Industry view on the EU authorisation procedure of plant protection products

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29 October 2018

Update on active substance evaluation

Trends: new active substances

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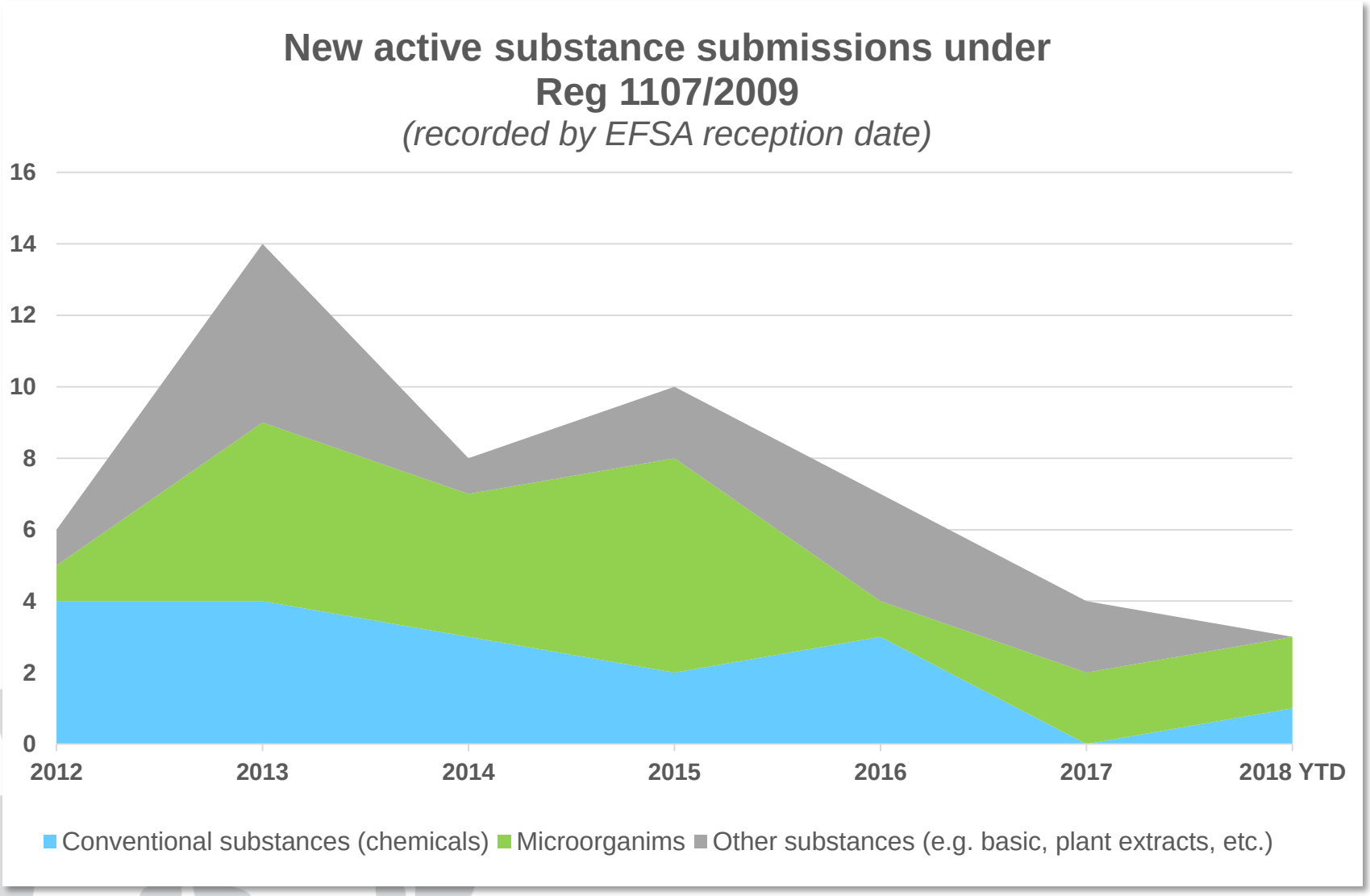
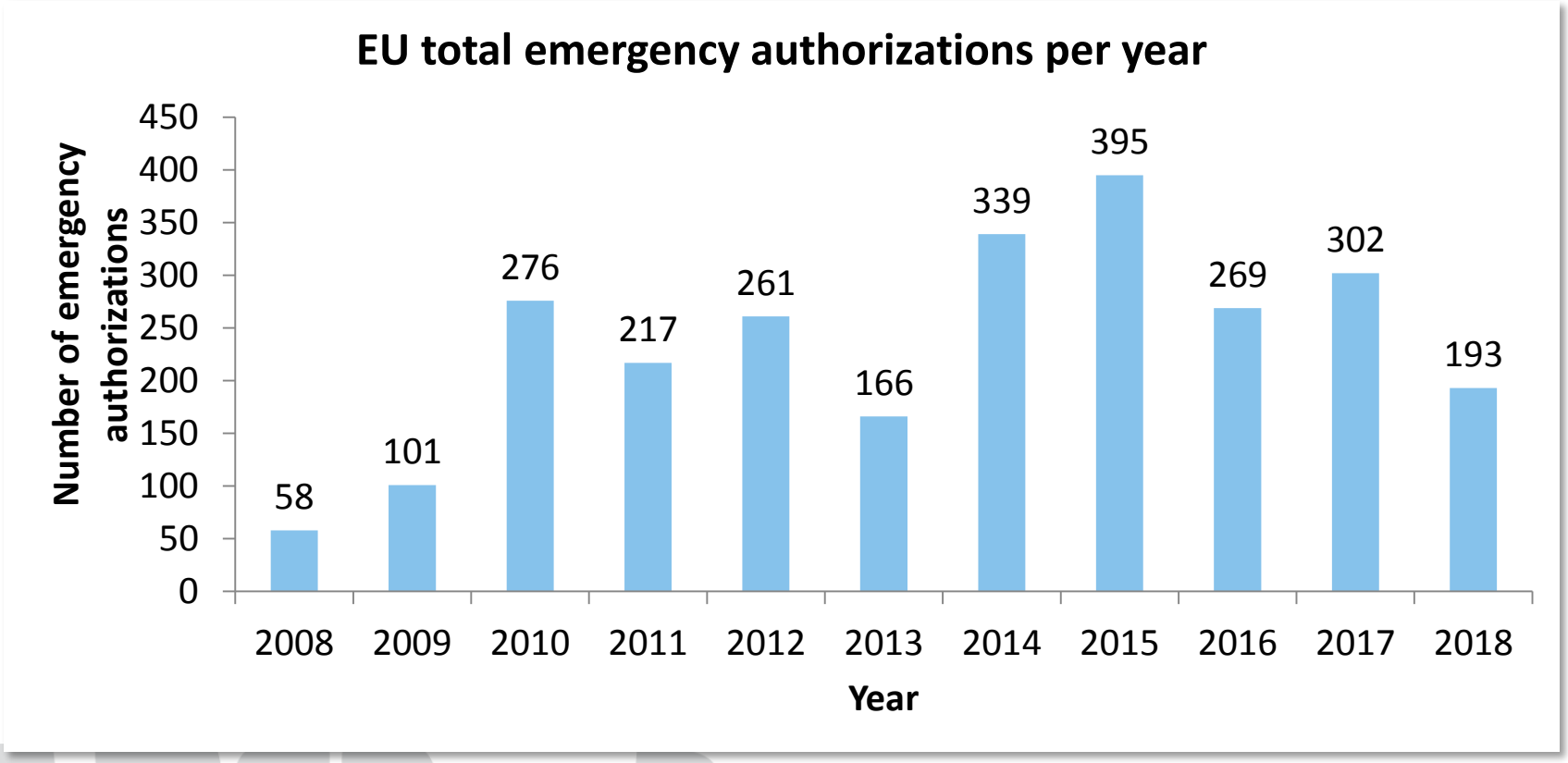


