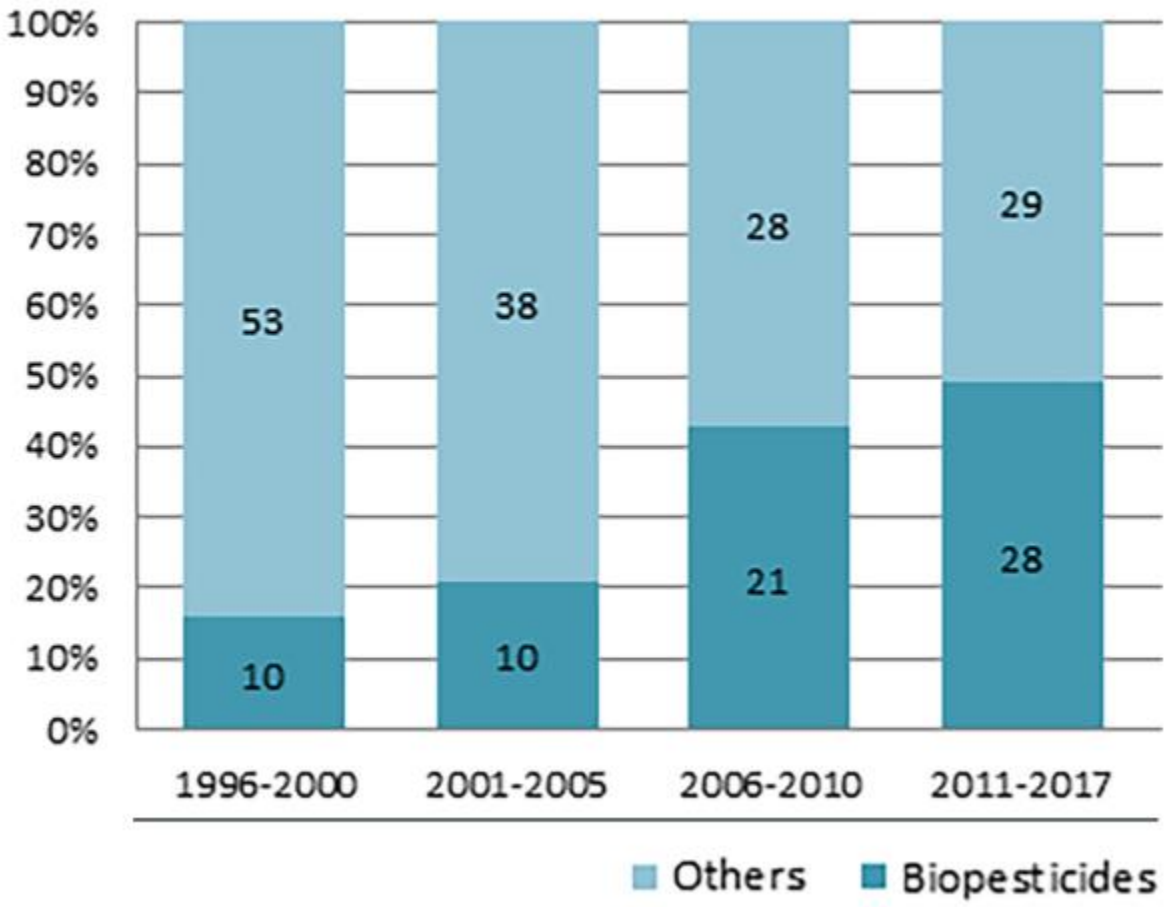
APPLICATION FOR NEW ACTIVE SUBSTANCES SINCE 1996



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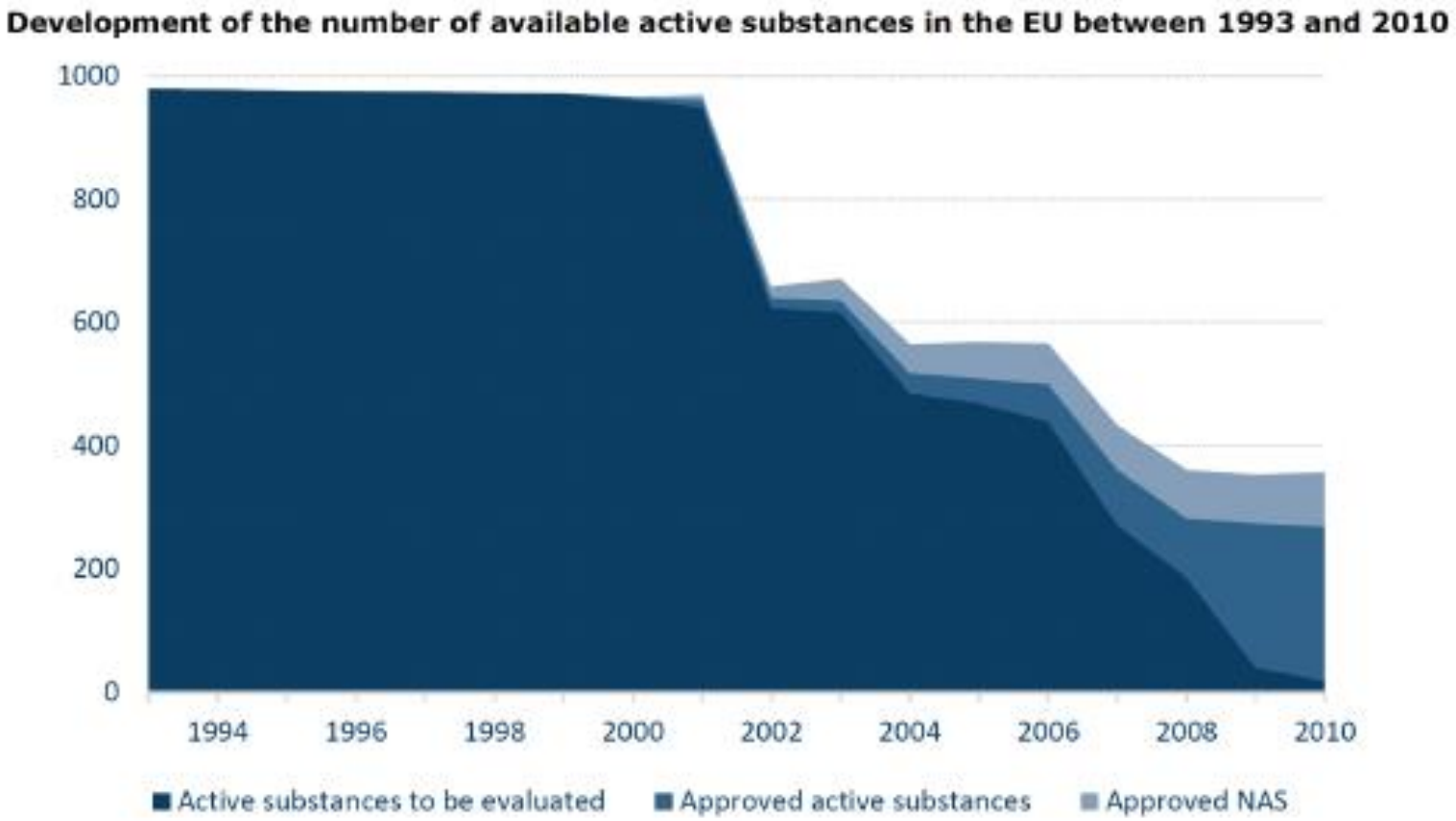
Availability of active substances