Trends: emergency authorisations

- Increased number of crop protection needs addressed through emergency authorisations



- Annual average nearly tripled from previous legislation (Dir 91/414) (2008-2010 average = 145)

Trends

- Number of submissions of new chemical active substance is decreasing
  - Only two new chemical active substances submitted between July 2016 and September 2018
- Use of Article 53 emergency authorisations is increasing
- Current review process is challenging for applicants: outcome is increasing unpredictable and conservative
- Reasons for non-approval evolving
  - Impact of EFSA identified data gaps & issues (e.g. where assessment can not be finalised)
  - Level of Commission and MS support?
- Impact of cut-off criteria?
- Further non-approvals (renewals) expected in 2018

Issues

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AIR 5

- AIR5 Reg 2018/155 published Jan 2018, working doc March ‘18
- 66 substances, expiring 2022-2024

➢ **Dialogue for submission preparation is key**

Confirmatory data

- Commission reply to Ombudsman 14 February 2018
- Commission cautiously using confirmatory data provisions, but must be clearly justified

Low risk active substances

- Criteria: Reg 2017/1432 published August 2017
- Commission preparing a guidance document

➢ **Strict criteria, only few will meet the criteria**

Active substance issues

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Co-formulants (Annex III, unacceptable co-formulants)

- Commission developing 2 draft regulations expected in SCOPAFF late 2018 or early 2019
  (1) criteria & methodology inclusion of substances in Annex III
  (2) list of substances to populate Annex III
  - ➢ **Co-formulants should be assessed under REACH**

EFSA evaluation

- Classification proposals – joint template in preparation
- Genotoxicity raised in number of cases

➢ **Dialogue with applicants is essential**

➢ **MS participation in peer review commenting and meetings is key**

ED Criteria

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- **Criteria: entered in force on 10 May 2018**
  - Officially apply as from **10 November 2018**
  - Applied to all substances submitted after this date, and…
  - …to all on-going pending applications (not yet voted in SCOPAFF)
  - ➢ Criteria not supported

- **EFSA-ECHA technical guidance**
  - Published by EFSA and ECHA on 7 June 2018
  - ➢ Not consistent with criteria

- **Amendment to derogation**
  - Shift from negligible **exposure** to negligible **risk**
  - Discussed in SCOPAFF on 23-24 October 2018
  - ➢ 14 Member States supported, 7 against, 7 no position

Pollinators

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- **3 Neonicotinoids (NNI) restrictions**
  - Restrictions voted 27 April: still approved but for greenhouse use only
  - Grace period of max 6 months (sale/use) – latest by 19 December 2018
  - EFSA published assessment of derogations in 7 MS (RO, BG, EE, FI, LV, LT, HU)
  - Court ruling: actions by Bayer and Syngenta were dismissed, action by BASF "largely upheld" due to lack of impact assessment
- **Bee guidance**
  - New "implementation plan" discussed in October SCOPAFF
  - ➢ Reopen scientific discussion (EFSA, MS, COM), Industry proposed technical options for refinement
- **EU Pollinators initiative:**
  - DG Env published an EU initiative on Wild Pollinators on 1 June
  - No legislative change, to be reviewed in 2020
  - Actions (e.g. monitoring) - some done (NNI suspensions) or planned (GD plan)
  - Pilot project on monitoring of PPP in bee products
  - ➢ ECPA will continue to offer expertise

GFL & transparency

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Background

- REFIT of General Food Law (GFL), Reg 178/2002
- Commission communication in response to ECI glyphosate

Commission legislative proposal

- Issued **11 April 2018**
- Amends Reg 178/2002 + 8 sectorial Regs, **incl. Reg 1107/2009**
- To be finalized by end March 2019, application from late 2020

Key provisions

- Complete dossiers supporting applications for EU authorisations will be made public “without delay”

➢ Improved transparency supported

➢ Protect CBI until EFSA opinion publication

➢ Controlled data disclosure

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Update on product authorisation