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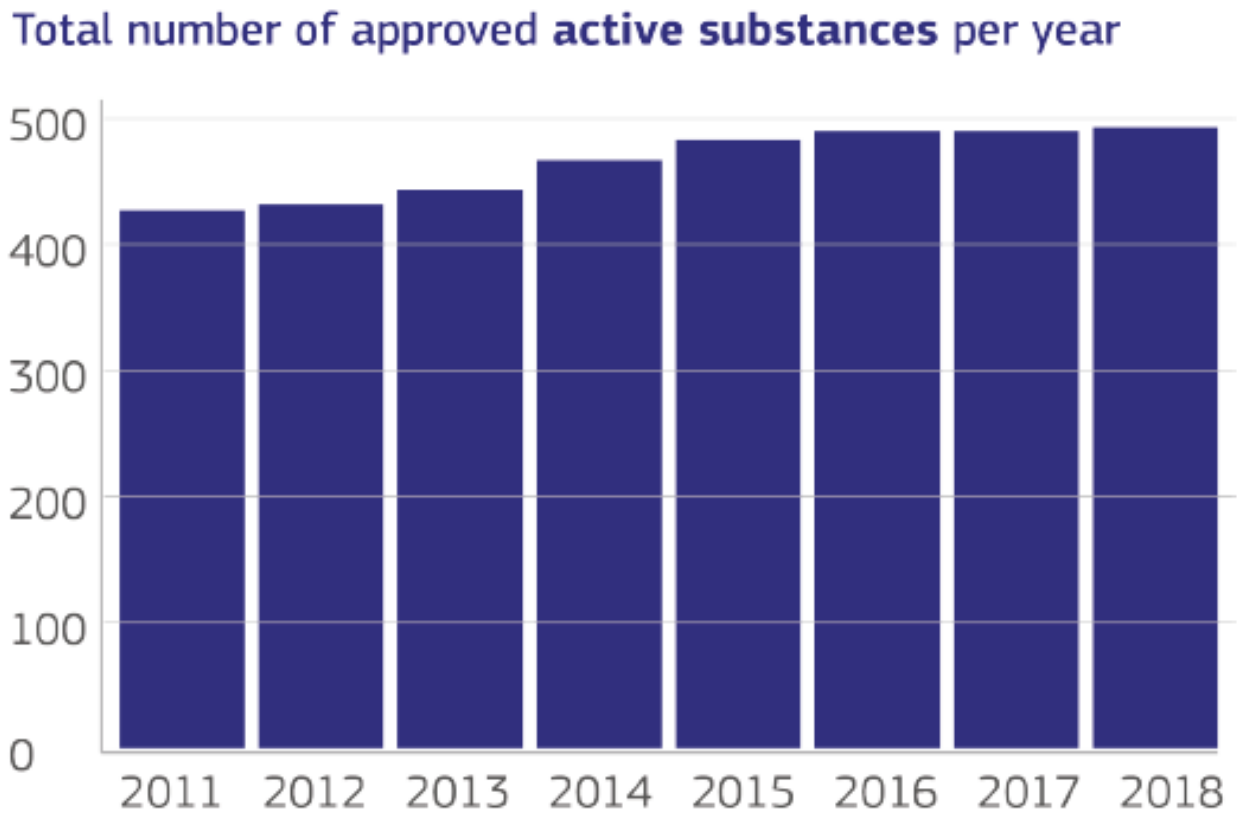
Availability of active substances



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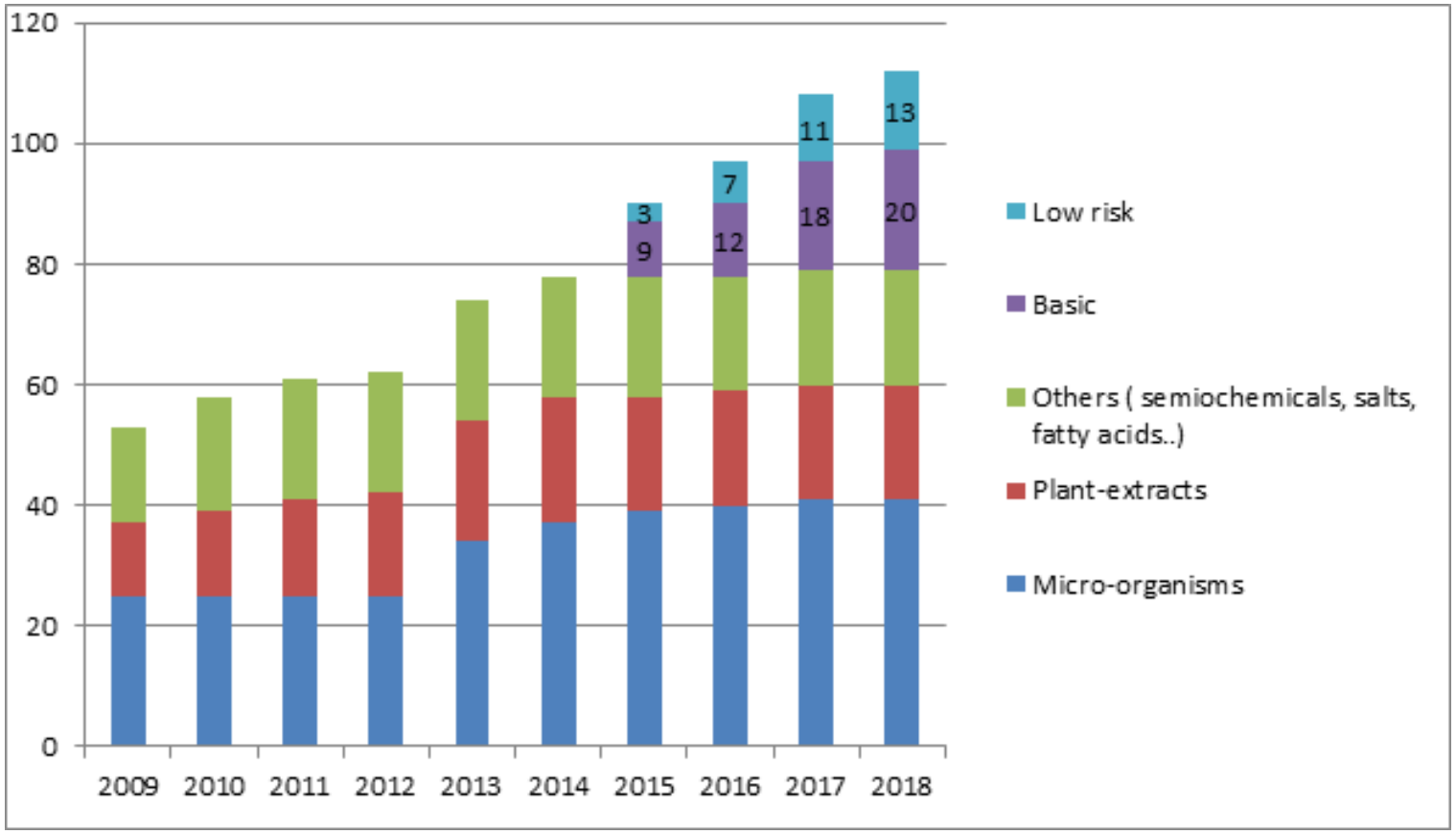
Availability of Low Risk Substances