zRMS Registrations
New Formulations

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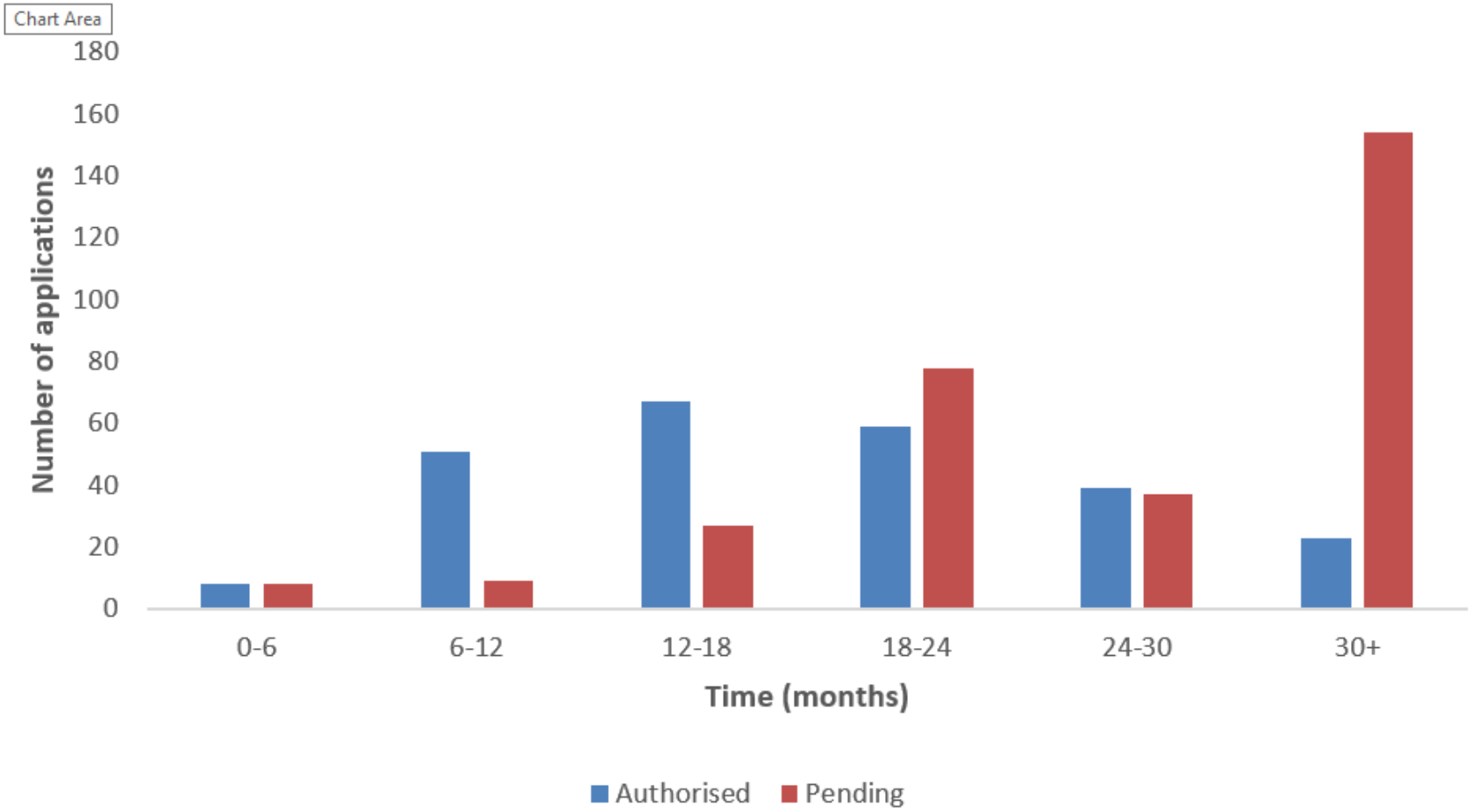

- For those authorised: average time taken around 18 months
- Lots still pending: 86% for more than 18 months

cMS Registrations
New Formulations

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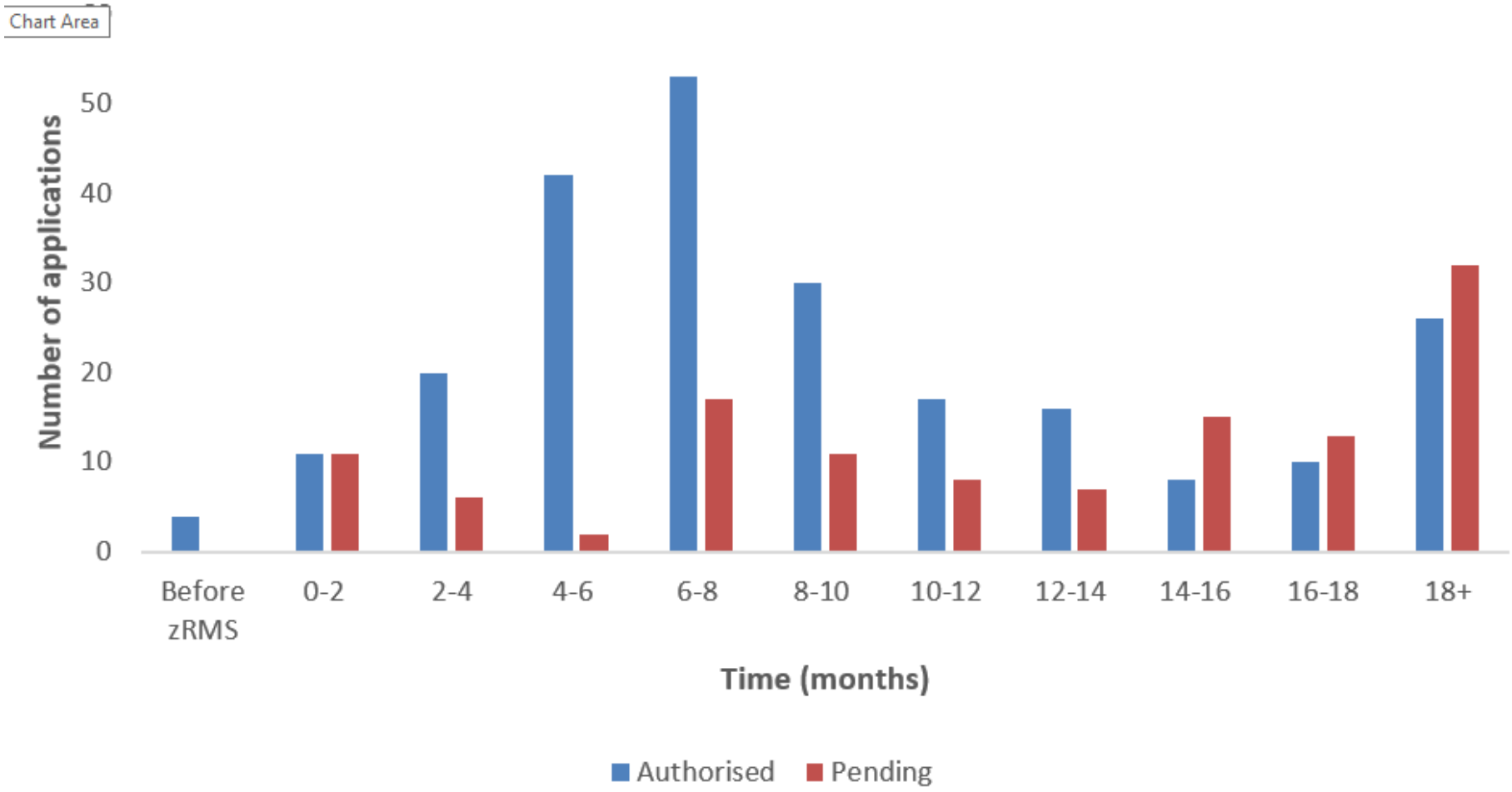

- For those authorised: average time taken around 9 months
- Lots still pending: 86% for more than 4 months