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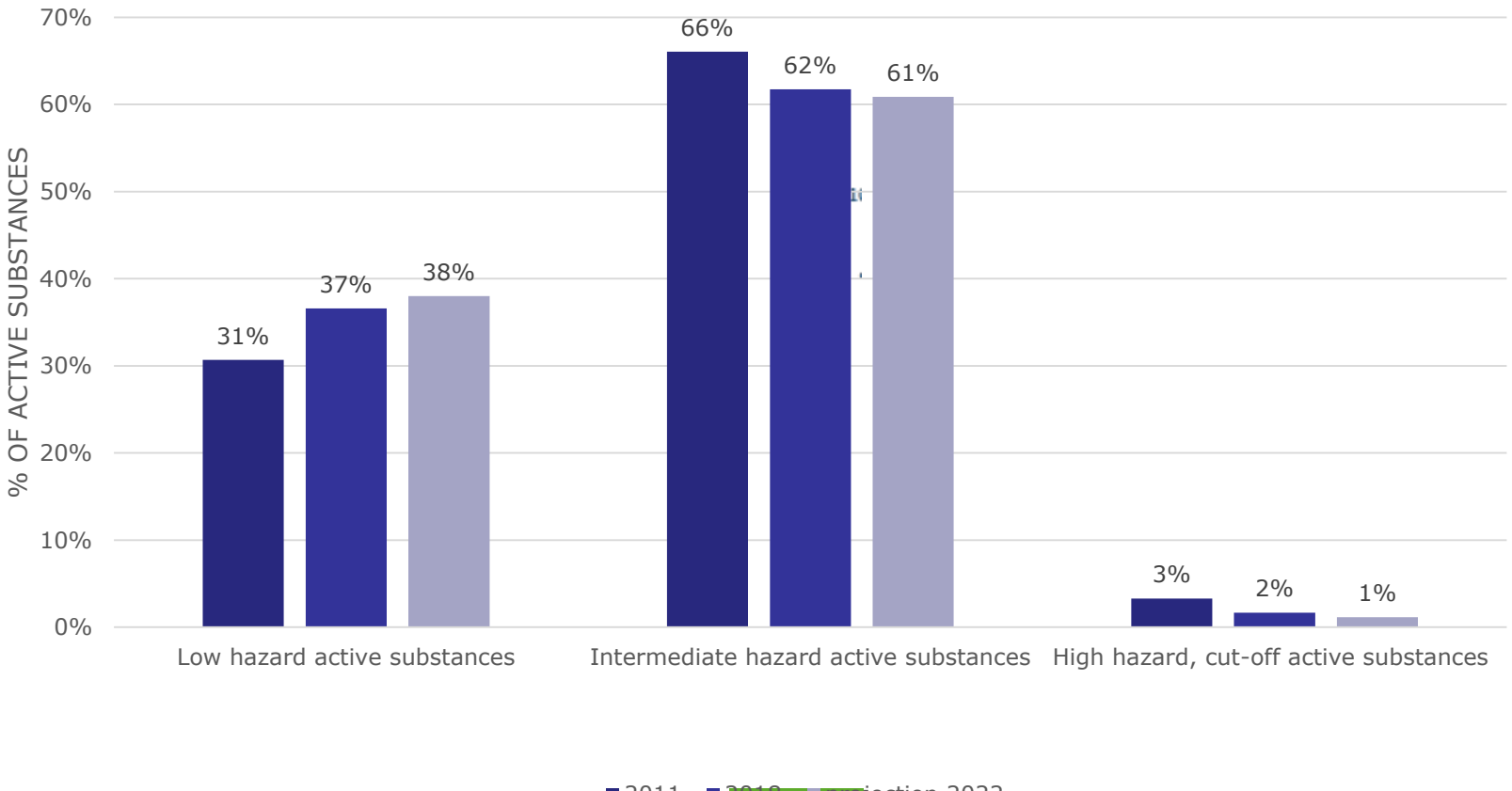
Hazard Profiles of Active Substances



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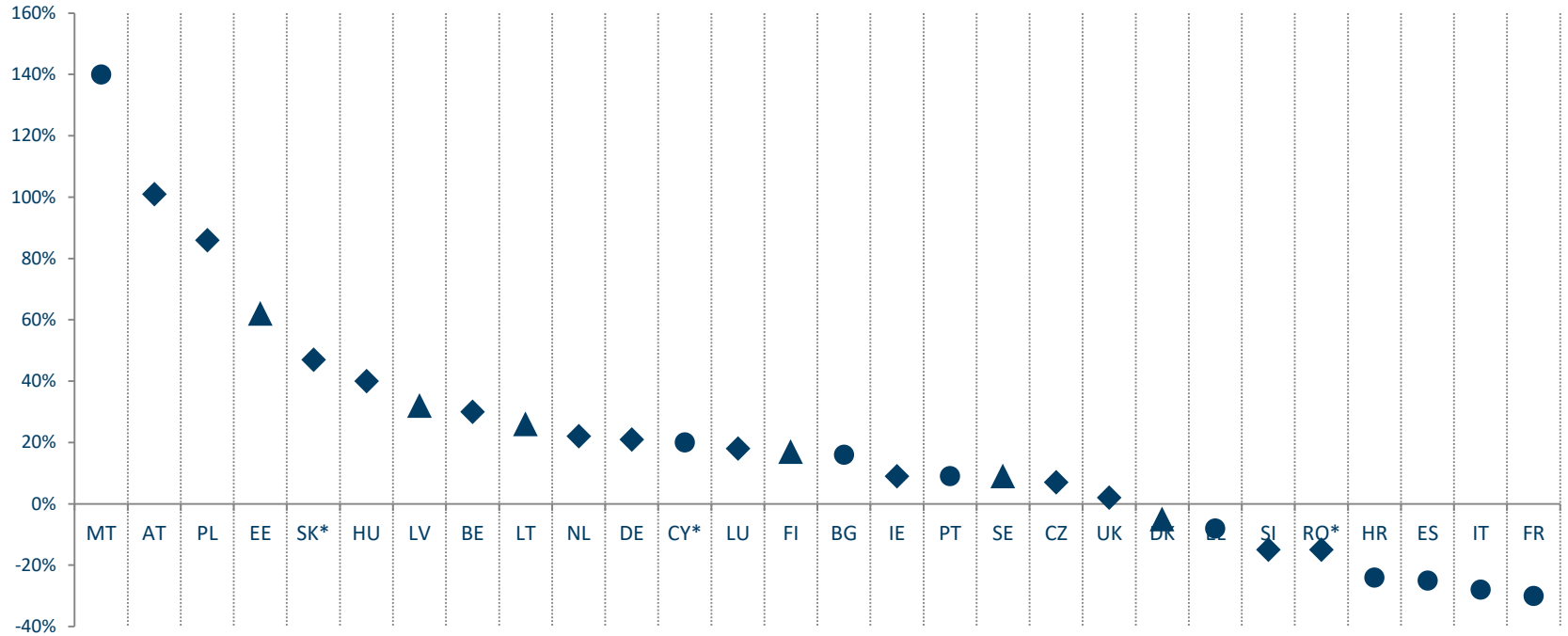
Availability of Plant Protection Products