Mutual Recognition

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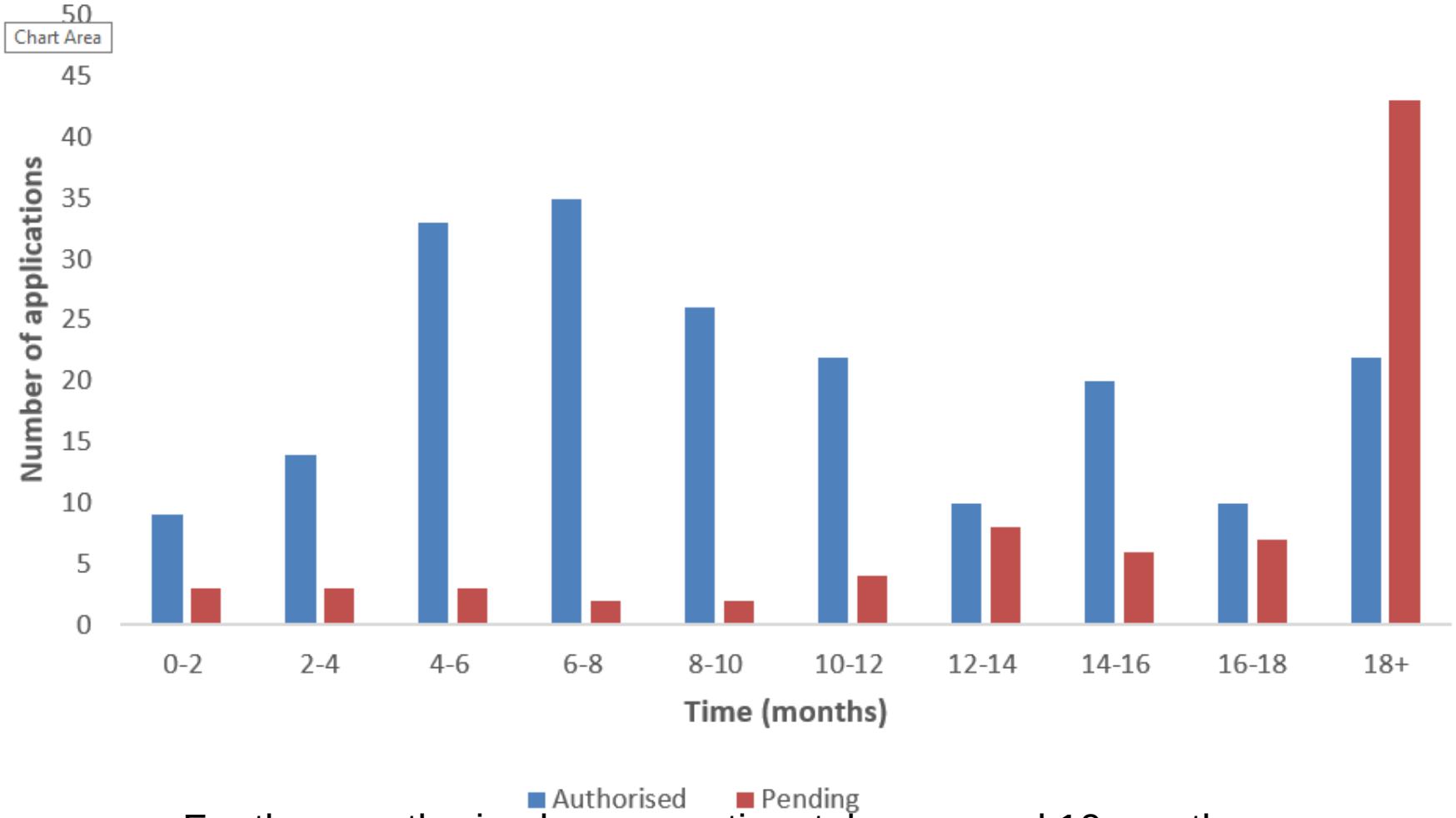

- For those authorised: average time taken around 10 months
- Among pending ones: 79% for over three times the prescribed timeline

Products evaluation

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- **Member States capacity limitations**
  - Delays in the evaluation by the zRMS
  - Brexit: zRMS have been re-allocated - For on-going evaluations, applicants have to address an alternative zRMS if they feel the necessity.
- **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

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

REFIT of Reg 1107/2009 and Reg 396/2005

Review reports

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Commission

Consultant report

RefIt COM working doc

SAM report

SAPEA

2018					2019		
Feb	March	July	Sept	Dec	Feb	June	Nov

Parliament

EPRS report

Poc report

Plenary vote

PEST report

SUD report

ECPA view

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- **EU has strictest autorisation process**
- **Improve implementation of Reg 1107/2009 and 396/2005**
  - Trust for zonal work share
  - Guidance fit for purpose
  - Align approval and MRL setting
- **EU agriculture needs to remain competitive**
  - Difficulty to bring innovative solutions to market
  - Emergency autorisation not preferred but necessary
  - AS under renewal already evaluated at EU level as safe

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Technical guidance documents

Introduction

- Guidance documents are key to functioning of Reg 1107/2009 but have **major implications for applicants as well as for risk assessors and risk managers** at the national and EU level.
  - Guidance documents have substantially **increased resource** needs in both industry and authorities **without evidence of previous lack of protection**
  - Regulators at EU and Member State level are highlighting they have inadequate capacity to manage the **additional complexity** – thus impacting on the quality of the evaluation process

- Important changes are needed in procedures for guidance document development to ensure:
  - **Workable and predictable** process
  - Guidance documents are **'fit for purpose' to support evaluations and decision making** procedures (active substances and products).