Percentage change in PPP availability in 2014-2016 compared to 2008-2010, based on Member State survey. Triangles represent the northern zone, diamonds represents the central zone and circles represent the southern zone. *Data incomplete for Romania, Slovakia and Cyprus

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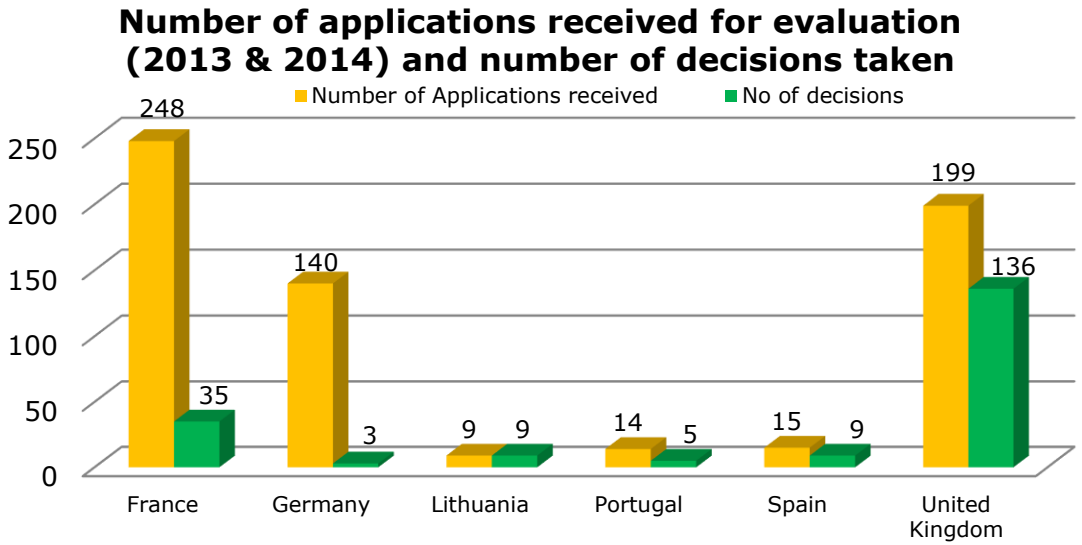
Overview Report on Audits: Significant Delays !



- The vast majority of applications is made to only few MS, whereas the decisions are significantly delayed.

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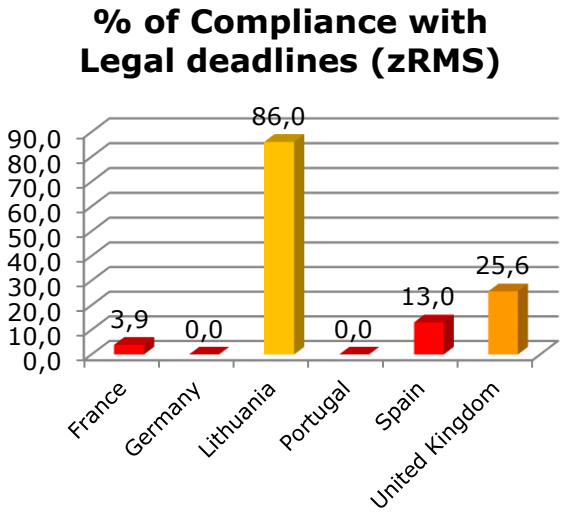
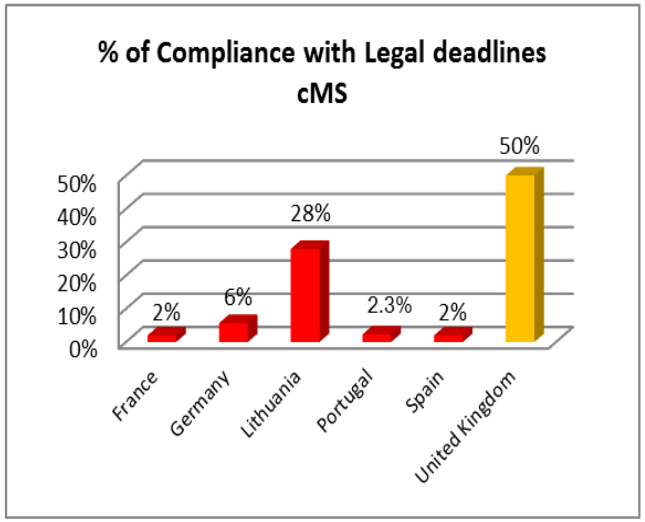
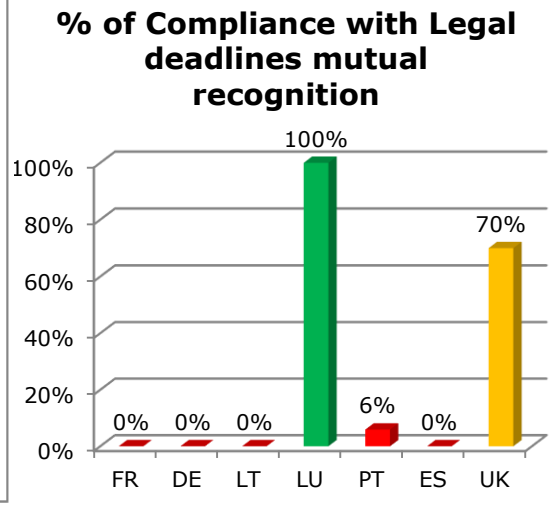
Overview Report on Audits: Significant Delays







- Legal deadlines are hardly respected by any Member State, 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 - Reasons for Delays:

- National requirements:
  - Applied in 6 out of 7 Member States
  - Not foreseen in the legislation
  - Additional burden for applicants
  - Hamper co-operation between Member States 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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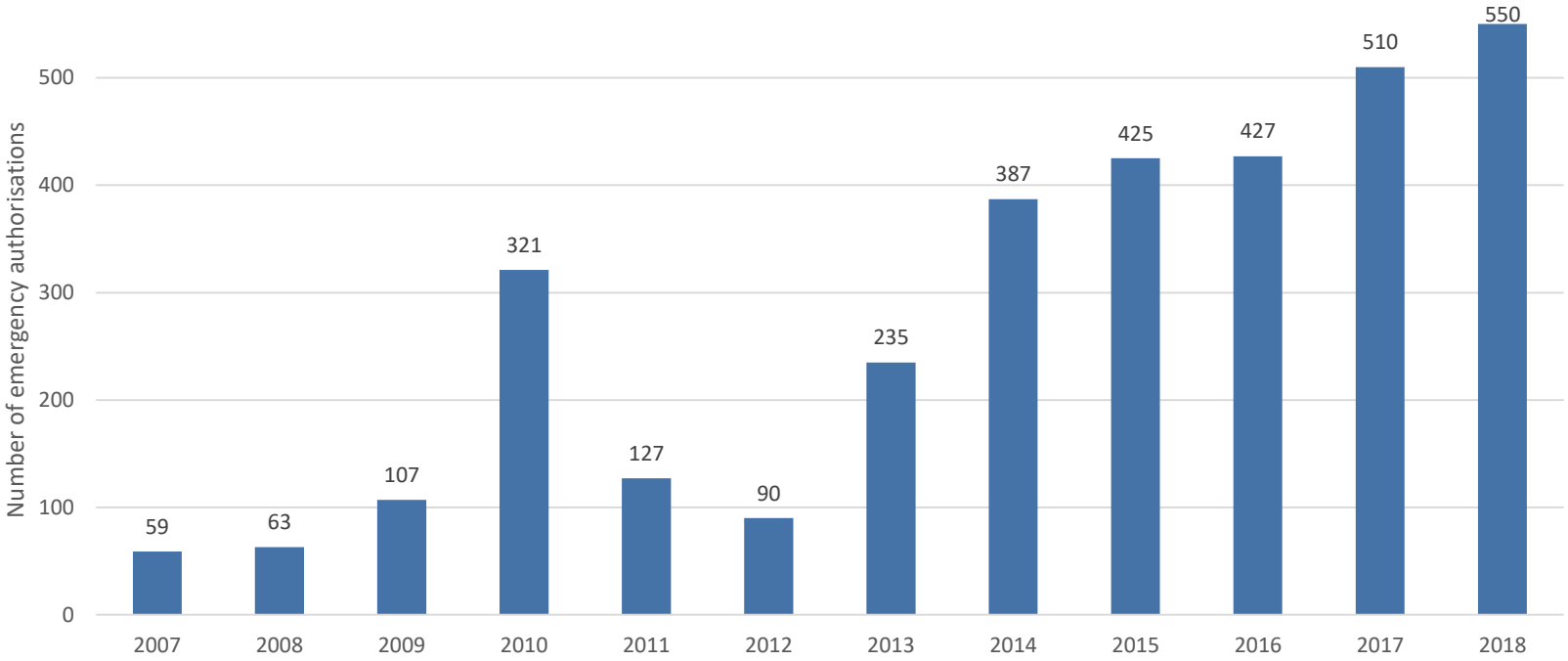
One way out – Emergency Authorisations