Increasing complexity

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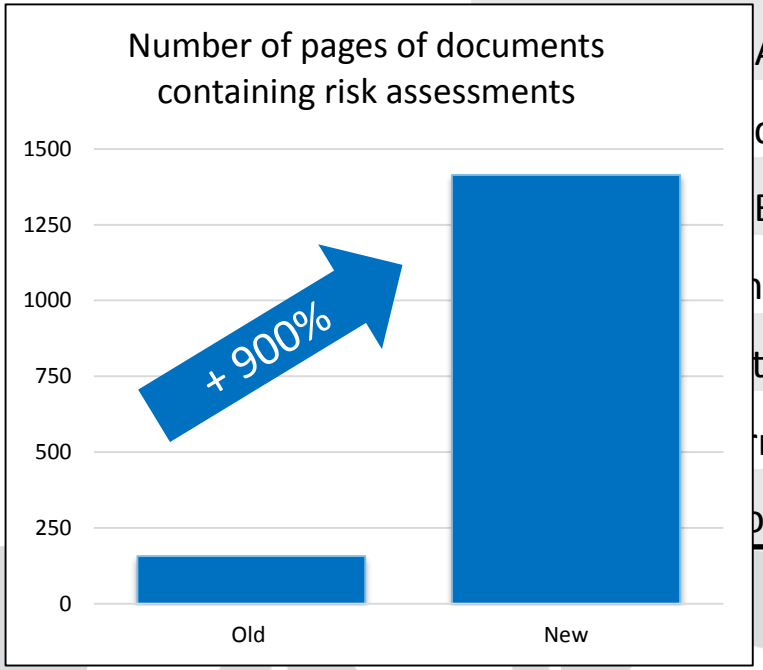
- **EFSA is producing a significant amount of output**

Example just for Environment



	Page numbers	
Area	Old guidance	New guidance/opinion
quatic	62	268 + 145
Bees	3	268
nd mammals	74	358
terrestrial plants	5	163
restrial arthropods	6	212
organisms	7	248

Slide: Patrick Kabouw (BASF)

Example of increased complexity – Non Target Plant scientific opinion

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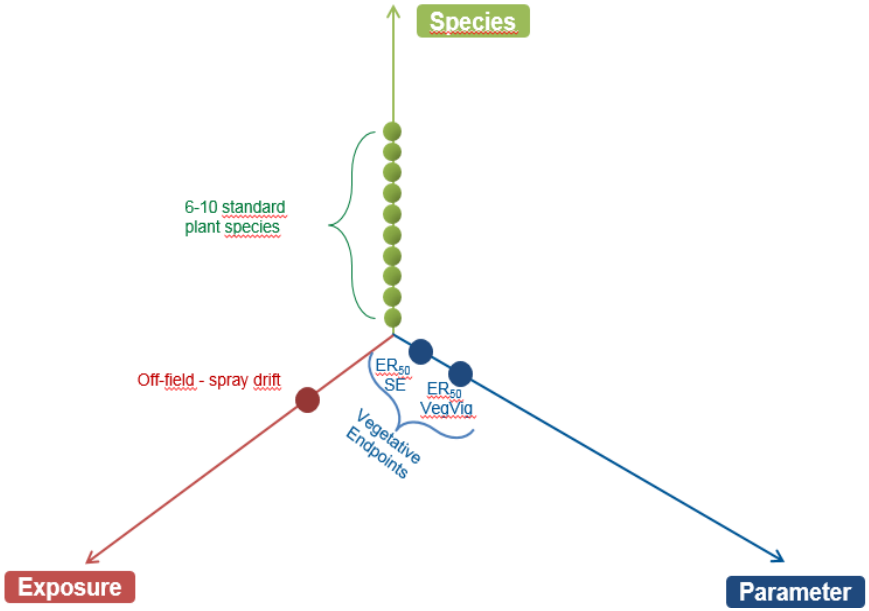
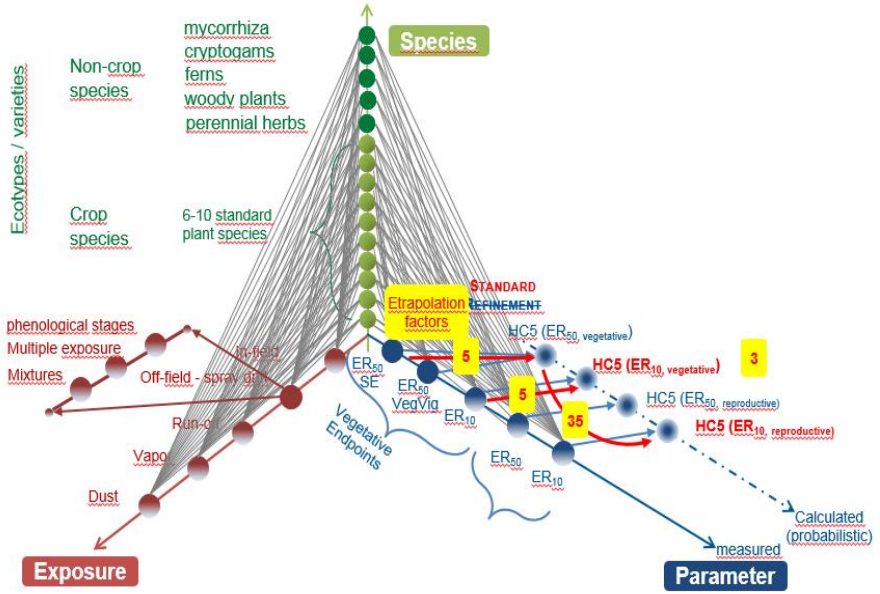


Current risk assessment scheme



Proposed risk assessment scheme in EFSA scientific opinion

Without demonstrating that the previous risk assessment scheme was inadequate

Protection goals

- **4 scientific guidance documents are planned to address the risk assessment of PPPs on:**

Non-target Arthropods

In-soil organisms

Non-target Plants

Amphibians & Reptiles

→ Before actual guidance documents can be written – there is a need to AGREE on what to protect, when, where and how much = **define Protection Goals**

→ This is a pending task for Risk Managers (Commission + Member States) on all 4 topics… to start in 2019

- **It is essential to select appropriate PGs and their suitable translation into practical risk assessment terms**
- **They should take into account agricultural and societal demands**

Proliferation of overly conservative EFSA scientific opinions & guidance documents

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- Recent guidance documents substantially increased resource needs of both industry and authorities **without being supported by evidence of a lack of protection**
- Tiered Risk Assessment Approach is being undermined (i.e. everything fails 1st tier) / Field studies are effectively being removed as risk assessment tool
- More species / more tests / more parameters. But no agreed methods
- High concerns over the extreme conservatism of proposed protection goals
- Increasing ecological modelling approaches and conservative exposure modelling

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Counterfeit & Illegal pesticides : a growing issue

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Counterfeit and Illegal Pesticides in Europe

GLOBAL

THE CRIME IS HIGHLY PROFITABLE

Counterfeit and illegal pesticides sales could create

THE **4th LARGEST BUSINESS** IN THE INDUSTRY

EUROPE

Counterfeit and illegal pesticides represent

ALMOST **14%** of the EU pesticides market[2-3]

In Europol's operation **Silver Axe** in 2015, 2017 and 2018

OVER **670 tons** OF COUNTERFEIT OR ILLEGAL PESTICIDES WERE SEIZED

Tested and approved legal pesticides are used responsibly as an essential part of agriculture. Pesticides control the pest, weeds, and diseases that attack our food crops. Without crop protection, including legal pesticides, global crop losses to pests could reach 80 percent.[1]

The trade in **counterfeit and illegal pesticides** has been growing, with increasing quantities produced, marketed and sold by organised crime network, presenting real risks to farmer's health, the environment and the economy.

Potential impacts on the Food Chain

- **Reputational damage for producers and suppliers**
  - Ensure your farmers/growers use only legally registered products
- **Food export bans**
  - Simple process to mitigate risk

European industry (2016 and 2017) raised anti-CF awareness to:

- **~ 100,000 farmers**
- **~ 9,000 distributors**

Help needed from Food Chain partners to increase regularity and relevance of anti-CF message to farmers

Anti-CF campaign in Poland (March-April October-December 2017)

- **Dedicated website: http://bezpiecznauprawa.org/**
  - **No. of impressions – 1 638 324**
  - **No. of page views – 6 833**

- **Wide media campaign**
  Over 170 media publications

PSOR campaign dedicated tools online

Educational video published on YouTube on 6 November

Wide promotion in media and social media

27,317 views

FB Agronews
Reach: **10 413 people reached**
Reactions: 26
Comments: 1
Shares: 4

Reach: **4496 people reached**
Reactions: 67
Comments: 6
Shares: 18

Reach: **12 155 people reached**
Reactions: 117
Comments: 6
Shares: 17

Social media:
25 posts
140,073 people reached
1,527 interactions

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THANK YOU