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Neonicotinoids *(clothianidin, thiamethoxam, 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 to permanent greenhouses
- February 2018: EFSA report on broad review of 2013 restrictions – no fundamental change compared to 2016
- Restrictions to greenhouses adopted in May 2018
- Withdrawal of renewal applications for clothianidin and thiamethoxam – no application expected for imidacloprid

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Neonicotinoids – Emergency authorisations

- Several Member States grant since 2013 repeatedly authorisations under Article 53 of the PPP Regulation for the three restricted neonicotinoids for the same uses and covering large parts of their territories
- Regulation 1107/2009 allows so when there is a danger to plant health that cannot be controlled by other reasonable means (including non-chemical measures)
- Commission asked EFSA to assess whether the authorisations granted in 2017 fulfil the requirements in Article 53
- EFSA found this NOT to be the case for about 1/3
- Commissioner Andriukaitis asked the Ministers of the Member States to commit not to grant these again – two responded positively
- For the other two, the Commission has prepared legally binding Decisions preventing them from repeating the emergency authorisations

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Neonicotinoids – Emergency authorisations

Situation for sugar beets since 2018

Member State	Number of Emergency Authorisations for neonics	Sugar Beet
1. Austria	3	3
2. Belgium	7	5
3. Spain	1	1
4. Finland	3	3
5. Hungary	7	2
6. Lithuania	5	1
7. Poland	5	2
8. Romania	6	1
9. Denmark	4	4
10. Slovakia	1	1

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Next renewal of approval for glyphosate

- Renewal Regulation adopted on 12 December 2017
- Approval period 5 years
- Next renewal process has to start in December 2019
- No individual Member States willing to become Rapporteur or co-Rapporteur
- 4 Member States have agreed to form the 'Assessment Group on Glyphosate' and act jointly as rapporteurs: FR, HU, NL, SE
- 12 companies have set up a Task Force 'GTF2'

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European Citizens Initiative

- Submission of European Citizens Initiative '*Ban glyphosate and Protect People and the Environment from Toxic Pesticides*' on 6 October 2017 with 3 aims:
  - Ban glyphosate
  - Increase transparency in the assessment procedures for pesticides
  - EU-wide reduction targets for pesticide use in view of a pesticide-free future
- Commission met the organisers on 23 October 2017
- Hearing in the European Parliament on 20 November 2017
- Commission response adopted on 12 December 2017
- Announcement of amendments of General Food Law to increase transparency by May 2018

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Amendment of GFL on Transparency

- Improves and clarifies **the rules on transparency** (in particular as regards scientific studies supporting risk assessment)

- Increased **reliability, objectivity and independence of studies used by EFSA** in its risk assessment (mainly **authorisation dossiers)**.

In particular the **reply to the ECI highlighted** the need to:

- involve more public authorities in the process of deciding which studies need to be conducted;
- enhance auditing of compliance with GLP principles;
- publication of full study reports to increase transparency while respecting confidential business information;
- exceptionally commission ad-hoc studies in specific cases.

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Latest developments

- Increasing resistance to extensions of approvals when the renewal process cannot be completed in time
  - Votes against or abstentions in the Standing Committee – although all Member States are systematically delayed
  - Objections in the European Parliament (non-binding)
- Objection in the European Parliament against the change of the Uniform Principles that would allow implementation of a part of the EFSA Bee Guidance
- Objections in the European Parliament against setting Import Tolerances (MRLs) for no longer approved active substances
- Decisions on chlorpyrifos and chlorpyrifos-methyl

Thank you for your attention!

For further information:

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

https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids_en

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

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